Xtant Medical Holdings, Inc.
Form POS AM
June 17, 2016

As filed with the Securities and Exchange Commission June 17, 2016

Registration Statement No. 333-203492

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1 TO

POST-EFFECTIVE AMENDMENT NO. 2 TO

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

XTANT MEDICAL HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**20-5313323**
(State or other jurisdiction of incorporation or	(Primary Standard Industrial	(I.R.S. Employer Identification No.)

organization) Classification Code Number)

664 Cruiser Lane

Belgrade, Montana 59714

(406) 388-0480

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

John Gandolfo

Chief Financial Officer

Xtant Medical Holdings, Inc.

664 Cruiser Lane

Belgrade, Montana 59714

(406) 388-0480

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Travis Leach

Ballard Spahr LLP

One East Washington Street, Suite 2300

Phoenix, Arizona 85004

(602) 798-5444

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. þ

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller Reporting Company þ

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this

Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

This Amendment No. 1 (this "Amendment") to Post-Effective Amendment No. 2 to the registration statement on Form S-1 (File No. 333-203492) (the "Registration Statement"), which was amended by Post-Effective Amendment No. 1 filed with the Securities and Exchange Commission on August 25, 2015, is being filed by Xtant Medical Holdings, Inc. (the "Company") pursuant to (i) Section 10(a)(3) of the Securities Act of 1933, as amended, to update the Registration Statement, which was previously declared effective by the Securities and Exchange Commission (the "SEC") on September 8, 2015. No additional securities are being registered under this Amendment.

The information included in this Amendment updates and supplements the Registration Statement contained therein. No additional securities are being registered under this Amendment. All applicable SEC registration fees were paid at the time of the filing of the original Registration Statement.

The information in this prospectus is not complete and may be changed. The selling stockholder may not sell these securities until the registration statement filed with the Securities and Exchange Commission becomes effective. This prospectus is not an offer to sell these securities, and the selling stockholder is not soliciting offers to buy these securities in any state where the offer or sale of these securities is not permitted.

SUBJECT TO COMPLETION, DATED JUNE 17, 2016

PRELIMINARY PROSPECTUS

2,000,000 Shares

Common Stock

This prospectus relates to the sale of up to 2,000,000 shares of our common stock by Aspire Capital Fund, LLC. Aspire Capital Fund, LLC is also referred to in this prospectus as Aspire Capital or the selling stockholder. The prices at which the selling stockholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the selling stockholder. However, as of June 13, 2016, we may receive proceeds of up to $7,562,561 million from the sale of our common stock to the selling stockholder pursuant to a Common Stock Purchase Agreement entered into with the selling stockholder on March 16, 2015, as amended and restated on April 17, 2015. We previously received proceeds of $2,437,439 as a result of sales of our common stock to the selling stockholder pursuant to the Common Stock Purchase Agreement.

The selling stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See “Plan of Distribution” for more information. The selling stockholder is an “underwriter” within the meaning of the Securities Act of 1933, as amended. We have paid all applicable expenses of registering these shares at the time of the initial filing of the Registration Statement. All selling and other expenses incurred by the selling stockholder will be paid by the selling stockholder.

Our common stock is traded on the NYSE MKT under the ticker symbol “XTNT.” On June 13, 2016, the last reported sale price per share of our common stock was $2.13 per share.

You should read this prospectus and any prospectus supplement, together with additional information described under the heading “Where You Can Find More Information,” carefully before you invest in any of our securities.

Investing in our securities involves a high degree of risk. See “Risk Factors” on page 4 this prospectus.

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 , 2016.

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This prospectus relates to the offering of our common stock by the selling stockholder. You should read this prospectus, the documents incorporated by reference into this prospectus, and any prospectus supplement or free writing prospectus that we may authorize for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus entitled “Incorporation of Certain Information by Reference” and “Where You Can Find More Information.” These documents contain important information that you should consider when making your investment decision.

