Table of Contents

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, 2019

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: **Common Stock, par value $0.01 per share** (Title of class)

Securities registered pursuant to Section 12(g) of the Act: **None**

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

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

As of June 30, 2019, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant was approximately $ 539,757,783 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 21, 2020 was 39,731,078 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.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

From time to time, in reports filed with the U.S. Securities and Exchange Commission (including this 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, our 2020 guidance, 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 U.S. Securities and Exchange Commission, including as described in "Risk Factors" included in Item 1A of 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.

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 helping to restore peripheral nerve function and quality of life to patients with physical damage or transection to peripheral nerves by providing innovative, clinically proven and economically effective repair solutions for surgeons and health care providers. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body. Every day, people suffer traumatic injuries or undergo surgical procedures that impact the function of their peripheral nerves. Physical damage to a peripheral nerve, or the inability to properly reconnect peripheral nerves, can result in the loss of muscle or organ function, the loss of sensory feeling, or the initiation of pain.

Axogen's platform for peripheral nerve repair features a comprehensive portfolio of products, including Avance® Nerve Graft, a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site; Axoguard® Nerve Connector, a porcine submucosa extracellular matrix ("ECM") coaptation aid for tensionless repair of severed peripheral nerves; Axoguard® Nerve Protector, a porcine submucosa ECM product used to wrap and protect damaged peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments; Axoguard® Nerve Cap, a porcine submucosa ECM product used to protect a peripheral nerve end and separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma; and Avive® Soft Tissue Membrane, a processed human umbilical cord intended for surgical use as a resorbable soft tissue barrier. 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, the United Kingdom, South Korea and several other European and international 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. 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 can form a neuroma which may send altered signals to the brain resulting in the sensation of pain. This abnormal section of 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 and inflammation. Finally, when a woman 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 and the potential risk of a symptomatic neuroma. When a woman chooses an autologous breast reconstruction after a mastectomy, sensation can, in certain cases, be returned through surgical intervention.

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 arm and hand) as well as nerve injuries caused by dental, orthopedic and other surgical procedures. Avance Nerve Graft provides surgeons an implant with the micro-architecture of a human nerve. This structure is essential and allows 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 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 barrier.

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 some restoration of function but may be limited by mechanisms of nerve healing 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; and/or
ii. Cells to regenerate or remodel the scaffold.

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. Avive Soft Tissue Membrane is a resorbable soft tissue covering to separate tissues in the surgical bed.

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.

Every day patients suffer traumatic bodily injuries 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 surgery procedures, OMF, 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 woman undergoes autologous breast reconstruction after a mastectomy, she receives the shape of a natural breast, but oftentimes without experiencing any return of sensory feeling. This forfeiture of sensation can have a profound effect on the woman'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 patients' 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 nerve 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, subsequently, repair the resulting nerve gap or appropriately terminate 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, 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 reporting 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 $2k to $4k, 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 availabity 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 covering. 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 for 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, 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 US 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 Upper Extremity Compression 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 US 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 Upper Extremity Compression 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 new and 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. 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. The size of this market opportunity is challenging to identify as the cause of the chronic pain is often not diagnosed and there has not historically been a 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 the 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.

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 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 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 Avance process, 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 that 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;
- Used to repair severed peripheral nerve tissue.
- Alleviates tension at the repair site;
- Remodels into the patient's own tissue instead of degrading;
- Reduces the number of required sutures (versus direct repair with suture) (Boechstyns, Jhand Surg. 2013;38:2405-2411);
- Moves the location of sutures away from the coaptation face;
- Reduces potential for fascicular mismatch;
- Allows visualization of underlying peripheral nerve ends;
- Provides a physical barrier preventing infiltration of surrounding tissues into the coaptation site and the potential for axonal sprouting outside the coaptation site;
- 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:

- Protect damaged peripheral nerves or nerve repair sites from surrounding tissue;
- 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 bioscaffold 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 instead of degrading;
- Easily conforms and provides 360 degree wrapping of damaged peripheral nerve tissue;
- Supports the body's own natural wound healing;
- 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 18-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 to keep tissue surfaces apart. 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 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.

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 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:

- Reduce painful neuroma formation; and
- Reduce pain.

Axoguard Nerve Cap has the following advantages:

- Separates the nerve end from surrounding tissue, neurotrophic factors and mechanical stimulation;
- Reduces painful neuroma formation;
- Can be sutured to surrounding soft tissue to anchor the nerve end;
- Material gradually remodels into the patient's own tissue to protect the nerve end; and
- Semi-translucent to allow for easy visualization of the nerve end during entubulation.

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 will continue to provide service and support for the existing systems in the market place.

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 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:

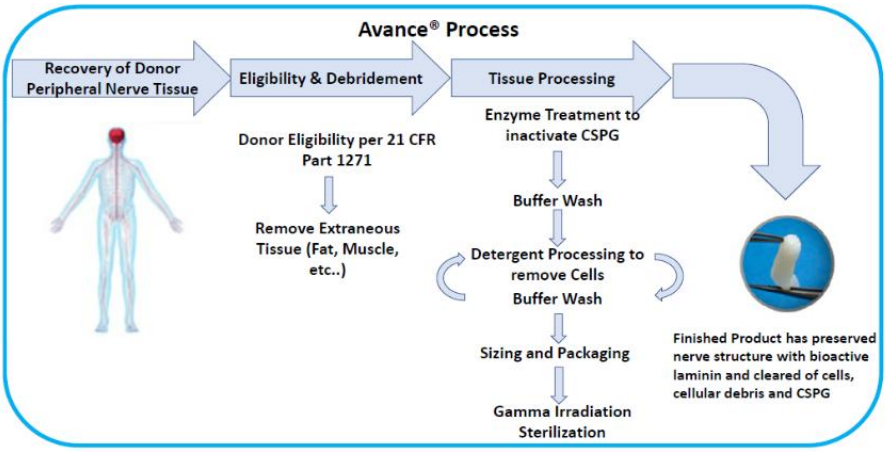
- Capable of measuring the innervation density of any skin surface;
- Portable and easy to use;
- Strong aluminum design is resistant to bending;
- Bright colors allow for clear discrimination between discs;
- Clear numbering allows users to interpret results; and
- Reusable carry case protects discs.

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.

The current CTS Agreement terminates December 31, 2021, 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 14. Commitments and Contingencies - Service Agreements.

Axogen is renovating a property it acquired which is located near the CTS facility and comprised of a 70,000 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 14. 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.

We 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, we are 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 asCybernetics Research Laboratories ("CRL"), Tucson, Arizona. Viron 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 the developing market of peripheral nerve repair and regeneration, 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, 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, oral and maxillofacial surgeons who repair damaged oral nerves and certain 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, 2019, Axogen had over one hundred 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 2,000 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®). Six of the above mentioned publications and more than 65 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 2019, we trained three-quarters of hand and microsurgery surgeon fellows in the U.S. through such courses and training. The Company provides education on peripheral nerve repair through its "Advances and Best Practices in Nerve Repair" national programs ("National Programs") as well as local and regional educational events. In calendar years 2017, 2018 and 2019, we conducted 15, 18, and 26 National Programs, respectively, and we expect to offer a similar range of programs in 2020. These efforts are supported by on-line tools and discussion forums such as Nerve Matters, an on-line community of peripheral nerve surgeons where the surgeons can ask questions, present cases and share findings in the area of peripheral nerve repair.

Execute the Sales Process and Expand the Axogen Sales Team

Axogen provides full sales and distribution services through both a direct sales force and independent sales agencies. As of December 31, 2019, Axogen had 109 direct sales professionals and 19 independent sales agencies in the U.S. Approximately 10% of global product revenue came from the direct channel. By the end of 2020, Axogen anticipates the number of direct sales professionals in the U.S. will increase to between approximately 126 to 131. Axogen's product portfolio is available in 13 countries outside the U.S. through a number of independent in country distributors. Axogen provides support and resources for independent agencies and distributors both within and outside the United States. Axogen provides its 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 the Axogen products. While surgeons make the decision to implant Axogen's products in appropriate patients, hospitals make the decision to purchase the products from Axogen. In today's budget constrained environment, hospital committees review new technologies for cost effectiveness as well as quality. Axogen believes that it has 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 exists 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 United States and by striving to build an outstanding internal team of technical and clinical experts.

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

Axogen has established educational conferences, presentations, webinars and surgical resident and fellow training that we believe is positioning us as a 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 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℠) of hollow tube conduits and Avance Nerve Graft to support the transition to a biological product is in process 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℠) is currently enrolling. A registry study of Avive Soft Tissue Membrane in acute trauma have been initiated and subjects are being monitored for follow-up. Finally, the Company has expanded RANGER to include an additional study arm called Sensation-NOW for breast neurotization and a contemporary cohort control for RANGER (MATCH℠) 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, Avive Soft Tissue Membrane and the Axoguard product lines 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 in expanding 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 the 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.0000000000000216. At the 2019 American Society for Surgery of the Hand Annual Conference, the RANGER Investigator Team presented on the updated RANGER Registry findings. The team reported overall meaningful recovery ranging from 82-84% and no safety concerns. A meta-analysis of available clinical outcomes data from published papers on the leading synthetic collagen conduit showed meaningful improvement in only 40-74% of cases bridging a gap in the nerve. This data was further verified in a review of autograft alternative in the 2016 edition of Hand Clinics. A similar meta-analysis for nerve autograft reported meaningful improvement in 60-88% of nerve repairs.

International Opportunity for Revenue

Axogen currently focuses on the U.S. market, with additional foreign distribution and sales in Canada, United Kingdom, South Korea and certain other countries. The need for the surgical repair of damaged or transected nerves is a global issue. Through its ex-U.S. revenue, 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 is currently renewing the Axoguard Nerve Connector and Nerve Protector CE Mark and although we believe such renewal is imminent, it has taken longer than anticipated and could experience continued delays. Until such renewal Axogen is able to sell only those products that are currently in inventory in the E.U., which inventory has not been sufficient to satisfy all product sales, and will no longer be available after February 2020. Although Axoguard product revenue in Europe is not material, the inability to supply physicians who wish to use Axoguard could have a negative effect on Axogen's planned expansion in the E.U. Avance Nerve Graft has been granted marketing authorization in Germany and commercial operations will begin in 2020. Currently, Avive Soft Tissue Membrane, Axoguard Nerve Cap and Axotouch Two Point Discriminator are only available in the United States, 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 commercial use in most countries. Avance Nerve graft has achieved NICE approval in the UK for digital nerve repair and reimbursement approval in South Korea 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 - Axogen's 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, 2019, 2018, and 2017, Axogen recognized grant revenue of approximately $301,000, $195,000 and $56,000, respectively. For the years ended December 31, 2019, 2018 and 2017, Axogen spent approximately $17.5 million, $11.8 million, and $6.7 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 competitors 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 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. In the event of default, licensors may also terminate an agreement (after written notice) if Axogen fails to cure a breach. The license agreements contain the following key terms:

- Payment of annual license maintenance fees, some of which may be credited against future royalty payments;
- Payment of royalty fees of 1%-3% based on net revenue of the licensed products, the level depending on the agreement, which may include a minimum quarterly royalty payment with discounts off royalty rates when royalty stacking applies;
- Payment of a percentage of sublicense fees received;
- Reimbursement of certain legal expenses incurred for patent prosecution and defense; and
- Other payments of various amounts based on achieving certain milestones.

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 nineteen issued U.S. patents, about fifteen pending U.S. patent applications (including those for which Axogen has received a notice of allowance) and on the order of seventy international patents and patent applications with regard to its peripheral nerve products and other related technologies. The following table identifies the issued U.S. patents owned or licensed by Axogen with regard to

its peripheral nerve products and other related technologies, including the patent number, the title of each patent, and the estimated expiration date of each patent.

Patent No.	Title	Estimated expiration date
US 6,972,168	Materials and Methods for Nerve Grafting, Selection of Nerve Grafts, and in vitro Nerve Tissue Culture	August 2022
US 7,402,319	Cell Free Tissue Replacement for Tissue Engineering	September 2023
US 7,732,200	Materials and Methods for Nerve Grafting, Selection of Nerve Grafts, and in vitro Nerve Tissue Culture	December 2023
US 6,696,575	Biodegradable, electrically conducting polymer for tissue engineering applications	March 2022
US 7,851,447	Materials and Methods for Nerve Repair	November 2023
US 8,545,485	Nerve Elevator and Method of Use	May 2032
US 8,758,794	Cell Free Tissue Replacement for Tissue Engineering	September 2023
US 8,986,733	Materials and Methods for Nerve Repair	August 2022
US D777,917	Two Point Discriminator Sensory Measurement Device	January 2032
US 9,690,975	Quantitative Structural Assay of a Nerve Graft	July 2035
US 9,572,911	Method for Decellularization of Tissue Grafts	March 2034
US 9,629,997	Materials and Methods for Protecting Against Neuromas	December 2033
US 9,996,729	Quantitative Structural Assay of a Nerve Graft	May 2035
US 9,597,429	Cell-Free Tissue Replacement for Tissue Engineering	September 2023
US 9,402,868	Materials and Methods for Nerve Grafting	August 2022
US 10,311,281	Quantitative Structural Assay of a Nerve Graft	May 2035
US 10,342,562	Capture-Tool for Manipulating and Entubulating Nerves	May 2037
US 10.441,304	Surgical Tool for Tissue Sizing and Transection	September 2037
US 10,441,681	Materials and Methods for Nerve Grafting	February 2023

With respect to our Avance Nerve Graft we have patent protection through at least September 2023 in the United States. 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.

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.

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 import 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 more than one hundred registered trademarks and has filed more than two hundred additional trademark applications worldwide to protect its trade names. We believe these registrations allow 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.

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 name 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, US State regulations and the guidelines of the AATB.

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. Enrollment of the additional subjects is underway and enrollment is expected to be completed by no later than the end of the second quarter 2020.

- 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 March2013, 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.

The Food and Drug Administration Safety and Innovation Act, referred to herein as FDASIA (Public Law 112-144), which was signed into law on July 9, 2012, 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 upon submission. For Axogen fiscal year 2020, this fee for a BLA requiring clinical data is $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 2020, the program fee has been established at $325,000. 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.

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 in December 2017 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.

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, 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 US. 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 AvanceNerve 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, 2019, six publications and more than 65 scientific conference presentations have been generated to date from the registry. The RANGER Study is an observational study in current enrollment. It is designed to allow enrollment of up to a total of 5,000 subjects over the next several years. 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 the BLA submission, Axogen will submit an interim report in the BLA 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. We anticipate having approximately 300 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. The study is currently enrolling and 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 clinical evidence submissions for Axoguard 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.

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 of the additional subjects is underway and no outcome data is available at this time.

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. Additional enrollment is on hold while the initial pilot subjects complete their study evaluations.

Axogen is conducting REPOSE, 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 or painful neuroma. The first phase, a non-randomized pilot has completed enrollment. The second phase, a prospective, randomized controlled study planned, is actively enrolling. Overall enrollment is targeted at enrollment of up to 101 subjects, with approximately 15 in the open pilot phase followed by 86 in the randomized phase. The study will assess pain scores, quality of life and health outcomes over a 12-month follow-up period. Enrollment has been initiated.

In addition to these clinical research programs, Axogen is developing additional clinical trials in peripheral nerve repair, 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 Axogen's ability to obtain regulatory approval and continue to market its 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 concerning the Avance Nerve Graft or Avive Soft Tissue Membrane products. Eight adverse events have been reported by Cook Biotech for the Axoguard products (one each in 2013, 2014, 2015 and 2016 and two each in 2017, 2018 and 2019). Axogen reported one (1) biological deviation in 2019 for quality system issues related to human tissue distribution (no patient safety issues were involved). 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 eight 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 the 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 Medical Devices related to nerve repair.

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 is currently renewing the Axoguard product CE Mark and although we believe such renewal is imminent, it has taken longer than anticipated and

could experience continued delays. Until such renewal Axogen is able to sell only those Axoguard products that are currently in inventory in the E.U., which inventory has not been sufficient to satisfy all product sales, and will no longer be available after February, 2020. Although Axoguard product revenue in Europe is not material, the inability to supply physicians who wish to use Axoguard could have a negative effect on Axogen's planned expansion in the E.U.

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 three (3) years 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 revenues and expenses.

The UK left the E.U. in January 2020. From now until December 31, 2020, E.U. Law will remain applicable thus the placement on the market of medical devices may continue uninterrupted on both sides of the English Channel and the notified body certificates will remain valid while the UK and E.U. negotiate 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 a 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 currently expect no delay in shipment of human tissue products into the UK in 2020. 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.

At this time it is unclear whether Axoguard will need a new and separate marketing authorization in the UK post-Brexit. According to recent guidance issued by the UK government, any new rules will take effect on Jan. 1, 2021 and companies can "use the CE marking" if they are placing goods on the UK market during the transition period, currently expected to last through 2020. Legislation has been recently proposed in Parliament that would update the UK regulatory framework for human and veterinary medicines, clinical trials and medical devices. We anticipate new rules to be developed over the next several months.

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 both Canada 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 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.

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. We are not including the information contained at http://www.Axogeninc.com, or at any other website.

Employees

At December 31, 2019, Axogen had approximately 394 total employees, including approximately 23 part-time employees and approximately 371 full-time employees. As of the date of this annual report on Form 10-K Axogen has not had a work stoppage and no employees are represented by a labor union. Axogen believes its relationship with its employees is satisfactory.

Executive Officers of the Registrant

The following table lists the names and positions of the individuals who are, as of February 24, 2020, executive officers of Axogen:

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

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

Karen Zaderej, Chairman, Chief Executive Officer and President (Age 58)

Ms. Zaderej has served as Axogen's President, Chief Executive Officer, a member of our board of directors (the "Board of Directors") since September 2011 and became the Chairman of our Board of Directors in May 2018. She has served as the Chief Executive Officer of Axogen, and a member of Axogen's board of directors since May 2010. Ms. Zaderej joined Axogen in May 2006 and served as Vice President of Marketing and Sales from May 2006 to October 2007 and as Chief Operating Officer from October 2007 to May 2010. From October 2004 to May 2006, Ms. Zaderej worked for Zaderej Medical Consulting, a consulting firm she founded, which assisted medical device companies in building and executing 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, and research & development, as well as ran a manufacturing business. Ms. Zaderej is a Director of Viveve Medical, Inc., a public women's intimate health company. Ms. Zaderej has a MBA from the Kellogg Graduate School of Business and a BS in Chemical Engineering from Purdue University.

Peter Mariani, Chief Financial Officer (Age 56)

Mr. Mariani has been Axogen's Chief Financial Officer since March 2016. Prior to joining Axogen, he served as Chief Financial Officer of Lensar, Inc, a privately held laser refractive cataract surgery company, from July 2014 through January 2016, which was sold in December 2015. From June 2011 to June 2014 Mr. Mariani served as Chief Financial Officer of Hansen Medical, a publicly traded medical device company developing robotic solutions for intravascular procedures. From 2007 through 2010 Mr. Mariani served as Chief Financial Officer for two privately held companies: Harlan Laboratories (2007 – 2009); and BMW Constructors (2009 – 2010). From 1994 through 2006 Mr. Mariani 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 Corporation as Director of Corporate Financial Reporting where he supported the initial public offering of Guidant Corporation and ultimately served as Vice President, Controller and Chief Accounting Officer. Mr. Mariani's experience at Guidant Corporation 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 where 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 Corporation to Boston Scientific Corporation, Mr. Mariani 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. Mr. Mariani received a Bachelor of Science Degree in Accounting from Indiana University.

Gregory G. Freitag, JD, CPA, General Counsel and Director (Age 58)

Mr. Freitag, JD, CPA, has been Axogen's General Counsel and a member of our Board of Directors since September 2011. He was Axogen's Chief Financial Officer from September 2011 to May 2014 and August 2015 to March 2016, and its Senior Vice President Business Development from May 2014 to October 2018. He was Chief Executive Officer, Chief Financial Officer and a board member of LecTec Corporation, an IP licensing and holding company that merged with Axogen in September 2011, from June 2010 through September 2011. From May 2009 to the present, Mr. Freitag has been a principal of FreiMc, LLC, a healthcare and life science consulting and advisory firm he founded that provides strategic guidance and business development advisory services. Prior to founding FreiMc, LLC, Mr. Freitag was a Director of Business Development at Pfizer Health Solutions, a former subsidiary of Pfizer, Inc., from January 2006 to May 2009. From July 2005 to January 2006, Mr. Freitag worked for Guidant Corporation in its business development group. Prior to Guidant Corporation, Mr. Freitag was the Chief Executive Officer of HTS Biosystems, a biotechnology tools start-up company, from March 2000 until its sale in early 2005. Mr. Freitag was the Chief Operating Officer, Chief Financial Officer and General Counsel of Quantech, Ltd., a public point of care diagnostic company, from December 1995 to March 2000. Prior to that time, Mr. Freitag practiced corporate law in Minneapolis, Minnesota. Mr. Freitag is also a director of PDS Biotechnology Corporation (NASDAQ: PDSB), a clinical stage biopharmaceutical company developing immunotherapies for cancer and other disease areas such as infectious disease. Mr. Freitag holds a JD from the University of Chicago and a BA Economics & Business and Law & Society from Macalester College, Minnesota.

