

The information contained in this preliminary prospectus supplement is not complete and may be changed. This prospectus supplement and the accompanying prospectuses are part of registration statements filed with the United States Securities and Exchange Commission. This prospectus supplement and the accompanying prospectuses are not an offer to sell these securities and neither we, the selling shareholder nor the underwriters are soliciting offers to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

Subject to Completion, Dated November 15, 2017

PRELIMINARY PROSPECTUS SUPPLEMENT
 (To Prospectuses dated December 11, 2015 and October 11, 2017)



Shares of Common Stock

This prospectus supplement relates to a total offering of _____ shares of our common stock. We are offering _____ shares of our common stock, and the selling shareholder identified in this prospectus supplement is offering 1,000,000 shares of our common stock. We will not receive any of the proceeds from the sale of common stock by the selling shareholder.

Our common stock is traded on The Nasdaq Capital Market (“Nasdaq”), under the symbol “AXGN.” On November 14, 2017, the last sale price of our common stock, as reported on Nasdaq, was \$24.80 per share.

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. THESE RISKS ARE DESCRIBED UNDER THE CAPTION “RISK FACTORS” BEGINNING ON PAGE S-6 OF THIS PROSPECTUS SUPPLEMENT.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectuses. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	\$	\$
Underwriting discounts and commissions(1)	\$	\$
Proceeds, before expenses, to us	\$	\$
Proceeds, before expenses, to the selling shareholder	\$	\$

(1) See “Underwriting” for a complete description of the compensation payable to the underwriters.

The selling shareholder has granted the underwriters an option to purchase up to an aggregate of 150,000 additional shares from the selling shareholder and we have granted the underwriters an option to purchase up to an aggregate of _____ additional shares from us, in each case, at the public offering price, less the underwriting discounts and commissions, for a period of 30 days following the date of this prospectus supplement. The underwriters shall purchase the additional shares, if any, from us and the selling shareholder on a pro rata basis based on the number of shares offered by us and the selling shareholder hereby.

The underwriters expect to deliver the shares to purchasers against payment on or about _____, 2017 through the book-entry facilities of The Depository Trust Company.

Book-Running Manager
Leerink Partners

Co-Managers

Cantor

JMP Securities

Prospectus Supplement dated _____, 2017

TABLE OF CONTENTS
PROSPECTUS SUPPLEMENT

	<u>Page</u>
About this Prospectus Supplement	S-iii
Prospectus Supplement Summary	S-1
The Offering	S-3
Risk Factors	S-5
Special Note Regarding Forward-Looking Statements	S-23
Use of Proceeds	S-24
Market Price of Our Common Stock	S-25
Dividend Policy	S-26
Selling Shareholder	S-27
Dilution	S-28
Capitalization and Indebtedness	S-29
Underwriting	S-30
Material U.S. Federal Income Tax Considerations for Non-U.S. Holders	S-35
Description of Capital Stock	S-38
Where You Can Find More Information; Incorporation of Certain Information by Reference	S-40
Legal Matters	S-41
Experts	S-41

COMPANY PROSPECTUS

	<u>Page</u>
About this Prospectus	1
About AxoGen, Inc.	1
Risk Factors	3
Cautionary Note Regarding Forward-Looking Statements	3
Use of Proceeds	3
Plan of Distribution	3
Legal Matters	5
Experts	5
Where You Can Find More Information	5
Information Incorporated by Reference	6

SELLING SHAREHOLDER PROSPECTUS

	<u>Page</u>
About this Prospectus	ii
Prospectus Summary	1
The Offering	2
Special Note Regarding Forward-Looking Statements	3
Use of Proceeds	4
Selling Shareholder	5
Plan of Distribution	7
Description of Capital Stock	9
Where You Can Find More Information	11
Incorporation of Certain Information by Reference	11
Legal Matters	12
Experts	12

You should rely only on the information contained in, or incorporated by reference into, this prospectus supplement or the accompanying prospectuses. Neither we, the selling shareholder nor the underwriters have authorized anyone to provide you with different information, and we, the selling shareholder and the underwriters do not take any responsibility for, and can provide no assurance as to the reliability of, any information that others may provide you. Neither we, the selling shareholder nor the underwriters are making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information contained in this

[Table of Contents](#)

prospectus supplement or the accompanying prospectuses is accurate on any date other than the date set forth on the front of the document or that any information we have incorporated by reference in this prospectus supplement or the accompanying prospectuses is accurate on any date other than the date of the applicable document incorporated by reference.

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in three parts. The first part is this prospectus supplement, which describes the specific terms of this offering of shares of common stock and adds to and updates the information contained in the accompanying prospectuses. The second part, the Company Prospectus, as supplemented by this prospectus supplement, is part of a “shelf” registration statement on Form S-3 (File No. 333-207829) that we initially filed with the United States Securities and Exchange Commission (the “SEC”) on November 5, 2015, and that was declared effective by the SEC on December 11, 2015 (the “2015 Registration Statement”). The common stock offered by us is registered on the 2015 Registration Statement. The third part, the Selling Shareholder Prospectus, as supplemented by this prospectus supplement, is part of a “shelf” registration statement on Form S-3 (File No. 333-220770) that we initially filed with the SEC on October 2, 2017, and that was declared effective by the SEC on October 11, 2017 (the “2017 Registration Statement” and together with the 2015 Registration Statement, the “Registration Statements”). The common stock offered by the selling shareholder is registered on the 2017 Registration Statement. The Company Prospectus and the Selling Shareholder Prospectus provide more general information, some of which may not apply to this offering. This prospectus supplement is a supplement to the Company Prospectus and the Selling Shareholder Prospectus with respect to the shares registered under the relevant registration statement.

This prospectus supplement contains information about the common stock offered hereby and may add to, update or change information in the accompanying prospectuses. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectuses, you should rely on the information in this prospectus supplement.

Before buying any of the shares of common stock offered hereby, we urge you to read carefully this prospectus supplement and the accompanying prospectuses, together with the additional information described in the section entitled “Where You Can Find More Information; Incorporation of Certain Information by Reference.”

We and the selling shareholder are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where it is lawful to do so. Neither this prospectus supplement, nor either of the accompanying prospectuses, constitute an offer to sell or the solicitation of an offer to buy any shares other than the registered shares to which it relates, nor does this prospectus supplement or any of the accompanying prospectuses constitute an offer to sell or the solicitation of an offer to buy shares in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

This prospectus supplement and the accompanying prospectuses contain summaries of certain provisions contained in some of the documents described herein and therein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of the documents referred to herein have been filed, or will be filed or incorporated by reference as exhibits to the registration statement, and you may obtain copies of those documents as described below under “Where You Can Find More Information; Incorporation of Certain Information by Reference.”

Unless otherwise noted or unless the context requires otherwise, all references in this prospectus to the “company,” “we,” “us,” “our,” “AxoGen, Inc.” and “AxoGen” mean AxoGen, Inc. and its subsidiaries.

AxoGen, Inc. and our logo are our trademarks. This prospectus supplement and the accompanying prospectuses also include trademarks, tradenames and service marks that are the property of us and of other organizations. Solely for convenience, our trademarks and tradenames referred to in this prospectus supplement and the accompanying prospectuses appear without any “™”, “©” or “®” symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of any applicable licensor, to these trademarks and tradenames.

PROSPECTUS SUPPLEMENT SUMMARY

This summary description about us and our business highlights selected information contained elsewhere in, or incorporated by reference into, this prospectus supplement or the accompanying prospectuses. This summary does not contain all of the information you should consider before investing in our common stock. You should carefully read this entire prospectus supplement and the accompanying prospectuses, including each of the documents incorporated by reference in this prospectus supplement and the accompanying prospectuses, before making an investment decision.

About AxoGen, Inc.

Overview

We are a global leader in innovative surgical solutions for peripheral nerve injuries. 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 restoring nerve function and quality of life to patients with peripheral nerve injuries 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. Damage to a peripheral nerve can result in the loss of muscle or organ function, the loss of sensory feeling, or the initiation of pain.

Our portfolio of products includes Avance Nerve Graft, an off-the-shelf processed human nerve allograft for bridging severed 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 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, and Avive Soft Tissue Membrane, a minimally processed human umbilical cord membrane that may be used as a resorbable soft tissue covering to separate tissue layers and modulate inflammation in the surgical bed. Along with these core surgical products, we also offer AcroVal Neurosensory & Motor Testing System and AxoTouch Two-Point Discriminator. These evaluation and measurement tools assist health care professionals in detecting changes in sensation, assessing return of sensory, grip, and pinch function, evaluating effective treatment interventions, and providing feedback to patients on nerve function. Our full portfolio of products is available in the United States and the Avance Nerve Graft and AxoGuard products are also available in Canada, the United Kingdom, and several other European and international countries.

We began marketing products in 2008 and our revenues have increased from \$4.8 million in 2011 to \$41.1 million in 2016. Revenues for the nine months ended September 30, 2017 were \$43.5 million.

Gross profit for the year ended December 31, 2016 and the nine months ended September 30, 2017 was \$34.6 million and \$36.8 million, respectively, while our loss from operations was \$8.1 million and \$6.1 million for the years ended December 31, 2016 and the nine months ended September 30, 2017, respectively. We have continued to broaden our sales and marketing focus, which we expect to have a continuing positive contribution to our revenue growth in the long term.

Avance Nerve Graft and Avive Soft Tissue Membrane are processed in the United States at our processing facility in Dayton, Ohio. AxoGuard Nerve Connector and AxoGuard Nerve Protector are manufactured in the United States by Cook Biotech Incorporated and are exclusively distributed by us worldwide. The AcroVal Neurosensory and Motor Testing System and AxoTouch Two Point Discriminator are contract manufactured by Viron Technologies, LLC. (formerly Cybernetics Research Laboratories) (“Viron”) in Tucson, Arizona. Viron supplies the AcroVal and AxoTouch unpackaged and they are packaged at our distribution facility in Burleson, Texas.

Peripheral Nerve Repair Market

Based on our estimates, we believe the U.S. peripheral nerve injury (“PNI”) market for our current product portfolio for Extremity Trauma, Oral and Carpal Tunnel is nearly \$2.0 billion (the “Market”). We estimate that the Extremity Trauma portion of the Market is approximately \$1.5 billion. The estimated size of the Extremity Trauma portion of the market is based upon epidemiological studies regarding the general number of trauma patients, physician interviews and incidence of PNI in the population. We believe that, each year in the United States, more than 1.4 million people suffer traumatic injuries to peripheral nerves, resulting in over 700,000 extremity nerve repair procedures.

We estimate that the Oral portion of the Market is approximately \$293 million. This estimate is based upon research that has indicated approximately 80,000 PNI occur in the U.S. each year that are related to third molar extractions, anesthetic injections, dental implants and benign pathology. AxoGen has applied the average sales price of the Avance Nerve Graft and AxoGuard Nerve Protector that address Oral PNI in order to derive the Oral portion of the Market.

[Table of Contents](#)

We estimate that the Carpal Tunnel portion of our market is approximately \$188 million, or 118,000 procedures. According to literature, there are approximately 500,000 primary carpal tunnel and 53,000 primary cubital tunnel relief surgeries performed annually in the United States. For carpal tunnel, we estimate that our addressable market is the 20% of carpal tunnel surgeries that require revision procedures to address the recurrence of symptoms. From the 53,000 primary cubital tunnel surgeries, we estimate that our addressable market is 18,000 of such surgeries comprised of revision and primary interventions. As a result, we estimate that approximately 100,000 carpal tunnel revision surgeries and 18,000 total cubital tunnel procedures are addressable each year in the United States to mitigate the recurrence of symptoms. These revision and primary surgeries are required due to compression of the nerve due to soft tissue attachments from the surrounding tissue or tissue infiltration entrapping the nerve. To prevent additional recurrences, surgeons will opt to use a nerve protection product such as the AxoGuard Nerve Protector. In order to derive the Carpal Tunnel portion of the Market, AxoGen multiplied the average sales price of our AxoGuard Nerve Protector by the number of estimated procedures.

Although our existing products in the Extremity Trauma, Oral and Carpal Tunnel are our prime revenue sources today, expansion opportunities in breast reconstruction, lower extremity surgery, head and neck surgery, urology, the surgical intervention for pain and nerve repair areas offer us new and expanded revenue opportunities beyond the current market. We recently determined to prioritize our development efforts in breast reconstruction, where we began market development activities late last year and expect to launch a new application in breast reconstruction later this year.

Breast reconstruction neurotization provides a new opportunity for women following a mastectomy. Currently, when a woman undergoes breast reconstruction, she gets the shape of a breast, but does not recover sensory feeling. This forfeiture of sensation can have a profound effect contributing to quality of life issues such as depression and other emotional challenges. According to market data, more than 20,000 women in 2015 chose autologous flap reconstruction following a mastectomy. Excluding those procedures that are not able to be neurotized, and factoring in that 66% of all reconstructive breast procedures were bilateral, we estimate that the market size is at least \$140 million, with potential to be greater depending on the chosen repair technique (including the determination of whether one or two nerves are repaired per breast) and which of our products is used.