We are only responsible for the information contained in, or incorporated by reference into, this prospectus, in any prospectus supplement or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide any information other than that contained in this prospectus, in any prospectus supplement or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. The selling stockholder is offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where such offers and sales are permitted. The information in this prospectus, in any prospectus supplement or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "Cautionary Note Regarding Forward-Looking Statements."

Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® and ™ symbols, 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 that the applicable owner will not assert its rights, to these trademarks and tradenames.

Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to "Xtant," "the Company," "we," "us," "our" and similar references refer to Xtant Medical Holdings, Inc. and its subsidiaries.

SUMMARY

This summary highlights certain information about us, this offering and selected information contained in the prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of the Company and this offering, we encourage you to read and consider the more detailed information in the prospectus, including "Risk Factors" and the financial statements and related notes.

About Xtant Medical Holdings, Inc.

We operate through our subsidiaries Bacterin International, Inc. ("Bacterin International") and X-spine Systems, Inc. ("X-spine"). Through Bacterin International, we develop, manufacture and market biologics products to domestic and international markets. Our bone graft products are used in a variety of applications including enhancing fusion in spine surgery, relief of back pain through facet joint stabilization, promotion of bone growth in foot and ankle surgery, promotion of skull healing following neurosurgery and subchondral bone repair in knee and other joint surgeries. Our acellular dermis scaffolds are utilized in wound care and plastic and reconstructive procedures. Bacterin International also develops custom surgical instruments for use with our allografts, and we produce and distribute OsteoSelect® DBM putty, an osteoinductive product used by surgeons as a bone void filler in the extremities and pelvis. X-spine is a global developer, manufacturer and marketer of implants and instruments for surgery of the spine and sacroiliac joint. X-spine's product emphasis is the minimally invasive approach to the treatment of degenerative spine disorders. X-spine's global strategy is to advance minimally invasive technologies for the treatment of degenerative spinal disorders, while supporting established spinal fusion markets.

We are a Delaware corporation. Our principal executive offices are located at 664 Cruiser Lane, Belgrade, Montana 59714. Our telephone number is (406) 388-0480 and our website address is www.xtantmedical.com. Information contained in, or that can be accessed through, our website is not part of this prospectus.

Recent Developments

On July 31, 2015, we acquired 100% of the outstanding capital stock of X-spine, pursuant to a definitive stock purchase agreement by and among the Company, X-spine and the owners of the issued and outstanding shares of X-spine's capital stock (the "Sellers"). We refer to this transaction as the "acquisition." As a result of the acquisition, Bacterin International and X-spine now operate as wholly owned subsidiaries of Xtant, which prior to changing its name on July 31, 2015 was known as Bacterin International Holdings, Inc. The acquisition was financed through cash and stock with a purchase price of approximately $90.0 million, consisting of approximately $60.0 million in cash,

approximately $13.0 million in debt repayment and approximately $17.0 million in shares of our common stock. Based on an agreed upon fixed price per share of $4.00, approximately 4.24 million shares of our common stock were issued to the Sellers at the closing of the acquisition. All of the shares of common stock issued to the Sellers were issued in a private offering and are subject to securities law and contractual restrictions on transferability. The shares issued to the Sellers, along with $6.0 million of the cash portion of the acquisition consideration, are also subject to an escrow agreement to satisfy indemnification claims that may arise pursuant to the stock purchase agreement. For additional information on the acquisition, see “Business – The Acquisition.”

Concurrently with the acquisition, we completed an offering of $65.0 million aggregate principal amount of the notes in a private offering to qualified institutional buyers, as defined in Rule 144A under the Securities Act of 1933, as amended (the “Securities Act”). Certain private investment funds for which OrbiMed Advisors LLC (“OrbiMed”), one of our existing stockholders, serves as the investment manager (the “OrbiMed purchasers”) purchased $52.0 million aggregate principal amount of the notes directly from us in the offering. The investment banking firm acting as initial purchaser in the offering (the “initial purchaser”) purchased the remaining $13.0 million aggregate principal amount of the notes. We granted the initial purchaser a 30-day option to purchase up to an additional $9.75 million aggregate principal amount of the notes from us. On August 10, 2015, the initial purchaser exercised its option with respect to an additional $3.0 million aggregate principal amount of the notes. Additionally, concurrently with the acquisition, we borrowed an additional $18.0 million under an amended and restated credit agreement with ROS Acquisition Offshore LP (“ROS”).