Eric A. Sandberg, Chief Commercial Officer (Age 55)

Mr. Sandberg has served as Axogen's Chief Commercial Officer since January 2019. From 2016 until joining Axogen, he served as the Chief Executive Officer of Visura Technologies, Inc., a cardiologist-founded medical device company. From 2016 until 2018, Mr. Sandberg served as the Chief Business Officer of Rhythm Therapeutics, Inc., an electrophysiologist-founded preclinical biotechnology company. From 2014 until 2016, he served as the President and Chief Executive Officer of Tangent Medical Technologies, Inc., a medical device company. Mr. Sandberg also served as Senior Vice President, Sales at CardioDx, Inc., a molecular diagnostics company, from 2008 until 2013. Prior to joining CardioDx, Inc., Mr. Sandberg worked at Russell Reynolds Associates and held leadership positions across sales, marketing, corporate accounts, and business development at Guidant Corporation and Boston Scientific. Mr. Sandberg currently serves as an observer on the Board of Directors of Visura Technologies, Inc. Mr. Sandberg earned an MBA from Harvard Business School and a Bachelor of Science degree in mechanical engineering from Bradley University in Peoria, IL.

Mark Friedman, Ph.D., Vice President of Regulatory Affairs and Quality Assurance(Age 62)

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 25 years of experience in developing and directing regulatory strategy and quality systems for medical products, including 15 years with start-up medical product firms. Dr. Friedman has a Ph.D. in Chemistry specializing in protein biochemistry from the University of Cincinnati. Dr. Friedman sits on various agency committees for the Alliance of Regenerative Medicine, Medical Device Manufacturer's

Association and American Association of Tissue Banks, working on improving regulatory laws and standards for regenerative products and medical devices.

Maria Martinez, Chief Human Resources Officer (Age 52)

Ms. Martinez has served as Axogen's Chief Human Resources Officer since October 2018. From January 2018 until joining Axogen as Chief Human Resources Officer, Ms. Martinez provided consulting services related to human resources through her consulting firm MDM Consulting Services, LLC. Prior to founding MDM , she was Chief Human Resources Officer at HSNi, a $3.5B interactive multichannel retailer overseeing nearly seven thousand employees in nine locations. Ms. Martinez joined HSNi in July 2010 and served as SVP Talent Management until she assumed the role of Chief Human Resources Officer. Prior to joining HSNi, Ms. Martinez was Vice President of Human Resources with Laser Spine Institute, LLC., a minimally invasive spine surgery company, having started with them in 2008. From 2007 to 2008, she worked at Bausch + Lomb, Inc. where she served as Director, Human Resources US Pharmaceuticals and, from 2005 to 2007, Ms. Martinez was Sr. Director, Human Resources Corporate with Darden Restaurants, Inc. Prior to 2005, Ms. Martinez held positions related to the field of human resources.

Ms. Martinez has a Master of Arts in Industrial/Organizational Psychology from the Florida Institute of Technology, Melbourne, FL and a Bachelor of Arts in Psychology; Bachelor of Arts in French, Minor in Italian from the University of South Florida, Tampa, FL.

Isabelle Billet, Chief Strategy and Business Development Officer (Age 58)

Ms. Billet has served as Axogen's Chief Strategy and Business Development Officer since October 2018. From July 2013 until joining Axogen as Chief Strategy and Business Development Officer, Ms. Billet worked for IBHC Advisors LLC, a consulting firm she founded which assisted medical device companies in their organic and inorganic growth strategies and supported private equity firms on their investment strategy and due diligence. From 2010 to 2013, Ms. Billet worked at Cardinal Health, Inc where she served as Senior Vice President of Marketing and Innovation for the Medical segment focusing on their private brand portfolio development. From 2005 to 2010, she was Vice President Marketing and New Business Development for C.R. Bard Medical division. She worked for Johnson and 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 US. Ms. Billet spent the first 7 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, a medical device company exclusively focused in Labor and Delivery and Neonates Intensive Care. She has an MBA from EM Lyon Business School, France and Cranfield School of Management, UK and a Doctorate in Pharmacy from Montpellier University in France.

Erick DeVinney, Vice President of Clinical and Translational Sciences (Age 44)

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. Erick has over 14 years of experience in the successful planning and management of clinical development. Prior to joining Axogen Mr. DeVinney served as Manager of Clinical Operations for Angiotech Pharmaceuticals from 2005 to 2007 and Clinical Program Lead for Pharmaceutical Research Associates International from 2001 to 2005. Mr. DeVinney has been involved in the successful submission of numerous 510(k), IDE and NDA applications. He has a BS in Chemistry from Virginia Commonwealth University.

Mike Donovan, Vice President of Operations (Age 55)

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.

Angelo G. Scopelianos, Ph.D., Vice President of Research and Development (65)

Dr. Scopelianos has served as Axogen's Vice President of Research and Development since September 2018. 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: Rutgers University, Princeton University and NJ Institute of Technology; the Johnson & Johnson Philip B. Hofmann Award for technical achievements in scientific research; and an Honorary Doctor of Science Degree bestowed by the State University of New York.

ITEM 1A. RISK FACTORS

Axogen's business involves a number of risks, some of which are beyond its control. The risk and uncertainties described below are not the only ones the Company faces. Set forth below is a discussion of the risks and uncertainties that management believes to be material to Axogen.

Risks Related To The Company

Axogen has not experienced positive cash flow from its operations, and the ability to achieve positive cash flow from operations will depend on increasing revenue from distribution of its products, which may not be achievable.

Axogen has historically operated with negative cash flow from its operations. As of December 31, 2019, Axogen had an accumulated deficit of approximately $180 million. If revenue does not increase as anticipated, then it will continue to experience negative cash flows and adverse operating conditions. Axogen's continuing capital needs and other factors could cause the Company to raise additional funds through public or private equity offerings, debt financings or from other sources. The sale of additional equity may result in dilution to Axogen's shareholders. There is no assurance that Axogen will be able to secure funding on terms acceptable to it, or at all.

Axogen's revenue growth depends on its ability to expand its sales force, increase distribution and sales to existing customers and develop new customers, and there can be no assurance that these efforts will result in significant increases in sales.

Axogen is in the process of investing in its distribution and sales channels composed of a combination of its direct sales force and independent agencies/distributors to allow it to increase distribution and sales to existing customers and reach new customers. There can be no assurance that these efforts will be successful in expanding Axogen's revenue. Axogen currently distributes tissue and sells products directly through its sales force and indirectly through agency relationships. Axogen is engaged in an initiative to build and further expand sales and marketing capabilities. The incurrence of these expenses impacts Axogen's operating results, and there can be no assurance of their effectiveness. If Axogen is unable to develop its sales force, increase sales to existing customers and attract new customers, it may not be able to grow revenue or maintain its current level of revenue generation.

Axogen's revenue depends primarily on four products.

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

The Axoguard Nerve Connector and 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; except that 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 Axogen 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 Axogen 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. Nerve Connector and Axoguard Nerve Protector and Cook Biotech is the contract manufacture for our Axoguard Nerve Cap. Although there are products that Axogen believes it could develop or obtain that would replace the Axoguard products obtained through the agreements with Cook Biotech, the loss of the ability to sell the Axoguard Nerve Connector and Protector products, and the Axoguard Nerve Cap if it becomes a significant product line, could have a material adverse effect on Axogen's business until other replacement products are available.

Axogen's success will be dependent on continued acceptance of its products by the medical community.

Continued market acceptance of Axogen's products will depend on its ability to demonstrate that its products are an attractive alternative to existing or new nerve reconstruction treatment options including both surgical techniques and products. The Company's ability to do so will depend on surgeons' evaluations of clinical safety, efficacy, ease of use, reliability, and cost-effectiveness, including insurance reimbursement, of Axogen's nerve repair products. For example, although Axogen's Avance Nerve Graft follows stringent safety standards, including sterilization by gamma irradiation, Axogen believes 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 the results of our operations may be adversely affected.

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

Axogen is highly dependent on its ability to recover human peripheral nerve tissue from tissue donors for its Avance Nerve Graft product and acquire birth tissue for its 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 Axogen's reputation for its 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 Axogen's 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 Axogen products, technologies, and tissue recovery and processing procedures from others engaged in tissue recovery. In addition, unfavorable reports could make families of potential donors or donors themselves from whom Axogen is 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 negative consequences for Axogen's revenue, operating results and continued operations.

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

Any failure in the physical infrastructure of Axogen's facilities, including the facility it licenses from CTS, could lead to significant costs and disruptions that could reduce its revenues and harm its business reputation and financial results. Any natural or man-made event that impacts Axogen's ability to utilize its facilities could have a significant impact on its operating results, reputation and ability to continue operations. This includes termination of the CTS Agreement which is 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 Axogen upon 6 months prior notice whereby such notice cannot be provided until March 1, 2021. Axogen believes it can find and make operational a new licensed facility in less than six months, if required. 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 our 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 its production or distribution facilities. Although Axogen has business interruption insurance which would, in instances other than service agreement termination, cover certain costs, it may not cover all costs nor help to regain Axogen's standing in the market.

Axogen must maintain high quality processing of its products.

Axogen's Avance Nerve Graft is processed through its Avance Process which requires careful calibration and precise, high-quality processing and manufacturing. Its Avive Soft Tissue Membrane is also human tissue that requires skill in its processing. Achieving precision and quality control requires skill and diligence by its personnel. If it fails to achieve and maintain these high levels of quality control and processing standards, including avoidance of processing errors, defects or product failures, Axogen could experience recalls or withdrawals of its product, delays in delivery, cost overruns or other problems that would adversely affect its business. Axogen reported one (1) biological deviations in 2019 for quality system issues related to human tissue distribution (no patient safety issues were involved) and corrective action was taken without a material adverse consequence to Axogen. Axogen cannot completely eliminate the risk of errors, defects or failures. In addition, Axogen may experience difficulties in scaling-up processing of its 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 Axogen is unable to process and produce its human tissue products on a timely basis, at acceptable quality and costs, and in sufficient quantities, or if it experiences unanticipated technological problems or delays in production, its business would be adversely affected.

Delays, interruptions or the cessation of production by Axogen's third party suppliers of important materials or delays in qualifying new materials, may prevent or delay Axogen's 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. Axogen does not have written contracts with any of its single source suppliers, and at any time they could stop supplying Axogen's orders. FDA review of a new supplier may be required if these materials become unavailable from Axogen's current suppliers. Although there may be other suppliers that have equivalent materials that would be available to Axogen, FDA review of any alternate suppliers, 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 Axogen's third party suppliers of important materials, or any delay in qualifying new materials, if necessary, would prevent or delay Axogen's ability to manufacture products. In addition, an uncorrected impurity, a supplier's variation in a raw material or testing, either unknown to Axogen or incompatible with its manufacturing process, or any other problem with Axogen's materials, testing or components, would prevent or delay its ability to process tissue. These delays may limit Axogen's ability to meet demand for its products and delay its clinical trial, which would have a material adverse impact on its business, results of operations and financial condition.

The failure of third parties to perform many necessary services for the commercialization of Avance Nerve Graft and Avive Soft Tissue Membrane, including services related to recovery/acquisition, distribution and transportation, would impair Axogen's ability to meet commercial demand.

Axogen relies upon third parties for certain recovery/acquisition, distribution and transportation services for its Avance Nerve Graft and Avive Soft Tissue Membrane. In accordance with product specifications, third parties ship Avance Nerve Graft in specially validated shipping containers at frozen temperatures. If any of the third parties that Axogen relies upon in its 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 to Axogen, or

encounter physical damage or natural disaster at their facilities, Axogen's ability to deliver product to meet commercial demand may be significantly impaired.

Axogen is dependent on its relationships with independent agencies to generate revenue.

Axogen derives material revenues through its relationships with independent agencies. In 2019 approximately 10% of global product revenue was generated through independent agencies. If certain agency relationships were terminated or discontinued for any reason, it could materially and adversely affect Axogen's ability to generate revenues and profits. If Axogen required additional agencies it may not be able to find additional agencies who will agree to market and distribute Axogen's products on commercially reasonable terms, if at all. If Axogen is unable to establish new agency relationships or renew certain current distribution agreements on commercially acceptable terms, its operating results could suffer.

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

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

Axogen's operating results will be harmed if it is unable to effectively manage and sustain its future growth or scale its operations.

There can be no assurance that Axogen will be able to manage its future growth efficiently or profitably. Its business is unproven on a large scale and actual revenue and operating margins, or revenue and margin growth, may be less than expected. If Axogen is unable to scale its production capabilities efficiently or maintain pricing without significant discounting, it may fail to achieve expected operating margins, which would have a material and adverse effect on its operating results. Growth may also stress Axogen's ability to adequately manage its operations, quality of products, safety and regulatory compliance. If growth significantly decreases it will negatively impact Axogen's cash reserves, and it may be required to obtain additional financing, which may increase indebtedness or result in dilution to shareholders. Further, there can be no assurance that Axogen would be able to obtain additional financing on acceptable terms if all at.

There may be significant fluctuations in Axogen's operating results.

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

Axogen's revenues depend upon prompt and adequate reimbursement from public and private insurers and national health systems.

Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental change. The ability of a hospital or an ambulatory surgery center ("ASC") to pay fees for Axogen's 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 Connector, Axoguard Nerve Cap, Axoguard Protector, 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 leading to a 78% increase in Medicare payment for nerve allograft repair in ambulatory surgery centers beginning January 1, 2020.

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 United States, 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 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 consider the Avance Nerve Graft 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. We are actively working to reverse these non-coverage decisions but cannot provide assurance that we will 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. 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 cost-effective 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 adverse effect on our business and business operations.

We are party to a number of pending lawsuits and other disputes which may have an adverse impact on our business, operations or financial condition.

We are or may become a party to pending lawsuits and other disputes, including patent, product liability, securities violations or other lawsuits. These current and future matters, including the Einhorn securities litigation decribed in Item -3 Legal Proceedings, may result in a loss of patent protection, reduced revenue, incurrence of significant liabilities and diversion of our management's time, attention and resources. Given the uncertain nature of litigation and other disputes generally, we are not able in all cases to estimate the amount or range of loss that could result from an unfavorable outcome in these current matters. In view of these uncertainties, the outcome of these matters may result in charges in

excess of any established reserves, and, to the extent available, liability insurance. Even claims without merit could subject us to adverse publicity and require us to incur significant legal fees. While Axogen currently carries liability insurance, protracted litigation and other disputes, including any adverse outcomes, may have an adverse impact on our business, operations or financial condition.

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

Although Axogen is not currently subject to any product liability proceedings and it has no provision for product liability disbursements, it may incur material liabilities relating to product liability claims in the future, including product liability claims arising out of the usage of Axogen products. Although Axogen currently carries product liability insurance in an amount it believes is consistent with industry averages, its insurance coverage and any provision it may maintain in the future for product related liabilities may not be adequate and Axogen's business could suffer material adverse consequences.

Technological change could reduce demand for Axogen's products.

The medical technology industry is intensely competitive. Axogen competes 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.

Axogen products compete with autograft, hollow-tube conduits, commercially available wraps and amnion products, as well as with alternative medical procedures. For the foreseeable future, Axogen believes 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 Axogen 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 Axogen's products in the future. Unlike allografts, synthetic tissue technologies are not dependent on the availability of human or animal tissue. Although Axogen's 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. Axogen 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 Axogen's competitors will not develop products that have superior performance or are less expensive relative to Axogen's products rendering Axogen's 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 Axogen's limited resources, its smaller size and its relatively early stage, Axogen may face competitive challenges from these new products or existing products and barriers that are difficult to overcome and could negatively impact its growth. Finally, a Chinese company provides a human peripheral nerve allograft in China, however, such product is not sold in markets of interest of Axogen because of Axogen's IP protection in its identified markets.

Axogen may be unsuccessful in commercializing its products outside the U.S.

To date, Axogen has focused its commercialization efforts in the U.S., except for minor revenues in certain countries outside the U.S. Axogen intends to expand distribution and sales in these and other countries 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 Axogen's portfolio of products is complex. Avance Nerve Graft is distributed in Canada, United Kingdom, and certain other countries. Axogen received approval to distribute Avance Nerve Graft in

Germany in December 2019 and is making plans for a market launch in Germany in 2020. Distribution in Spain currently allows only for compassionate use. Axogen is not seeking approval for France and Italy at this time. Avive Soft Tissue Membrane is currently available in the U.S. and select other countries for expansion. Cook Biotech is currently renewing the Axoguard Nerve Connector and Nerve Protector CE Mark and although we believe such renewal is imminent, it has taken longer than anticipated and could experience continued delays. Until such renewal Axogen is able to sell only those products that are currently in inventory in the E.U., which inventory has not been sufficient to satisfy all product sales, and will no longer be available after February, 2020. Although Axoguard product revenue in Europe is not material, the inability to supply physicians who wish to use Axoguard could have a negative effect on Axogen's planned expansion in the E.U.

In addition, the United Kingdom exited the E.U. ("Brexit") and Axogen cannot be sure what changes could occur or the cost of regulatory compliance with both the United Kingdom and E.U. Until such time as Axogen can obtain, if at all, the necessary registrations and approvals for its products, material expansion beyond the United States will be limited. Finally, the cost of regulatory compliance for sales outside the U.S. can be significant and time consuming.

Further, Axogen will need to either enter into distribution agreements with third parties or develop a direct sales force in foreign markets. If it does not obtain adequate levels of reimbursement from third party payers outside of the U.S., it may be unable to develop and grow its 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 Axogen is unable to successfully commercialize its products internationally, its long-term growth prospects may be limited.

If Axogen does not manage tissue and tissue donation in an effective and efficient manner, it could adversely affect its business.

Many factors affect the supply, quantity and timing of donor medical releases, such as effectiveness of donor screening, the effective recovery of tissue, the timely receipt, recording, review and approval of required medical and testing documentation, changes in donor eligibility criteria and employee loss and turnover in Axogen's and its contractor's recovery department. Axogen can provide no assurance that tissue recovery or donor medical releases will occur at levels that will maximize processing efficiency and minimize Axogen's costs.

If Axogen does 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, such as effectiveness of predicting demand, effectiveness of preparing manufacturing to meet demand, efficiently meeting product mix and product demand requirements and product expiration. Axogen may be unable to manage its inventory efficiently, keep inventory within expected budget goals, keep its work-in-process inventory on hand or manage it efficiently, control expired product or keep sufficient product on hand to meet demand. Finally, Axogen can provide no assurance that it can keep inventory costs within its target levels. Failure to do so may harm long term growth prospects.

Axogen's failure to protect its technology systems and comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against Axogen, and adversely impact Axogen's operating results.

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.

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 United States, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to 4% of the annual global revenues of the noncompliant company. The recent implementation of the GDPR has increased Axogen's responsibility and liability in relation to personal data that Axogen processes, including in clinical trials, and Axogen 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 Axogen's cost of doing business.

Compliance with applicable data privacy and security laws and regulations (together with applicable industry standards) may increase Axogen's costs of doing business. In this regard and in light of the CCPA's implementation, Axogen expects that there will be other proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the E.U. and other jurisdictions, and Axogen cannot determine the impact such future laws, regulations and standards may have on its business.

Axogen's management has broad discretion in the use of Axogen's 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.

Axogen's management has broad discretion in the use of Axogen's 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 Axogen's 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 Axogen does not invest or apply its cash and cash equivalents in ways that enhance shareholder value, Axogen may fail to achieve expected financial results, which could cause its stock price to decline.

Axogen incurs costs as a result of operating as a public company, and its management is required to devote substantial time to compliance initiatives.

As a public company, Axogen incurs 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. Axogen's 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 Axogen's business. In addition, activity by shareholders or others that bring into question aspects of Axogen's 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 Axogen's stock and can result in substantial time and financial resources being expended to address the situation.

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 and financial condition could be harmed.

Our business and financial performance could be adversely affected, directly or indirectly, by disasters, by terrorist activities or by international hostilities.

Neither the occurrence nor the potential impact of disasters (such as hurricanes and other natural disasters), terrorist activities and international hostilities can be predicted. However, these occurrences could impact Axogen 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 disasters, terrorist activities or international hostilities affect the financial markets or the economy in general or in any particular region.

Axogen's 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 disasters or terrorist activities or international hostilities 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.

Risks Related to the Regulatory Environment in which Axogen Operates

Axogen's business is subject to continuing regulatory compliance by the FDA and other authorities which is costly and could result in negative effects on its business.

Axogen is 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 United States and other jurisdictions in which we conduct business. These include, for example, anti-kickback laws, false claims laws, health care fraud laws, and anti-bribery laws such as the United States 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 United States, 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"), 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 Axogen 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 that could have a material adverse effect.

Our products are also subject to regulation by the FDA in the U.S. The FDA regulates the development, clinical testing, marketing, distribution, manufacturing, labeling, and promotion of biological products, such as that of Axogen's Avance Nerve Graft product. The FDA requires the approval of a biological product, like Avance Nerve Graft, through a BLA prior to marketing. Although 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 Axogen: (1) transitions

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) conducts a phase 3 clinical trial to demonstrate safety, purity and potency of Avance Nerve Graft under an SPA; (3) continues to comply with the requirements of 21 CFR Part 1271; and (4) exercises 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 FDA requirements for Human Cellular and Tissue-based Products (HCT/P) under 21 CFR Part 1271 regulations and U.S. State regulations. 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 Axogen expects 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 Axogen's device products or enhancements of marketed products or that Axogen's Avance Nerve Graft will meet FDA's requirements for continued marketing and transition to a BLA or ultimately an approved BLA. FDA review of Axogen's devices or biological products may encounter significant delays during FDA's premarket review process that would adversely affect Axogen's ability to market its products or enhancements. In addition, there can be no assurance that Axogen 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 Axogen 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 Axogen's operations. Axogen, and its 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 Axogen is 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 Axogen's products may harm its reputation or the image of its products in the marketplace, or result in injuries that lead to product liability suits, which could be costly to Axogen's business or result in FDA sanctions if the company is deemed to have engaged in off-label promotion. Axogen is seeking a biologics license through the BLA process for specific uses of Avance Nerve Graft under specific circumstances. Its promotional materials and training methods must comply with FDA requirements and other applicable laws and regulations, including the prohibition against off-label promotion. Axogen's 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 Axogen cannot prevent a physician from using its 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 Axogen's products and if the FDA determines that Axogen's promotional or training materials constitute the unlawful promotion of an off-label use, it could request that Axogen modify its 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 Axogen 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, Axogen's reputation could be damaged and the use of its products in the marketplace could be impaired.