In addition, in the United States, there are approximately 700,000 total knee replacements per year and 310,000 total hip replacements per year. We estimate that 6% of patients have neuropathic pain with total knee replacements and total hip replacements and more than 60,000 have neuropathic pain post-joint replacement. We believe if we proceed with entering this area in the future it would increase the market for our products by approximately \$125 million.

Corporate Information

We were incorporated in Minnesota in 1977. Our principal offices are located at 13631 Progress Boulevard, Suite 400, Alachua, Florida 32615. Our telephone number is (386) 462-6800. We have two wholly owned subsidiaries, AxoGen Corporation, a Delaware corporation, and AxoGen Europe GmbH, a limited liability corporation with its corporate seat in Vienna, Austria. Our web address is www.axogeninc.com. We have not incorporated by reference the information on our website into either of the Registration Statements of which this prospectus supplement forms a part, and you should not consider it to be a part of the Registration Statements.

Our reports that have been filed with the SEC, are available on our website free of charge, including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, Forms 3, 4 and 5 filed on behalf of directors and executive officers and any amendments to such reports filed pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Copies of this prospectus supplement and the accompanying prospectuses may also be obtained without charge electronically or by paper by contacting Investor Relations, c/o AxoGen, Inc., 13631 Progress Boulevard, Suite 400, Alachua, Florida 32615 or by calling (386) 462-6800.

[Table of Contents](#)

THE OFFERING

Selling shareholder	EW Healthcare Parters L.P., formerly named Essex Woodlands Fund IX, L.P. (“selling shareholder”)
Common stock offered by the selling shareholder	shares, plus up to an additional 150,000 shares if the underwriters exercise in full their option to purchase additional shares.
Common stock offered by us	shares, plus up to an additional shares if the underwriters exercise in full their option to purchase additional shares.
Common Stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise in full their option to purchase additional shares).
Underwriters’ option to purchase additional shares	We and the selling shareholder have granted the underwriters an option to purchase up to an aggregate of additional shares of our common stock, at the public offering price, less the underwriting discounts and commissions. If the underwriters exercise such option, the underwriters will purchase the additional shares from us and the selling shareholder on a pro rata basis based on the number of shares offered by us and the selling shareholder hereby. The option is exercisable, in whole or in part, for a period of 30 days following the date of this prospectus supplement.
Use of proceeds	We currently intend to use the net proceeds from the sale of the shares sold by us in this offering for general corporate purposes. See “Use of Proceeds” in this prospectus supplement. We will not receive any proceeds from the sale of the shares of common stock offered hereby by the selling shareholder.
Risk factors	Investing in our common stock involves a high degree of risk. See risk factors described under the caption “Risk Factors” in this prospectus supplement, as well as the other information set forth in this prospectus supplement and the accompanying prospectuses and in the documents incorporated by reference into this prospectus supplement and the accompanying prospectuses, for a discussion of factors that you should carefully consider before deciding to invest in our common stock.
Nasdaq Capital Market symbol	AXGN.

The number of shares of common stock to be outstanding after this offering is based on 33,393,804 shares outstanding on September 30, 2017, and excludes:

- 44,843 shares of common stock issuable upon the exercise of a warrant outstanding as of September 30, 2017, at an exercise price of \$2.23 per share;
- 4,215,522 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2017, at a weighted average exercise price of \$5.94 per share;
- 268,925 shares of common stock subject to vesting of performance stock units and restricted stock unit awards outstanding as of September 30, 2017;
- 2,113,604 shares of common stock available for future issuance as of September 30, 2017 under our AxoGen 2010 Stock Incentive Plan, as amended and restated (the “Stock Incentive Plan”); and
- 600,000 shares of common stock available for future issuance as of September 30, 2017 under our AxoGen 2017 Employee Stock Purchase Plan (the “2017 ESPP”).

[Table of Contents](#)

Unless otherwise indicated, all information in this prospectus supplement assumes no exercise of outstanding options or warrants after September 30, 2017, and no exercise by the underwriters of their option to purchase additional shares of our common stock from us and the selling shareholder.

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information set forth in this prospectus supplement and the accompanying prospectuses, and in the documents incorporated by reference into this prospectus supplement and the accompanying prospectuses, before deciding to purchase shares of our common stock. If any of the events, contingencies, circumstances or conditions described in the risks below actually occurs, our business, financial condition or results of operations could be seriously harmed. The trading price of our common stock could, in turn, decline and you could lose all or part of your investment.

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 sales of its products, which may not be achievable.

AxoGen has historically operated with negative cash flow from its operations. As of September 30, 2017, AxoGen had an accumulated deficit of approximately \$126 million. If AxoGen product sales do 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 sales to existing customers and develop new customers, and there can be no assurance that these efforts will result in significant increase in sales.

AxoGen is in the process of investing in its sales channels composed of a combination of its direct sales force and independent distributors to allow it to increase sales to existing customers and reach new customers. There can be no assurance that these efforts will be successful in expanding AxoGen's product sales. AxoGen currently sells products directly through its employees and indirectly through distributor 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 three products.

Substantially all of AxoGen's revenue is currently derived from only three products, the Avance Nerve Graft, AxoGuard Nerve Protector and AxoGuard Nerve Connector, for the treatment of peripheral nerve damage. Its ability to generate revenue is dependent on the success of these products. Accordingly, any disruption in AxoGen's ability to generate revenue from the sale of any of these products will have a material adverse impact on its business, results of operations, financial condition and growth prospects. Although AxoGen has launched other products, such as the Avive Soft Tissue Membrane, there can be no assurance that this, or other products, will provide significant revenue.

The AxoGuard products are only available through an exclusive distribution agreement with Cook Biotech Incorporated, West Lafayette, Indiana ("Cook Biotech"). The agreement runs through August 27, 2022. 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. Although there are products that AxoGen believes it could develop or obtain that would replace the AxoGuard products obtained through the agreement with Cook Biotech, the loss of the ability to sell the AxoGuard products 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 nerve reconstruction treatment options and provide appropriate solutions for nerve

repair. Its ability to do so will depend on surgeons' evaluations of clinical safety, efficacy, ease of use, reliability, and cost-effectiveness 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. Furthermore, AxoGen believes that even if its products receive general acceptance within the medical community, acceptance and clinical recommendations by influential surgeons will be important to the commercial success of AxoGen's products.

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 tissue from tissue donors for its Avance Nerve Graft product and 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 Community Blood Center (d/b/a Community Tissue Services) ("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 facility service agreement which can occur upon 18 months' prior notice from either party. Although AxoGen believes it can find and make operational a new facility in less than six months, the regulatory process for approval of facilities is time-consuming and unpredictable. AxoGen's ability to 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. 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 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, one of the chemicals AxoGen uses in the processing of Avance Nerve Graft is no longer manufactured by the original single source provider. AxoGen has inventory of such chemical which it believes provides more than one year of production. AxoGen is currently evaluating multiple avenues including new suppliers of the chemical and acceptable substitutes for the chemical; however, failure to produce and qualify a substitute prior to current inventory being depleted would have a material adverse impact on AxoGen. In addition, some of the test results, packaging and reagents/chemicals AxoGen uses in its manufacturing process are also obtained 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. U.S. Food and Drug Administration ("FDA") approval 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 approval 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, distribution and transportation, would impair AxoGen's ability to meet commercial demand.

AxoGen relies upon third parties for certain recovery, distribution and transportation services. 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, 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 distributors to generate revenue.

AxoGen derives material revenues through its relationships with distributors. If such distributor relationships were terminated for any reason, it could materially and adversely affect AxoGen's ability to generate revenues and profits. AxoGen intends to obtain the assistance of additional distributors to continue its sales growth. It may not be able to find additional distributors who will agree to market and distribute its products on commercially reasonable terms, if at all. If AxoGen is unable to establish new distribution relationships or renew 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 senior management team. Competition for experienced management personnel in the healthcare industry is intense. If one or more of AxoGen's senior 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 senior 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 hospitals to pay fees for AxoGen's products depends in part on the extent to which reimbursement for the costs of such materials and related treatments will continue to be available from governmental health administration authorities, private health coverage insurers and other organizations. Major third party payers of hospital services and hospital outpatient services, including Medicare, Medicaid and private healthcare insurers, annually revise their payment methodologies which can result in stricter standards for reimbursement of hospital and/or surgeon charges for certain medical procedures or the elimination of reimbursement. Further, Medicare, Medicaid and private healthcare insurer cutbacks could create downward price pressure on AxoGen's products.

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 reserves 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 consistent with industry averages, its insurance coverage and any reserves 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 companies 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 sale. 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. Finally, 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. Due to its limited resources, its smaller size and its relatively early stage, AxoGen may face competitive challenges and barriers that are difficult to overcome and could negatively impact its growth.

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 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. Avive Soft Tissue Membrane is only available in the U.S. and has not, as of this time period, received any regulatory registration allowing for sales outside the U.S. Additionally, AxoGen will need to either enter into distribution agreements with third parties or develop a direct sales force in these 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 product sales internationally. Outside of the U.S., reimbursement systems vary significantly by country. Many foreign markets have government-managed healthcare systems that govern reimbursement for medical devices and procedures. Additionally, some foreign 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, 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 payment obligations under the MidCap Financial Trust Term Loan Agreement and Revolving Loan Agreement may adversely affect our financial position and our ability to obtain additional funds, and may increase our vulnerability to economic or business downturns.

On October 25, 2016 (the "Closing Date"), AxoGen and its wholly owned subsidiary, AxoGen Corporation ("AC"), each as borrowers, entered into the term loan agreement (the "MC Term Loan Agreement") with the lenders party thereto and MidCap Financial Trust ("MidCap"), as administrative agent and lender. Under the MC Term Loan Agreement, MidCap provided AxoGen a term loan in the aggregate principal amount of \$21 million (the "Term Loan"). On the Closing Date AxoGen and AC, each as borrows, also entered into a Credit and Security Agreement (Revolving Loan) (the "Revolving Loan Agreement") with the lenders party thereto and MidCap, as administrative agent and a lender. Under the Revolving Loan Agreement, MidCap has agreed to lend AxoGen up to \$10 million under a revolving credit facility (the "Revolving Loan") which amount may be drawn down by AxoGen based upon an available borrowing base. The Revolving Loan may be increased to up to \$15 million at AxoGen's request and with the approval of MidCap. As of the Closing Date, AxoGen's borrowing base under the Revolving Loan provided availability of approximately \$5.4 million of which AxoGen borrowed \$4 million. The MC Term Loan Agreement, Revolving Loan Agreement and the indebtedness pursuant thereto are secured by substantially all of AxoGen's tangible and intangible assets.

Outstanding debt could have important negative consequences to the holders of AxoGen's securities, including the following:

- a portion of our cash flow from operations will be needed to pay debt service and will not be available to fund future operations;
- AxoGen is required to maintain certain covenants, the breach of which would result in default under the MC Term Loan Agreement and Revolving Loan Agreement;

- AxoGen has increased vulnerability to adverse general economic and industry conditions; and
- AxoGen may be vulnerable to higher interest rates because interest expense on the Term Loan in limited circumstances could increase.

Payment requirements under the MC Term Loan Agreement and the Revolving Loan Agreement increase AxoGen's cash burden. AxoGen's future operating performance is subject to market conditions and business factors that are beyond its control. If AxoGen's cash flows and capital resources are insufficient to allow AxoGen to make required payments, AxoGen may have to reduce or delay capital expenditures, sell assets, seek additional capital or restructure or refinance its debt. If AxoGen raises funds by selling additional equity, such sale would result in dilution to its shareholders. There is no assurance that if AxoGen is required to secure funding it can do so on terms acceptable to it, or at all. Failure to pay interest or the principal amount when due would result in a default under the MC Term Loan Agreement and Revolving Loan Agreement and result in foreclosure on AxoGen's assets which would have a material adverse effect.

The MC Term Loan Agreement and Revolving Loan Agreement each contain certain covenants and failure to comply with the terms of such indebtedness could result in a default that could have material adverse consequences for us.

The MC Term Loan Agreement and the Revolving Loan Agreement each contain covenants that place restrictions on AxoGen's operations, including, without limitation, covenants related to debt restrictions, investment restrictions, dividend restrictions, restrictions on transactions with affiliates and certain revenue covenants. AxoGen's ability to comply with these covenants may be affected by general economic and industry conditions, as well as market fluctuations and other events beyond AxoGen's control. AxoGen does not know if it will be able to satisfy all such covenants in the future. AxoGen's breach of the covenants could result in a default under such agreements. In the event of a default under such agreements, the lender could require AxoGen to repay some of its outstanding debt prior to maturity, and/or to declare all amounts borrowed by it, together with accrued interest, to be due and payable. In the event that this occurs, AxoGen may be unable to repay all such accelerated indebtedness. Any indebtedness that it incurs under the MC Term Loan Agreement and Revolving Loan Agreement is secured by substantially all of its tangible and intangible assets. If AxoGen defaults under the indebtedness secured by its assets, those assets would be available to the secured creditors to satisfy AxoGen's obligations to the secured creditors.