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On March 31, 2016, the credit agreement was amended to extend the time frame during which interest can accrue on loans in lieu of making interest payments from December 31, 2015 to March 31, 2016, and to lower the minimum required liquidity amount to $500,000 or more prior to June 30, 2016. At all times after June 30, 2016 and until January 1, 2017, we are required to maintain a minimum liquidity amount of $2,500,000 or greater.

On April 14, 2016, we issued in a private placement to the OrbiMed purchasers $2,238,166.45 aggregate principal amount of promissory notes.

On May 25, 2016, we entered into a Loan and Security Agreement (the "LSA") with Silicon Valley Bank, a California corporation (the "Bank"), pursuant to which the Bank agreed to provide us with a revolving line of credit in the aggregate principal amount of $6,000,000, bearing interest at a floating per annum rate equal to one percentage point (1.00%) above the Prime Rate (as that term is defined in the LSA). The line of credit is secured by a first priority perfected security interest in certain of our assets in favor of the Bank. The maturity date of the revolving line of credit is May 25, 2019.

The Offering

Common stock offered by the selling stockholder	Up to 2,000,000 shares
Common stock outstanding	12,135,150 shares (as of June 13, 2016)
Use of proceeds	The selling stockholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive up to $10 million in proceeds from the sale of our common stock to the selling stockholder under the Purchase Agreement (as defined below). Any proceeds from the selling stockholder that we receive under the Purchase Agreement are expected to be used for working capital and general corporate purposes.
NYSE MKT Ticker Symbol	Our common stock is listed on the NYSE MKT under the ticker symbol "XTNT."
Risk Factors	Investing in our securities involves a high degree of risk. You should carefully review and consider the "Risk Factors" section of this prospectus, as well as the other information included or incorporated by reference into this prospectus, including our financial statements and the notes thereto, for a discussion of factors to consider before deciding to invest in shares of our common stock.

The number of shares of our common stock outstanding excludes, as of June 13, 2016:

- 582,706 shares issuable upon the exercise of outstanding stock options with a weighted average exercise price of $10.88 per share;

- 1,278,566 shares issuable upon the exercise of outstanding warrants with a weighted average exercise price of $8.45 per share; and

- Approximately 470,000 shares available for issuance under our Amended and Restated Equity Incentive Plan.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the outstanding options or warrants described above.

We entered into a Common Stock Purchase Agreement on March 16, 2015, as amended and restated on April 17, 2015 (the "Purchase Agreement"), with Aspire Capital Fund, LLC (referred to in this prospectus as "Aspire Capital" or the "selling stockholder") which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of our shares of our common stock over the approximately 24-month term of the Purchase Agreement. On April 17, 2015, the Purchase Agreement was amended and restated to reflect our move from the NYSE MKT to the OTCQX marketplace. A copy of the Purchase Agreement, as amended and restated, is attached as an exhibit to the registration statement of which this prospectus is a part.

Pursuant to the terms of the Purchase Agreement, in connection with entering into the Purchase Agreement, we issued 207,182 shares of our common stock (the "Initial Purchase Shares") to Aspire Capital for $750,000 in aggregate proceeds. We also issued 154,189 shares of our common stock to Aspire Capital as a commitment fee (the "Commitment Shares"). Subsequent to the issuance of the Initial Purchase Shares and the Commitment Shares, pursuant to the Purchase Agreement, we issued to Aspire Capital 417,000 shares of our common stock for $1,387,439 in aggregate proceeds.