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

Axogen's 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 Axogen.

The FDA considers Axogen's 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, Axogen's Avance Nerve Graft product 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 Axogen's compliance with a transition plan established by the FDA. See "Business — Government Regulations — U.S. Government Regulation Review." Axogen has 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, Axogen can commercially distribute Avance Nerve Graft until the FDA makes a final determination on an Avance Nerve Graft BLA submission, assuming Axogen remains in compliance with the transition plan and exercises due diligence in executing the transition plan. In the event that the FDA becomes dissatisfied with Axogen's 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 Axogen to distribute Avance Nerve Graft product in accordance with the transition plan, Axogen would no longer be able to distribute Avance Nerve Graft, which would have a material adverse effect on Axogen's operations and financial viability. In addition, if Axogen does not meet the conditions of the transition plan, or fails 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 Axogen's operations and financial viability.

Axogen's 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 its business.

Axogen is subject to accreditation such as that by the AATB and as a Verified-Accredited Wholesale Distributor by National Association of Boards of Pharmacy. Axogen has registration requirements such as that with ISO 13485 registration bodies. These accreditations and regulations can affect distribution and sale of Axogen products on a state-by-state basis, within the United States and also affects distribution and sale of Axogen products outside of the United States. The loss of accreditation or registration could keep Axogen from selling and distributing its products which may have negative effects on its business.

Axogen's Axoguard and Avive products are subject to FDA and other regulatory requirements.

Axogen's Axoguard product line is regulated as a medical device 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. Axogen distributes for Cook Biotech Axoguard Nerve Connector and Axoguard Protector products and Cook Biotech is responsible for the regulatory compliance of these products. 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. Axogen is responsible for the regulatory compliance of the Axoguard Nerve Cap. Axogen has 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 Axogen or Cook Biotech fails to comply with applicable regulatory requirements, the FDA could deny or withdraw 510(k) clearance for the Axoguard products, or impose civil penalties, including fines, product seizures or product recalls and, in certain cases, criminal sanctions.

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 Axogen remove the product from the market until a BLA is approved. If Axogen fails 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.

Axogen's Axotouch product is subject to FDA and other regulatory requirements.

Axogen's Axotouch product is regulated as a medical device 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. If Axogen fails to comply with applicable regulatory requirements, the FDA could deny or withdraw 510(k) clearance for the product, or impose civil penalties, including fines, product seizures or product recalls and, in certain cases, criminal sanctions.

Defective Axogen product could lead to recall or other negative business conditions.

If Axogen's products are defective or otherwise pose safety risks, the FDA could require their recall or Axogen may initiate a voluntary recall of its 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 Axogen's products would divert managerial and financial resources and have an adverse effect on its business, results of operations and financial condition. A recall could harm Axogen's reputation with customers and negatively affect its sales. Axogen may initiate recalls involving some of its products in the future that it determines do not require notification of the FDA. If the FDA were to disagree with Axogen's determinations, it could request that it report those actions as recalls, and take regulatory or enforcement action against Axogen or the product.

If Axogen's products cause or contribute to a death, a serious injury or any adverse reaction involving a communicable disease related to its products, or malfunction in certain ways, it 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 Axogen fails to report these events to the FDA within the required timeframes, or at all, the FDA could take regulatory or enforcement action against Axogen. Any adverse event involving Axogen's 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 Axogen defending itself in a lawsuit, would require the dedication of time and capital, distract management from operating its business, and may harm Axogen's reputation, business, results of operations and financial condition.

Axogen's operations must comply with FDA and other governmental requirements.

Axogen's operations require it to comply with the FDA's and other governmental authorities' laws and regulations regarding the manufacture and production of medical products, which is costly and could subject Axogen 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". Any of these actions could impair Axogen's ability to produce its products in a cost-effective and timely manner in order to meet customer demands. Axogen may also be required to bear other costs or take other actions that may have an adverse impact on its future revenue and its ability to generate profits. Furthermore, Axogen's key material suppliers, licensors and or other contractors may not continue to be in compliance with all applicable regulatory requirements, which could result in Axogen's failure to produce its products on a timely basis and in the required quantities, if at all.

Distribution of Axogen human tissue products outside the U.S. are subject to foreign regulatory requirements that vary from country to country. In the European Union ("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. Axogen 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 Axogen's future growth and compliance with such requirements could place a significant financial burden on Axogen.

In addition, the United Kingdom exited the E.U. ("Brexit") and Axogen cannot be sure what changes could occur or the cost of regulatory compliance with both the United Kingdom and E.U. Until such time as Axogen can obtain, if at all, the necessary registrations and approvals for its products, material expansion beyond the United States will be limited. Finally, the cost of regulatory compliance for sales outside the U.S. can be significant and time consuming.

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

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

Axogen is required to perform a clinical trial for its 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, and is subject to factors within and outside of Axogen's control. The outcome of this trial is uncertain.

Axogen 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 is designed to assess the outcome of peripheral nerve repair in approximately 170 subjects in up to 20 centers. The study completed initial subject enrollment in January 2019. No outcome data is available at this time. As required by the SPA and agreed to by FDA and Axogen, 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 which confirmed the expanded sample size and allowed the study enrollment target to be increased by 50 subjects, to a total target of 220 subjects. Axogen may add up to five new study centers, for a total of 25 centers, to support enrollment and currently has

125 centers engaged. Axogen restarted enrollment of subjects and expects to complete enrollment during the summer of 2020 no later than the end of second quarter 2020.

Axogen is 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. If the FDA is unable to agree with Axogen, or Axogen is unable to meet the standards required of it by the FDA, regarding preclinical studies, clinical studies and CMC, the approval of Axogen's BLA would not occur or be delayed.

Axogen continues to work diligently with the FDA and, in this context, continues to distribute the Avance Nerve Graft products. The FDA will end the period of enforcement discretion upon a final determination of Axogen's BLA submission or if 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., not progressing toward study completion or BLA submission in a timely or adequate fashion). 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 Avance Nerve Graft, and Axogen's business and financial condition 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 Axogen's interpretation of the data from its non-clinical studies and clinical trials and may require the company to pursue additional non-clinical studies or clinical trials, or not approve Axogen's BLA. If Axogen is unable to demonstrate the safety and efficacy of its product through its 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.

Axogen will rely on third parties to conduct its clinical trial and they may not perform as contractually required or expected.

Axogen will rely on third parties, such as contract research organizations ("CROs"), medical institutions, clinical investigators and contract laboratories to conduct its clinical trial and certain nonclinical studies. Axogen and its CROs are required to comply with all applicable regulations governing clinical research, including good clinical practice, or GCP. The FDA enforces these regulations through periodic inspections of trial sponsors, principal investigators, CROs and trial sites. If Axogen or its CROs fail to comply with applicable FDA regulations, the data generated in its clinical trials may be deemed unreliable and the FDA may require Axogen to perform additional clinical trials before approving its applications. Axogen cannot be certain that, upon inspection, the FDA and similar foreign regulatory authorities will determine that Axogen's clinical trial complies or complied with clinical trial regulations, including GCP. In addition, Axogen's clinical trial must be conducted with product produced under applicable cGMP regulations. Failure to comply with the clinical trial regulations may require Axogen to repeat clinical trials, which would delay the regulatory approval process. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to Axogen's clinical protocols or regulatory requirements or for other reasons, Axogen's non-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and it would not be able to obtain regulatory approval for its products on a timely basis, if at all, and its business, results of operations, financial condition and growth prospects would be adversely affected. Furthermore, Axogen's third party clinical trial investigators may be delayed in conducting its clinical trials for reasons outside of their control.

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

In addition to the FDA requirements for biological products, Avance Nerve Graft will continue to be subject to, as is Avive Soft Tissue Membrane, various requirements for human tissue under 21 CFR Part 1271 controls. 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 Axogen operates and have led to increased enforcement actions, which affects the conduct of its business. In addition, new guidance was issued by the FDA in late 2017 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 is being evaluated by the Company.

Additional regulations or guidance documents may be implemented by the FDA in the future. These changes may require 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 which 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. Axogen makes payments to certain of its 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 which prevents Axogen from receiving payment for services it renders, or which prevents it from paying tissue banks or certain of its clients for the services they render for Axogen, its business could be materially and adversely affected.

Axogen has engaged, through its marketing employees, independent sales agents and sales representatives in ongoing efforts designed to educate the medical community as to the benefits of Axogen products, and Axogen intends to continue its educational activities. Although Axogen believes that NOTA permits payments in connection with these educational efforts as reasonable payments associated with the processing, transportation and implantation of Axogen products, payments in connection with such education efforts are not exempt from NOTA's restrictions and Axogen's inability to make such payments in connection with its education efforts may prevent it from paying Axogen sales representatives for their education efforts and could adversely affect Axogen's business and prospects. No federal agency or court has determined whether NOTA is, or will be, applicable to every allograft nerve tissue-based material which Axogen's processing technologies may generate. Assuming that NOTA applies to Axogen's processing of allograft nerve and umbilical cord tissue, Axogen believes that it complies 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 Axogen's 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 Axogen's 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 Axogen 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 Axogen's business and the industry in which it operates.

Healthcare policy changes may have a material adverse effect on Axogen.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (the "Act"), which Act substantially changes the way healthcare is financed by both governmental and private insurers, and encourages improvements in the quality of healthcare items and services. While implementation of the Act has been uneven, several provisions significantly impact

the biotechnology and medical device industries and could have a material adverse impact on numerous aspects of Axogen's business.

This Act includes, among other things, the following measures:

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research;
- reporting and disclosure requirements on healthcare manufacturers for any "transfer of value" made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests ("Sunshine Act");
- payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- a new abbreviated pathway for the licensure of biologic products that are demonstrated to be biosimilar or biosimilar and interchangeable with a licensed biologic product.

There are also a number of states (such as Vermont, Massachusetts, Minnesota) with their own Sunshine Acts-type reporting and disclosure requirements on healthcare manufacturers for any "transfer of value" made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests, for applicable entities within that state.

In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system. Certain of these proposals could limit the prices Axogen is able to charge for its products or the amounts of reimbursement available for its products and could also limit the acceptance and availability of its products. The adoption of some or all of these proposals could have a material adverse effect on Axogen's business, results of operations and financial condition.

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 Axogen does business. Axogen 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 Axogen's 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 Axogen's future operating results.

Risks Related to Axogen's Intellectual Property

Failure to protect Axogen's IP rights could result in costly and time-consuming litigation and its loss of any potential competitive advantage.

Axogen's success will depend, to a large extent, on its ability to successfully obtain and maintain patents, prevent misappropriation or infringement of 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 Axogen's patented and patent-pending technologies will provide it with a competitive advantage, that Axogen 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 Axogen's. Moreover, Axogen can provide no assurance that confidentiality agreements with its 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, if not impossible, to predict the outcome of such litigation. A failure by Axogen to protect its IP, or a breach by third parties of agreements aimed at protecting Axogen's IP, could have a materially adverse effect on its business and operating results and its ability to successfully compete in its industry.

Future protection for Axogen's proprietary rights is uncertain, and may impact its ability to successfully compete in its industry.

The degree of future protection for Axogen's proprietary rights is uncertain. Axogen cannot ensure that:

- it, or its licensors, were the first to make the inventions covered by each of Axogen's patents;
- it, or its licensors, were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of Axogen's technologies;
- any of Axogen's pending patent applications will result in issued patents;
- any of Axogen's issued patents or those of its licensors are valid and enforceable;
- any patents issued to Axogen or its collaborators will provide any competitive advantages or will not be challenged by third parties;
- it 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 Axogen relies on to protect its IP underlying its products are adequate to prevent third parties from using, disclosing or misappropriating that IP, all of which could harm its ability to compete in the market.

Axogen's commercial success depends in part on its ability and the ability of its 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 Axogen or collaborators and licensors of employing their proprietary technology in Axogen products, or in the materials or processes used to make Axogen products, without authorization. Any legal action against Axogen collaborators, licensors or it claiming damages and/or seeking to enjoin Axogen's commercial activities relating to the affected products, materials and processes could, in addition to subjecting Axogen to potential liability for damages, require it or its collaborators and licensors to obtain a license to continue to utilize the affected materials or processes or to manufacture or market the affected products. Axogen cannot predict whether it or its 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 Axogen were unable to obtain such a license, it and its collaborators and licensors may be unable to continue to utilize the affected materials or processes, or manufacture or market the affected products, or Axogen may be obligated by a court to pay substantial royalties and/or other damages to the patent holder. Even if Axogen 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 Axogen's prospects for profitability. Accordingly, Axogen cannot predict whether, or to what extent, the commercial value of the affected product or products or Axogen's 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 its core business. Axogen and its licensors may be unable to obtain and enforce IP rights to adequately protect its products and related IP.

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 negatively impact our future financial condition and results of operations.

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

A third party may claim an ownership interest in one or more of Axogen's patents or other IP. A third party could bring legal actions against Axogen claiming it infringes their patents or proprietary rights, and seek monetary damages

and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While Axogen believes it owns the right, title and interest in the patents for which it or its licensors have applied and Axogen's 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 Axogen's patents or IP, it cannot guarantee that a third party will not assert a claim or an interest in any of such patents or IP. If Axogen becomes involved in any litigation, it could consume a substantial portion of Axogen's resources and cause a significant diversion of effort by Axogen's technical and management personnel regardless of the outcome of the litigation. If any of these actions were successful, in addition to any potential liability for damages, Axogen could be required to obtain a license to continue to manufacture or market the affected product, in which case Axogen may be required to pay substantial royalties or grant cross-licenses to Axogen's patents. Axogen cannot, however, assure that any such license will be available on acceptable terms, if at all. Ultimately, Axogen could be prevented from commercializing a product or be forced to cease some aspect of its 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 Axogen's business, financial condition, and results of operations. 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.

Axogen depends on maintenance of exclusive licenses.

Axogen depends fundamentally on keeping and satisfying the terms of exclusive licenses of its nerve repair technologies from UFRF and UTA. Nonetheless, a disagreement between Axogen and either licensor could have a negative impact on its ability to operate its business effectively. In addition, Axogen could learn that the technologies it has 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 Axogen's business.

Axogen trademarks are valuable

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 and, in part, differentiate us from our competitors increases and as a result, 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 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, 2019, approximately 41.4% 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 Axogen's 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 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 and other factors that may not be tied to the financial performance of Axogen;
- performance by Axogen in the execution of its 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 United States 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. In the past, and several recent situations, following periods of volatility in the market price of a company's securities, securities class action litigation has been initiated against such company. Axogen has experienced such situation and is subject to a class action. Litigation initiated against us, including that which we are currently involved, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

On January 9, 2019, Plaintiff Neil Einhorn, on behalf of himself and others similarly situated, filed a putative class action complaint 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. Fl.). 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 and are currently awaiting the court's ruling.

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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

The Company 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 the Company leases its approximately nineteen thousand square foot corporate headquarters facility in the Progress Center at 13631 Progress Boulevard, Alachua, Florida 32615 (the "Primary Premises"). The annual cost for the Primary Premises ranges from approximately $353 to $363 through the end of the term of the lease, which expires on October 31, 2021. On January 23, 2017 the Company entered into a lease (the "First Expansion Lease") with SNH for one thousand four hundred square feet at 13709 Progress Boulevard, Alachua, Florida 32615 (this property was purchased by Nucleic Acids Licensing, LLC in February 2019) (the "First Expansion Premises") adjacent to the Primary Premises. The Company has entered into the Second Expansion Lease and Third Expansion Lease, as defined below, which relate to properties that are adjacent to the Primary Premises and First Expansion Premises resulting in the Company having approximately eighteen thousand square feet for its corporate headquarters and certain research space in the Progress Center in Alachua, Florida.

On November 19, 2018, the Company entered into a Lease (the "Second Expansion Lease") with SNH for two thousand eight hundred square feet at 13709 Progress Boulevard, Suites S-160, S-162 and S-164, Alachua, Florida 32615 (the "Second Expansion Premises"). Pursuant to the Second Expansion Lease, the Company is to use the Second Expansion Premises for general office uses. The Second Expansion Lease commenced December 1, 2018 and expires November 30, 2020. The annual cost of the Second Expansion Premises is approximately $45 for the first twelve months of the term and $46 for the final twleve months. The Company is also obligated to pay for certain taxes, insurance costs and electricity costs incurred by SNH.

On November 19, 2018, AC entered into a Lease (the "Third Expansion Lease") with SNH for two thousand square feet at 13709 Progress Boulevard, Suites S-175, S-177 and S-179, Alachua, Florida 32615 (the "Third Expansion Premises"). Pursuant to the Third Expansion Lease, the Company is to use the Third Expansion Premises for general office and biomedical research uses. The Third Expansion Lease commenced December 1, 2018 and its term expires November 30, 2020. The annual cost of the Third Expansion Premises is approximately $37 for the first twelve months of the term and $35 for the final eleven months. The Company is also obligated to pay for certain taxes, insurance costs and electricity costs incurred by SNH.

On November 21, 2018, the Company, 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, the Company 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 annual rental cost of the entire Burleson Facility is now approximately $113 through December 31, 2020, $116 for the calendar year 2021 and until April 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 26, 2018 (the "Ashley Avenue Lease Effective Date"), the Company entered into a Lease (the "Ashley Avenue Lease") with Ashley Avenue Associates I, LLC., a Delaware limited liability company ("Ashley"), for the lease by the Company of approximately fifteen thousand square feet of office space on the second floor of the building located at 1000 N. Ashley Drive, Tampa, Florida 33602 (the "Ashley Avenue Premises"). Pursuant to the Ashley Avenue Lease, the Company will use the Ashley Avenue Premises for general office purposes. The initial term of the Ashley Avenue Lease commenced on December 1, 2018 and expires on November 30, 2020. The Company has an option to terminate the lease after eighteen months by providing Ashley with four months advance written notice. The rental cost for the Ashley Avenue Premises was approximately $381 for the first twelve-month period, and approximately $360 for the final eleven month period. The Company is also obligated to pay for its pro rata share of the building's property taxes, utilities, administrative costs, common area maintenance and management fees, excluding any capital improvements or any damage due to fire, hurricane or other casualty.

On September 20, 2018, the Company 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 intends to construct and complete on or before September 30, 2020, on an area of land in Tampa, Florida. Pursuant to the Heights Union lease, the Company will use the Heights Union Premises for general office, medical laboratory, training and meeting purposes. The annual costs of the Heights Union Premises ranges from approximately $2.4 million to $3.3 million during the term of the lease. Axogen believes it 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, Axogen 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 terminates December 31, 2021, subject to earlier termination by either party for cause (subject to the non-terminating party's right to cure, in certain circumstances), or without cause upon 6 months' 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.

Effective June 8, 2018, AC 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 AC of certain real property located in Vandalia, Ohio comprised of a 70,000 square foot building on approximately 8.6 acres of land. AC 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, Axogen leases space and maintains records at certain other facilities, including Axogen's prior corporate headquarters at 1407 South Kings Highway, Texarkana, Texas 75501.

The aggregate cost of all of Axogen's and its subsidiaries' properties is approximately $1.9 million per year. Axogen believes that its facilities will be sufficient to operate its 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 and are currently awaiting the court's ruling.. Plaintiff is seeking compensatory damages, reimbursement of expenses and costs, including counsel and expert fees and such other relief as the court deems just and proper. 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.

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

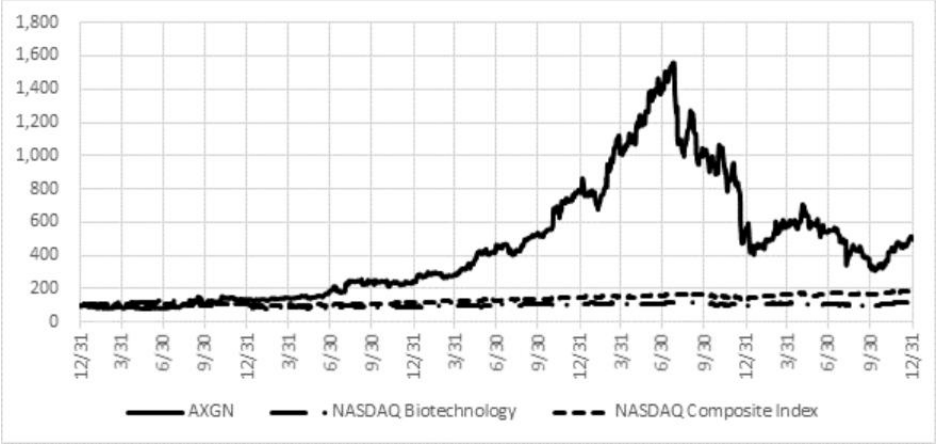
Axogen's common stock is traded on the Nasdaq Capital Market under the symbol "AXGN." On February 21, 2020, the last reported closing sale price of the Company common stock on the Nasdaq Capital Market was $14.70 per share.

Shareholders

As of February 21, 2020, the Company had 39,730,976 shares of common stock outstanding, and approximately 240 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. The Company estimates that there are more than 9,769 individual owners. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Note 11 "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, 2019 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, 2014 to December 31, 2019. 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 2019.

Recent Sales of Unregistered Securities

We had no sales of unregistered securities in 2019.