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.

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.

In our annual report on Form 10-K for the year ended December 31, 2016 we reported a material weaknesses in our internal control as of December 31, 2016 relating to the design and operation of key controls around the calculations of significant judgment and estimates and quarterly cycle count procedures related to consigned inventories. These control deficiencies are not expected to result in any changes of prior period financial statements or previously released financial results.

In an attempt to remediate these material weaknesses, we have made the following changes to the design of our internal controls over financial reporting:

- improved procedures to test, evaluate and document the assumptions utilized in significant estimates; and
- enhanced the scope and procedures of the testing and documentation of quarterly cycle counts of consignment inventory.

Although these changes have been made, the material weaknesses or deficiencies will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Weaknesses or deficiencies in our internal control over financial reporting may be identified when we assess the effectiveness of our internal control over financial reporting as of December 31, 2017, or during the audit by our independent registered public accounting firm of our internal control over financial reporting as of December 31, 2017.

Although we have taken actions to correct the control deficiencies we identified and to strengthen our internal control over financial reporting, we cannot assure you that we will not discover other 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, terrorist activities and international hostilities can be predicted. However, these occurrences could impact us directly as a result of damage to our facilities or by preventing us from conducting our business in the ordinary course, or indirectly as a result of their impact on our customers, suppliers or other counterparties. We could also suffer adverse consequences to the extent that disasters, terrorist activities or international hostilities affect the financial markets or the economy in general or in any particular region.

Our ability to mitigate the adverse consequences of such occurrences is in part dependent on the quality of our resiliency planning, and our ability, if any, to anticipate the nature of any such event that occurs. The adverse impact of 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 and healthcare professionals, such as physicians, hospitals and those to whom and through whom we may market our products. We are subject to scrutiny under 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, physician self-referral laws, false claims laws, criminal health care fraud laws, and anti-bribery laws such as the United States Foreign Corrupt Practices Act. Violations of these laws are 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 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 and restricting the ability to sell products that would 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 medical devices, such as the AxoGuard products, and biological products, such as the Avance® Nerve Graft product. The Avive Soft Tissue Membrane is processed and distributed in accordance with FDA requirements for Human Cellular and Tissue-based Products ("HCT/Ps") under 21 CFR Part 1271 regulations. The FDA requires the approval of a biological product, like the Avance® Nerve Graft product, through a biologic license application ("BLA") prior to marketing. Although the Avance® Nerve Graft product has not yet been approved by FDA through a BLA, FDA is permitting the product to be distributed, subject

to FDA enforcement discretion, provided that AxoGen: (1) transitions to compliance with section 501(a)(2)(B) of the FD&C Act, the current Good Manufacturing Practice (“cGMP”) regulations in 21 CFR Parts 210 and 211 and the biologic regulations in 21 CFR Parts 600-610 prior to initiation of a phase 3 clinical trial designed to demonstrate the safety, purity, and potency of the Avance® Nerve Graft; (2) conducts a phase 3 clinical trial to demonstrate safety, purity and potency of the Avance® Nerve Graft under a special protocol assessment (“SPA”); (3) continues to comply with the HCT/P 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” in our annual report on Form 10-K for the year ended December 31, 2016.

The FDA also requires certain medical devices, such as the AxoGuard® products, to be cleared through the 510(k) premarket notification process prior to marketing. The FDA’s premarket review process for new and modified devices 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 achieve the primary endpoints in the phase 3 clinical trial or ultimately obtain BLA approval. 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 also must comply with FDA’s medical device requirements and must only use labeling that is consistent with the specific indication(s) for use included in the FDA 510(k) clearance for the devices. The Avive© Soft Tissue Membrane must be processed and distributed in accordance with FDA requirements for HCT/Ps under 21 CFR Part 1271 regulations including being minimally manipulated, intended only for homologous use, not combined with any other article except water, crystalloids, or a sterilizing, preserving, or storage agent, and not having a systemic effect. Failure to meet these requirements could result in the FDA regulating the Avive Soft Tissue membrane as a biological product, like the Avance Nerve Graft. 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 suspension, debarment 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 approval requirements for a Biologics License Application ("BLA"). 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" in our annual report on Form 10-K for the year ended December 31, 2016. AxoGen has continued to communicate with the FDA's Center for Biologics Evaluation and Research ("CBER") since the acceptance of the transition plan on clinical trial design, preclinical studies, Chemistry, Manufacturing, and Controls ("CMC") for the Avance® Nerve Graft, and other issues related to the effective investigational new drug application. Subject to the FDA's enforcement discretion, AxoGen can commercially distribute the 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 and sell the Avance Nerve Graft product in accordance with the transition plan, AxoGen would no longer be able to sell the Avance Nerve Graft product, 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. AxoGen has registration requirements such as that with the National Association of Boards of Pharmacy and 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 product 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 the AxoGuard product line and Cook Biotech is responsible for the regulatory compliance of the AxoGuard product line. Cook Biotech has obtained a 510(k) premarket clearance from the FDA for porcine (pig) small intestine submucosa for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. Cook Biotech has also obtained a 510(k) premarket clearance for the AxoGuard Nerve Protector for the repair of peripheral nerve injuries in which there is no gap or where a gap closure is achieved by flexion of the extremity. 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 HCT/Ps under 21 CFR Part 1271 regulations, U.S. State regulations and the guidelines of the American Association of Tissue Banks (AATB). If AxoGen fails to comply with applicable regulatory requirements, the FDA could require AxoGen to stop selling Avive, or impose civil penalties, including fines, product seizures or product recalls and, in certain cases, criminal sanctions.

AxoGen's AxoTouch and AcroVal products are subject to FDA and other regulatory requirements.

AxoGen's AxoTouch and AcroVal products are regulated as medical devices 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 these products, 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 market withdrawals 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" in our annual report on Form 10-K for the year ended December 31, 2016. 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 manufacturing operations must comply with FDA and other governmental requirements.

AxoGen's manufacturing 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" in our annual report on Form 10-K for the year ended December 31, 2016. 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 sales 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.

Sales 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 will be 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 voted to exit the European Union (“Brexit”) and the timing and scope remain unclear. AxoGen’s current notified body for its CE Mark for AxoGuard products is in the United Kingdom. To date there is no business disruption, but AxoGen cannot be sure what changes could occur. If the notified body must change to an E.U. member there could be an interruption in sales in the E.U. Cost of regulatory compliance with both the United Kingdom and E.U. could be significant and time consuming.

Clinical trials can be long, expensive and 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 Investigational New Drug Application (“IND”) for the Avance Nerve Graft in April 2013 and the IND went into effect in March 2015. The phase 3 clinical trial was initiated in the second quarter of 2015. Additionally, AxoGen was audited by the FDA at its processing facility in March 2013, March 2015 and October 2016 and its Distribution Facility in October 2015. The quality system was found to be in compliance with 21 CFR Part 1271. 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., 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 the 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 sell 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 trials and certain nonclinical studies. AxoGen and its CROs are required to comply with all applicable regulations governing clinical research, including good clinical practice (“GCP”) regulations. 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, the Avance Nerve Graft will continue to be subject to, as is the 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/Ps. 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. 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" in our annual report on Form 10-K for the year ended December 31, 2016. These regulations can also increase the cost of tissue recovery activities. Additionally, the 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 infections 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 "ACA"), which substantially changes the way healthcare is financed by both governmental and private insurers, and encourages improvements in the quality of healthcare items and services. This Act significantly impacts the biotechnology and medical device industries and could have a material adverse impact on numerous aspects of AxoGen's business.

The ACA includes, among other things, the following measures:

- a 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the U.S., with limited exceptions, beginning in 2013, which has been suspended through 2017, absent additional Congressional action;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research;
- new reporting and disclosure requirements on certain medical device and pharmaceutical 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");
- an amendment to the intent requirement of the federal Anti-Kickback and criminal health care fraud statutes, so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;
- 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;
- an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate; and
- a new abbreviated pathway for the licensure of biologic products that are demonstrated to be biosimilar or interchangeable with a licensed biologic product.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. The current Presidential Administration and U.S. Congress have attempted and will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. It is uncertain the extent to which any such changes, if made, may impact our business or financial condition.

There are also a number of states (such as Vermont, Massachusetts, Minnesota) with their own Sunshine Acts that implement the reporting and disclosure requirements on medical device and pharmaceutical manufacturers for any "transfer of value" made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests.

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 to limit the growth of healthcare costs, 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 and other third party payors could reduce the amount of approved reimbursement for procedures using AxoGen's products or deny coverage altogether. 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" in our annual report on Form 10-K for the year ended December 31, 2016. 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, trade secrecy agreements or similar agreements intended to protect unpatented technology will provide the intended protection. 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 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 which 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 will be 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 its business rights; or
- the measures AxoGen relies on to protect its IP underlying their products may not be adequate to prevent third parties from using its technology, 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 research or develop 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. For example, U.S. patents covering the formulations used in our AxoGuard product line, which are held by Cook Biotech, are scheduled to expire through November 2018. Although we expect that Cook Biotech is using best efforts to take any action possible to extend the life of these patents, there can be no assurance that any action is possible or action taken will be successful. If these patents expire while we have the right to distribute and market the AxoGuard products, it could adversely affect our ability to successfully execute our business strategy to maximize the value of AxoGuard products and could likely 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 you 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 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 UT where the original technologies are purported to have been invented. Though AxoGen makes an effort to follow these agreements strictly, a disagreement between AxoGen and either party could have a negative impact on its ability to operate its business effectively. In addition, AxoGen could learn that the technologies it has licensed from UFRF and UT do not perform as purported, are not efficacious, or are not the property of UFRF or UT, or some similar problem with the license, any of which would have an immediate and negative impact on AxoGen's business.

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 Nasdaq 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

[Table of Contents](#)

a depressive effect on the market price for our common stock. As of October 31, 2017, approximately 28.6% 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 Nasdaq under the symbol "AXGN." The stock market in general, and the market for medical device 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:

- limited daily trading volume resulting in the lack of a liquid market;
- 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. Litigation initiated against us, 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.

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

The operation and expansion of our business will continue to require funding. In addition, the MC Term Loan Agreement and Revolving Loan Agreement prohibit us from paying cash dividends to our shareholders. Accordingly, 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 you purchase shares of common stock, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur. Investors seeking cash dividends in the foreseeable future should not purchase our common stock.

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

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

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

In general, Section 302A.673 of the MBCA prohibits a public Minnesota corporation from engaging in a business combination with an interested shareholder for a period of four years after the date of the transaction in which the person became an interested shareholder, unless the business combination is approved in a prescribed manner. The term “business combination” includes mergers, asset sales and other transactions resulting in a financial benefit to the interested shareholder. An “interested shareholder” is a person who is the beneficial owner, directly or indirectly, of 10% or more of a corporation’s voting stock or who is an affiliate or associate of the corporation, and who, at any time within four years before the date in question, was the beneficial owner, directly or indirectly, of 10% or more of the corporation’s voting stock. Section 302A.673 does not apply if a committee of our Board of Directors consisting of all of its disinterested directors (excluding current and former officers) approves the proposed transaction or the interested shareholder’s acquisition of shares before the interested shareholder becomes an interested shareholder.

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

Risks Related to This Offering

Management will have broad discretion as to the use of the proceeds we receive from this offering, and we may not use the proceeds effectively.

Our management will have broad discretion in the application of the net proceeds we receive from this offering, including for any of the purposes described in the section entitled “Use of Proceeds” of this prospectus supplement, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially. Our management could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business and cause the price of our common stock to decline.

If you purchase shares of common stock in this offering, you will experience immediate and substantial dilution in the net tangible book value of your shares.

Investors purchasing shares of common stock in this offering will pay a price per share that substantially exceeds the as adjusted book value per share of our tangible assets as of September 30, 2017 after subtracting our liabilities. Our net tangible book value as of September 30, 2017 was approximately \$9,601,000, or approximately \$0.29 per share of our common stock. Based on the public offering price of \$ _____ per share, and after deducting underwriting discounts

and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2017 would have been approximately \$, or approximately \$ per share of our common stock.

This dilution is due to the substantially lower price paid by some of our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering, and the exercise of stock options granted to our employees. In addition, we have a significant number of stock options outstanding. The exercise of any of these options would result in additional dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. Further, because we will need to raise additional capital to fund our future activities, we may in the future sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. Future issuances of common stock or common stock-related securities, together with the exercise of outstanding options, if any, may result in further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section titled “Dilution” of this prospectus supplement.