We also entered into a registration rights agreement with Aspire Capital (the "Registration Rights Agreement"), in which we agreed to file one or more registration statements, including the registration statement of which this prospectus is a part, as permissible and necessary to register under the Securities Act of 1933, as amended (the "Securities Act"), the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of June 13, 2016, there were 12,135,150 shares of our common stock outstanding, all of which was held by non-affiliates. If all of the 2,000,000 shares of our common stock offered hereby were issued and outstanding as of June 13, 2016, such shares would represent 17.2% of the non-affiliate shares of common stock outstanding as of June 13, 2016.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering 2,000,000 shares of our common stock under the Securities Act, which includes 207,182 Initial Purchase Shares, 154,189 Commitment Shares that have already been issued to Aspire Capital, an additional 417,000 shares of common stock that we have issued to Aspire Capital as of August 24, 2015 pursuant to the terms of the Purchase Agreement, and 1,221,629 shares of common stock which we may issue to Aspire Capital. All 2,000,000 shares of common stock are being offered pursuant to this prospectus. Under the terms of the Purchase Agreement, the proceeds from the sale of our common stock to Aspire Capital may not exceed $10 million.

On any trading day on which the closing sale price of our common stock exceeds $1.00 per share, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice (each a "Purchase Notice") directing Aspire

Capital (as principal) to purchase up to 50,000 shares of our common stock per trading day, provided that the aggregate price of such purchase shall not exceed $500,000 per trading day, up to $10.0 million of our common stock in the aggregate at a per share price (the "Purchase Price") calculated by reference to the prevailing market price of our common stock (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for 50,000 shares and the closing sale price of our stock is equal to or greater than $1.00 per share of common stock, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of our common stock on the next trading day (the "VWAP Purchase Date"), subject to a maximum number of shares we may determine (the "VWAP Purchase Share Volume Maximum") and a minimum trading price (the "VWAP Minimum Price Threshold") (as more specifically described below). The purchase price per share pursuant to such VWAP Purchase Notice (the "VWAP Purchase Price") is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than $1.00 per share (the "Floor Price"). The Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

RISK FACTORS

Our business and an investment in our securities are subject to a variety of risks. The following risk factors describe some of the most significant events, facts or circumstances that could have a material adverse effect upon our business, financial condition, results of operations, ability to implement our business plan and the market price for our securities. Many of these events are outside of our control. If any of these risks actually occurs, our business, financial condition or results of operations may be materially adversely affected. In such case, the trading price of our common stock could decline and investors in our common stock could lose all or part of their investment.

Risks related to the Aspire Capital transaction

The sale of our common stock to Aspire Capital may cause substantial dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.

We are registering for sale the 154,189 Commitment Shares, 207,182 Initial Purchase Shares and 417,000 additional purchase shares that we have already issued to Aspire Capital pursuant to the terms of the Purchase Agreement, and 1,221,629 additional shares that we may sell to Aspire Capital under the Purchase Agreement. The number of shares ultimately offered for sale by Aspire Capital under this prospectus is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase Agreement. Depending upon market liquidity at the time, sales of shares of our common stock under the Purchase Agreement may cause the trading price of our common stock to decline.

As of June 13, 2016, we have received proceeds of $2,437,439 as a result of sales of our common stock to Aspire Capital pursuant to the Purchase Agreement. In the future, we may receive proceeds of up to $7,562,561 from the sale of our common stock to Aspire Capital pursuant to the Purchase Agreement. Aspire Capital may ultimately purchase all, some or none of the remaining $7,562,561 million of common stock, and may sell all, some or none of our shares that it holds or comes to hold under the Purchase Agreement. Sales by Aspire Capital of shares acquired pursuant to the Purchase Agreement under the registration statement, of which this prospectus is a part, may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital in this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

Trends, Risks and Uncertainties Related to Our Business

Pricing pressure and cost containment measures could have a negative impact on our future operating results.