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,				
	2019	**2018**	**2017**	**2016**	**2015**
Statement of Operations Data:					
Revenues	$ 106,712	$ 83,937	$ 60,426	$ 41,108	$ 27,331
Cost of goods sold	17,349	12,923	9,311	6,467	4,848
Gross Profit	89,363	71,014	51,115	34,641	22,483
Costs and Expenses:					
Sales and marketing	71,950	56,617	37,636	28,426	20,089
Research and development	17,514	11,773	6,699	4,212	3,237
General and administrative	31,305	23,124	14,731	10,133	8,423
Total costs and expenses	120,769	91,514	59,066	42,771	31,749
Loss from operations	(31,406)	(20,500)	(7,951)	(8,130)	(9,266)
Other income (expense):					
Investment income	2,364	1,525	—	—	—
Interest expense	(40)	(1,127)	(2,217)	(5,386)	(3,989)
Interest expense - deferred financing costs	—	(81)	(246)	(875)	(128)
Loss on extinguishment of debt	—	(2,186)	—	—	—
Other (expense)	(53)	(28)	(31)	(20)	27
Total other income (expense)	2,271	(1,897)	(2,494)	(6,281)	(4,090)
Net loss	(29,135)	(22,397)	(10,445)	(14,411)	(13,356)
Loss per common share - basic and diluted	(0.74)	(0.60)	(0.31)	(0.47)	(0.51)

	2019	**2018**	**2017**	**2016**	**2015**
Balance Sheet Data:					
Total current assets	$ 135,021	$ 150,953	$ 55,741	$ 44,037	$ 35,051
Total assets	154,643	160,173	58,875	46,360	36,700
Total current liabilities	20,880	13,044	13,719	11,081	3,709
Total long-term obligations, net of current maturities and deferred financing fees	1,610	147	19,974	20,358	24,795
Total liabilities	22,490	13,191	33,693	31,439	28,504
Total shareholders' equity	132,153	146,982	25,182	14,921	8,196

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.

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 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 inervation density of any surface area of the skin. Our portfolio of products is available in the United States, Canada, the United Kingdom, South Korea and several European and other international countries.

Revenue from the distribution of Axogen's peripheral nerve repair products, the Avance Nerve Graft, Axoguard Nerve Connector and Axoguard Nerve Protector 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. Axogen revenues increased in 2019 compared to 2018 primarily as a result of continuing revenue growth through product penetration in, and increases of the number of, active accounts, and to a lesser extent, the development and growth of new accounts.

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. Each new period of measurement is thus benefited from growth in active accounts which may include those that were new accounts in the prior measurement period. Axogen has continued to broaden its sales and marketing focus which is expected to have a positive contribution to its revenue growth in the long term. In 2019, the Company continued to invest in the development of our commercial team, infrastructure capabilities, clinical studies, product development and research, as well as surgeon education. As a result, the growth in these expenses outpaced our revenue growth.

Results of Operations

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)			
Revenues	$ 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)	0.0	(1,127)	(1.4)
Interest expense — deferred financing costs	—	0.0	(81)	0.0
Loss on extinguishment of debt	—	0.0	(2,186)	(2.7)
Other expense	(53)	0.0	(28)	0.0
Total other expense	2,271	2.1	(1,897)	(2.3)
Net Loss	$ (29,135)	(27.3)%	$ (22,397)	(26.7)%

Revenues

Revenues 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 the Company's 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 revenues, 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 the Company's surgeon education program; and (d) increased marketing activity. As a percentage of revenues, 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 the Company's growth, including professional fees, salaries, and an increase of $1,982 of non-cash stock compensation. As mentioned above, the Company also recorded $2,467 of legal fees associated the Litigation. As a percentage of revenues, 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 Axogen's product development and clinical efforts substantially focused on its Biologics License Application, or BLA, for the 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. Axogen continues to conduct product development efforts focused on both new peripheral nerve products and new peripheral nerve applications for our existing products. Axogen pursues research grants to support research and early product development. Axogen's 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 revenues.

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 the Company 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

Axogen 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.

Comparison of the Years Ended December 31, 2018 and 2017

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,			
	2018		2017	
	Amount	% of Revenue	Amount	% of Revenue
	(dollars in thousands)			
Revenues	$ 83,937	100.0 %	$ 60,426	100.0 %
Cost of goods sold	12,923	15.4	9,311	15.4
Gross profit	71,014	84.6	51,115	84.6
Costs and expenses:				
Sales and marketing	56,617	67.5	37,636	62.3
Research and development	11,773	14.0	6,699	11.1
General and administrative	23,124	27.5	14,731	24.4
Total costs and expenses	91,514	109.0	59,066	97.8
Loss from operations	(20,500)	(24.4)	(7,951)	(13.2)
Other income (expense):				
Investment income	1,525	1.8	—	0.0
Interest expense	(1,127)	(1.4)	(2,217)	(3.7)
Interest expense — deferred financing costs	(81)	0.0	(246)	(0.4)
Loss on extinguishment of debt	(2,186)	(2.7)	—	0.0
Other expense	(28)	0.0	(31)	0.0
Total other expense	(1,897)	(2.3)	(2,494)	(4.1)
Net Loss	$ (22,397)	(26.7)%	$ (10,445)	(17.3)%

Revenues

Revenues for the year ended December 31, 2018 increased 38.9% to $83,937 as compared to $60,426 for the year ended December 31, 2017. This increase was primarily a result of continuing growth in active accounts from improved penetration within these active accounts, as well as an increase in the number of active accounts. In the fourth quarter of 2018, we had 712 active accounts, an increase of 20% from 591 at the end of 2017. In addition, the Company received grant revenue of $195 in the year ended December 31, 2018, as compared to grant revenue of $56 in the year ended December 31, 2017.

Gross Profit

Gross profit for the year ended December 31, 2018 increased 38.9% to $71,014 as compared to $51,115 for the year ended December 31, 2017. This increase was consistent with and primarily attributable to the increased revenues in 2018. Gross profit margin in 2018 was unchanged at 84.6% as compared to 84.6% in 2017.

Costs and Expenses

Total cost and expenses increased 54.9% to $91,514 for the year ended December 31, 2018 as compared to $59,066 for the year ended December 31, 2017. 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 the Company's growth. As a percentage of revenues, total cost and expenses increased to 109.0% in 2018 compared to 97.8% in 2017.

Sales and marketing expenses increased 50.4% to $56,617 for the year ended December 31, 2018 as compared to $37,636 for the year ended December 31, 2017. 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 the Company's surgeon education program; and (d) increased marketing activity. As a percentage of revenues, sales and marketing expenses were 67.5% for the year ended December 31, 2018 compared to 62.3% for the year ended December 31, 2017.

General and administrative expenses increased 57.0% to $23,124 for the year ended December 31, 2018 as compared to $14,731 for the year ended December 31, 2017. The increase was primarily the result of increased expenses related to infrastructure expansion to support the Company's growth, including professional fees, salaries, and $4,007 of non-cash stock compensation. As a percentage of revenues, general and administrative expenses increased to 27.5% for the year ended December 31, 2018 compared to 24.4% for the year ended December 31, 2017.

Research and development expenses increased 75.7% to $11,773 in the year ended December 31, 2018 as compared to $6,699 for the year ended December 31, 2017. Research and development costs include Axogen's product development and clinical efforts substantially focused on its Biologics License Application, or BLA, for the Avance Nerve Graft and the RECON and RANGER studies. These activities vary from quarter to quarter due to the timing of certain projects. The increase in expenses for 2018 relate to expenditures for these clinical activities, including the pivotal clinical trial to support the BLA, and hiring additional personal to support clinical and product development activity as well as expenses associated with the new processing facility. It is expected that costs associated with the BLA will continue to increase as we continue to invest in completing the license application. Axogen continues to conduct product development efforts focused on both new peripheral nerve products and new peripheral nerve applications for our existing products. Axogen pursues research grants to support research and early product development. Axogen's increased product and clinical pipeline development initiatives contributed to the increase in research and development expenses in 2018, with grant revenue offsetting a portion of this activity. As a result, research and development expenses increased to 14.0% in 2018 from 11.1% in 2017, as a percentage of revenues.

Other Income and Expenses

For the year ended December 31, 2018, we recognized $1,525 of investment income from our asset management and cash investment sweep accounts that were opened during the second quarter of 2018. As a result of the prepayment in full of the Term Loan and Revolving Loan with MidCap, as defined in "Term and Revolving Loan Agreements" below, during the second quarter of 2018, interest expense decreased 49.2% to $1,127 in 2018 as compared to $2,217 for the year ended December 31, 2017, and interest expense – deferred financing costs decreased 67.1% to $81 for the years ended December 31, 2018 as compared to $246 for the year ended December 31, 2017. 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. Other expenses decreased 9.7% to $28 for the year ended December 31, 2018, as compared to $31 for the year ended December 31, 2017.

Income Taxes

Axogen had no income tax expenses or income tax benefit for 2018 or 2017 due to incurrence of net operating loss for the year, the benefits of which have been fully value allowed. Axogen does not believe there are any additional tax expenses or benefits currently available.

Liquidity and Capital Resources

Cash Flow Information

As of December 31, 2019, the Company had cash, cash equivalents, investments, and restricted cash of $102,510, a decrease of $20,095 from $122,605 at December 31, 2018, primarily as a result of the net operating cash flow of $19,872 and capital outlays of $4,664 for the build out of the Company's Axogen Processing Center, or APC, in Vandalia, Ohio. These expenditures were offset by proceeds throughout the year from stock option exercises of $4,002. Cash disbursements in 2018 included $25,599 for the prepayment in full of the Term Loan and Revolving Loan with MidCap, as defined in "Term and Revolving Loan Agreements" below, and $5,030 for the acquisition of the APC.

Axogen had working capital of approximately $114,141 and a current ratio of 6.5 at December 31, 2019, compared to working capital of $137,909 and a current ratio of 11.6 at December 31, 2018. The decrease in working capital at December 31, 2019 as compared to December 31, 2018, was primarily due to the use of working capital to fund operations, including increased compensation from hiring additional personnel to support the business, the payment in 2019 of the 2018 performance bonus, 2018 annual sales awards and related costs. In addition, working capital has also been utilized to commence the buildout of our APC facility.

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

If Axogen needs additional capital in the future, it 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 Axogen's shareholders. There is no assurance that Axogen will be able to secure funding on terms acceptable to it, 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 Axogen as needed, Axogen may be required to take certain action, such as slowing sales and marketing expansion, delaying regulatory approvals or reducing headcount.

Net Cash Used in Operating Activities

Axogen used $19,872 of cash for operating activities in 2019, as compared to using $17,862 of cash for operating activities in 2018. This increase in cash used in operating activities was primarily attributed to the increase in the net loss, accounts receivable and inventory for the year ended December 31, 2019 as compared to 2018, partially offset by the decrease in accounts payable and accrued expenses and non-cash stock compensation during 2019.

Net Cash Provided by/Used in Investing Activities

Investing activities for 2019 provided $27,271 of cash as compared to using $98,193 during 2018. The Company allowed short term investments to mature or sold short term investments to fund the operations. These inflows of cash were offset by the increase in purchases of property and equipment, primarily our facility in Vandalia, Ohio.

Net Cash Provided by Financing Activities

Financing activities in 2019 provided $4,031 of cash as compared to providing $109,842 of cash in 2018. The decrease was the result of the net proceeds of the May 2018 public stock offering in the prior year. The prior year also included a $25,599 of payments to extinguish the Company's debt, including the prepayment of the Term Loan and Revolving Loan with MidCap, as defined in "Term and Revolving Loan Agreements" below, and related fees. Proceeds from the exercise of stock options provided $4,002, $3,884 and $1,434 of cash for the years ended December 31, 2019, 2018 and 2017, respectively.

Operating Cash Requirements

On July 9, 2019, Axogen 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 14 Commitment and Contingencies in the Notes to the Condensed Financial Statements). The Company anticipates spending up to approximately $37,737 for renovations, equipment and furniture over the next twelve months and up to $40,906 over the next 18 months.

As previously disclosed the Company previously 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. Pursuant to the Heights Union lease, the Company will use the Heights Union Premises for general office, medical laboratory, training and meeting purposes. The Company anticipates occupying the premises by the second quarter of 2020. Associated with the lease, the Company anticipates spending up to $7,490 for leasehold improvements, equipment and furniture and fixtures over the next twelve months.

As of December 31, 2019, we had cash, cash equivalents, investments and restricted cash totaling $102,510 and total current liabilities of $20,880. 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, the Company entered into Term Loan and a Revolving Loan with MidCap Financial Trust ("MidCap") maturing on May 1, 2021.

The Company had 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, the Company exercised its 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, the Company charged to interest expense the unamortized deferred financing costs associated with the Term Loan of $473.

The Company 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, the Company exercised its option to terminate and paid $2,958 to prepay the Revolving Loan in full, which amount included fees of $236.

Contractual Obligations and Commitments

The following table summarizes our obligations with regard to our contractual obligations as of December 31, 2019, 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
APC Commitment	$ 43,601	$ 37,737	$ 5,864	$ -	$ -
Tampa Commitment	9,833	7,490	2,343	-	-
Operating leases	41,720	2,664	6,580	5,225	27,251
Finance Leases	52	19	29	4	-
	$ 95,206	47,910	14,816	5,229	27,251

Service Agreements disclosed in Footnote 14 Commitments and Contingencies do not have annual firm commitments.

As noted above, on July 9, 2019, the Company entered into the Design-Build Agreement with CRB, pursuant to which CRB will renovate and retrofit the property. Once completed, the Company will use the property for material processing, medical laboratory, general office, training and meeting purposes. The Design-Build Agreement contains several design phase milestones beginning in July 2019 and sets the date for Substantial Completion (as defined in the Design-Build Agreement) in the third quarter of 2020, subject to adjustment in accordance with the terms of the Design-

Build Agreement. The estimated cost pursuant to the Design-Build Agreement is $30,400. Additional costs associated with the renovation, purchasing of furniture and equipment, validation and certification of the property are estimated to be $14,400. These capital expenditure costs will be incurred as they arise until the anticipated full transition of material processing to the property by early 2022.

The Company expects 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. The economic development grants are subject to certain job creation milestones by 2023 and related contingencies.

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) the Company agreed to issue and sell 700,000 shares of the Company's 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 the Company's 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. The Company and 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. The Company received net proceeds of approximately $15,655 after deducting the underwriting discounts and commissions and estimated offering expenses.

On May 8, 2018, the Company 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 the Company agreed to issue and sell 3,000,000 shares of the Company's common stock in an underwritten registered public offering at an offering price of $41.00 per share (the "2018 Offering"). The Company 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 the Company 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

Axogen does 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 the Company's financial condition and results of operations is based upon the Company's consolidated financial statements which have been prepared in accordance with accounting principles generally accepted in the United States ("USGAAP"). 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 Note 3 – Summary of Significant Accounting Policies to our 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

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 significant 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 a significant 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 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 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 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. 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.

Allowance for Doubtful Accounts Receivable

We evaluate the collectability of accounts receivable to determine the appropriate allowance for doubtful accounts. In determining the amount of the allowance, we consider the aging of account balances, historical credit losses, customer-specific information and other relevant factors. We review accounts receivable and adjust the allowance based on current circumstances and charge off uncollectible receivables against the allowance when all attempts to collect the receivable have failed. Our history of write-offs against the allowance has not been significant. The allowance for doubtful accounts balance was $1,092 and $1,117 at December 31, 2019 and 2018, respectively.

Investments

The Company invests primarily in U.S. Government securities, corporate bonds, commercial paper and asset-backed securities 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.

Inventories

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, 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 distributed 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.

Share-Based Compensation

The Company 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.

The Company 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.

The Company 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.

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

Leases

The Company adopted ASU No. 2016-02—Leases (Topic 842), as of January 1, 2019, (the "Application Date") 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 modified retrospective approach provides a method for recording on the balance sheet as of January 1, 2019, leases that have commenced on or before the Application Date.

The Company elected the package of practical expedients permitted under the transition guidance, which allowed us to not reassess whether any existing contracts contain a lease, to not reassess historical lease classification as operating or finance leases, and to not reassess initial direct costs. The Company also elected the practical expedient allowing us to not separate the lease and non-lease components for all classes of underlying assets, apart from equipment. The Company did not elect the practical expedient to use hindsight to determine the lease term for leases at January 1, 2019.

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.

Adoption of the new standard resulted in the recording of right-to-use assets and lease liabilities of approximately $3,786 and $3,823, respectively, and the derecognition of capital lease assets, capital lease liabilities, and operating lease deferred rent of $96, $63, and $70, respectively, as of January 1, 2019 with zero cumulative-effect adjustment to retained earnings. The new standard did not materially impact our consolidated net earnings.

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

The Company is 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.

The Company invests its cash primarily in money market accounts, U.S. government agencies and securities, corporate bonds and commercial paper. Although the Company believes its 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 Company to credit risk consist of cash and cash equivalent balances and investments in corporate bonds. Certain of Axogen's cash and cash equivalents balances exceed FDIC insured limits or are invested in money market accounts with investment banks that are not FDIC-insured. The Company places its cash and cash equivalents in what it believes to be credit-worthy financial institutions. As of December 31, 2019, $35,224 of the cash and cash equivalents balance was in excess of FDIC limits.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Axogen, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, shareholders' equity, and cash flows, for the years ended December 31, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for the years ended December 31, 2019 and 2018, 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, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

Basis for Opinions

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, and implantable tissue and devices (finished goods) and are valued at the lower of cost or net realizable value. The Company reviews inventory quantities to assess whether inventory will expire prior to being sold. 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

February 24, 2020

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM 2017

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

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of operations, shareholders' equity and cash flows for the year ended December 31, 2017 of Axogen, Inc. and Subsidiaries (the "Company"), and the related notes and financial statement schedules listed in the index appearing under item 15(a)(2) (collectively referred to as the "consolidated financial statements").

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the Company's results of operations and cash flows for the year ended December 31, 2017 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

The Company's management is responsible for these consolidated 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. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audit of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Lurie, LLP

Minneapolis, Minnesota
February 28, 2018

We served as the Company's auditor from 2004 to 2018

AXOGEN, INC.
CONSOLIDATED BALANCE SHEETS
December 31, 2019 and 2018
(In Thousands, Except Share Amounts)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 35,724	$ 24,294
Restricted cash	6,000	6,000
Investments	60,786	92,311
Accounts receivable, net of allowance for doubtful accounts of $1,092 and $1,117, respectively	16,944	15,321
Inventory	13,861	11,982
Prepaid expenses and other	1,706	1,045
Total current assets	135,021	150,953
Property and equipment, net	14,887	8,039
Operating lease right-of-use assets	3,133	—
Finance lease right-of-use assets	87	—
Intangible assets	1,515	1,181
Total assets	$ 154,643	$ 160,173
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	19,130	12,998
Current maturities of long term obligations	1,736	28
Contract liabilities, current	14	18
Total current liabilities	20,880	13,044
Long Term Obligations, net of current maturities	1,595	35
Other long-term liabilities	—	70
Contract liabilities	15	42
Total liabilities	22,490	13,191
Commitments and contingencies - see Note 14		
Shareholders' equity:		
Common stock, $0.01 par value per share; 100,000,000 shares authorized; 39,589,755 and 38,900,875 shares issued and outstanding	396	389
Additional paid-in capital	311,618	297,319
Accumulated deficit	(179,861)	(150,726)
Total shareholders' equity	132,153	146,982
Total liabilities and shareholders' equity	$ 154,643	$ 160,173

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

AXOGEN, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
Years ended December 31, 2019, 2018 and 2017
(In Thousands, Except Per Share Amounts)

	2019	2018	2017
Revenues	$ 106,712	$ 83,937	$ 60,426
Cost of goods sold	17,349	12,923	9,311
Gross profit	89,363	71,014	51,115
Costs and expenses:			
Sales and marketing	71,950	56,617	37,636
Research and development	17,514	11,773	6,699
General and administrative	31,305	23,124	14,731
Total costs and expenses	120,769	91,514	59,066
Loss from operations	(31,406)	(20,500)	(7,951)
Other income (expense):			
Investment income	2,364	1,525	—
Interest expense	(40)	(1,127)	(2,217)
Interest expense — deferred financing costs	—	(81)	(246)
Loss on extinguishment of debt	—	(2,186)	—
Other expense	(53)	(28)	(31)
Total other income (expense), net	2,271	(1,897)	(2,494)
Net Loss	(29,135)	(22,397)	(10,445)
Weighted average common shares outstanding — basic and diluted	39,235	37,127	33,323
Loss per common share — basic and diluted	$ (0.74)	$ (0.60)	$ (0.31)

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

AXOGEN, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
Years ended December 31, 2019, 2018 and 2017
(In Thousands)

	Common Stock		Additional Paid-in	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Deficit	Equity/(Deficit)
Balance, December 31, 2016	33,009	$ 330	$ 132,475	$ (117,884)	$ 14,921
Stock-based compensation	—	—	3,609	—	3,609
Exercise of stock options	536	5	1,429	—	1,434
Issuance of common shares	805	8	15,655	—	15,663
Net loss	—	—	—	(10,445)	(10,445)
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 and employee stock purchase plan	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

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

AXOGEN, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2019, 2018 and 2017
(In Thousands)

	Year Ended		
	December 31, 2019	December 31, 2018	December 31, 2017
Cash flows from operating activities:			
Net loss	$ (29,135)	$ (22,397)	$ (10,445)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	933	774	488
Amortization of right-of-use assets	1,821	—	—
Amortization of intangible assets	123	77	79
Impairment loss on intangible assets	104	—	—
Amortization of deferred financing costs	—	81	246
Loss on disposal of equipment	—	1	—
Loss on extinguishment of debt	—	2,186	—
Provision for bad debt	514	852	223
Provision for inventory writedown	1,887	1,343	1,438
Changes in investment gains and losses	(972)	(721)	—
Share-based compensation	10,304	7,606	3,609
Change in operating assets and liabilities:			
Accounts receivable	(2,136)	(5,108)	(3,236)
Inventory	(3,767)	(6,009)	(3,295)
Prepaid expenses and other	(661)	(192)	(342)
Accounts payable and accrued expenses	2,920	3,711	1,927
Operating lease obligations	(1,773)	—	—
Cash paid for interest portion of finance leases	(4)	—	—
Contract and other liabilities	(30)	(66)	70
Net cash used in operating activities	(19,872)	(17,862)	(9,238)
Cash flows from investing activities:			
Purchase of property and equipment	(4,664)	(6,282)	(1,105)
Purchase of investments	(121,074)	(114,736)	—
Proceeds from sale of investments	153,571	23,146	—
Cash payments for intangible assets	(562)	(321)	(187)
Net cash provided by / (used for) investing activities	27,271	(98,193)	(1,292)
Cash flows from financing activities:			
Proceeds from issuance of common stock	—	132,964	15,891
Cash paid for equity offering	—	(257)	(228)
Borrowing on revolving loan	—	26,253	57,599
Payments on revolving loan and prepayment penalties	—	(30,489)	(57,624)
Repayments of long-term debt and prepayment penalties	—	(22,513)	(21)
Cash paid for debt portion of finance leases	29	—	—
Proceeds from exercise of stock options	4,002	3,884	1,434
Net cash provided by financing activities	4,031	109,842	17,022
Net increase in cash, cash equivalents, and restricted cash	11,430	(6,213)	6,492
Cash, cash equivalents, and restricted cash, beginning of period	30,294	36,507	30,015
Cash, cash equivalents and restricted cash, end of period	$ 41,724	$ 30,294	$ 36,507
Supplemental disclosures of cash flow activity:			
Cash paid for interest	$ 34	$ 1,325	$ 2,198
Supplemental disclosure of non-cash investing and financing activities:			
Acquisition of fixed assets in accounts payable and accrued expenses	$ 3,212	$ 335	$ 55
Capital lease additions	$ —	$ —	$ 62
Right-of-use asset and operating lease liability (Adoption of ASC 842)	$ 26	$ —	$ —

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

AXOGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019, 2018 and 2017
(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, 2019 and December 31, 2018 and for the three years ended December 31, 2019. 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 a global provider of innovative surgical solutions for physical damage or transection to peripheral nerves. Axogen is focused specifically on the science, development and commercialization of technologies for peripheral nerve regeneration and repair. Axogen's products are designed to restore nerve function and are used to treat patients with physical damage or transection to peripheral nerves by providing innovative, clinically proven and economically effective repair solutions for surgeons and health care providers. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body. 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 portfolio of products includes Avance Nerve Graft, an 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 membrane that may be used as a resorbable soft tissue covering to separate tissues in the surgical bed. Along with these core surgical products, Axogen also offers the Axotouch Two-Point Discriminator a measurement tool for use by healthcare professionals detect changes in sensation. The Company's portfolio of products is available in the United States, Canada, Germany, South Korea and other European and international 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 (formerly Cybernetics Research Laboratories) ("Viron") Tucson, Arizona. Viron 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, 2019, $35,224 of the cash and cash equivalents balance was in excess of FDIC limits. As of December 31, 2019 and 2018, the Company had restricted cash balances of $6,000 as collateral for an irrevocable standby letter of credit.