Future sales of our common stock could cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market following this offering, or the perception that these sales might occur, may reduce the prevailing market price of our common stock and make it more difficult for you to sell your common stock at a time and price that you deem appropriate. In addition, any sales of securities by us or existing shareholders could have a material adverse effect on the market price of our common stock.

For example, pursuant to a registration rights agreement with the selling shareholder, we have filed a registration statement that registers for resale an aggregate of 4,861,111 shares of common stock held by the selling shareholder. Even after the offering of common stock by the selling shareholder, any shares that remain unsold but covered by the registration statement are freely tradeable without restriction under the Securities Act of 1933, as amended (the “Securities Act”), subject to a contractual lockup agreement with the underwriters for the 180 days immediately following the date of this prospectus supplement. Our directors and executive officers have also entered into 90-day lockup agreements with the underwriters in connection with this offering. See “Underwriting.”

In addition, we may need to raise additional capital to fund our future activities. We may raise money through additional public or private offerings of our equity securities or equity-linked securities, or through other means. Any sales of our equity or equity-linked securities could have a material adverse effect on the market price of our common stock.

Further, we have a significant number of stock options and warrants outstanding. If a substantial number of shares of common stock underlying these options and warrants are sold, or if it is perceived that they will be sold, in the public market, it could have a material adverse effect on the market price of our common stock.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in, or incorporated by reference into, this prospectus supplement or the accompanying prospectuses constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements other than statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements frequently, but not always, use the words “may”, “estimate”, “projects”, “intends”, “plans”, “believes”, “anticipates” or “expects” or similar words and may include statements concerning our strategies, goals and plans. Forward-looking statements may include, without limitation, statements regarding our assessment on our internal control over financial reporting, our growth, our earnings 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.

All forward-looking statements are based on management’s present expectations of future events and are subject to a number of assumptions that could cause actual results to differ materially from those described in the forward-looking statements. Forward-looking statements should be evaluated together with the many risks and uncertainties that affect our business and market, including those risks and uncertainties discussed in the following documents:

- the risk factors contained in this prospectus supplement under the caption “Risk Factors”;
- our most recent annual report on Form 10-K, including the sections entitled “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”;
- our quarterly reports on Form 10-Q; and
- our other SEC filings.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in, or incorporated by reference into, this prospectus supplement or the accompanying prospectuses might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only of the date the statement is made. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or otherwise, except as may be required by applicable law. All subsequent forward-looking statements attributable to us are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

USE OF PROCEEDS

We expect to receive net proceeds of approximately \$ in this offering, or \$ if the underwriters exercise in full their option to purchase additional shares, after deducting the underwriting discounts and commissions and estimated expenses payable by us.

We currently intend to use the net proceeds from the sale of the shares sold by us in this offering for general corporate purposes. The expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures will depend on numerous factors. As a result, our management will have broad discretion in applying the net proceeds from this offering, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially. Our management could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock.

We will not receive any of the proceeds from the sale of shares by the selling shareholder. The selling shareholder will receive all of the proceeds from the sale of shares offered by the selling shareholder hereby. We have agreed to pay all costs, expenses and fees relating to the registration of such shares. The selling shareholder will pay any underwriting fees, discounts and commissions and/or similar charges incurred in connection with the sale of shares by the selling shareholder.

MARKET PRICE OF OUR COMMON STOCK

The following table shows, for the periods indicated, the high and low bid sales per share of our common stock as reported by Nasdaq.

	High	Low
2015		
First quarter	\$ 4.24	\$ 2.90
Second quarter	\$ 3.59	\$ 2.95
Third quarter	\$ 5.74	\$ 3.04
Fourth quarter	\$ 5.95	\$ 3.90
2016		
First quarter	\$ 5.60	\$ 4.52
Second quarter	\$ 6.88	\$ 4.90
Third quarter	\$ 9.88	\$ 6.41
Fourth quarter	\$ 9.28	\$ 7.65
2017		
First quarter	\$ 11.25	\$ 8.75
Second quarter	\$ 16.90	\$ 10.05
Third quarter	\$ 19.45	\$ 14.30
Fourth quarter (through November 14, 2017)	\$ 25.15	\$ 18.10

On November 14, 2017, the last reported sale price of our common stock on Nasdaq was \$24.80 per share. On November 14, 2017, there were approximately 271 holders of record and approximately 17 beneficial holders of our common stock.



DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain our future earnings, if any, for use in our business and therefore do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion.

SELLING SHAREHOLDER

The shares of common stock being offered by the selling shareholder, EW Healthcare Parters L.P., formerly named Essex Woodlands Fund IX, L.P. (“Essex”), are shares of common stock previously issued and sold to Essex pursuant to a Securities Purchase Agreement, dated as of August 26, 2015 (the “Purchase Agreement”). Under the Purchase Agreement, Essex purchased 4,861,111 shares of our common stock (the “Essex Shares”) at a price of \$3.60 per share. In connection with the sale of the Essex Shares to Essex, we entered into a Registration Rights Agreement with Essex, dated as of August 26, 2015 (the “Registration Rights Agreement”), pursuant to which we provided certain registration rights to Essex with respect to the Essex Shares.

The first column in the table below identifies the selling shareholder. The second column lists the number of shares of common stock beneficially owned by the selling shareholder prior to the offering. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to our common stock. Generally, a person “beneficially owns” shares of our common stock if the person has or shares with others the right to vote those shares or to dispose of them, or if the person has the right to acquire voting or disposition rights within 60 days. The third column lists the aggregate number of shares of common stock being offered hereby by the selling shareholder. The fourth and fifth columns list the number of shares of common stock and percentage of our outstanding common stock to be held by the selling shareholder assuming the sale of all of the offered shares, based on 33,393,804 shares outstanding on September 30, 2017 and the sale by us of _____ shares in this offering.

Name of Selling Shareholder	Number of Shares of Common Stock Owned Prior to Offering	Number of Shares Offered	Number of Shares of Common Stock Owned After Offering(1)	Percentage of Class Following the Offering(1)
EW Healthcare Parters L.P.(2)	4,861,111	1,000,000		

- (1) Represents the number of shares of common stock that will be beneficially owned by the selling shareholder after completion of this offering based on the assumption that all of the shares offered for sale in this offering will be sold.
- (2) Essex Woodlands Fund IX-GP, L.P. (the “Fund IX-GP”) is the general partner of Essex. Essex Woodlands IX, LLC (the “Fund IX, LLC”) is the general partner of the Fund IX-GP. Fund IX, LLC holds sole voting and dispositive power over the shares held by Essex. The managers of the Fund IX, LLC are Martin P. Sutter, R. Scott Barry, Ronald Eastman, Guido J. Neels (also a member of our Board of Directors), Petri Vainio and Steve Wiggins (collectively, the “Managers”), and may exercise voting and investment control over the shares only by the majority action of the Managers. Each individual Manager, the Fund IX-GP and Fund IX, LLC disclaim beneficial ownership over the shares except to the extent of his or its respective pecuniary interest therein. The address for these entities is 21 Waterway Avenue, Suite 225, The Woodlands, Texas 77380.

Except for the sale and issuance of the shares of common stock, and except as otherwise disclosed in this prospectus supplement, the selling shareholder has not had any material relationship with us, or any of our predecessors or affiliates, within the past three years.

DILUTION

Investors purchasing shares of our common stock in this offering will suffer immediate and substantial dilution in the net tangible book value per share of common stock.

Our net tangible book value as of September 30, 2017 was approximately \$9,601,000, or \$0.29 per share of common stock. Net tangible book value per share is calculated by subtracting our total liabilities less the contingent consideration from our total tangible assets, which is total assets less intangible assets and goodwill, and dividing this amount by the number of shares of common stock outstanding.

After giving effect to the sale by us of shares of our common stock at the public offering price of, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of September 30, 2017 would have been \$, or \$ per share of common stock. This represents an immediate increase in the net tangible book value of \$ per share to our existing shareholders and an immediate and substantial dilution in net tangible book value of \$ per share to new investors.

The following table, in conjunction with the preceding paragraph, illustrates this per share dilution:

Public offering price per share	\$
Historical net tangible book value per share as of September 30, 2017	\$
Increase per share attributable to new investors	\$
As adjusted net tangible book value per share after this offering	\$
Dilution per share to investors in this offering	\$

The information above assumes that the underwriters do not exercise their option to purchase additional shares. If the underwriters exercise in full their option to purchase additional shares, the as adjusted net tangible book value after this offering would increase to approximately \$ per share, representing an increase to existing shareholders of approximately \$ per share, and there would be an immediate dilution of approximately \$ per share to new investors in this offering.

The information in the above table is based on 33,393,804 shares outstanding on September 30, 2017, and excludes:

- 44,483 shares of common stock issuable upon the exercise of a warrant outstanding as of September 30, 2017, at an exercise price of \$2.23 per share;
- 4,215,522 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2017, at a weighted average exercise price of \$5.94 per share;
- 268,925 shares of common stock subject to vesting of performance stock units and restricted stock unit awards outstanding as of September 30, 2017;
- 2,113,604 shares of common stock available for future issuance as of September 30, 2017 under the Stock Incentive Plan; and
- 600,000 shares of common stock available for future issuance as of September 30, 2017 under the 2017 ESPP.

To the extent that any of these outstanding options are exercised, any of these restricted stock units or performance stock units vest, or we issue additional shares under the Stock Incentive Plan or 2017 ESPP, there will be further dilution to new investors. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. The issuance of these securities could result in further dilution to new investors.

CAPITALIZATION AND INDEBTEDNESS

The following table describes our unaudited cash and cash equivalents, the current portion of liabilities and total capitalization as of September 30, 2017:

- on an actual basis; and
- on an as adjusted basis to give effect to the sale of _____ shares of common stock offered by us at the public offering price of \$ _____ per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table in conjunction with the section of this prospectus supplement captioned “Use of Proceeds” as well as our “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements, including the related notes, incorporated by reference in this prospectus supplement and the accompanying prospectuses, and in our annual report on Form 10-K for the year ended December 31, 2016 and our quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2017.

	As of September 30, 2017	
	Actual	As Adjusted
	(unaudited, in thousands except share and per share data)	
Cash and cash equivalents	\$ 22,041	\$ _____
Total current liabilities	\$ 11,138	\$ _____
Long-term debt (1)	\$ 20,356	\$ _____
Shareholders’ equity:		
Common stock, \$0.01 par value; 50,000,000 shares authorized (actual and as adjusted); 33,393,804 shares issued and outstanding (actual), 34,393,804 shares issued and outstanding (as adjusted) (2)	334	
Additional paid-in capital (3)	136,048	
Accumulated deficit	(125,830)	
Total shareholders’ equity	10,552	
Total capitalization	\$ 30,908	\$ _____

- (1) On October 25, 2016, AxoGen and AxoGen Corporation, each as borrowers, entered into a term loan agreement with MidCap Financial Trust, for a total of \$21,000,000, net of \$663,946 of unamortized financing fees at September 30, 2017, and \$771,185 at December 31, 2016. The loan has a fifty-four month term and requires interest only payments for the first twenty-four months, and thereafter, thirty monthly payments of principal and interest until the end of the term. Interest is payable monthly at 8.00% per annum plus the greater of LIBOR or 0.5% which as of September 30, 2017, resulted in an 8.5% rate.
- (2) AxoGen had 33,393,804 shares issued and outstanding on September 30, 2017, excluding: (i) 44,483 shares of common stock issuable upon the exercise of a warrant outstanding as of September 30, 2017 at an exercise price of \$2.23 per share, (ii) 4,215,522 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2017 at a weighted average exercise price of \$5.94 per share, (iii) 268,925 shares of common stock subject to vesting of performance stock units and restricted stock unit awards outstanding as of September 30, 2017, (iv) 2,113,604 shares of common stock available for future issuance as of September 30, 2017 under the Stock Incentive Plan and (v) 600,000 shares of common stock available for future issuance as of September 30, 2017 under the 2017 ESPP.
- (3) As adjusted represents additional paid-in capital attributable to the sale by us of shares in this offering, net of estimated issuance costs of \$ _____.

UNDERWRITING

Leerink Partners LLC is acting as representative of each of the underwriters named below and as sole book-running manager for this offering. Subject to the terms and conditions set forth in the underwriting agreement among us, the selling shareholder and the underwriters, we and the selling shareholder have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us and the selling shareholder, the number of shares of common stock set forth opposite its name below.

<u>Underwriter</u>	<u>Number of Shares</u>
Leerink Partners LLC	
Cantor Fitzgerald & Co.	
JMP Securities	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of the shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We and the selling shareholder have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representative has advised us and the selling shareholder that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ _____ per share. After the initial offering of the shares, the public offering price, concession or any other term of the offering may be changed by the representative.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us and the selling shareholder. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares of our common stock.