Pricing pressure has increased in our industry due to continued consolidation among healthcare providers, trends toward managed care, the shift towards government becoming the primary payor of healthcare expenses, and government laws and regulations relating to reimbursement and pricing generally. Pricing pressure, reductions in reimbursement levels or coverage or other cost containment measures could unfavorably affect our future operating results and financial condition.

Many competitive products exist and more will be developed, and we may not be able to successfully compete because we are smaller and have fewer financial resources.

Our business is in a very competitive and evolving field. Rapid new developments in this field have occurred over the past few years, and are expected to continue to occur. Other companies already have competing products available or may develop products to compete with ours. Many of these products have short regulatory timeframes and our competitors, many with more substantial development resources, may be able to develop competing products that are equal to or better than ours. This may make our products obsolete or undesirable by comparison and reduce our revenue. Our success will depend, in large part, on our ability to maintain a competitive position concerning our intellectual property, and to develop new technologies and new applications for our technologies. Many of our competitors have substantially greater financial and technical resources, as well as greater production and marketing capabilities, and our ability to compete remains uncertain.

The medical community and the general public may perceive synthetic materials and growth factors as safer, which could have a material adverse effect on our business.

Members of the medical community and the general public may perceive synthetic materials and growth factors as safer than our allograft-based bone tissue products. Our products may be incapable of competing successfully with synthetic bone graft substitutes and growth factors developed and commercialized by others, which could have a material adverse effect on our business, financial condition and results of operations.

Negative publicity concerning methods of human tissue recovery and screening of donor tissue in the industry in which we operate may reduce demand for our allografts and impact the supply of available donor tissue.

Media reports or other negative publicity concerning both improper methods of tissue recovery from donors and disease transmission from donated tissue may limit widespread acceptance of our allografts. Unfavorable reports of improper or illegal tissue recovery practices, both in the United States 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. Potential patients may not be able to distinguish our allografts, technologies and the tissue recovery and the processing procedures from those of our competitors or others engaged in tissue recovery. In addition, families of potential donors may become reluctant to agree to donate tissue to for-profit tissue processors.

We are highly dependent on the availability of human donors; any disruptions could cause our customers to seek alternative providers or technologies.

We are highly dependent on our ability to obtain donor cadavers as the raw material for many of our products. The availability of acceptable donors is relatively limited and we compete with many other companies for this limited availability. The availability of donors is also impacted by regulatory changes, general public opinion of the donor process and our reputation for our handling of the donor process. In addition, due to seasonal changes in the mortality rates, some scarce tissues are at times in short supply. Any disruption in the supply of this crucial raw material could have significant consequences for our revenue, operating results and continued operations.

We are not currently profitable and we will need to raise additional funds in the future; however, additional funds may not be available on acceptable terms, or at all.

We have substantial operating expenses associated with the sales and marketing of our products. The sales and marketing expenses are anticipated to be funded from operating cash flow. There can be no assurance that we will have sufficient access to liquidity or cash flow to meet our operating expenses and other obligations. If we do not increase our revenue or reduce our expenses, we may need to raise additional capital, which would result in dilution to our stockholders, or seek additional loans. The incurrence of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. Financing may not be available in amounts or on terms acceptable to us, if at all. Any failure by us to raise additional funds on terms favorable to us, or at all, could result in our inability to pay our expenses as they come due, limit our ability to expand our business operations, and harm our overall business prospects.

We may not be able to raise capital or, if we can, it may not be on favorable terms. We may seek to raise additional capital through public or private equity financings, partnerships, joint ventures, disposition of assets, debt financings or restructuring, bank borrowing or other sources. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, products and/or potential markets. If adequate funds are not otherwise available, we would be forced to curtail operations significantly, including reducing our sales and marketing expenses which could negatively impact product sales and we could even be forced to cease operations, liquidate our assets and possibly even seek bankruptcy protection.

We will need to continue to innovate and develop new products.