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, 2019	December 31, 2018
Cash and cash equivalents	$ 35,724	$ 24,294
Restricted cash	6,000	6,000
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 41,724	$ 30,294

Investments

The Company invests primarily in U.S. Government securities, corporate bonds, commercial paper and asset-backed securities 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.

Revenue Recognition

On January 1, 2018, the Company adopted Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) No. 606, “Revenue from Contracts with Customers”, utilizing the modified retrospective method applied to contracts that were not completed. The adoption of the standard did not have a material impact on the timing and amounts of the Company’s revenue, processes or internal controls. Upon adoption, the Company did not have any material remaining performance obligations, significant judgements, or material costs to obtain or fulfill contracts with its customers.

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 significant 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 a significant 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 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 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 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. 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, 2018	$ 11,065	32	69
Closing, December 31, 2018	15,321	18	42
Increase (decrease)	4,256	(14)	(27)
Opening, January 1, 2019	$ 15,321	18	42
Closing, December 31, 2019	16,944	14	15
Increase (decrease)	1,623	(4)	(27)

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 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 $1,092 and $1,117 at December 31, 2019 and 2018, 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.

Inventories

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, 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 distributed 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.

Leases

The Company adopted Accounting Standards Update ("ASU") No. 2016-02—Leases (Topic 842) ("ASU 2016.02"), as of January 1, 2019, (the "Application Date") 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 modified retrospective approach provides a method for recording on the balance sheet as of January 1, 2019, leases that have commenced on or before the Application Date.

The Company elected the package of practical expedients permitted under the transition guidance, which allowed us to not reassess whether any existing contracts contain a lease, to not reassess historical lease classification as operating or finance leases, and to not reassess initial direct costs. The Company also elected the practical expedient allowing us to not separate the lease and non-lease components for all classes of underlying assets, apart from equipment. The Company did not elect the practical expedient to use hindsight to determine the lease term for leases at January 1, 2019.

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.

Adoption of the new standard resulted in the recording of right-to-use assets and lease liabilities of approximately $3,786 and $3,823, respectively, and the derecognition of capital lease assets, capital lease liabilities, and operating lease deferred rent of $96, $63, and $70, respectively, as of January 1, 2019 with zero cumulative-effect adjustment to retained earnings. The new standard did not materially impact our consolidated net earnings.

Net Loss Per Share

Basic and diluted net loss per share is computed in accordance with FASB ASC 260, "Earnings Per Share" (ASC 260), by dividing the net loss by the weighted average number of common shares outstanding during the period. Since the Company has experienced net losses for all periods presented, options and awards of 1,556,818, 2,621,440 and 2,253,399 which were outstanding as of December 31, 2019, 2018 and 2017, respectively, were not included in the computation of diluted net loss per shares because dilutive shares are not factored into the calculation of net loss per share when a loss applicable to common shares as they would be anti-dilutive. See additional outstanding shares as disclosed in Note 11, "Equity Compensation Plans" that could potentially be dilutive.

Research and Development Costs

Research and development costs are expensed as incurred and were $17,514, $11,773 and $6,699 for the years ended December 31, 2019, 2018 and 2017, 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, 2019, 2018 and 2017 was $10,304, $7,606,and $3,609, 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 Multi-Point 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 11 – 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 revenues and expenses during the reporting period. Management believes the critical accounting policies regarding revenue recognition, allowance for uncollectible accounts receivable, investments, inventories and share-based employee compensation affect our 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 February 2016, the FASB issued ASU 2016-02. This update will increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This update is effective for annual and interim reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. In July 2018, the FASB issued ASU No. 2018-11, Targeted Improvements to ASC 842, Leases ("ASU 2018-11"). ASU 2018-11 provided entities with an alternative modified transition method to elect not to recast the comparative periods presented when adopting ASC 842. The impact of the adoption is disclosed in the Leases section of Note 3, Summary of Significant Accounting Policies.

In August 2018, the FASB issued ASU No. 2018-15, Guidance on Cloud Computing Arrangements ("ASU 2018-15"). 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. Specifically, the ASU amends ASC 350 to include in its scope implementation costs of a CCA that is a service contract and clarifies that a customer should apply ASC 350-40 to determine which implementation costs should be capitalized. This update is effective for annual and interim reporting periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact this standard will have on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. We will adopt ASU 2016-13 as of January 1, 2020. We are currently evaluating the impact the standard may have on our consolidated financial statements.

In May 2019, the FASB issued ASU No. 2019-04, Codification Improvements to Topic 326, Financial Instruments – Credit Losses, Topic 815, Derivatives and Hedging and Topic 825, Financial Instruments ("ASU 2019-04"). ASU 2019-04 clarifies certain aspects of accounting for credit losses, hedging activities, and financial instruments. This update is effective fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently assessing the impact the guidance will have on its consolidated financial statements.

In May 2019, the FASB issued ASU No. 2019-05, Targeted Transition Relief ("ASU 2019-05"). ASU 2019-05 provides transition relief for entities adopting ASU 2016-13, Measurement of Credit Losses on Financial Instruments. The amendment allows entities to irrevocably elect, upon adoption of ASU 2016-13, the fair value option on financial instruments that (1) were previously recorded at amortized costs and (2) are within the scope of ASC 326-20, Financial Instruments – Credit Losses: Measured at Amortized Costs, if the instruments are eligible for the fair value option under ASC 825-10, Financial Instruments: Overall. This update is effective fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently assessing the impact the guidance will have on its consolidated financial statements.

In November 2019, the FASB issued ASU No. 2019-11, Credit Losses (Topic 326), Codification Improvements to Topic 326, Financial Instruments – Credit Losses. This amendment amends certain aspects of the new credit loss standard, ASU 2016-13 (ASC 326). As the Company has not adopted ASU 2016-13, the effective date of this amendment is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. We will adopt ASU 2016-13 as of January 1, 2020. The Company is currently assessing the impact the guidance will have on its consolidated financial statements.

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.

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.

4. Inventories

Inventories are comprised of unprocessed tissue, work-in-process, Avance Nerve Graft, Axoguard Nerve Connector, Axoguard Nerve Protector, Avive Soft Tissue Membrane, Axoguard Nerve Cap, 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 and consist of the following:

	December 31, 2019	December 31, 2018
Finished goods	$ 10,403	$ 9,194
Work in process	730	454
Raw materials	2,728	2,334
Inventories	$ 13,861	$ 11,982

For the years ended December 31, 2019, 2018 and 2017, the Company had recorded a provision for inventory write-downs of $1,887, $1,343 and $1,438, respectively, primarily relating to product expiration.

5. Fair Value of Investments

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.

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, 2019:

	(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

	(Level 1)	(Level 2)	(Level 3)	Total
December 31, 2018				
Assets:				
Money market funds	$ 12,947	$ —	$ —	$ 12,947
U.S. government securities	15,923	—	—	15,923
Corporate bonds	—	31,495	—	31,495
Commercial paper	—	27,869	—	27,869
Asset-backed securities	—	17,025	—	17,025
Total assets	$ 28,870	$ 76,389	$ —	$ 105,259

There were no changes in the levels or methodology of the measurement of financial assets or liabilities during the year ended December 31, 2019 and December 31, 2018. The maturity date of all of the Company's investments is less than one year.

6. Property and Equipment

Property and equipment consist of the following:

	December 31, 2019	December 31, 2018
Furniture and equipment	$ 2,059	$ 1,763
Leasehold improvements	2,203	1,151
Processing equipment	2,772	2,349
Land	731	731
Projects in process	10,886	4,906
Property and equipment, at cost	18,651	10,900
Less: accumulated depreciation and amortization	(3,764)	(2,861)
Property and equipment, net	$ 14,887	$ 8,039

Depreciation expense for the years ended December 31, 2019, 2018 and 2017 was $933, $774 and $488, respectively.

7. Intangible Assets

The Company's intangible assets consist of the following:

	December 31, 2019	December 31, 2018
License agreements	$ 1,067	$ 1,034
Less: accumulated amortization	(647)	(553)
License agreements, net	$ 420	$ 481
Trademarks	334	255
Patents	845	500
Less: accumulated amortization	(84)	(55)
Patents, net	$ 761	$ 445
Intangible assets, net	$ 1,515	$ 1,181

License agreements are being amortized over periods ranging fromseventeen to twenty years. Patents are being amortized over periods up to twenty years. Amortization expense for 2019, 2018 and 2017 was approximately $123, $77 and $79, respectively. In January 2019, the Company rebranded its logo and product name designs, as a result the Company recorded a $104 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, 2019, future amortization of patents and license agreements are as follows:

Year Ending December 31,	
2020	137
2021	137
2022	138
2023	119
2024	47
Thereafter	603
TOTAL	1,181

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 $2,119, $1,661 and $1,195 for the years ended December 31, 2019, 2018 and 2017, respectively, and are included in sales and marketing expense on the accompanying consolidated statements of operations.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consists of the following:

	December 31, 2019	December 31, 2018
Accounts payable	$ 8,262	$ 4,517
Accrued expenses	3,237	2,004
Accrued compensation	7,631	6,477
Accounts Payable and Accrued Expenses	$ 19,130	$ 12,998

9. Term Loan Agreements and Long-Term Debt

Term Loan Agreement and Long-Term Debt consist of the following:

	December 31, 2019	December 31, 2018
Equipment Lease Agreement with Cisco Capital for a total lease amount of $59 which has a 36 month term and requires no lease payments for the first three months of the lease and 33 equal payments of principal and interest until the end of the term. Interest on the lease is payable monthly at 3.5% per annum.	—	15
Equipment Lease Agreement with Raymond Leasing Corporation for a total lease amount of $30 which has a 48 month term with equal payments for principal and interest until the end of the term. Interest on the lease is payable monthly at 6.7% per annum.	—	22
Equipment Lease Agreement with B&B Office Systems for a total lease amount of $32 which has a 60 month term with equal payments for principal and interest until the end of the term. Interest on the lease is payable monthly at 8.5% per annum.	—	26
Total	—	63
Less current revolving loan	—	—
Less current maturities of long-term debt	—	(28)
Long-term portion	$ —	$ 35

Credit Facilities

MidCap Term Loan Agreement

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

The Company had 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, the Company exercised its 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, the Company charged to interest expense the unamortized deferred financing costs associated with the Term Loan of $473.

The Company 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, the Company exercised its option to terminate and paid $2,958 to prepay the Revolving Loan in full, which amount included fees of $236.

10. 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.

Public Offerings

On May 8, 2018, the Company 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 the Company agreed to issue and sell 3,000,000 shares of the Company's common stock in an underwritten registered public offering at an offering price of $41.00 per share (the "2018 Offering"). The Company 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 the Company received proceeds of approximately $132,707 from the sale of the shares (including the sale of450,000 additional shares issued upon exercise of the 2018 Offering Underwriters' overallotment option), after deducting the underwriting discounts and commissions and estimated offering expenses.

11. 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").

Stock Incentive Plan

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, 2019, 3,265,188 shares of common stock were available for issuance under the New Axogen Plan.

The options granted to employees prior to July 1, 2017 typically vest25% one year after the grant date and 12.5% every six months thereafter for the remaining three-year 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-year 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 fromseven to ten years.

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 $10,304, $7,606 and $3,609 for the fiscal year ended December 31, 2019, 2018, and 2017, respectively.

The Company estimates the fair value of each option award issued under such plans on the date of grant using a Multiple Point 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 2019 and 2018 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, 2017:	4,304,201	$ 7.28	5.39	$ 90,473
Granted	656,250	29.48		
Forfeited	(40,473)	9.56		
Exercised	(1,026,807)	3.72		
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
Vested and expected to vest	3,420,181	$ 12.69	5.68	$26,074
Exercisable at December 31, 2019	2,099,616	$ 7.90	4.10	$22,712

Restricted and Performance Stock Units	Number of Shares Outstanding	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2017:	610,730	$ 21.14
Granted	516,433	23.34
Released	(7,150)	8.95
Forfeited	(13,650)	25.89
Outstanding at December 31, 2018:	1,106,363	22.18
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

The intrinsic value of equity awards exercised during the years ended December 31, 2019, 2018 and 2017 was $9,553, $34,229 and $7,783, respectively. As a result of the Company's full valuation allowance on its net deferred tax assets, no tax benefit was recognized related to the exercises of stock options. 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 2019, 2018 and 2017, $4,002, $3,884 and $1,434, 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 total fair value of restricted stock vested during 2019, 2018 and 2017 was $1,467, $196 and $108. The Company issues registered shares of common stock to satisfy stock option exercises and restricted stock grants.

As of December 31, 2019, there was$19,460 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 2.14 years for stock options and2.63 years for restricted stock awards.

On December 18, 2017, 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 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. The Company estimated 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 will record 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 and can range from zero to 200,000 shares. The fair value of the common stock on the grant date was $16.88 on December 17, 2019, $19.17 on December 27, 2018 and $27.00 on December 18, 2017. The total unrecognized future compensation expense related to this PSU, assuming achievement of 100% of the target award is $17,682. Assuming the minimum of 0% and the maximum of 100% payout opportunity for the PSU, the range of total future compensation expense related to this PSU award is between $0 and $17,682 as of December 31, 2019.

Employee Stock Purchase Plan

The 2017 ESPP, which was effective as of January 1, 2018, allows for eligible employees to acquire shares of our 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, 2019 , there were 600,000 shares of common stock authorized for issuance under the 2017 ESPP and450,305 were available for future issuance.

Valuation and Expense Information Under FASB ASC 718

The Company estimates the fair value of each option grant using a Multiple Point Black-Scholes option-pricing model which uses a weighted average of historical volatility and peer company volatility. The Company determines the expected life 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.

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

Year ended December 31,	2019	2018	2017
Expected term (in years)	5.76	6.22	6.16
Expected volatility	54.97 %	50.99 %	50.43 %
Risk free rate	1.71 %	2.70 %	2.12 %
Expected dividends	— %	— %	— %

The fair value of restricted stock awards is based on the market value of the Company's common stock on the date of the 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, 2019, 2018 and 2017, respectively, was as follows:

	2019	2018	2017
Stock options	$ 18.07	$ 15.05	$ 8.41
Restricted and performance stock units	17.60	23.34	26.24

12. 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	2019	2018	2017
Deferred tax assets:			
Net operating loss carryforwards	$ 36,250	$ 30,588	$ 27,578
Inventory write down	317	273	206
Depreciation	136	117	—
Amortization	—	—	23
Interest limitation	—	336	—
Allowance for doubtful accounts	274	285	117
Right-of-use liability	837	—	—
Stock-based compensation	3,140	2,335	520
Total deferred tax assets	40,954	33,934	28,444
Deferred tax liabilities:			
Depreciation	—	—	(81)
Amortization	(206)	(43)	—
Right-of-use asset	(809)	—	—
Contract liabilities	(7)	(15)	(6)
Net deferred tax assets	39,932	33,876	28,357
Valuation allowance	$ (39,932)	$ (33,876)	$ (28,357)

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, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
Federal tax rate	21.0 %	21.0 %
State Taxes - Net of Federal Benefit	4.1	4.1
Permanent items and other deductions	(4.3)	(0.5)
Valuation allowance	(20.8)	(24.6)
Effective income tax rate	__ %	__ %

As of December 31, 2019 and 2018, 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, 2019. The valuation allowance increased by $6,056 and 5,519 during 2019 and 2018, primarily as a result of current year increase in the net operating loss carry forward. During 2017, the valuation allowance decreased by $10,754, 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, 2019, the Company had tax-effected net operating loss carry forwards of approximately $36,250 to offset future taxable income which expire in various years through 2039. 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 2017, 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 2017, 2018 and 2019 due to incurrence of net operating losses. The Company does not believe there are any additional tax refund opportunities currently available.

13. 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 $988, $650 and $439 in matching funds during the years ended December 31, 2019, 2018 and 2017, respectively.

14. Commitments and Contingencies

We lease 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; we recognize lease expense for these leases on a straight-line basis over the lease term.

Certain of our 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 our lease obligations and right-to-use assets.

Certain of our 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. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants.

The Company 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 the Company leases its approximately nineteen thousand square foot corporate headquarters facility in the Progress Center at 13631 Progress Boulevard, Alachua, Florida 32615 (the "Primary Premises"). The annual cost for the Primary Premises ranges from $353 to $363 through the end of the term of the lease, which expires on October 31, 2021. On January 23, 2017 the Company entered into a lease (the "First Expansion Lease") with SNH for one thousand four hundred square feet at 13709 Progress Boulevard, Alachua, Florida 32615 (this property was purchased by Nucleic Acids Licensing, LLC in February 2019) (the "First Expansion Premises") adjacent to the Primary Premises. The Company has entered into the Second Expansion Lease and Third Expansion Lease, as defined below, which relate to properties that are adjacent to the Primary Premises and First Expansion Premises resulting in the Company having approximately twenty thousand square feet for its corporate headquarters and certain research space in the Progress Center in Alachua, Florida.

On November 19, 2018, the Company entered into a Lease (the "Second Expansion Lease") with SNH for two thousand eight hundred square feet at 13709 Progress Boulevard, Suites S-160, S-162 and S-164, Alachua, Florida 32615 (the "Second Expansion Premises"). Pursuant to the Second Expansion Lease, AC is to use the Second Expansion Premises for general office uses. The Second Expansion Lease commenced December 1, 2018 and expires November 30, 2020. The annual cost of the Second Expansion Premises is approximately $45 for the first twelve months of the term and $46 for the final twelve months. The Company is also obligated to pay for certain taxes, insurance costs and electricity costs incurred by SNH.

On November 19, 2018, AC entered into a Lease (the "Third Expansion Lease") with SNH for two thousand square feet at 13709 Progress Boulevard, Suites S-175, S-177 and S-179, Alachua, Florida 32615 (the "Third Expansion Premises"). Pursuant to the Third Expansion Lease, the Company is to use the Third Expansion Premises for general office and biomedical research uses. The Third Expansion Lease commenced December 1, 2018 and its term expires November 30, 2020. The annual cost of the Third Expansion Premises is approximately $37 for the first twelve months of the term and $35 for the final eleven months. The Company is also obligated to pay for certain taxes, insurance costs and electricity costs incurred by SNH.

On November 21, 2018, the Company, 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, the Company 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 annual rental cost of the entire Burleson Facility is now approximately $113 through December 31, 2020,$116 for the calendar year 2021 and until April 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 26, 2018, the Company entered into a Lease (the "Ashley Avenue Lease") with Ashley Avenue Associates I, LLC., a Delaware limited liability company ("Ashley"), for the lease by the Company of approximately fifteen thousand square feet of office space on the second floor of the building located at 1000 N. Ashley Drive, Tampa, Florida 33602 (the "Ashley Avenue Premises"). Pursuant to the Ashley Avenue Lease, the Company will use the Ashley Avenue Premises for general office purposes. The initial term of the Ashley Avenue Lease commenced on December 1, 2018 and expires on November 30, 2020. The Company has an option to terminate the lease after eighteen months by providing Ashley with four months advance written notice. The rental cost for the Ashley Avenue Premises will be $381 for the first twelve month period, and$360 for the final eleven month period. The Company will also be obligated to pay for its pro rata share of the building's property taxes, utilities, administrative costs, common area maintenance and management fees, excluding any capital improvements or any damage due to fire, hurricane or other casualty.