	<u>Per Share</u>	<u>Total</u>	
		<u>Without Option</u>	<u>With Option</u>
Public offering price	\$	\$	\$
Underwriting discounts and commissions	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$
Proceeds, before expenses, to the selling shareholder	\$	\$	\$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$500,000. We also have agreed to reimburse the underwriters for certain of their expenses, as set forth in the underwriting agreement. The underwriters have agreed to reimburse us for certain out-of-pocket expenses incurred in connection with this offering.

Option to Purchase Additional Shares

We and the selling shareholder have granted the underwriters an option to purchase up to an aggregate of _____ additional shares of common stock, at the public offering price, less the underwriting discounts and commissions, for a period of 30 days following the date of this prospectus supplement. If the underwriters exercise such option, the underwriters shall purchase the additional shares from us and the selling shareholder on a pro rata basis based on the number of shares offered by us and the selling shareholder hereby, and each underwriter will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares from us and the selling shareholder proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, the selling shareholder, and our executive officers and directors have agreed not to sell or transfer any common stock or securities convertible into or exchangeable or exercisable for common stock, for 90 days (180 days for the selling shareholder) after the date of this prospectus supplement without first obtaining the written consent of Leerink Partners LLC on behalf of the underwriters. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock;
- sell any option or contract to purchase any common stock;
- purchase any option or contract to sell any common stock;
- grant any option, right or warrant for the sale of any common stock;
- otherwise dispose of or transfer any common stock;
- request or demand that we file a registration statement related to the common stock; or
- enter into any swap or other agreement or any transaction that transfers, in whole or in part, the economic consequence of ownership of any common stock, whether any such swap, agreement or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

The underwriters have agreed to permit one of our directors to sell up to 125,000 shares of our common stock beginning 15 days after the date of this prospectus supplement.

The Nasdaq Capital Market Listing

Our common stock is listed on The Nasdaq Capital Market under the symbol "AXGN."

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representative may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option described above. The underwriters may close out any covered short position by either exercising their option or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position

is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the closing of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representative has repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Capital Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representative will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Some of the underwriters and certain of their affiliates may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us and our affiliates, for which they may in the future receive customary fees, commissions and expenses.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Perella Weinberg Partners ("Perella Weinberg"), a FINRA member, is acting as our independent financial advisor in connection with the offering. We have agreed with Perella Weinberg to pay certain fees upon the successful completion of this offering and to reimburse certain expenses incurred in connection with the engagement. Perella Weinberg is not acting as an underwriter and will not sell or offer to sell any securities and will not identify, solicit or engage directly with potential investors. In addition, Perella Weinberg will not underwrite or purchase any of the offered securities or otherwise participate in any such undertaking.

Selling Restrictions

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area (each, a "Relevant Member State"), no offer of shares may be made to the public in that Relevant Member State other than:

- A. to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- B. to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the

Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representative; or

C. in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares shall require the Company or the representative to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that it is a “qualified investor” within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive. In the case of any shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representative has been obtained to each such proposed offer or resale.

We, the representative and each of our and the representative’s and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

This prospectus supplement has been prepared on the basis that any offer of shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly, any person making or intending to make an offer in that Relevant Member State of shares which are the subject of the offering contemplated in this prospectus supplement may only do so in circumstances in which no obligation arises for the company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the company nor the underwriters have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for the company or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression “an offer to the public” in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in the Relevant Member State by any measure implementing the Prospectus Directive in the Relevant Member State and the expression “Prospectus Directive” means Directive 2003/71/EC (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

Notice to Prospective Investors in Canada

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Any discussion of taxation and related matters contained in this document does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the Securities and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby

[Table of Contents](#)

made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the Securities or with respect to the eligibility of the Securities for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the Securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

The following is a summary of the material U.S. federal income tax consequences to a non-U.S. holder (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering as of the date hereof. Except where noted, this summary deals only with common stock that is held as a capital asset as defined for purposes of Section 1221 of the United States Internal Revenue Code of 1986, as amended (the “Code”).

A “non-U.S. holder” means a person (other than a partnership, or entity or arrangement treated as a partnership for U.S. federal income tax purposes) that is not, for U.S. federal income tax purposes, any of the following:

- an individual citizen or resident of the United States;
- a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if it (1) is subject to the primary supervision of a court within the United States and one or more United States persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a United States person.

This summary is based upon provisions of the Code and U.S. Treasury regulations, administrative rulings and judicial decisions as of the date hereof. Those authorities may be changed, perhaps retroactively, so as to result in U.S. federal income tax consequences different from those summarized below. We have not sought, and will not seek, any ruling from the United States Internal Revenue Service (the “IRS”) with respect to the tax consequences discussed herein, and there can be no assurance that the IRS will not take a position contrary to the tax consequences discussed below or that any position taken by the IRS would not be sustained. This summary does not address all aspects of U.S. federal income taxes, such as the Medicare contribution tax on net investment income, and does not deal with foreign, state, local or other tax considerations that may be relevant to non-U.S. holders in light of their particular circumstances. In addition, it does not describe the U.S. federal income tax consequences applicable to you if you are subject to special treatment under the U.S. federal income tax laws (including if you are a U.S. expatriate, “controlled foreign corporation,” “passive foreign investment company,” a person who holds or receives our common stock pursuant to the exercise of an employee stock option or otherwise as compensation, a bank, financial institution or other financial services entity, a foreign government or governmental entity, a broker or dealer in foreign currencies, an insurance company, tax-exempt organization, pension plan, real estate investment trust, corporation that accumulates earnings to avoid U.S. federal income tax, person who use or are required to use mark-to-market accounting, person that holds our shares as part of a “straddle,” a “hedge,” a “conversion transaction,” “synthetic security,” integrated investment or other risk reduction strategy, or a partnership or other pass-through entity for U.S. federal income tax purposes). We cannot assure you that a change in law will not alter significantly the tax considerations that we describe in this summary.

If a partnership (or any entity treated as such for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner generally will depend upon the status of the partner and the activities of the partnership. If you are a partner of a partnership (or any entity treated as such for U.S. federal income tax purposes) holding our common stock, you should consult your tax advisors regarding the tax consequences of the purchase, ownership or disposition of our common stock.

If you are considering the purchase of our common stock, you should consult your own tax advisors concerning the particular U.S. federal income tax consequences to you of the purchase, ownership or disposition of our common stock, as well as the consequences to you arising under the laws of any other taxing jurisdiction.

Dividends

Distributions on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder’s adjusted tax basis in the common stock, but not below zero. Any remaining excess will be treated as capital gain subject to the rules discussed under “Gain on Disposition of Common Stock.”

Dividends paid to a non-U.S. holder of our common stock generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. However, dividends that are effectively connected with the conduct of a trade or business by the non-U.S. holder within the United States (and, if required by an applicable income tax treaty, that are attributable to a U.S. permanent establishment of the non-U.S. holder) are not subject to withholding, provided certain certification and disclosure requirements are satisfied, including providing us and/or our paying agent with a validly executed IRS Form W-8ECI. Instead, such dividends are subject to U.S. federal income tax on a net income basis in the same manner as if the non-U.S. holder were a “United States person,” as defined under the Code. Any such effectively connected dividends received by a foreign corporation may be subject to an additional “branch profits tax” at a 30% rate or such lower rate as may be specified by an applicable income tax treaty.

A non-U.S. holder of our common stock who wishes to claim the benefit of an applicable income tax treaty rate and avoid backup withholding, as discussed below, for dividends will be required (a) to complete the applicable IRS Form W-8 certifying under penalty of perjury that such holder is not a United States person and is eligible for treaty benefits or (b) if our common stock is held through certain foreign intermediaries, to satisfy the relevant certification requirements of applicable U.S. Treasury regulations.

A non-U.S. holder of our common stock eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Gain on Disposition of Common Stock

Subject to the discussion of backup withholding and FATCA below, any gain realized on the disposition of our common stock generally will not be subject to U.S. federal income tax unless:

- the gain is effectively connected with a trade or business of the non-U.S. holder in the United States (and, if required by an applicable income tax treaty, is attributable to a United States permanent establishment of the non-U.S. holder);
- the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of that disposition, and certain other conditions are met; or
- we are or have been a “U.S. real property holding corporation,” or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding such disposition or the holder’s holding period in the common stock.

A non-U.S. holder described in the first bullet point immediately above will be subject to tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates applicable to such holder as if it were a United States person. In addition, if a non-U.S. holder described in the first bullet point immediately above is a corporation for U.S. federal income tax purposes, it may be subject to the branch profits tax equal to 30% of its effectively connected earnings and profits or at such lower rate as may be specified by an applicable income tax treaty.

An individual non-U.S. holder described in the second bullet point immediately above will be subject to a flat 30% tax on the gain derived from the sale, which may be offset by U.S. source capital losses, even though the individual is not considered a resident of the United States, provided such non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

For purposes of the third bullet point immediately above, a corporation generally is a USRPHC if the fair market value of its United States real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe we are not and do not anticipate becoming a USRPHC for U.S. federal income tax purposes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we became a USRPHC, a non-U.S. holder would not be subject to U.S. federal income tax on a sale, exchange or other taxable disposition of our common stock by reason of our status as a USRPHC so long as our common stock is regularly traded on an established securities market (within the meaning of the applicable regulations) and such non-U.S. holder does not own and is not deemed to own (directly, indirectly or constructively) more than 5% of our outstanding common stock at any time during the shorter of the five year period ending on the date of disposition and such holder’s holding period.

However, no assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each non-U.S. holder the amount of dividends paid to such holder and the tax withheld with respect to such dividends, regardless of whether withholding was required. Copies of the information returns reporting such dividends and withholding may also be made available to the tax authorities in the country in which the non-U.S. holder resides under the provisions of an applicable income tax treaty.

A non-U.S. holder will be subject to backup withholding for dividends paid to such holder unless such holder certifies under penalty of perjury that it is a non-U.S. holder (and the payor does not have actual knowledge or reason to know that such holder is a United States person as defined under the Code), or such holder otherwise establishes an exemption.

Information reporting and, depending on the circumstances, backup withholding will apply to the proceeds of a sale of our common stock within the United States or conducted through certain U.S.-related financial intermediaries, unless the beneficial owner certifies under penalty of perjury on an applicable IRS Form W-8 that it is a non-U.S. holder (and the payor does not have actual knowledge or reason to know that the beneficial owner is a United States person as defined under the Code), or such owner otherwise establishes an exemption.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Additional Withholding Requirements

Under Sections 1471 through 1474 of the Code (such Sections commonly referred to as "FATCA"), a 30% U.S. federal withholding tax may apply to any dividends paid on our common stock, and, for a disposition of our common stock occurring after December 31, 2018, the gross proceeds from such disposition, in each case paid to (i) a "foreign financial institution" (as specifically defined in the Code) that does not provide sufficient documentation, typically on IRS Form W-8BEN-E, evidencing either (x) an exemption from FATCA or (y) its compliance (or deemed compliance) with FATCA (which may alternatively be in the form of compliance with an intergovernmental agreement with the United States) in a manner that avoids withholding, or (ii) a "non-financial foreign entity" (as specifically defined in the Code) that does not provide sufficient documentation, typically on IRS Form W-8BEN-E, evidencing either (x) an exemption from FATCA or (y) adequate information regarding certain substantial U.S. beneficial owners of such entity (if any). If a dividend payment is both subject to withholding under FATCA and subject to the withholding tax discussed above under "Dividends," the withholding under FATCA may be credited against, and therefore reduce, such other withholding tax. You should consult your own tax advisor regarding these requirements and whether they may be relevant to your ownership and disposition of our common stock.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to, our amended and restated articles of incorporation and our restated bylaws, as amended to the date of this prospectus supplement, which have been publicly filed with the SEC. See “Where You Can Find More Information; Incorporation of Certain Information by Reference.” In addition, please refer to our other publicly filed documents incorporated herein by reference which describe our outstanding warrants, registration rights, equity incentive plans and other securities.

COMMON STOCK

Under our articles of incorporation, as amended to date, we are authorized to issue up to 50,000,000 shares of common stock, par value \$0.01 per share. As of October 31, 2017, 33,456,091 shares of common stock were issued and outstanding.

Dividends, Voting Rights and Liquidation

The holders of shares of our common stock: (i) have equal, ratable rights to dividends from funds legally available therefor, when, as and if declared by the Board of Directors, (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 our 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, our articles of incorporation or our 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

Wells Fargo Bank, N.A. is the transfer agent and registrar for our common stock.

Minnesota Anti-Takeover Laws

We are 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 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.

Registration Rights

In connection with the execution of the Purchase Agreement, we entered into the Registration Rights Agreement with the selling shareholder, pursuant to which we granted the selling shareholder certain demand and “piggy-back” registration rights with respect to its shares of our common stock. The resale of all of the selling shareholder’s shares has been registered pursuant to the Registration Rights Agreement.