The markets for our products and services are characterized by rapid technological change, frequent new introductions, changes in customers' demands and evolving industry standards. Accordingly, we will need to continue to innovate and develop additional products. These efforts can be costly, subject to long development and regulatory delays and may not result in products approved for sale. These costs may hurt operating results and may require additional capital. If additional capital is not available, we may be forced to curtail development activities. In addition, any failure on our behalf to react to changing market conditions could create an opportunity for other market participants to capture a critical share of the market within a short period of time.

Our success will depend on our ability to engage and retain qualified technical personnel who are difficult to attract.

Our success will depend on our ability to attract and retain qualified technical personnel to assist in research and development, testing, product implementation, low-scale production and technical support. The demand for such personnel is high and the supply of qualified technical personnel is limited. A significant increase in the wages paid by competing employers could result in a reduction of our technical work force and increases in the wage rates that we must pay or both. If either of these events were to occur, our cost structure could increase and our growth potential could be impaired.

Loss of key members of our management whom we need to succeed could adversely affect our business.

We are highly dependent on the services of key members of our management team, and the loss of any of their services could have an adverse effect on our future operations. We do not currently maintain key-man life insurance policies insuring the life of any member of our management team.

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

Any failure in the physical infrastructure of our facilities or services could lead to significant costs and disruptions that could reduce our revenues and harm our business reputation and financial results. We are highly reliant on our Belgrade, Montana facilities. Any natural or man-made event that impacts our ability to utilize these facilities could have a significant impact on our operating results, reputation and ability to continue operations. The regulatory

process for approval of facilities is time-consuming and our ability to rebuild facilities would take a considerable amount of time and expense and cause a significant disruption in service to our customers. Further, the FDA or some other regulatory agency could identify deficiencies in future inspections of our facilities or our supplies that could disrupt our business, reducing profitability.

Future revenue will depend on our ability to increase sales.

We currently sell our products through direct sales by our employees and indirectly through distributor relationships. We incurred increased sales and marketing expenses in building and expanding our direct sales force, and there can be no assurance that we will generate increased sales as a result of this effort.

There may be fluctuations in our operating results, which will impact our stock price.

Significant annual and quarterly fluctuations in our results of operations may be caused by, among other factors, our volume of revenues, the timing of new product or service announcements, releases by us and our competitors in the marketplace of new products or services, seasonality and general economic conditions. There can be no assurance that the level of revenues achieved by us in any particular fiscal period will not be significantly lower than in other comparable fiscal periods. Our expense levels are based, in part, on our expectations as to future 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.

Our revenues will depend upon prompt and adequate coverage and reimbursement from public and private insurers and national health systems.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental change. The ability of hospitals to pay fees for allograft bone tissue 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. In the United States, healthcare providers who purchase our products generally rely on these third-party payors to pay for all or a portion of the cost of our products in the procedures in which they are employed. Because there is often no separate reimbursement for our products, the additional cost associated with the use of our products can impact the profit margin of the hospital or other health care facility where the surgery is performed. Some of our target customers may be unwilling to purchase our products if they are able to procure less expensive alternatives. In addition, major third-party payors 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 charges for certain medical procedures or the elimination of or reduction in reimbursement. Further, Medicare, Medicaid and private healthcare insurer cutbacks could create downward price pressure on our products.

Our operating results will be harmed if we are unable to effectively manage and sustain our future growth.

We might not be able to manage our future growth efficiently or profitably. Our business is unproven on a large scale and actual revenue and operating margins, or revenue and margin growth, may be less than expected. If we are unable to scale our production capabilities efficiently, we may fail to achieve expected operating margins, which would have a material and adverse effect on our operating results. Growth may also stress our ability to adequately manage our operations, quality of products, safety and regulatory compliance. In order to grow, we may be required to obtain additional financing, which may increase our indebtedness or result in dilution to our stockholders. Further, there can be no assurance that we would be able to obtain any additional financing.

We may be subject to product liability litigation that could be expensive, and our insurance coverage may not be adequate in a catastrophic situation.