On September 20, 2018, the Company 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 onehundred and fifty thousand square foot office building that Heights Union intends to construct and complete on or before September 30, 2020, on an area of land in Tampa, Florida. Pursuant to the Heights Union lease, the Company will use the Heights Union Premises for general office, medical laboratory, training and meeting purposes. The annual costs of the Heights Union Premises ranges from $2,400 to $3,308 during the term of the lease. Axogen believes it can obtain certain economic incentives from state authorities associated with the employment at the facility; such incentives are not expected to be a material offset to the expenses of the project as a whole.

In addition, Axogen leases space and maintains records at certain other facilities, including the Company's prior corporate headquarters at 1407 South Kings Highway, Texarkana, Texas 75501.

The components of total lease expense for the year ended December 31, 2019 were as follows:

For the Fiscal Year Ended December 31, 2019:		Amount
Finance lease costs		
Amortization of right-to-use assets	$	22
Interest on lease liabilities		4
Operating lease costs		1,910
Short term lease costs		41
Variable lease costs		17
Total lease cost	$	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, 2019 was as follows:

		Amount
Operating Leases		
Operating lease right-of-use assets	$	3,133

Current maturities of long-term obligations	$	1,719
Long term obligations	$	1,565
Finance Leases		
Finance lease right-of-use assets	$	87
Current maturities of long-term obligations	$	17
Long term obligations	$	30

Other information related to leases was as follows:

		Amount
Cash paid for amounts included in the measurement of operating lease liabilities	$	1,773
Right-to-use assets obtained in exchange for new finance lease liabilities	$	16
Weighted-average remaining lease term - finance leases		3
Weighted-average remaining lease term - operating leases		2
Weighted-average discount rate - finance leases		7.28%
Weighted-average discount rate - operating leases		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, 2019 were as follows:

Year Ending December 31,		Operating Leases		Finance Leases
2020		2,664		19
2021		4,007		19
2022		2,573		10
2023		2,581		3
2024		2,644		1
Thereafter		27,251		—
Total Future Minimum Lease Payments	$	41,720	$	52
Less future payments for leases that have not yet commenced		(38,246)		—
Less imputed interest on commenced leases		(190)		(5)
Total Lease Liability	$	3,284	$	47

The lease for office space in Tampa, Florida with Heights Union, LLC, a Florida limited liability company, has not commenced and is therefore not included in the measurement of right-to-use assets and lease liabilities.

As previously disclosed in our 2018 Annual Report on Form 10-K, which followed the lease accounting guidance prior to our adoption of ASC 842, future commitments relating to noncancelable operating and capital leases as of December 31, 2018 were as follows:

Year Ending December 31,	Operating	Capital
2019	1,866	28
2020	2,540	13
2021	3,970	15
2022	2,518	7
2023	2,574	—
Thereafter	30,111	—
Total	$ 43,579	$ 63

Total rent expense for the Company's leased office and lab space for the years ended December 31, 2019, 2018 and 2017 was $16, $484 and $494, respectively.

Service Agreements

On August 6, 2015, Axogen entered into a License and Services 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. Subsequent to the year ended December 31, 2018, on February 22, 2019, Axogen Corporation and CTS entered into a fourth amendment to the License and Services Agreement wherein the term of the agreement was extended such that the Occupancy Date in section 12.01 of the agreement shall end on December 31, 2021, 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 by Axogen without cause upon six 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, which has been determined to be an embedded operating lease. 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. 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 $2,148 for the year ended December 31, 2019, $1,931 for the year ended December 31, 2018 and $1,409 for the year ended December 31, 2017.

In December 2011, the Company also 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 a BLA for Avance Nerve Graft.

In August 2008, the Company entered into an agreement to distribute the Axoguard Nerve Connector and Nerve Protector 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 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 products. Under the Distribution Agreement, Axogen provides purchase orders to Cook Biotech, and Cook Biotech fulfills the purchase orders.

In June 27, 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 Axogen 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 four products, Avance Nerve Graft, Axoguard Nerve Protector, Axoguard Nerve Connector and Avive Soft Tissue Membrane. 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 revenues, as well as a potential harm to the Axogen's business reputation and financial results. The CTS agreement terminates December 31, 2021, 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 by Axogen without cause, upon 6 months' prior notice, whereby notice cannot be provided prior to March 1, 2021. Although Axogen believes it can find and make operational a new facility in less than six months if required. 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 our 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 70,000 square foot building on approximately 8.6 acres of land. The Company paid $731 for the land and is recorded as Land within our property and equipment account on our 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.

On July 9, 2019, Axogen 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. 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 2020, subject to adjustment in accordance with the terms of the Design-Build Agreement. The estimated cost pursuant to the Design-Build Agreement is $29,000. Additional costs associated with the renovation, purchasing of furniture and equipment, validation and certification of the APC are estimated to be $14,400. These capital expenditure costs will be incurred as they arise until the anticipated full transition of material processing to the APC by early 2022.

As of December 31, 2019, the Company has recorded $6,066 related to renovations and design build. 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.

As previously disclosed the Company previously 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. Pursuant to the Heights Union lease, the Company will use the Heights Union Premises for general office, medical laboratory, training and meeting purposes. The Company anticipates occupying the premises by the second quarter of 2020. Associated with the lease, the Company anticipates spending up to $9,833 for leasehold improvements, equipment and furniture and fixtures. As of December 31, 2019, the Company has recorded $441 of leasehold improvements to the new facility.

Litigation

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 and are currently awaiting the court's ruling. Plaintiff is seeking compensatory damages, reimbursement of expenses and costs, including counsel and expert fees and such other relief as the court deems just and proper. 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.

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.

15. Quarterly Results of Operations (Unaudited)

The following is a summary of the quarterly results of operations for the years ended December 31, 2019 and 2018:

	Quarter				
	First	Second	Third	Fourth	Total
2019					
Revenues	$ 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)
2018					
Revenues	$ 17,260	$ 20,584	$ 22,660	$ 23,433	$ 83,937
Gross profit	14,547	17,478	19,196	19,793	71,014
Net loss	(5,644)	(7,427)	(4,102)	(5,224)	(22,397)
Loss per common share - basic and diluted	(0.16)	(0.20)	(0.11)	(0.13)	(0.60)

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

The Company maintains "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.

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, 2019 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 disclosure controls and procedures as of December 31, 2019. 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 disclosure controls and procedures 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, 2019. This report states that the internal control over financial reporting was effective and appears on page 81 of this Annual Report on Form 10-K.

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 2020 annual meeting, and is incorporated herein by reference.

Information required by this item concerning compliance with Section 16(a) of the Exchange Act, as amended, will be set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for our 2020 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 2020 annual meeting, and is incorporated herein by reference.

The Board of Directors adopted a Code of Ethics, which is posted on our website http://ir.Axogeninc.com/governance.cfm 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 Company's chief executive officer, principal accounting officer or controller, or persons performing similar functions) the Company intends 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 2020 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 2020 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 2020 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 2020 annual meeting, and is incorporated herein by reference.

PART IV

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.

Schedule II – Valuation and Qualifying Accounts

AXOGEN, INC.
SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS
THREE YEARS ENDED DECEMBER 31, 2019, 2018 AND 2017

	Balance at Beginning of Year	Additions	Deductions (Chargeoffs)	Balance at End of Year
Allowance for doubtful accounts				
2017	272	223	(34)	461
2018	461	852	(196)	1,117
2019	1,117	514	(539)	1,092
Valuation allowance for deferred tax assets				
2017	39,111	—	(10,754)	28,357
2018	28,357	5,519	—	33,876
2019	33,876	5,977	—	39,853

(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.
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	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).
**10.7.1	Executive Employment Agreement, effective as of October 15, 2007, by and between Axogen Corporation and Karen Zaderej (incorporated by reference to Exhibit 10.8.1 to the Company's Current Report on Form 8-K filed on October 6, 2011).
10.9.1	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).
10.9.2	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).
10.9.3	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).
10.9.4	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).
**10.10.1	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).
**10.10.2	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).
**10.11.1	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).
**10.11.2	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).

Exhibit Number	Description
**10.11.3	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).
**10.11.4	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).
**10.11.5	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).
10.12.1	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).
10.12.2	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).
10.12.3	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).
10.12.4	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)
10.13	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).
10.13.1	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).
10.15	Securities Purchase Agreement dated as of November 12, 2014, between Axogen, Inc., and PDL BioPharma, Inc. (incorporated by reference to Exhibit 10.4 to Amendment No. 1 on Form 8-K/A to the Company's Current Report on Form 8-K filed on November 13, 2014, filed on February 4, 2015).
10.16	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).
10.17	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).

Exhibit Number	Description
**10.18	Executive Employment Agreement, dated as of February 25, 2016, by and between Axogen Corporation and Peter Mariani (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed on May 4, 2016).
**10.19	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).
* 10.20	Credit and Security Agreement (Term Loan), dated as of October 25, 2016, by and among Axogen, Inc., Axogen Corporation, MidCap Financial Trust, MidCap Funding XIII Trust and MidCap Funding V Trust (incorporated by reference to Exhibit 10.20 to the Company's annual report on Form 10-K for the year ended December 31, 2016, filed on March 1, 2017).
* 10.21	Credit and Security Agreement (Revolving Loan), dated as of October 25, 2016, by and among Axogen, Inc., Axogen Corporation and MidCap Financial Trust (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).
10.22	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).
*10.23	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).
**10.24	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).
10.25	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).
**10.26	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).
10.27	Underwriting Agreement by and between the Company, EW Healthcare Partners L.P. and Leerink Partners LLC, as representative of the underwriters named therein, dated November 16, 2017 (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on November 16, 2017).
**10.28	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).

Exhibit Number	Description
10.29	Current Premises Election Notice, dated as of April 10, 2018, by and between Axogen Corporation andSNH 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).
10.30	Underwriting Agreement by and among the Company, Jefferies LLC and Leerink Partners LLC, as representatives of the underwriters named therein, dated May 8, 2018 (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on May 14, 2018).
10.31	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).
**10.32	Executive Employment Agreement dated September 4, 2018, 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 September 7, 2018).
10.33	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).
10.34	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).
10.35	Agreement of Lease dated October 26, 2018, by and between Ashley Avenue Associates I, LLC and Axogen Corporation (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 29, 2018).
**10.36	Executive Employment Agreement, dated as of October 29, 2018, by and between Axogen Corporation and Isabelle Billet (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on October 29, 2018).
**10.37	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).
**10.38	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).
**10.39	Executive Employment Agreement, dated as of October 29, 2018, by and between Axogen Corporation and Maria Martinez (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed on October 29, 2018).
10.40	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).
10.41	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).

Exhibit Number	Description
10.42	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).
**10.43	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).
**10.44	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).
**10.45	Executive Employment Agreement dated as of January 21, 2019, by and between Axogen Corporation and Eric Sandberg (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 22, 2019).
**10.46	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).
**10.47	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).
10.48	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).
10.49	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).
**10.50	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).
***+10.51	Nerve End Cap Supply Agreement, dated June 27, 2017, by and between Cook Biotech Incorporated and Axogen Corporation.
+21.1	Subsidiaries of the Registrant.
+23.1	Consent of Lurie, LLP.
+23.2	Consent of Deloitte & Touche, LLP.
++24.1	Power of Attorney.
+31.1	Certification of Principal Executive Officer.
+31.2	Certification of Principal Financial Officer.

Exhibit Number	Description
+++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.
+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
February 24, 2020

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 Director (Principal Executive Officer)	February 24, 2020
/s/ Peter Mariani Peter Mariani, CFO (Principal Financial Officer) (Principal Accounting Officer)	February 24, 2020
/s/ Gregory G. Freitag Gregory G. Freitag, General Counsel and Director	February 24, 2020
/s/ Dr. Mark Gold Mark Gold, M.D. Director	February 24, 2020
/s/ Guido J. Neels Guido J. Neels Director	February 24, 2020
/s/ Robert J. Rudelius Robert J. Rudelius Director	February 24, 2020
/s/ Amy Wendell Amy Wendell Director	February 24, 2020
/s/ Quentin S. Blackford Quentin S. Blackford Director	February 24, 2020
/s/ Alan M. Levine Alan M. Levine Director	February 24, 2020

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, the only class of securities of Axogen, Inc., a Minnesota corporation (the "Company"), registered under Section 12 of the Securities Exchange Act of 1934, as amended, is common stock, par value $0.01 per share ("Common Stock"). The Company's Common Stock is listed on the Nasdaq Capital Market under the symbol "AXGN".

Under the Company's Amended and Restated Articles of Incorporation (the "Articles"), the Company is authorized to issue up to 100,000,000 shares of Common Stock, par value $0.01 per share. As of February 21, 2020, 39,731,078 shares of Common Stock were issued and outstanding.

Dividends, Voting Rights and Liquidation

The holders of shares of Common Stock: (i) have equal, ratable rights to dividends from funds legally available therefor, when, as and if declared by the Board of Directors of the Company, (ii) are entitled to share ratably in all assets available for distribution to holders of shares of Common Stock upon liquidation, dissolution or winding up of the Company's affairs, (iii) do not have preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions applicable thereto and (iv) are entitled to one vote per share on all matters which shareholders may vote on at all meetings of shareholders. Except as otherwise required by statute, the Articles or the Company's Amended and Restated Bylaws, all matters are decided by a majority vote of the number of shares entitled to vote at the time of the vote.

Transfer Agent and Registrar

Broadridge Corporate Issuer Solutions, Inc. is the transfer agent and registrar for the Company's Common Stock.

Minnesota Anti-Takeover Laws

The Company is governed by the provisions of Sections 302A.671, 302A.673 and 302A.675 of the MBCA. These provisions may discourage a negotiated acquisition or unsolicited takeover of the Company and deprive the Company's 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 the Company's 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 the Company's 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 the Company's 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.

Registration Rights

In connection with that certain Securities Purchase Agreement, dated as of August 26, 2015, between the Company and EW Healthcare Partners L.P., formerly named Essex Woodlands Fund IX, L.P. ("Essex"), the Company also entered into a Registration Rights Agreement with Essex, pursuant to which the Company granted Essex certain demand and "piggy-back" registration rights with respect to its shares of the Company's Common Stock. The resale of all of Essex's shares has been registered pursuant to the Registration Rights Agreement.

Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*".**

NERVE END CAP SUPPLY AGREEMENT

This Commercial Supply Agreement (this "Agreement") is entered into and effective this day of June, 2017, by and between Cook Biotech Incorporated, an Indiana corporation ("**COOK**"), having a place of business at 1425 Innovation Place, West Lafayette, Indiana 47906, and AxoGen Corporation, a Delaware corporation having a place of business at 13631, Suite 400, Progress Blvd, Alachua, FL, 32615 **("PURCHASER" or "DISTRIBUTOR")**

RECITALS

1. PURCHASER is engaged in the sale and marketing of medical devices;

2. COOK is engaged in the manufacture and sale of medical devices;

3. PURCHASER and COOK desire to have COOK manufacture certain medical devices for use in surgical procedures for peripheral nerve termination, for sale to and resale by PURCHASER.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the parties agree as follows:

Article 1, DEFINITIONS

As used in this Agreement the following words and phrases shall have the following meanings:

1.1 **"Affiliate"** of a party hereto shall mean any entity that controls or is controlled by such party, or is under common control with such party. For purposes of this definition, an entity shall be deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting equity of another entity (or other comparable ownership interest for an entity other than a corporation)..

1.2 **"Cancellation Foes"** shall be the fees payable by PURCHASER for modification or cancellation of a Finn Purchase Order.

1.3 **"Confidential Information"** shall mean all information and data provided by one party to the other party except any portion of such information and data which:

(i) is known to the recipient as evidenced by its written records before receipt thereof from the disclosing party;

(ii) is disclosed to the recipient by a third person who has the right to make such disclosure;

(iii) is or becomes part of the public domain through no fault of the recipient; or

(iv) the recipient can reasonably establish is independently developed by recipient without access to the information disclosed by the disclosing party.

1.4 **"Contract Requirements"** shall mean one hundred percent (100%) of the quantity of a Device used, sold and/or distributed by PURCHASER in the Territory.

1.5 **"Current Good Manufacturing Practices"** or **"cGMP"** shall mean the good manufacturing practices required by the FDA and set forth in the FD&C Act or FDA Regulations (including without limitation 21 CFR 820), policies or guidelines, in effect at any time during the term of this Agreement, for the manufacture of Devices.

1.6 **"Delivery Date"** shall mean the date that Device is delivered to a common carrier chosen by COOK.

1.7 **"Device or Devices"** shall mean the medical device(s) defined on **Exhibit "A"** attached hereto and by reference made a part hereof.

1.8 **"Device History Record"** shall mean a compilation of records containing the manufacturing history for the Device.

1.9 **"Device Master Record"** shall mean, with respect to the Device a compilation of records containing the procedures and specifications for the Device.

1.10 **"Distribution Agreement"** shall mean the Distribution Agreement between PURCHASER and COOK dated August 27, 2008 as amended.

1.11 **"Effective Date"** shall mean the date of this Agreement as set forth above.

1.12 **"FDA"** shall mean the United States Food and Drug Administration or any successor entity thereto.

1.13 **"FD&C Act"** shall mean the United States Federal Food, Drug and Cosmetic Act, as may be amended from time to time.

1.14 **"Lot"** shall mean a specific quantity of a Device comprising a number of Units mutually agreed upon between PURCHASER and COOK, and that (a) is intended to have uniform character and quality within specified limits, and (b) is manufactured according to a single manufacturing order during the same cycle of manufacturing.

1.15 **"Purchase Order"** shall mean written orders from PURCHASER to COOK which shall specify (a) the quantity of Devices ordered, (b) delivery dates, and (c) delivery destinations.

1.16 **"Regulatory Authority"** shall mean those agencies or authorities responsible for regulation of the Devices in United States.

1.17 **"Specifications"** shall mean the specifications for the Devices that are set forth on**Exhibit "A"** as may be modified by agreement of the parties hereto.

1.18. **"Territory"** shall mean worldwide.

Article 2, PURCHASE AND SUPPLY OF DEVICE

2.1 **Agreement to Purchase and Supply.** Pursuant to the terms and conditions of this Agreement, PURCHASER shall purchase from COOK the Contract Requirements of Device, and COOK shall use good faith efforts to manufacture and deliver to PURCHASER the Contract Requirements of Device in accordance with this Agreement. During the Term, COOK shall exclusively sell the Device to PURCHASER subject to the terms and conditions of this Agreement; for clarity, nothing in this Agreement will limit COOK's right to make, use, sell, offer to sell or import products other than the Device.

2.2 **Reproduction, Rework or Reprocessing.** If during the manufacture of any Lot, any reprocessing, rework, or reproduction is required in order to meet the Specifications, COOK shall conduct such reprocessing, rework, or reproduction in compliance with cGMPs. Any reprocessing, rework or reproduction which is not covered by cGMPs must be approved in writing by PURCHASER prior to implementation. Unless such reprocessing, rework or reproduction is required solely as a result of changes required to be made to the Specifications as agreed to by the parties, or the negligence or willful misconduct of PURCHASER, COOK shall be responsible for all costs and expenses incurred in connection with such reprocessing, rework or reproduction.

2.3 **Cook Storage.**

2.3.1 **Device Storage.** In no event shall COOK be required to store Devices for more than thirty (30) days after the Device is manufactured without COOK's prior written consent and PURCHASER' s agreement to reimburse COOK for all costs incurred in connection with such storage.

2.3.2 **Third Party Storage.** COOK shall be permitted to store Devices in third party storage facilities. After more than thirty (30) days from the date the Device is manufactured, COOK shall have no liability for, and PURCHASER releases all claims against COOK arising out of, any damage or loss to Devices, arising out of, or in connection with, the storage in such third-party facility.

2.4 **PURCHASER Storage, Records, Distribution and Labeling**

2.4.1 **Storage and Distribution.** PURCHASER shall distribute, handle, store and warehouse Devices in a manner that is consistent with cGMP.

2.4.2 **Records.** PURCHASER shall maintain records and documentation relating to Devices in accordance with cGMP. Records shall include, without limitation, the name, address and telephone numbers of purchasers of Devices or products incorporating Devices and catalogue

and lot numbers for such products or Devices. COOK shall have reasonable access to review and inspect such records.

2.4.3 **Labeling.** PURCHASER shall label all products incorporating Devices in compliance with cGMP, 21 CFR Part 801.

2.5 **PURCHASER Efforts**. PURCHASER shall use commercially reasonable efforts to promote, train the sales force on and solicit the sale of all Devices within the Field in the Territory, and use its commercially reasonable efforts to not promote or solicit the sale of the Device for use outside of the Field unless agreed to by the parties.

Article 3, FORECASTS, ORDERS, and CAPACITY

3.1 Forecasts and Order Limits. PURCHASER will provide COOK with an initial stocking order of Devices. Commencing on the date of this Agreement through the Term, PURCHASER shall provide to COOK weekly purchase orders. Such purchase orders will become the standard for this Agreement and continue for the Term without regard to any termination of the Distribution Agreement. Notwithstanding anything else contained herein, in no event shall COOK be obligated to accept an order for a quantity of the Device for any single month which is in excess of two hundred percent (200%) of the average number delivered to PURCHASER in three (3) months prior to such single month.