WHERE YOU CAN FIND MORE INFORMATION;

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

We file annual, quarterly and current reports, proxy statements and other documents with the SEC, under the Exchange Act. You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our reports, proxy statements and other documents filed electronically with the SEC are available at the website maintained by the SEC at <http://www.sec.gov>. You can read and copy reports and other information concerning us at the offices of the Financial Industry Regulatory Authority, located at 1735 K Street, Washington D.C. 20006. We also make available free of charge on or through our Internet website, <http://www.axogeninc.com>, our annual, quarterly and current reports, and, if applicable, amendments to those reports, filed or furnished pursuant to Section 13(a) of the Exchange Act, as soon as reasonably practicable after we electronically file such reports with the SEC. Information on our website is not a part of this prospectus supplement, the Company Prospectus, the Selling Shareholder Prospectus or the Registration Statements.

The SEC allows us to "incorporate by reference" in this prospectus supplement information that we file with the SEC, which means we can disclose important information to you by referring you to other documents that contain that information. The information we incorporate by reference is considered to be part of this prospectus supplement and information we later file with the SEC will automatically update and supersede the information in this prospectus. The following documents filed by us with the SEC pursuant to Section 13 of the Exchange Act (File No. 001-36046) and any future filings under Sections 13(a), 13(c), 14 or 15 (d) of the Exchange Act, except for information furnished under Item 2.02 or 7.01 of Current Report on Form 8-K, or exhibits related thereto, made after the date of the respective Registration Statements and prior to effectiveness of the respective Registration Statements and before the termination of the offering are incorporated by reference herein:

- (1) our annual report on Form 10-K filed on March 1, 2017 for the fiscal year ended December 31, 2016 (including certain information incorporated by reference therein from our Definitive Proxy Statement on Schedule 14A for our 2017 annual meeting of shareholders filed with the SEC on April 7, 2017);
- (2) our quarterly report on Form 10-Q filed on May 4, 2017 for the period ended March 31, 2017, our quarterly report on Form-10-Q filed on August 2, 2017 for the period ended June 30, 2017 and our quarterly report on Form 10-Q filed on November 1, 2017 for the period ended September 30, 2017;
- (3) our current reports on Form 8-K filed on January 3, 2017, January 26, 2017, May 30, 2017 and July 18, 2017 (as amended by our Current Report on Form 8-K/A filed on July 20, 2017); and
- (4) the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on August 6, 2013, including any amendment or report filed for the purpose of updating such description.

Any statement contained in this prospectus supplement, the accompanying prospectuses or in a document incorporated or deemed to be incorporated by reference into this prospectus supplement or the accompanying prospectuses will be deemed to be modified or superseded to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request, orally or in writing, a copy of these documents, which will be provided to you at no cost, by contacting: Investor Relations, c/o AxoGen, Inc., 13631 Progress Boulevard, Suite 400, Alachua, Florida 32615. Our telephone number is (386) 462-6800.

LEGAL MATTERS

Legal matters with respect to the securities offered hereby are being passed upon for us by DLA Piper LLP (US). Certain legal matters will be passed upon on behalf of the underwriters by Latham & Watkins LLP. Reed Smith LLP is acting as counsel to the selling shareholder.

EXPERTS

The consolidated financial statements and schedule of AxoGen, Inc. and its subsidiaries as of December 31, 2016 and 2015, and for each of the years in the two-year period ended December 31, 2016, and management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2016 have been incorporated by reference herein in reliance upon the reports of Lurie, LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

PROSPECTUS

\$100,000,000



Common Stock

This prospectus relates to offers and resales of up to \$100,000,000 of shares of our common stock. We will bear all costs, expenses and fees in connection with the registration of these securities.

We will provide the specific terms of these offerings in one or more supplements to this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. The prospectus supplement and any related free writing prospectus may also add, update or change information contained in this prospectus. You should carefully read this prospectus, the applicable prospectus supplement and any related free writing prospectus, as well as any documents incorporated by reference, before buying any of the common shares being offered.

Our common stock trades on the NASDAQ Capital Market under the symbol "AXGN." On November 4, 2015, the last reported sale price of our common stock on the NASDAQ Capital Market was \$4.81 per share.

As of November 4, 2015, the aggregate market value of our outstanding common stock held by non-affiliates, or public float, was approximately \$107,173,188, based on 29,885,688 shares of outstanding common stock, of which approximately 7,604,360 shares were held by affiliates, and a price of \$4.81 per share, which was the last reported sale price of our common stock on The NASDAQ Capital Market on November 4, 2015. Pursuant to General Instruction I.B.6 of Form S-3, during the prior 12 calendar month period that ends on and includes the date of this prospectus we have offered our common stock having a maximum aggregate offering price of \$20,252,299. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities registered on this registration statement in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75.0 million.

Investing in our securities involves a high degree of risk. You should carefully review and consider the risks and uncertainties described under the heading "Risk Factors" on page 3 of this prospectus and in any applicable prospectus supplement, any free writing prospectus or any documents incorporated by reference.

This prospectus may not be used to offer or sell any securities unless accompanied by a prospectus supplement.

The securities described in this prospectus may be sold directly by us to investors, through agents designated from time to time or to or through underwriters or dealers, on a continuous or delayed basis. For additional information on the methods of sale, you should refer to the section entitled "Plan of Distribution" in this prospectus and in the applicable prospectus supplement. If any agents or underwriters are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such agents or underwriters and any applicable fees, commissions, discounts and over-allotment options will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds that we expect to receive from such sale will also be set forth in a prospectus supplement.

Neither the U.S. Securities and Exchange Commission (the "SEC") nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

This prospectus is dated December 11, 2015.

TABLE OF CONTENTS

About This Prospectus	1
About AxoGen, Inc	1
Risk Factors	3
Cautionary Note Regarding Forward-Looking Statements	3
Use of Proceeds	3
Plan of Distribution	3
Legal Matters	5
Experts	5
Where You Can Find More Information	5
Information Incorporated by Reference	6

About This Prospectus

This prospectus is part of a registration statement on Form S-3 that we filed with the SEC utilizing a “shelf” registration process. Under this shelf registration process, we may offer our common stock in one or more offerings, up to a total dollar amount of \$100,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we offer common stock under this prospectus, we will provide a prospectus supplement that will contain more specific information about the terms of the offering. We may also add, update or change in the prospectus supplement any of the information contained in this prospectus or in the documents that we have incorporated by reference into this prospectus. We urge you to carefully read this prospectus and any applicable prospectus supplement, together with the information incorporated by reference herein as described under the headings “Where You Can Find More Information” and “Information Incorporated by Reference” before buying any of the securities being offered. **THIS PROSPECTUS MAY NOT BE USED TO OFFER OR SELL SECURITIES UNLESS IT IS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.**

You should rely only on the information that we have provided or incorporated by reference in this prospectus, any applicable prospectus supplement and any related free writing prospectus that we may authorize to be provided to you. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus that we may authorize to be provided to you. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement or any related free writing prospectus, or any sale of a security.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading “Where You Can Find Additional Information.” In this prospectus, unless the context specifically indicates otherwise, the terms “the Company,” “AxoGen,” “we,” “us” and “our” refer to AxoGen, Inc. and its subsidiaries.

About AxoGen, Inc.

We are a leading medical technology company dedicated to peripheral nerve repair. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body and their damage can result in the loss of muscle function and/or feeling.

Nerves can be damaged in a number of ways. When a nerve is cut due to a traumatic injury or surgery, 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. This type of injury generally requires a surgical repair. The traditional gold 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. In addition, compression on a nerve or blunt force trauma can cause nerve injuries that alter the signal conduction of the nerve and may require 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 offer a full suite of surgical nerve repair solutions including Avance® Nerve Graft, a proprietary off-the-shelf processed nerve allograft (human nerve tissue obtained from a donor) used for bridging severed nerves without the comorbidities associated with a nerve autograft additional surgical site, such as loss of feeling where the nerve was removed and potential pain at the donor site. The Company’s AxoGuard® line of products is made of porcine submucosa extracellular matrix, or ECM. AxoGuard® Nerve Connector is used as a coaptation aid to facilitate the tensionless repair of severed nerves, and

[Table of Contents](#)

AxoGuard® Nerve Protector is used to wrap and protect injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments.

AxoGen's products are used by surgeons during surgical interventions to repair a wide variety of nerve injuries throughout the body. These injuries range from a simple laceration of a finger to a complex brachial plexus injury (an injury to the network of nerves that originate in the neck) as well as nerve injuries caused by dental 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 discontinuities up to 70mm in length. Additionally, Avance® Nerve Graft has product and sales synergies with AxoGuard® Nerve Protector and AxoGuard® Nerve Connector. AxoGuard® products 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 and form a tissue similar to the outermost layer of the nerve (nerve epineurium).

We have reported a net loss of approximately \$17,710,000 and \$14,557,000 for the years ended December 31, 2014 and 2013, respectively, and a net loss of approximately \$9,745,000 and \$11,219,000 for the nine months ended September 30, 2015 and 2014, respectively.

We were incorporated under the laws of Minnesota in 1977. Our principal executive offices are located at 13631 Progress Boulevard, Suite 400, Alachua, Florida 32615 and our telephone number is (386) 462-6800. Our website address is www.axogeninc.com. We have included our website address in this prospectus solely as an inactive textual reference. The information contained on, or that can be accessed through, our website is not part of this prospectus.

Risk Factors

Investing in our securities involves a high degree of risk. Before purchasing our securities, you should carefully consider the risks and uncertainties described under “Risk Factors” in Item 1A of our most recent Annual Report on Form 10-K for the year ended December 31, 2014 and filed with the SEC on March 5, 2015, as well as information incorporated by reference into this prospectus, any applicable prospectus supplement or any free writing prospectus. If any of these risks were to occur, our business, financial condition or results of operations would likely suffer. In that event, the value of our securities could decline, and you could lose part or all of your investment. The risks and uncertainties we describe are not the only ones facing us. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

Cautionary Note Regarding Forward-Looking Statements

Certain statements contained or incorporated by reference into this prospectus, any applicable prospectus supplement and any free writing prospectus, constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Securities Exchange Act"). These forward-looking statements may concern possible or anticipated future results of operations or business developments. These statements are based on management’s current expectations or predictions of future conditions, events or results based on various assumptions and management’s estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as “expects”, “anticipates”, “intends”, “plans”, “believes”, “seeks”, “estimates”, “projects”, “forecasts”, “may”, “should”, 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 product development, product potential, regulatory environment, sales and marketing strategies, capital resources or operating performance. The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the statements. Forward-looking statements 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 in the Company’s filings with the SEC, including as described in “Risk Factors” contained or incorporated by reference in this prospectus and in any related free writing prospectus and any applicable prospectus supplement, and in our most recent Annual Report on Form 10-K, as well as any amendments thereto reflected in subsequent filings with the SEC.

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 the Company assumes no responsibility to update any forward-looking statements except as required by law.

Use of Proceeds

Except as described in any prospectus supplement or in any related free writing prospectus that we may authorize to be provided to you, we currently intend to use the net proceeds from the sale of the securities offered hereby for continued product commercialization and marketing efforts, development of product pipeline, including product line extension, and for general corporate purposes, including working capital, acquisitions, capital expenditures and repayment of indebtedness.

Our management will retain broad discretion over the allocation of the net proceeds from the sale of the securities. We have no current understandings, agreements or commitments for any material acquisitions.

Plan of Distribution

We may sell the securities, from time to time, to or through underwriters, dealers or agents, or directly to one or more purchasers pursuant to:

- underwritten public offerings;
- negotiated transactions;
- block trades;
- “at the market offerings,” within the meaning of Rule 415(a)(4) of the Securities Act, to or through a market maker or into an existing trading market, on an exchange or otherwise, at prevailing market prices; or

Table of Contents

- through a combination of these methods.

We may distribute securities from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

A prospectus supplement or supplements will describe the terms of the offering of the securities, including:

- the name or names of the underwriters, if any;
- if the securities are to be offered through the selling efforts of brokers or dealers, the plan of distribution and the terms of any agreement, arrangement, or understanding entered into with broker(s) or dealer(s) prior to the effective date of the registration statement, and, if known, the identity of any broker(s) or dealer(s) who will participate in the offering and the amount to be offered through each;
- the purchase price of the securities and the proceeds we will receive from the sale;
- if any of the securities being registered are to be offered otherwise than for cash, the general purposes of the distribution, the basis upon which the securities are to be offered, the amount of compensation and other expenses of distribution, and by whom they are to be borne;
- any delayed delivery arrangements;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any agency fees or underwriting discounts and other items constituting agents' or underwriters' compensation;
- any public offering price;
- any discounts, commissions or commissions allowed or reallowed or paid to dealers;
- the identity of any finders, if applicable, and the material relationships between such finders and AxoGen, Inc. (the "Registrant"), or the Registrant's officers, directors, principal shareholders, finders, promoters or underwriters; and
- any securities exchange or market on which the securities may be listed.

Only underwriters named in the prospectus supplement will be underwriters of the securities offered by the prospectus supplement.