We may incur material liabilities relating to product liability claims, including product liability claims arising out of the use of our products. We currently carry product liability insurance, however, our insurance coverage may not be adequate and our business could suffer material adverse consequences due to product liability claims.

Litigation may result in financial loss and/or impact our ability to sell our products going forward.

We intend to vigorously defend any existing or future litigation that we may be involved in but there can be no assurance that we will prevail in these matters. An unfavorable judgment or settlement may result in a financial burden on us. An unfavorable judgment or settlement may also result in restrictions on our ability to sell certain products and therefore may impact future operating results. Moreover, costs, fees, expenses, settlement amounts, judgments or other liabilities associated with such matters may not be covered by our insurance and we may be have to pay out-of-pocket. Company stockholders who collectively own approximately 588,000 shares of our common stock and warrants to purchase additional shares have made claims that our board of directors breached its fiduciary duties in connection with the X-spine acquisition and the financing thereof, which they allege was on commercially unreasonable terms and did not serve the Company's best interests. No lawsuit has been filed. The Company believes the claims are without merit. If we are required to pay a significant amount to resolve a demand from these stockholders, it could have a material adverse effect on our liquidity, business and financial condition, and efforts required to resolve the demand could distract management from operating our business.

Failure of our information technology systems could disrupt our business.

Our operations depend on the continued performance of our information technology systems. Despite security measures and other precautions we have taken, our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptions. Sustained failure of our information technology systems could disrupt our business operations. In addition, some of our contracts impose obligations related to information we may have in physical or electronic formats, and any breach or failure of our information technology systems could result in breach of contract claims and other damages.

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

Our success will depend, to a large extent, on our ability to successfully obtain and maintain patents, prevent misappropriation or infringement of intellectual property, maintain trade secret protection, and conduct operations without violating or infringing on the intellectual property rights of third parties. There can be no assurance that our patented and patent-pending technologies will provide us with a competitive advantage, that we will be able to develop or acquire additional technology that is patentable, or that third parties will not develop and offer technologies which are similar to ours. Moreover, we can provide no assurance that confidentiality agreements, trade secrecy agreements or similar agreements intended to protect unpatented technology will provide the intended protection. Intellectual property 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 us to protect our intellectual property could have a materially adverse effect on our business and operating results and our ability to successfully compete in this industry.

We may not be able to obtain or protect our proprietary rights relating to our products without resorting to costly and time-consuming litigation.

We may not be able to obtain, maintain and protect certain proprietary rights necessary for the development and commercialization of our products or product candidates. Our commercial success will depend in part on obtaining and maintaining patent protection on our products and successfully defending these patents against third-party challenges. Our ability to commercialize our products will also depend in part on the patent positions of third parties, including those of our competitors. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict with certainty the scope and breadth of patent claims that may be afforded to other companies' patents. We could incur substantial costs in litigation if we are required to defend against patent suits brought by third parties, or if we initiate suits to protect our patent rights.

In addition to the risks involved with patent protection, we also face the risk that our competitors will infringe on our trademarks. Any infringement could lead to a likelihood of confusion and could result in lost sales. There can be no assurance that we will prevail in any claims we make to protect our intellectual property.

Future protection for our proprietary rights is uncertain which may impact our ability to successfully compete in our industry. The degree of future protection for our proprietary rights is uncertain. We cannot ensure that:

- we were the first to make the inventions covered by each of our patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;
- any of our issued patents or those of our licensors will be valid and enforceable;
- any patents issued to us or our collaborators will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties;

- we will develop additional proprietary technologies that are patentable;

- the patents of others will not have a material adverse effect on our business rights; or

- the measures we rely on to protect the intellectual property underlying our products will be adequate to prevent third parties from using our technology, all of which could harm our ability to compete in the market.

Our success depends on our ability to avoid infringing on the intellectual property rights of third parties, which could expose us to litigation or commercially unfavorable licensing arrangements.