3.2 **Purchase Orders**. Prior to or on the tenth (10^{h}) calendar day of each month, PURCHASER shall submit Purchase Orders to COOK covering PURCHASER's purchases of Device pursuant to this Agreement at a minimum to replenish its stocking order pursuant to Section 3.1**.** PURCHASER shall not, without the written consent of COOK, designate a delivery date in a Purchase Order earlier than Thirty (30) calendar days from the date PURCHASER submits the Purchase Order. COOK shall provide a confirmation of receipt of each Purchase Order setting forth the delivery date that COOK will meet for such order. Upon PURCHASER's receipt of the confirmation, such Purchase Order shall become a "Firm Purchase Order." If COOK is unable to meet the specified delivery date, COOK shall so notify PURCHASER and provide to PURCHASER an alternative delivery date which shall not be more than fifteen (15) calendar days later than the initial delivery date designated by PURCHASER in its Purchase Order. In the event that PURCHASER modifies or cancels a Firm Purchase Order without COOK's written consent, PURCHASER shall pay a cancellation fee equal to fifty percent (50%) of the Purchase Price of the Devices for such Purchase Order. To the extent of any conflict between Purchase Orders submitted by PURCHASER and this Agreement, this Agreement shall control.

Article 4, PRICE

4.1 **Device Purchase Price**. The price to be paid by PURCHASER for Devices ("Purchase Price") shall be set forth in **Exhibit "B"** attached hereto and by reference made a part hereof.

4.2 **Purchase Price Adjustment**. Prior to the start of each calendar year, starting for the calendar year 2019, the parties will negotiate in good faith an increase in the Purchase

Price based on changes in the Consumer Price Index and royalty obligations of COOK, and any adjustment as required in this Section 4.2. Upon thirty (30) days written notice to DISTRIBUTOR, COOK may adjust the price of the Device during the Term to reflect changes in the cost of materials, wages and FDA or other regulatory testing requirements paid by COOK in connection with the manufacture of the device, without written agreement of DISTRIBUTOR. In no event shall COOK make such an adjustment more than once in any given twelve month period, and unless COOK demonstrates that a greater increase is needed due to increased cost of materials or FDA or other regulatory testing requirements for the Device, in no event shall any increase in the Purchase Price be more than the percentage increase of the Consumer Price Index for that year, with the following two exceptions ("Greater Increase Conditions"): 1) COOK reasonably demonstrates to DISTRIBUTOR that a greater increase in the Purchase Price is needed due to an unusual increase in the cost of direct Device materials, in which case the increase in the Purchase Price of a unit of product shall be less than or equal to the increase in the direct material costs of the Device on a per unit basis; or 2) COOK reasonably demonstrates to DISTRIBUTOR that a greater increase in the Purchase Price is needed due to the direct costs of new testing requirements for the Device from the FDA or another regulatory agency, in which case the increase in the Purchase Price of a unit of product shall be less than or equal to the increase in the costs of the End Cap Device due to the direct costs of new testing requirements on a per unit basis. If COOK claims a Greater Increase Condition exists, DISTRIBUTOR may audit the claimed Greater Increase Condition in the following manner: during normal business hours upon reasonable notice COOK will allow a certified public accountant representing DISTRIBUTOR and reasonably acceptable to COOK and who enters into a reasonable confidentiality agreement with COOK, to visit the offices of COOK to inspect books and records directly related to the Greater Increase Condition in sufficient detail to verify the existence of the Greater Increase Condition. In the event the claimed Greater Increase Condition is shown not to exist, COOK will reimburse DISTRIBUTOR for the reasonable cost of such audit and the Purchase Price will not be adjusted for the claimed Greater Increase Condition. ***"Consumer Price Index"*** means the consumer price index for all urban consumers as published by the Bureau of Labor Statistics of the U.S. Department of Labor or any successor agency that assumes responsibility for the preparation of such index.

Article 5, SHIPMENT AND INVOICING

5.1 **Delivery Terms.** COOK shall pack the Device with regularly used packing material, shall label the Device in accordance with PURCHASER's supplied label content and formatting conforming to governmental regulation, and Devices shall be delivered to PURCHASER, or to a location designated by PURCHASER in the Purchase Order, in finished packaged form ready for sale to end-users DDP (Incoterms, 2010) PURCHASER's facility in Burlington, Texas, by a common carrier designated by COOK, at COOKS' s expense. Title to the Device shall pass to Distributor when delivered to PURCHASER's facility pursuant to the terms set forth above.

5.2 **Shipment Out of U.S.** PURCHASER will be the exporter of record for any Device shipped outside of the United States. PURCHASER warrants that all shipments of Device outside of the United States will be made in compliance with all applicable United States export laws and regulations, including the Export Administration Act, and all applicable import laws and regulations.

5.3 **Payment Terms.** PURCHASER shall pay COOK for the Device net thirty (30) days from the date of the receipt of proper invoice for the Device where such invoice shall be delivered along with the relevant shipment of the Device. Payments shall be made in U.S. dollars by check delivered to COOK by overnight delivery with a reputable overnight delivery service. Each invoice shall be payable by PURCHASER in accordance with the terms noted above. Payments not received within the times noted above shall bear interest at the lesser of (a) the maximum rate permitted by law, and (b) 1.5% per month on the outstanding balance compounded monthly.

5.4 **Default in Payment Obligations.** In addition to all other remedies available to COOK in the event of a PURCHASER default, if PURCHASER fails to make payments as required hereunder, COOK may refuse all further Purchase Orders, refuse to manufacture Devices until PURCHASER's account is paid in full, modify the foregoing terms of payment, place the account on a letter of credit basis, require full or partial payment in advance, suspend deliveries of Devices until PURCHASER provides assurance of performance reasonably satisfactory to COOK, and/or take other reasonable means as COOK may determine.

Article 6, ACCEPTANCE OF DEVICE

6.1 **Device Conformity.** Within thirty (30) calendar days from the date of shipment of the Device to PURCHASER, PURCHASER shall determine whether Device conforms to the Specifications.

6.1.1 If (a) any shipment of Device conforms to the Specifications, or (b) PURCHASER fails to notify COOK within the applicable time period that any shipment of Device does not conform to the Specifications, then PURCHASER shall be deemed to have accepted the Device and waived its right to revoke acceptance.

6.1.2 If PURCHASER believes any shipment of Device does not conform to the Specifications, including after acceptance as to those Specifications that cannot be inspected for conformity until the Device package is opened ("Post Acceptance Conformity"), it shall notify COOK by telephone including a detailed explanation of the non-conformity and shall confirm such notice in writing via overnight or e-mail delivery to COOK. Upon receipt of such notice, COOK will investigate such alleged non-conformity, and (i) if COOK agrees such Device is non-conforming, deliver to PURCHASER a corrective action plan within thirty (30) calendar days after receipt of PURCHASER's written notice of non-conformity, or such additional time as is reasonably required if such investigation or plan requires data from sources other than PURCHASER or COOK, or (ii) if COOK disagrees with PURCHASER's determination that the shipment of Device is non-conforming, COOK shall so notify PURCHASER by telephone within the fifteen (15) calendar day period and confirm such notice in writing by overnight or e-mail delivery.

6.1.3 if the parties dispute whether a shipment of Device is conforming or non-conforming, including Post Acceptance Conformity, the shipment of Device will be submitted to a mutually acceptable laboratory or consultant for resolution, whose determination of conformity or non-conformity, and the cause thereof of non-conformity, shall be binding upon the parties. The

PURCHASER shall bear the costs of such laboratory or consultant, except as set forth in Section 6.2.3.

6.2 **Remedies for Non Conforming Device.**

6.2.1 In the event COOK agrees that the Devices are non-conforming or the laboratory determines that the Devices are non-conforming, COOK shall replace such non-conforming Devices as soon as commercially reasonable.

6.2.2 PURCHASER shall pay for all Devices, including replacement Devices, except as specifically set forth in Section 6.2.3.

6.2.3 In the event COOK agrees, or the laboratory or consultant determines, that the Devices are non conforming solely as a result of the negligence or willful misconduct of COOK, then, to the extent paid for by PURCHASER, COOK will credit the Purchase Price for the replacement Device to PURCHASER, and shall bear the costs of such laboratory or consultant.

Article 7, TERM AND TERMINATION

7.1 **Term.** The term of this Agreement commences on the Effective Date and continues in full force and effect until August 27, 2027 unless extended by mutual agreement of the parties or earlier terminated in accordance with this Article 7 (the "Term").

7.2 **Early Termination**. Either party may terminate this Agreement, effective immediately, without demand or judicial resolution, upon written notice to the other party, in the event of any of the following:

(i) a breach of any obligation to pay money under this Agreement, unless such obligation is disputed in good faith by the non-paying party, which breach is not cured within thirty (30) days after receiving written notice of such breach from the non-breaching party;

(ii) a breach of any non-monetary representation or warranty or obligation contemplated in this Agreement, which breach is not cured within sixty (60) calendar days after receiving written notice of such breach from the non-breaching party;

(iii) the other party's inability to pay its debts as the same become due; any assignment by the other party for the benefit of its creditors; the appointment of a receiver, liquidator, or committee of creditors for all or substantially all of the other party's business or assets; the filing of a petition for voluntary or involuntary bankruptcy or similar proceeding by or against the other party or the liquidation of the other party;

(iii) the expropriation, confiscation, or nationalization of all or substantially all of the other party's business or assets;

(iv) on a country-by-country basis, the introduction of any bill in the legislature of any national or governmental subdivision or the passage or issuance of any provision, statute, decree,

order, notice, rule or document having the force of law within any country within the Territory granting independent sales representatives, distributors, or dealers the right to receive extra contractual indemnification from principals upon the latter's termination or refusal to *renew* applicable agreements between the parties; or

(v) on a country-by-country basis, any change in the law which restricts, limits or prohibits the importation, sale, marketing or distribution of the Device.

7.3 **Additional Termination Rights.**

(i) After the fifth anniversary of the Term, either PURCHASER or Cook may terminate this Agreement, without cause, at any time upon ninety (90) days prior written notice of termination to Cook.

(ii) COOK may terminate this Agreement at any time upon written notice to PURCHASER with respect to any Device in any and all countries within the Territory based on: i) a third party allegation or a judgment issued by a court of proper jurisdiction that such Device infringes a third party patent not licensed to PURCHASER in a country where such Device is being marketed; or ii) PURCHASER's failure to generate commercially reasonable sales in Territory of Device 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.

7.4 **Additional Rights and Remedies.** Subject to Section 12.1, termination under this Article 7 shall be in addition to the other rights and remedies of the terminating party. Termination of this Agreement for any reason shall not relieve any party of any obligations accruing prior to such termination.

7.5 **Non-cancelable Costs and Expenses.** In the event of the termination or cancellation of this Agreement, except by PURCHASER as a result of a breach by COOK under Section 7.2, PURCHASER shall (a) reimburse COOK for all Device materials and components ordered prior to termination and not cancelable at no cost to COOK, and (b) pay COOK the cancellation fees as set forth in Section 3.2. In addition, in the event of termination or cancellation for any reason, PURCHASER shall pay prices described in Article 4 for (i) all work-in-process commenced by COOK and (ii) all finished goods of COOK. COOK shall ship such materials to PURCHASER pursuant to Section 5.1. PURCHASER shall make payment for all expenses described in this Section 7.5 thirty (30) days from the invoice date.

7.6 **Survival.** Termination, expiration, cancellation or abandonment of this Agreement through any means or for any reason, except as set forth in Section 7.1, shall be without prejudice to the rights and remedies of either party with respect to any antecedent breach of any of the provisions of this Agreement. The provisions of Articles 7, 11, 12, 13, 14, 15, 16 and 17 hereof shall survive expiration or termination of this Agreement.

Article 8, MANUFACTURE OF DEVICES

8.1 **Manufacture**. COOK shall manufacture Devices in accordance with cGMP, the Specifications and the Quality Technical Agreement Version -01 between the PURCHASER and COOK, as amended from time to time by agreement of PURCHASER and COOK. Manufacturing deviations and investigations which occur during manufacture of Devices and which do not cause the manufacture to be non-compliant with cGMP shall not be deemed to cause such Device to be non-conforming.

8.2 **Permits and Licenses.** PURCHASER shall have sole responsibility, at its expense, for obtaining all government and statutory permits, approvals, registrations, certificates and licenses, and shell satisfy all governmental and other statutory requirements necessary or required for the sale, marketing and commercialization of each Device manufactured by COOK hereunder. COOK shall be responsible, at its expense, to obtain and maintain all government and statutory permits, approvals, registrations, certificates and licenses required for it to carry out manufacturing obligations hereunder.

8.3 **Regulatory Requirements**. Each party promptly shall notify the other of new regulatory requirements of which it becomes aware which are relevant to the manufacture of Devices under this Agreement and which are required by the FDA, any other applicable regulatory authority or other applicable laws or governmental regulations, and shall confer with each other with respect to the best means to comply with such requirements.

8.4 **Changes in Manufacturing:**

8.4.1 **Changes to Device Master Record and Specifications.** COOK agrees to inform PURCHASER within fifteen (15) days of the result of any regulatory development or changes that materially affect the manufacture of the Devices. COOK shall notify PURCHASER of and require written approval from PURCHASER for changes to the Device Master Record prior to the manufacture of subsequent Lots of the Device.

8.4.2 **Device-Specific Changes.** If facility, equipment, process or system changes are required of COOK as a result of requirements set forth by the FDA or any other regulatory authority, and such regulatory changes apply primarily to the manufacture of the Device, then PURCHASER and COOK will review such requirements and agree in writing to such regulatory changes, and PURCHASER shall bear 100% of the reasonable costs thereof.

Article 9, REGULATORY

9.1 **Regulatory Approvals**. PURCHASER will be solely responsible for obtaining all regulatory approvals necessary for the sale, marketing and distribution of Devices or products incorporating Devices.

9.2 **Regulatory Authority Inspections**. COOK will notify PURCHASER within five (5) calendar days of all contacts with regulatory authorities (both written and verbal) related to Devices. COOK shall inform PURCHASER of the result of any regulatory inspection which directly affects the manufacture of Devices. In the event of an FDA inspection which directly involves a Device, PURCHASER shall be immediately informed of the issuance of the Notice of

Inspection (FDA Form 482). In the event that there are Inspectional Observations (FDA Form 483), PURCHASER shall be informed immediately and shall have the opportunity to review and provide COOK with comments to COOK's response. PURCHASER shall provide its comments to the response of these observations within ten (10) calendar days. The contents of COOK's response shall be determined by COOK in its sole discretion.

Article 10, TRADEMARKS AND PATENTS

10.1 PURCHASER grants to COOK a non-exclusive, royalty free license to use the PURCHASER's trademarks for the sole purpose of allowing COOK to fulfill its responsibilities under this Agreement. Such license shall not be transferable in whole or in part without prior written approval from PURCHASER, which will not be unreasonably withheld.

10.2 PURCHASER shall be solely responsible for selecting, registering and enforcing PURCHASER's trademarks used to identify the Device and except as set forth in Section 10.1 and shall have sole and exclusive rights in such PURCHASER Trademarks.

10.3 COOK acknowledges PURCHASER'S right, title and interest in the trade name that PURCHASER uses for the Device (provided such trade name does not use or incorporate or adopt any of the Trademarks or Cook's company names or any confusingly similar word or symbol), its trademarks and trade names listed in product sheets issued by PURCHASER (collectively "Purchaser Trademarks"), and COOK shall not at any time do or cause to be done any act or thing which directly or indirectly challenges, impairs or adversely affects the Purchaser Trademarks or PURCHASER's goodwill therein. COOK shall not acquire any right, title, or interest in the Purchaser Trademarks by virtue of the execution, performance or termination of this Agreement. COOK shall not use any Purchaser Trademark, without PURCHASER's prior written consent. All goodwill resulting from COOK's use of the Purchaser Trademarks shall inure to the benefit of PURCHASER. COOK will have no liability under this Agreement for any delay or failure to perform its obligations hereunder to the extent that such delay or failure is due to PURCHASER's failure to provide clear, timely and reasonable instructions with respect to COOKs use of Purchaser Trademarks in connection with the Device.

10.4 PURCHASER acknowledges COOK's exclusive right, title and interest in the trademarks and trade names listed in all catalog and product sheets issued by COOK (collectively "Cook Trademarks"), and PURCHASER shall not at any time do or cause to be done any act or thing which directly or indirectly challenges, impairs or adversely affects the Cook Trademarks or COOK's goodwill therein. PURCHASER shall not acquire any right, title, or interest in the Cook Trademarks by virtue of the execution, performance or termination of this Agreement. PURCHASER shall not use any Trademark, without COOK's prior written consent. Any goodwill resulting from PURCHASER's use of the Cook Trademarks shall inure to the benefit of COOK.

10.5 Except as provided expressly herein, PURCHASER may not use the Cook Trademarks or COOK's name in connection with the importation, marketing, distribution and sale of the Device. PURCHASER shall not use or adopt the Cook Trademarks or any confusingly similar word or symbol as part of its company name. PURCHASER shall submit to COOK for approval, prior to use,

distribution, or disclosure of any advertising, promotion or publicity media in which COOK's name or the Cook Trademarks are to be used. The package label for the Device processed by COOK and delivered pursuant to this Agreement shall be designed by PURCHASER and follow applicable laws and regulations including stating "Manufactured for AxoGen Corporation" or variations thereof in small print. PURCHASER shall be responsible for all costs of repackaging and re-labeling the Device and any revision of the Device brochures and other educational materials, to the extent such repackaging, re-labeling and/or revisions are required due to Purchaser Trademark issues that arise with respect to the Device. COOK shall be responsible for all costs of repackaging and relabeling the Device and any revision of the Device brochures and other educational materials, to the extent such repackaging, re-labeling and/or revisions are required due to Cook Trademark issues that arise with respect to the Device. Notwithstanding the foregoing, COOK shall have the right to review and request the correction or deletion, at PURCHASER's expense, of any misleading, or false material from any such media.

10.6 PURCHASER will be solely responsible, at its sole expense, for, and except as otherwise provided in this Agreement, shall have the sole right to make all decisions and determinations with respect to marketing and sales of the Device, all subject to and in compliance with all applicable laws and regulations and the terms and conditions of this Agreement.

10.7 COOK reserves the right to bring such legal action in the courts or administrative agencies of any country within the Territory as may be required to prevent the infringement, imitation, unauthorized sale, purchase or distribution, illegal use, or misuse of the Cook Trademarks or COOK's name. PURCHASER promptly shall notify COOK of any infringement, imitation, unauthorized sale, purchase or distribution, illegal use, or misuse of the Cook Trademarks or COOK's name which comes to PURCHASER's attention, and shall render any assistance which COOK may reasonably request in protecting the Cook Trademarks or COOK's name.

10.8 PURCHASER grants to COOK a non-transferable, irrevocable, non-exclusive, royalty free license under any and all Applicable Purchaser Patents, to manufacture and sell the Devices to be supplied to PURCHASER by COOK pursuant to this Agreement, for the sole purpose of allowing COOK to perform under this Agreement. "Applicable Purchaser Patents" shall mean any patent or patent application owned by PURCHASER including at least one claim that encompasses Devices or their use or manufacture. Such licenses shall not be transferable in whole or in part without prior written approval from PURCHASER, which will not be unreasonably withheld. Except for the rights expressly granted, no right, title, or interest of any nature whatsoever is granted under the Applicable Purchaser Patents whether by implication, estoppel, reliance, or otherwise, by PURCHASER to COOK. Accordingly, all rights with respect to any know-how, patent or other intellectual property rights that are not specifically granted herein are reserved by PURCHASER.

10.9 COOK grants to PURCHASER a non-transferable, irrevocable, non-exclusive, royalty free license under any and all Applicable COOK Patents, to use, offer to sell, sell and import the Devices supplied to PURCHASER by COOK pursuant to this Agreement, for the sole purpose of allowing PURCHASER to perform under this Agreement. "Applicable Cook Patents" shall mean any patent or patent application owned by COOK including at least one claim that encompasses Devices or their use. Such license shall not be transferable in whole or in part

without prior written approval from COOK, which will not be unreasonably withheld. Except for the rights expressly granted, no right, title, or interest of any nature whatsoever is granted under the Applicable Cook Patents whether by implication, estoppel, reliance, or otherwise, by COOK to PURCHASER. Accordingly, all rights with respect to any know-how, patent or other intellectual property rights that are not specifically granted herein are reserved by COOK.

Article 11, REPRESENTATIONS AND WARRANTIES

11.1 **Mutual Representations.** Each party hereby represents and warrants to the other party that (a) the person executing this Agreement is authorized to execute this Agreement; (b) this Agreement is legal and valid and the obligations binding upon such party are enforceable by their terms; and (c) the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument or understanding, oral or written, to which such party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

11.2 **COOK Warranty.** COOK represents and warrants that:

(a) the Devices shall be: (i) manufactured in accordance with cGMP and the Specifications; (ii) be true to label when packaged and delivered to PURCHASER; (iii) be free from defects in materials and workmanship; and (iv) shall have a minimum shelf life of fourteen (14) months from the date of delivery. COOK represents and warrants that it has obtained (or will obtain prior to manufacturing Devices), and will remain in compliance with during the term of this Agreement, all permits, licenses and other authorizations (the "Permits") which are required under federal, state and local laws, rules and regulations applicable to the manufacture only of Devices; provided, however, COOK shall have no obligation to obtain Permits relating to the sale, marketing, distribution or use of Devices or with respect to the labeling of Devices; and

(b) COOK agrees to undertake and to cause its suppliers, if any, to undertake such quality control and inspection procedures as required by the FDA ("Quality Plan"). COOK will, upon written request of the DISTRIBUTOR, share its Quality Plan with the DISTRIBUTOR prior to delivery of the initial Device order and on an annual basis thereafter. DISTRIBUTOR shall-have the right (at its expense) from time to time but no more frequently than once a calendar year, and upon reasonable advance written request and during normal business hours, to inspect the facilities of COOK and any manufacturing facilities, storage/handling facilities and any other facilities or entities used by COOK or third parties, on behalf of COOK for the supply, manufacture and storage of the Device to review their compliance with the requirements of Section 351 of the Public Health Services Act that apply to the Device and all other applicable laws and regulations for the Device in the United States or comparable laws and regulations of foreign regulatory authorities for the Territory; provided, however, if during the course of any such inspection DISTRIBUTOR determines that COOK is not in compliance with the requirements of the Quality Plan, including but not limited to compliance with Section 351 of the Public Health Services Act that apply to the Device or any other applicable laws and regulations that apply to the Device or comparable regulations of foreign regulatory authorities for Territory (a "Non-Compliant Item"), DISTRIBUTOR shall be permitted to perform such additional

inspections within a calendar year as are required for the sole purpose of confirming that COOK has corrected, and is then in compliance with, any Non-Complaint Item discovered in DISTRIBUTOR's immediately preceding inspection. Any information that DISTRIBUTOR learns in the course of such inspections shall be deemed the Confidential Information of COOK, subject to DISTRIBUTOR's confidentiality obligations hereunder, may be used by DISTRIBUTOR for the sole purpose of ensuring compliance by COOK with its obligations under this Section 11.2, and may not be otherwise used or disclosed by DISTRIBUTOR without the prior written consent of COOK. COOK shall not be required, in the course of such inspections to reveal any trade secrets to DISTRIBUTOR. DISTRIBUTOR agrees to work with COOK in order to assist its compliance with Section 351 of the Public Health Services Act as it applies to the End Cap Product and other applicable laws and regulations.