If underwriters are used in the sale, the obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Unless otherwise indicated in the prospectus supplement, subject to certain conditions, the underwriters will be obligated to purchase all of the securities offered by the prospectus supplement, other than securities covered by any over-allotment option. The securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Any initial public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time.

The securities may be sold to a dealer as principal. The dealer may resell the securities to the public at varying prices to be determined by the dealer at the time of resale. Any such dealer may be deemed to be an underwriter of the securities offered and sold.

We may sell securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

We may sell securities directly to one or more purchasers without using underwriters or agents. Underwriters, dealers and agents that participate in the distribution of the securities may be underwriters as defined in the Securities Act,

and any discounts or commissions they receive from us and any profit on their resale of the securities may be treated as underwriting discounts and commissions under the Securities Act.

If indicated in the applicable prospectus supplement, we may authorize underwriters or their other agents to solicit offers by certain institutional investors to purchase securities from us pursuant to contracts providing for payment and delivery at a future date. Institutional investors with which these contracts may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and others. In all cases, these purchasers must be approved by us. The obligations of any purchaser under any of these contracts will not be subject to any conditions except that (a) the purchase of the securities must not at the time of delivery be prohibited under the laws of any jurisdiction to which that purchaser is subject and (b) if the securities are also being sold to underwriters, the issuer(s) must have sold to these underwriters the securities not subject to delayed delivery. Underwriters and other agents will not have any responsibility in respect of the validity or performance of these contracts.

Agents, underwriters, dealers and remarketing firms may be entitled under relevant agreements entered into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act or to contribution with respect to payments which the agents, underwriters or dealers may be required to make.

Our common stock is listed on the NASDAQ Capital Market under the symbol "AXGN."

In connection with an offering, the underwriters may purchase and sell the offered securities in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of offered securities than they are required to purchase in an offering. Stabilizing transactions consist of certain bids or purchases made for the purpose of preventing or retarding a decline in the market price of the offered securities while an offering is in progress.

The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the underwriters have repurchased offered securities sold by or for the account of that underwriter in stabilizing or short-covering transactions.

These activities by the underwriters may stabilize, maintain or otherwise affect the market price of the offered securities. As a result, the price of the offered securities may be higher than the price that otherwise might exist in the open market. If these activities are commenced, they may be discontinued by the underwriters at any time.

Underwriters, dealers and agents, or their affiliates, may be customers of, engage in transactions with, or perform services for, us and our subsidiaries in the ordinary course of business.

Legal Matters

Unless otherwise indicated in the applicable prospectus supplement, the validity of the securities offered by this prospectus will be passed upon for us by DLA Piper LLP (US), Philadelphia, Pennsylvania.

Experts

The consolidated financial statements of AxoGen, Inc. and subsidiary as of December 31, 2014 and 2013, and for each of the years then ended have been incorporated by reference in this registration statement in reliance upon the report of Lurie, LLP (formerly known as Lurie Besikof Lapidus & Company, LLP), independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

Where You Can Find More Information

This prospectus is part of a registration statement that we filed with the SEC. Certain information in the registration statement has been omitted from this prospectus in accordance with the rules of the SEC. We are a public company and file proxy statements, annual, quarterly and special reports and other information with the SEC. The registration statement, such reports and other information can be inspected and copied at the Public Reference Room of the SEC located at 100 F Street, N.E., Washington D.C. 20549. Copies of such materials, including copies of all or any

portion of the registration statement, can be obtained from the Public Reference Room of the SEC at prescribed rates. You can call the SEC at 1-800-SEC-0330 to obtain information on the operation of the Public Reference Room. Such materials may also be accessed electronically by means of the SEC's home page on the Internet (<http://www.sec.gov>).

Our web site address is <http://www.axogeninc.com>. The information on our web site, however, is not and should not be deemed to be, a part of this registration statement.

You should rely only on the information provided in this prospectus. We have not authorized anyone to provide you with different information. You should not assume that the information in this document is accurate as of any date other than that on the front cover of this prospectus.

Information Incorporated by Reference

The SEC allows us to "incorporate by reference" the information we file with it, which means that we can disclose important information to you by referring to those documents. The information incorporated by reference is an important part of this prospectus. Any statement contained in a document which is incorporated by reference in this prospectus is automatically updated and superseded if information contained in this prospectus, or information that we later file with the SEC, modifies or replaces this information. We incorporate by reference the documents listed below and any future documents we subsequently file pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act (other than information furnished to, and not filed with, the SEC) prior to the termination of this offering:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC on March 5, 2015;
- the information specifically incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2014 from our Definitive Proxy Statement on Schedule 14A for the Annual Meeting of Shareholders held on May 28, 2015, filed with the SEC on April 15, 2015;
- our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2015, filed with the SEC on May 5, 2015;
- our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, filed with the SEC on August 6, 2015;
- our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2015, filed with the SEC on November 5, 2015;
- our Current Reports on Form 8-K filed with the SEC on February 4, 2015, February 4, 2015, February 5, 2015, March 13, 2015, April 22, 2015, June 19, 2015, August 6, 2015 (except with respect to Item 2.02 and Exhibit 99.1 furnished under Item 2.02 thereunder) and August 26, 2015; and
- the description of our common stock our registration statement on Form 8-A filed with the SEC on August 6, 2013, including any amendments or reports filed for the purpose of updating such description.

To receive a free copy of any of the documents incorporated by reference in this prospectus, other than any exhibits, unless the exhibits are specifically incorporated by reference into this prospectus, *call* or *write* us at the following address and telephone number:

AxoGen, Inc.
13631 Progress Boulevard, Suite 400
Alachua, Florida 32615
(386) 462-6800

PROSPECTUS



4,861,111 Shares of Common Stock

This prospectus relates to the resale or other disposition by the selling shareholder identified in this prospectus, from time to time, of up to 4,861,111 shares of our common stock.

We are not selling any shares of common stock under this prospectus and will not receive any of the proceeds from the sale or other disposition of common stock by the selling shareholder.

The selling shareholder or its pledgees, assignees, permitted transferees or other successors-in-interest may offer and sell or otherwise dispose of the shares of common stock described in this prospectus from time to time through public or private transactions at fixed prices, at prevailing market prices, at prices related to prevailing market prices, at varying prices determined at time of sale, or at privately negotiated prices. The selling shareholder will bear all commissions and discounts, if any, attributable to the sales of shares. We will bear all costs, expenses and fees in connection with the registration of the shares. See "Plan of Distribution" beginning on page 7 for more information about how the selling shareholder may sell or dispose of its shares of common stock.

Our common stock is traded on the NASDAQ Capital Market ("NASDAQ"), under the symbol "AXGN." The last reported sale of our common stock on the NASDAQ on September 29, 2017 was \$19.35 per share.

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. RISKS ASSOCIATED WITH AN INVESTMENT IN OUR SECURITIES WILL BE DESCRIBED IN THE APPLICABLE PROSPECTUS SUPPLEMENT AND CERTAIN OF OUR FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is October 11, 2017

TABLE OF CONTENTS

	<u>Page</u>
About this Prospectus	ii
Prospectus Summary	1
Special Note Regarding Forward-looking Statements	3
Use of Proceeds	4
Selling Shareholder	5
Plan of Distribution	7
Description of Capital Stock	9
Where You Can Find More Information	11
Incorporation of Certain Information by Reference	11
Legal Matters	12
Experts	12

You should rely only on the information provided in this prospectus (as supplemented and amended) as well as the information incorporated by reference. Neither we nor the selling shareholder have authorized anyone to provide you with different information. Neither we nor the selling shareholder are making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus (as supplemented and amended) or any documents incorporated by reference is accurate as of any date other than the date of the applicable document.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the U.S. Securities and Exchange Commission, referred to herein as the SEC, using a “shelf” registration process. Under a shelf registration process, the selling shareholder may from time to time sell the shares of common stock described in this prospectus and the accompanying prospectus supplement in one or more offerings.

We have not authorized anyone to give any information or to make any representation other than those contained or incorporated by reference in this prospectus (and in any supplement or amendment to this prospectus). We do not take any responsibility for, and can provide no assurance as to the reliability of any information that others may provide you. The selling shareholder is offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where it is lawful to do so. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any shares other than the registered shares to which they relate, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy shares in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus (as supplemented and amended) is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus is delivered or shares are sold on a later date.

You should read both this prospectus (as supplemented and amended) together with additional information described under the heading “Where You Can Find More Information; Incorporation of Certain Information by Reference” beginning on page 11 of this prospectus before deciding to invest in any of the shares being offered.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of the documents referred to herein have been filed, or will be filed or incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under “Where You Can Find More Information.”

PROSPECTUS SUMMARY

This summary description about us and our business highlights selected information contained elsewhere in this prospectus or incorporated in this prospectus by reference. This summary does not contain all of the information you should consider before investing in our common stock. You should carefully read this entire prospectus (as supplemented and amended), including each of the documents incorporated herein by reference, before making an investment decision. As used in this prospectus, the terms “we,” “us,” “our,” “AxoGen, Inc.” and “AxoGen” mean AxoGen, Inc. and its subsidiaries.

About AxoGen, Inc.

Overview

We are a global leader in innovative surgical solutions for peripheral nerve injuries. We are the only company focused specifically on the science, development and commercialization of technologies for peripheral nerve regeneration and repair. We are passionate about restoring nerve function and quality of life to patients with peripheral nerve injuries 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. Damage to a peripheral nerve can result in the loss of muscle or organ function, the loss of sensory feeling, or the initiation of pain.

Our portfolio of products includes Avance® Nerve Graft, an off-the-shelf processed human nerve allograft for bridging severed 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 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, and Avive® Soft Tissue Membrane, a minimally processed human umbilical cord membrane that may be used as a resorbable soft tissue covering to separate tissue layers and modulate inflammation in the surgical bed. Along with these core surgical products, we also offer AcroVal™ Neurosensory & Motor Testing System and AxoTouch™ Two-Point Discriminator. These evaluation and measurement tools assist health care professionals in detecting changes in sensation, assessing return of sensory, grip, and pinch function, evaluating effective treatment interventions, and providing feedback to patients on nerve function. Our portfolio of products is available in the United States, Canada, the United Kingdom, and several other European and international countries.

Corporate Information

We were incorporated in Minnesota in 1977. Our principal offices are located at 13631 Progress Boulevard, Suite 400, Alachua, Florida 32615. Our telephone number is (386) 462-6800. We have two wholly owned subsidiaries, AxoGen Corporation, a Delaware corporation, and AxoGen Europe GmbH, a limited liability corporation with its corporate seat in Vienna, Austria. Our web address is www.axogeninc.com. We have not incorporated by reference into this Registration Statement of which this prospectus forms a part, the information on our website and you should not consider it to be a part of this document.

Our reports that have been filed with the SEC, are available on our website free of charge, including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, Forms 3, 4 and 5 filed on behalf of directors and executive officers and any amendments to such reports filed pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Copies of this prospectus may also be obtained without charge electronically or by paper by contacting Investor Relations, c/o AxoGen, Inc., 13631 Progress Boulevard, Suite 400, Alachua, Florida 32615 or by calling (386) 462-6800.

In addition, we make available on our website (i) the charters for the committees of the Board of Directors, including the Audit Committee, Compensation Committee and Governance and Nominating Committee, and (ii) the company’s Code of Business Conduct and Ethics (“Code of Conduct”) governing its directors, officers and employees. Within the time period required by the SEC, we will post on our website any modifications to the Code of Conduct, as required by the Sarbanes-Oxley Act of 2002.

The public may also read and copy the materials we file with the SEC at its Public Reference Room at 100 F Street, N.E., Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site at <http://www.sec.gov> that contains reports, proxy and information statements and other information regarding companies that file electronically with the SEC.

THE OFFERING

Selling shareholder	EW Healthcare Partners L.P., formerly named Essex Woodlands Fund IX, L.P.
Common Stock that may be offered by the selling shareholder from time to time	Up to 4,861,111 shares of common stock.
Use of proceeds	We will not receive any proceeds from the sale or other disposition of the shares of common stock offered hereby.
Risk factors	Investing in our common stock involves a high degree of risk. See risk factors described under the heading “Risk Factors” in the accompanying prospectus supplement and in the documents incorporated by reference herein and therein for a discussion of factors that you should carefully consider before deciding to invest in our common stock.
NASDAQ Capital Market symbol	AXGN.

When we refer to the “selling shareholder” in this prospectus, we are referring to the entity named in this prospectus as the selling shareholder and, as applicable, any pledgee, assignee, permitted transferee or other successor-in-interest selling shares received after the date of this prospectus from the selling shareholder as a pledge, assignment or other transfer that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this prospectus, any prospectus supplement and in the documents incorporated by reference herein constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements frequently, but not always, use the words “may”, “estimate”, “projects”, “intends”, “plans”, “believes”, “anticipates” or “expects” or similar words and may include statements concerning our strategies, goals and plans. Forward-looking statements may include, without limitation, statements regarding our assessment on our internal control over financial reporting, our growth, our earnings 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.

All forward-looking statements are based on management’s present expectations of future events and are subject to a number of assumptions that could cause actual results to differ materially from those described in the forward-looking statements. Forward-looking statements should be evaluated together with the many risks and uncertainties that affect our business and market, including those risks and uncertainties discussed in the following documents:

- the risk factors contained in any prospectus supplement to this prospectus under the caption “Risk Factors”;
- our most recent annual report on Form 10-K, including the sections entitled “Business”, “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”;
- our quarterly reports on Form 10-Q; and
- our other SEC filings.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus, any prospectus supplement or in any document incorporated by reference in this prospectus might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only of the date of this prospectus, the date of any prospectus supplement or the date of the document incorporated by reference in this prospectus. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by applicable law. All subsequent forward-looking statements attributable to us are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of shares of our common stock sold pursuant to this prospectus by the selling shareholder. The selling shareholder will receive all of the proceeds from sales of our common stock sold pursuant to this prospectus.

We have agreed to pay all costs, expenses and fees relating to the registration of the shares of our common stock covered by this prospectus. The selling shareholder will pay any underwriting fees, discounts and commissions and/or similar charges incurred in connection with the sale or other disposition by it of the shares covered hereby.

SELLING SHAREHOLDER

The shares of common stock being offered by the selling shareholder, EW Healthcare Partners L.P., formerly named Essex Woodlands Fund IX, L.P. (“Essex”), are shares of common stock previously issued and sold to Essex pursuant to a Securities Purchase Agreement, dated as of August 26, 2015 (the “Purchase Agreement”). Under the Purchase Agreement, Essex purchased 4,861,111 shares of our common stock (the “Essex Shares”) at a public offering price of \$3.60 per share. In connection with the sale of the Essex Shares to Essex, we entered into a Registration Rights Agreement with Essex, dated as of August 26, 2015 (the “Registration Rights Agreement”), pursuant to which we provided certain registration rights to Essex with respect to the Essex Shares. The shares of common stock held by Essex and being registered hereunder are being registered pursuant to the terms of the Registration Rights Agreement.

Except for the sale and issuance of the shares of common stock, and except as otherwise disclosed in this prospectus, the selling shareholder has not had any material relationship with us, or any of our predecessors or affiliates, within the past three years. Guido J. Neels, one of the managers of Essex Woodlands Fund IX-GP, L.P. (the “Fund IX-GP”), currently serves as a director of the Company. The Fund IX-GP is the general partner of Essex.

We are registering the shares of common stock in order to permit the selling shareholder, or its permitted transferees or other successors-in-interest that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part, to offer the shares for resale from time to time.

The first column in the table below identifies the selling shareholder. The second column lists the number of shares of common stock beneficially owned by the selling shareholder as of September 30, 2017. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to our common stock. Generally, a person “beneficially owns” shares of our common stock if the person has or shares with others the right to vote those shares or to dispose of them, or if the person has the right to acquire voting or disposition rights within 60 days. The third column lists the aggregate number of shares of common stock that may be offered from time to time by this prospectus by the selling shareholder. The fourth and fifth columns list the number of shares of common stock and percentage of our outstanding common stock to be held by the selling shareholder assuming the sale of all of the shares registered for resale by the registration statement of which this prospectus is a part.

<u>Name of Selling Shareholder</u>	<u>Number of Shares of Common Stock Owned Prior to Offering</u>	<u>Maximum Number of Shares of Common Stock that may be Sold Pursuant to this Prospectus</u>	<u>Number of Shares of Common Stock Owned After Offering(1)</u>	<u>Percentage of Class Following the Offering(1)</u>
EW Healthcare Partners L.P., formerly named Essex Woodlands Fund IX, L.P.	4,861,111(2)	4,861,111(2)	☐	☐

- (1) On April 7, 2017, Essex Woodland Fund IX, L.P. changed its name to EW Healthcare Partners L.P. Represents the number of shares of common stock that will be beneficially owned by the selling shareholder after completion of this offering based on the assumptions that (i) all of the shares of common stock registered for resale by the registration statement of which this prospectus is a part will be sold, and (ii) no other shares of common stock will be acquired or sold by the selling shareholder before completion of this offering. However, the selling shareholder may sell all, part or none of its shares of common stock offered pursuant to this prospectus and may sell all, part or none of its common stock pursuant to one or more exemptions from the registration provisions of the Securities Act. Applicable percentage ownership following the offering is based on 33,393,804 shares of common stock that would be outstanding following the offering if all shares registered by this prospectus are sold in the offering.
- (2) Essex Woodlands Fund IX-GP, L.P. (the “Fund IX-GP”) is the general partner of Essex. Essex Woodlands IX, LLC (the “Fund IX, LLC”) is the general partner of the Fund IX-GP. Fund IX, LLC holds sole voting and dispositive power over the shares held by Essex. The managers of the Fund IX, LLC are Martin P. Sutter, R. Scott Barry, Ronald Eastman, Guido J. Neels (also a member of our Board of Directors), Petri Vainio and Steve Wiggins (collectively, the “Managers”), and may exercise voting and investment control over the shares only by the majority

[Table of Contents](#)

action of the Managers. Each individual Manager, the Fund IX-GP and Fund IX, LLC disclaim beneficial ownership over the shares except to the extent of his or its respective pecuniary interest therein. The address for these entities is 21 Waterway Avenue, Suite 225, The Woodlands, Texas 77380.

PLAN OF DISTRIBUTION

The selling shareholder may, from time to time, sell any or all of its shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in privately negotiated transactions. These sales may be at fixed prices, at prevailing market prices, at prices related to prevailing market prices, at varying prices determined at the time of sale or at privately negotiated prices. The selling shareholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- an underwritten offering on a firm commitment or best efforts basis;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- broker-dealers may agree with the selling shareholder to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling shareholder may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling shareholder may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling shareholder (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling shareholder does not expect these commissions and discounts to exceed what is customary in the types of transactions involved. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by the selling shareholder.

The selling shareholder may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by it and, if it defaults in the performance of its secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 supplementing or amending the list of selling shareholders to include the pledgee, transferee or other successors in interest as a “selling shareholder” under this prospectus.

The selling shareholder also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 supplementing or amending the list of selling shareholders to include the pledgee, transferee or other successors in interest as a “selling shareholder” under this prospectus.

[Table of Contents](#)

In connection with the sale of the shares of common stock or interests therein, the selling shareholder may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares of common stock in the course of hedging the positions they assume. The selling shareholder may also sell the shares of common stock short and deliver these securities to close out its short positions or to return borrowed shares in connection with such short sales, or loan or pledge the shares of common stock to broker-dealers that in turn may sell these securities. The selling shareholder may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares of common stock offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling shareholder and any broker-dealers or agents that are involved in selling the shares of common stock may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. In the event that the selling shareholder is deemed to be an “underwriter” within the meaning of Section 2(11) of the Securities Act, the selling shareholder will be subject to the prospectus delivery requirements of the Securities Act.

We are required to pay all fees and expenses incident to the registration of the shares of common stock. We have agreed to indemnify the selling shareholder against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The selling shareholder has advised us that it has not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of its shares of common stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares of common stock by the selling shareholder. If we are notified by the selling shareholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if required, we will file a supplement to this prospectus. If the selling shareholder uses this prospectus for any sale of the shares of common stock, it will be subject to the prospectus delivery requirements of the Securities Act, unless an exemption therefrom is available.

The anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934 may apply to sales of our common stock and activities of the selling shareholder.

There can be no assurance that the selling shareholder will sell any or all of the shares of common stock we registered on behalf of the selling shareholder pursuant to the registration statement of which this prospectus forms a part.

Once sold under the registration statement of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to, our amended and restated articles of incorporation and our restated bylaws, as amended to the date of this prospectus, which have been publicly filed with the SEC. See “Where You Can Find More Information” and “Incorporation of Certain Information by Reference.” In addition, please refer to our other publicly filed documents incorporated herein by reference which describe our outstanding warrants, registration rights, equity incentive plans and other securities.

COMMON STOCK

Under our articles of incorporation, as amended to date, we are authorized to issue up to 50,000,000 shares of common stock, par value \$0.01 per share. As of September 30, 2017, 33,393,804 shares of common stock were issued and outstanding.

Dividends, Voting Rights and Liquidation

The holders of shares of our common stock: (i) have equal, ratable rights to dividends from funds legally available therefor, when, as and if declared by the Board of Directors, (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 our 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, our articles of incorporation or our 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

Wells Fargo Bank, N.A. is the transfer agent and registrar for our common stock.

Minnesota Anti-Takeover Laws

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.

Registration Rights

In connection with the execution of the Purchase Agreement, we entered into the Registration Rights Agreement with Essex, pursuant to which we granted Essex certain demand and “piggy-back” registration rights with respect to its shares of our common stock.

**WHERE YOU CAN FIND MORE INFORMATION;
INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

We file annual, quarterly and current reports, proxy statements and other documents with the SEC, under the Securities Exchange Act of 1934, as amended, or the Exchange Act. You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our reports, proxy statements and other documents filed electronically with the SEC are available at the website maintained by the SEC at <http://www.sec.gov>. In addition, our common stock has been approved for quotation on the NASDAQ. You can read and copy reports and other information concerning us at the offices of the Financial Industry Regulatory Authority, located at 1735 K Street, Washington D.C. 20006. We also make available free of charge on or through our Internet website, <http://www.axogeninc.com>, our annual, quarterly and current reports, and, if applicable, amendments to those reports, filed or furnished pursuant to Section 13(a) of the Exchange Act, as soon as reasonably practicable after we electronically file such reports with the SEC. Information on our website is not a part of this registration statement.

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to certain shares of our common stock (the "Securities"). This prospectus, which constitutes a part of that registration statement, does not contain all the information contained in that registration statement and its exhibits. For further information with respect to the company and the Securities, you should consult the registration statement and its exhibits. The registration statement and any of its amendments, including exhibits filed as a part of the registration statement or an amendment to the registration statement, are available for inspection and copying through the SEC's public reference rooms listed above.

The SEC allows us to "incorporate by reference" in this prospectus information that we file with them, which means we can disclose important information to you by referring you to other documents that contain that information. The information we incorporate by reference is considered to be part of this prospectus and information we later file with the SEC will automatically update and supersede the information in this prospectus. The following documents filed by us with the SEC pursuant to Section 13 of the Exchange Act (File No. 001-36046) and any future filings under Sections 13(a), 13(c), 14 or 15 (d) of the Exchange Act, except for information furnished under Item 2.02 or 7.01 of Current Report on Form 8-K, or exhibits related thereto, made after the date of the initial registration statement and prior to effectiveness of the registration statement and before the termination of the offering are incorporated by reference herein:

- (1) our Annual Report on Form 10-K filed on March 1, 2017 for the fiscal year ended December 31, 2016;
- (2) our Quarterly Report on Form 10-Q filed on May 4, 2017 for the period ended March 31, 2017 and our Quarterly Report on Form-10-Q filed on August 2, 2017 for the period ended June 30, 2017;
- (3) our Current Reports on Form 8-K filed on January 3, 2017, January 26, 2017, May 30, 2017 and July 18, 2017 (as amended by our Current Report on Form 8-K/A filed on July 20, 2017); and
- (4) the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on August 6, 2013, including any amendment or report filed for the purpose of updating such description.

In addition, all documents subsequently filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of the initial registration statement and before effectiveness of the registration statement, and before the date any offering under this registration statement is terminated or complete, are deemed to be incorporated by reference into, and to be a part of, this prospectus and the accompanying prospectus supplement.

Any statement contained in this prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus and the accompanying prospectus supplement to the extent that a statement contained in this prospectus and the accompanying prospectus supplement or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus or the accompanying prospectus supplement modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus or the accompanying prospectus supplement.

[Table of Contents](#)

You may request, orally or in writing, a copy of these documents, which will be provided to you at no cost, by contacting: Investor Relations, c/o AxoGen, Inc., 13631 Progress Boulevard, Suite 400, Alachua, Florida 32615. Our telephone number is (386) 462-6800.

You should rely only on information contained in, or incorporated by reference into, this prospectus and any prospectus supplement. We have not authorized anyone to provide you with information different from that contained in this prospectus or incorporated by reference in this prospectus. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

LEGAL MATTERS

Legal matters with respect to the securities offered hereby are being passed upon for us by DLA Piper LLP (US).

EXPERTS

The consolidated financial statements and schedule of AxoGen, Inc. and its subsidiaries as of December 31, 2016 and 2015, and for each of the years in the two-year period ended December 31, 2016, and management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2016 have been incorporated by reference herein in reliance upon the reports of Lurie, LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

Shares



Common Stock

PROSPECTUS SUPPLEMENT

Book-Running Managers

Leerink Partners

Co-Managers

Cantor

JMP Securities

, 2017