COOK makes no representation or warranty with respect to printed materials supplied by PURCHASER or its consignee.

11.3 **Disclaimer of Warranties.** Except for those warranties set forth in Sections 11.1 and 11.2 of this Agreement, COOK makes no other warranties, written, oral, express or implied, with respect to Devices or the manufacture of Devices. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT HEREBY ARE DISCLAIMED BY COOK. NO WARRANTIES OF COOK MAY BE CHANGED BY ANY REPRESENTATIVES OF COOK. PURCHASER accepts Devices subject to the terms hereof.

11.4 **PURCHASER Warranties**. PURCHASER warrants that (a) it has the right to give COOK any information provided by PURCHASER hereunder, and that COOK has the right to use such information for the manufacture of Devices, and (b) PURCHASER has no knowledge of any (i) patents or other intellectual rights that would be infringed by COOK's manufacture of Devices under this Agreement, or (ii) proprietary rights of third parties which would be violated by COOK's performance hereunder.

Article 12, LIMITATION OF LIABILITY

12.1 **Limitation of Liability.** PURCHASER's sole and exclusive remedy for breach of this Agreement is limited to those remedies set forth in Article 6 and at COOK's decision, in COOK's sole discretion, to either replace the non-conforming Device or reimburse PURCHASER for the Purchase Price for the non-conforming Device. Under no circumstances shall COOK be liable for loss of use or profits or other collateral, special, consequential or other damages, losses, or expenses, including but not limited to the cost of cover or the cost of a recall in connection with or by reason of the manufacture and delivery of Devices under this Agreement whether such claims are founded in tort or contract. The foregoing constitutes the sole and exclusive remedy of PURCHASER and the sole and exclusive liability of COOK. All claims by PURCHASER for breach or default under this Agreement shall be brought within one (1) year after the cause of action accrued or shall be deemed waived. Notwithstanding the foregoing, in the event that COOK was negligent in the manufacture of the Device and such

negligence results in a recall of the Device, Cook shall be liable for the actual out of pocket costs related to such recall.

Article 13, INDEMNIFICATION

13.1 **PURCHASER Indemnification.** PURCHASER shall indemnify, defend and hold harmless COOK and its directors, officers, employees, subcontractors, agents and Affiliates from and against any and all liabilities, obligations, penalties, claims, judgments, demands, actions, disbursements of any kind and nature, suits, losses, damages, costs and expenses (including, without limitation, reasonable attorney's fees) arising out of or in connection with property damage or personal injury (including without limitation death) of third parties (collectively "Claims") in connection with (a) PURCHASER's storage, promotion, labeling, marketing, distribution, use or sale of Devices or products incorporating Devices, (b) PURCHASER's violation of any regulatory rules, regulations or laws relating to the sale, marketing or distribution of Devices or products incorporating Devices, (c) PURCHASER's negligence or willful misconduct, (d) PURCHASER's breach of this Agreement, or (e) any claim that the use, sale, manufacture, marketing or distribution of Devices or products incorporating Devices by COOK or PURCHASER violates the patent, trademark, copyright or other proprietary rights of any third party, except to the extent any of the foregoing (a) or (e) is caused solely by the negligence or willful misconduct of the Indemnified Parties or solely by the breach by COOK of its obligations under this Agreement.

13.2 **COOK Indemnification.** COOK shall indemnify, defend and hold harmless PURCHASER and its directors, officers, employees, subcontractors, agents and Affiliates from and against any and all Claims in connection with (a) Cook's violation of any regulatory rules, regulations or laws relating to the manufacturing of the Devices, (b) COOK's negligence or willful misconduct, or (c) COOK's breach of this Agreement, except to the extent any of the foregoing (a) is caused solely by the negligence or willful misconduct of the Indemnified Parties or solely by the breach by PURCHASER of its obligations under this Agreement.

13.3 **Indemnitee Obligations.** A party (the "Indemnitee") which intends to claim indemnification under this Article 13 shall promptly notify the other party (the "Indemnitor") in writing of any action, claim or other matter in respect of which the Indemnitee or other of its Affiliates, or any of their respective directors, officers, employees, subcontractors, or agents, intend to claim such indemnification; provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitee shall permit, and shall cause its Affiliates, and their respective directors, officers, employees, subcontractors and agents to permit, the Indemnitor, at its discretion, to settle any such action, claim or other matter, and the Indemnitee agrees to the complete control of such defense or settlement by the Indemnitor. Notwithstanding the foregoing, the Indemnitor shall not enter into any settlement that would adversely affect the indemnitee's rights hereunder, or impose any obligations on the Indemnitee in addition to those set forth herein, in order for it to exercise such rights, without Indemnitee's prior written consent, which shall not be unreasonably withheld or delayed. No such action, claim or other matter shall be settled without the prior written consent of the Indemnitor, which shall not be unreasonably withheld or delayed. The Indemnitee, its

Affiliates, and their respective directors, officers, employees, subcontractors and agents shall fully cooperate with the Indemnitor and its legal representatives in the investigation and defense of any action, claim or other matter covered by the indemnification obligations of this Article13. The Indemnitee shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense.

Article 14, INSURANCE

14.1 **PURCHASER Insurance.** PURCHASER shall procure and maintain during the Term of this Agreement and for a period one (1) year beyond the expiration date of Device, Commercial General Liability Insurance, including without limitation, Product Liability and Contractual Liability coverage (the "PURCHASER Insurance"). The PURCHASER Insurance shall cover amounts not less than ten million dollars ($10,000,000) combined single limit and shall be with an insurance carrier reasonably acceptable to COOK. COOK shall be named as an additional insured on the PURCHASER Insurance and PURCHASER promptly shall deliver a certificate of PURCHASER Insurance and endorsement of additional insured to COOK evidencing such coverage. If PURCHASER fails to furnish such certificates or endorsements, or if at any time during the Term of this Agreement COOK is notified of the cancellation or lapse of the PURCHASER Insurance, and PURCHASER fails to rectify the same within ten (10) calendar days after notice from COOK, in addition to all other remedies available to COOK hereunder, COOK, at its option, may obtain the PURCHASER Insurance and PURCHASER promptly shall reimburse COOK for the cost of the same. Any deductible and/or self insurance retention shall be the sole responsibility of PURCHASER.

14.2 **COOK Insurance**. COOK shall procure and maintain during the Term of this Agreement and for a period one (1) year beyond the expiration date of Device, Commercial General Liability Insurance, including without limitation, Product Liability and Contractual Liability coverage (the "COOK Insurance"). The COOK Insurance shall cover amounts not less than ten million dollars ($10,000,000) combined single limit. COOK promptly shall deliver a certificate of COOK Insurance to PURCHASER evidencing such coverage. Any deductible and/or self insurance retention shall be the sole responsibility of COOK.

Article 15, RECALL OF DEVICE

15.1 In the event PURCHASER shall be required to recall any Device because such Device may violate local, state or federal laws or regulations, the laws or regulations of any applicable foreign government or agency or the Specifications, or in the event that PURCHASER or COOK elects to institute a voluntary recall, PURCHASER shall be responsible for coordinating such recall. PURCHASER promptly shall notify COOK if any Device is the subject of a recall and provide COOK with a copy of all documents relating to such recall. COOK shall cooperate with PURCHASER in connection with any recall, at PURCHASER' s expense except as otherwise provided herein.

Article 16, INTELLECTUAL PROPERTY

16.1 **Existing Intellectual Property.** Except as the parties may otherwise expressly agree in writing, each party shall continue to own its existing patents, trademarks, copyrights, trade secrets and other intellectual property, without conferring any interests therein on the other party. Without limiting the generality of the preceding sentence, COOK shall retain all right, title and interest to its patents and trademarks arising under the United States Patent Act, the United States Trademark Act, the United States Copyright Act and all other applicable laws, rules and regulations (collectively, "COOK's Intellectual Property") that are incorporated in and related to all Devices. Without limiting the generality of the first sentence, PURCHASER shall retain all right, title and interest to its patents and trademarks arising under the United States Patent Act, the United States Trademark Act, the United States Copyright Act and all other applicable laws, rules and regulations (collectively, "PURCHASER's Intellectual Property") that are incorporated in and related to all Devices. Neither PURCHASER nor any third party shall acquire any right, title or interest in COOK's Intellectual Property or PURCHASER's Intellectual Property by virtue of this Agreement or otherwise, except to the extent expressly provided herein.

16.2 **Individually Owned Inventions.** Except as the parties may otherwise agree in writing, all Inventions (as defined herein) which are conceived, reduced to practice, or created by a party in the course of performing its obligations under this Agreement shall be solely owned and subject to use and exploitation by the inventing party without a duty to account to the other party. For purposes of this Agreement, "Invention" shall mean information relating to any innovation, improvement, development, discovery, computer program, device, trade secret, method, know- how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable.

16.3 **Jointly Owned Inventions**. All Inventions which are conceived, reduced to practice, or created jointly by the parties and/or their respective agents (i.e., employees or agents who would be or are properly named as co-inventors under the laws of the United States on any patent application claiming such inventions) in the course of the performance of this Agreement shall be owned jointly by the parties. Each party shall have full rights to exploit such Inventions for its own commercial purposes without any obligation to the other. The parties shall share equally in the cost of mutually agreed patent filings with respect to all such jointly owned Inventions. The decision to file for patent coverage on jointly owned Inventions shall be mutually agreed upon. Patent counsel for COOK shall file and prosecute patent applications based on such joint Inventions and, upon request in writing from PURCHASER, shall provide copies of all correspondence to and from patent office(s) to PURCHASER or counsel for PURCHASER and give reasonable consideration to comments received from PURCHASER or counsel for PURCHASER in such filing and prosecution.

16.4 **Disclaimer.** Except as otherwise expressly provided herein, nothing contained in this Agreement shall be construed or interpreted, either expressly or by implication, estoppel or otherwise, as: (i) a grant, transfer or other conveyance by either party to the other of any right, title, license or other interest of any kind in any of its Inventions or other intellectual property, (ii) creating an obligation on the part of either party to make any such grant, transfer or other conveyance or (iii) requiring either party to participate with the other party in any cooperative development program or project of any kind or to continue with any such program or project.

16.5 **Rights in Intellectual Property.** The party owning any Intellectual Property shall have the world wide right to control the drafting, filing, prosecution and maintenance of patents covering the Inventions relating to such Intellectual Property, including decisions about the countries in which to file patent applications. Patent costs associated with the patent activities described in this Section shall be borne by the sole owner. Each party will cooperate with the other party in the filing and prosecution of patent applications. Such cooperation will include, but not be limited to, furnishing supporting data and affidavits for the prosecution of patent applications and completing and signing forms needed for the prosecution, assignment and maintenance of patent applications.

16.6 **Confidentiality of Intellectual Property.** Intellectual Property shall be deemed to be the Confidential Information of the party owning such Intellectual Property. The protection of each party's Confidential Information is described in Article 17. Any disclosure of information by one party to the other under the provisions of this Article 17 shall be treated as the disclosing party's Confidential Information under this Agreement. It shall be the responsibility of the party preparing a patent application to obtain the written permission of the other party to use or disclose the other party's Confidential Information in the patent application before the application is filed and for other disclosures made during the prosecution of the patent application.

Article 17, CONFIDENTIAL INFORMATION, NONDISCLOSURE AND PUBLICITY

17.1 **Confidentiality.** It is contemplated that in the course of the performance of this Agreement each party may, from time to time, disclose Confidential Information to the other. Each party agrees to take all reasonable steps to prevent disclosure of Confidential Information to third parties. No provision of this Agreement shall be construed so as to preclude disclosure of Confidential Information as may be reasonably necessary to secure from any governmental agency necessary approvals or licenses or to obtain patents with respect to the Device.

17.2 **Litigation and Governmental Disclosure.** Each party may disclose Confidential Information hereunder to the extent such disclosure is reasonably necessary for prosecuting or defending litigation, complying with applicable governmental regulations or conducting pre-clinical or clinical trials, provided that if a party is required by law or regulation to make any such disclosure of the other party's Confidential Information it will, except where impractical for necessary disclosures, for example in the event of a medical emergency, give reasonable advance notice to the other party of such disclosure requirement and will use good faith efforts to assist such other party to secure a protective order or confidential treatment of such Confidential Information required to be disclosed.

17.3 **Limitation of Disclosure.** The parties agree that, except as otherwise may be required by applicable laws, regulations, rules or orders, including without limitation the rules and regulations promulgated by the United States Securities and Exchange Commission, and except as may be authorized in Section 18.4, no information concerning this Agreement and the transactions contemplated herein shall be made public by either party without the prior written consent of the other.

17.4 **Publicity and SEC Filings.** The parties agree that the public announcement of the execution of this Agreement shall only be by one or more press releases mutually agreed to by the parties. The failure of a party to return a draft of a press release with its proposed amendments or modifications to such press release to the other party within five (5) days of such party's receipt of such press release shall be deemed as such party's approval of such press release as received by such party. Each party agrees that it shall cooperate fully and in a timely manner with the other with respect to all disclosures to the Securities and Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of Confidential Information of either party included in any such disclosure.

17.5 **Duration of Confidentiality.** All obligations of confidentiality and non-use imposed upon the parties under this Agreement shall expire ten (10) years after the expiration or earlier termination of this Agreement; provided, however, that Confidential Information which constitutes the trade secrets of a party shall be kept confidential indefinitely, subject to the limitations set forth in Sections 17.3 through 17.5.

Article 18, FORCE MAJEURE

18.1 Any delay in the performance of any of the duties or obligations of either party hereto (except the payment of money) caused by an event outside the affected party's reasonable control shall not be considered a breach of this Agreement, and unless provided to the contrary herein, the time required for performance shall be extended for a period equal to the period of such delay. Such events shall include without limitation, acts of God; acts of public enemies; insurrections; riots; injunctions; embargoes; labor disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; floods; shortages of material or energy; delays in the delivery of raw materials; acts or orders of any government or agency thereof or other unforeseeable causes beyond the reasonable control and without the fault or negligence of the party so affected. The party so affected shall give prompt notice to the other party of such cause and a good faith estimate of the continuing effect of the force majeure condition and duration of the affected party's nonperformance, and shall take whatever reasonable steps are appropriate to relieve the effect of such causes as rapidly as possible. If the period of nonperformance by COOK because of COOK force majeure conditions exceeds ninety (90) calendar days, PURCHASER may terminate this Agreement by written notice to COOK. If the period of nonperformance by PURCHASER because of PURCHASER force majeure conditions exceeds ninety (90) calendar days, COOK may terminate this Agreement by written notice to PURCHASER.

Article 19, NOTICES

19.1 All notices hereunder shall be delivered personally or by facsimile (confirmed by overnight delivery), or by overnight delivery with a reputable overnight delivery service, to the following addresses of the respective parties:

If to COOK:
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906

Attn: President

If to PURCHASER:
Axogen, Inc.
13859 Progress Blvd, Suite 400
Alachua, FL 32615
Attn: General Counsel

Notices shall be effective upon receipt if personally delivered, on the day following the date of transmission if sent by facsimile, and on the second business day following the date of delivery to the overnight delivery service if sent by overnight delivery. A party may change its address listed above by notice to the other party given in accordance with this section.

Article 20, APPLICABLE LAW

20.1 This Agreement is being delivered and executed in the State of Indiana. In any action brought regarding the validity, construction and enforcement of this Agreement, it shall be governed in all respects by the laws of the State of Indiana, without regard to the principals of conflicts of laws. The courts of the State of Indiana shall have personal jurisdiction over the parties hereto in all matters arising hereunder, and venue for such suit will be in a state of federal court for the City of Bloomington, Indiana.

Article 21, ASSIGNMENT

21.1 Neither COOK nor PURCHASER may assign or transfer this Agreement or any of its rights or obligations hereunder without the prior written consent of the other party. Notwithstanding the foregoing, either party, without the consent of the other party, may assign this Agreement and all of its rights or obligations hereunder to a successor or an Affiliate, or in connection with a merger or sale of all or substantially all of the stock or assets of such assigning party to which this Agreement pertains; provided, that such assignee shall be obligated in writing to assume all of the assignor's obligations hereunder; provided that PURCHASER may not assign this Agreement, or its rights or obligations hereunder, to Boston Scientific or any of Boston Scientific's affiliates..

Article 22, TAXES

22.1 PURCHASER shall pay all national, state, municipal or other sales, use, excise, import, property, value added, or other similar taxes, assessments or tariffs assessed upon or levied against the sale of Device to PURCHASER pursuant to this Agreement or the sale or distribution of Device by PURCHASER (or at PURCHASER's sole expense, defend against the imposition of such taxes and expenses). COOK shall notify PURCHASER of any such taxes that any governmental authority is seeking to collect from COOK, and PURCHASER may assume the defense thereof in COOK's name, if necessary, and COOK agrees to fully cooperate in such defense to the extent of the capacity of COOK, at PURCHASER's expense. COOK shall pay all national, state, municipal or other taxes on the income resulting from the sale by COOK of the Device to PURCHASER under this Agreement, including but not limited to, gross income,

adjusted gross income, supplemental net income, gross receipts, excess profit taxes, or other similar taxes.

Article 23, SUCCESSORS AND ASSIGNS

23.1 This Agreement shall be binding upon and shall inure to the benefit of the parties hereto, their successors and permitted assigns.

Article 24, ENTIRE AGREEMENT

24.1 This Agreement constitutes the entire agreement between the parties concerning the subject matter hereof and supersedes all written or oral prior agreements or understandings with respect thereto.

Article 25, SEVERABILITY

25.1 If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

Article 26, WAIVER AND MODIFICATION OF AGREEMENT

26.1 No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both parties hereto. Failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

Article 27, INDEPENDENT CONTRACTOR

27A COOK shall act as an independent contractor for PURCHASER in providing the services required hereunder and shall not be considered an agent or joint venturer with PURCHASER.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed by their duly authorized representatives as of the later date written below.

"COOK"	**"PURCHASER"**
COOK BIOTECH INCORPORATED	AXOGEN CORPORATION
By: /s/ Umesh Patel	By: /s/ Karen Zaderej
Name: Umesh Patel	Name: Karen Zaderej
Title: President	Title: President and CEO
Date: 29 Jun 17	Date: 07-13-2017

Exhibit "A"

Device and Specifications

"Device" means extracellular *matrix ("ECM")* tissue technology which, a provided in the Specifications, is comprised of Small Intestinal Submucosa (*"SIS")* technology for use in the *Field* and in the form of a tubular cap closed at one end and open at the other, or in any other form agreed by the parties in writing during the Term to be added to this Agreement. *"Field" means* use in the peripheral nervous system and the central nervous system to cap off nerve stumps, and expressly excludes uses in the oral cavity for endodontic and periodontal applications and oral and maxillofacial surgery solely as they relate to dental, soft or hard, tissue repair or reconstruction.

Specifications:

As provided in Document Number: D00025721, Title CAPB-1LCHDFFTAG. Revision 1 attached hereto.

***

Exhibit "B"

Device Purchase Price:	**US$*** per unit**

EXHIBIT 21.1

SUBSIDIARY OF AXOGEN, INC.

As of December 31, 2019, 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 the Registration Statements of Axogen, Inc. on Form S-3 (File Nos. 333-224713, 333-220770 and 333-207829) and Form S-8 (File Nos. 333-227105, 333-222019, 333-218290, 333-211660, 333-201238, 333-177980, 333-230418, 333-233416 and 333-173539) of our report dated February 28, 2018, relating to the consolidated statements of operations, shareholders' equity and cash flows for the year ended December 31, 2017 of Axogen, Inc. and Subsidiaries, which appears in this Annual Report on Form 10-K of Axogen, Inc. for the year ended December 31, 2019.

/s/ LURIE, LLP

Minneapolis, Minnesota
February 24, 2020

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements Nos. 333-224713, 333-207829 and 333-220770 on Form S-3 and Registration Statements Nos. 333-227105, 333-222019, 333-218290, 333-211660, 333-201238, 333-177980, 333-230418, 333-233416 and 333-173539 on Form S-8 of our report dated February 24, 2020, 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 of Axogen, Inc. for the year ended December 31, 2019.

/s/ DELOITTE & TOUCHE LLP

Miami, Florida
February 24, 2020

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) 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: February 24, 2020

/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: February 24, 2020

/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, 2019 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
February 24, 2020

/s/ Peter Mariani
Peter Mariani
Chief Financial Officer
February 24, 2020