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

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

A third-party may claim an ownership interest in our intellectual property. While we believe we own 100% of the right, title and interest in the patents for which we have applied and our other intellectual property, including that which we license from third parties, we cannot guarantee that a third-party will not, at some time, assert a claim or an interest in any of such patents or intellectual property. A successful challenge or claim by a third party to our patents or intellectual property could have a significant adverse effect on our prospects.

Affiliates of OrbiMed may be able to exert significant influence over the Company.

Certain private investment funds for which OrbiMed Advisors LLC serves as the investment manager purchased $52 million of notes in our recent offering. In addition, affiliates of OrbiMed are significant shareholders and we owe affiliates of OrbiMed approximately $42 million in principal, plus interest and exit fees, pursuant to our Amended and Restated Credit Agreement. Accordingly, OrbiMed may be able to exert significant influence over the Company. Although OrbiMed has been a strong supporter of the Company, OrbiMed may have interests that differ, or, in some cases, conflict with, interests of other shareholders.

Growth through an acquisition presents certain risks to our business and operations.

The acquisition of X-spine and any other acquisitions we may pursue present numerous risks, including the following:

- the possibility that the expected benefits of the transactions may not materialize in the timeframe expected, or at all, or may be more costly to achieve than anticipated;

- the acquired assets may not produce as expected;
- we may be unable to successfully develop the assets;
- there may be adverse stockholder reaction to the acquisitions; and
- the integration of these transactions may divert the attention of our management and other key employees from ongoing business activities, including the pursuit of other opportunities that could be beneficial to us.

Any one or more of these factors could negatively affect our business, financial condition or results of operations.

We have made certain assumptions relating to the acquisition that may prove to be materially inaccurate.

We have made certain assumptions relating to the acquisition of X-spine that may be inaccurate. Accordingly, we may fail to realize the expected benefits of the acquisition, may incur higher-than-expected transaction and integration costs, may assume unknown liabilities and may experience general economic and business conditions that adversely affect the combined company following the acquisition. These assumptions relate to numerous matters, including:

- projections of X-spine's future results;
- our expected capital structure following the acquisition;
- the amount of goodwill and intangibles that will result from the acquisition;
- certain other purchase accounting adjustments that we expect will be recorded in our financial statements in connection with the acquisition;
- cost, cross-selling and balance sheet synergies;
- acquisition costs, including restructuring charges and transaction costs;

- our ability to maintain, develop and deepen relationships with X-spine's customers; and

- other financial and strategic risks of the acquisition.

There may be risks associated with the post-acquisition integration of X-spine, because X-spine has historically been operated as a privately owned company.

There may be risks associated with the post-acquisition integration of X-spine, because X-spine has historically been operated as a privately owned company. Public companies are subject to significant additional regulatory and reporting requirements. Senior management of public companies may be required to devote more of their time to meeting these additional requirements. X-spine's senior management has historically been actively involved in the revenue-generating activities of its operations. If these individuals are required to devote more time to the additional requirements of managing a public company, and we are unable to successfully transition some or all of their direct revenue-generating responsibilities to other suitable professionals, our business, results of operations and financial condition may suffer.

Our ability to use our net operating loss carry-forwards to offset future taxable income may become limited.

Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), imposes restrictions on the use of a corporation's net operating losses, as well as certain recognized built-in losses and other carryforwards, after an "ownership change" occurs. A Section 382 "ownership change" occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock (including certain "public groups" deemed created for Section 382 purposes) increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. It is possible that the issuance of common stock upon conversion of our notes could result in an ownership change under Section 382, and there can be no assurance that this will not happen. If an "ownership change" occurs, Section 382 would impose an annual limit on the amount of pre-change net operating losses and other losses we can use to reduce our taxable income generally equal to the product of the total value of our outstanding equity immediately prior to the "ownership change" (subject to certain adjustments) and the applicable federal long-term tax-exempt interest rate for the month of the "ownership change."

Because United States federal net operating losses generally may be carried forward for up to 20 years, the annual limitation may effectively provide a cap on the cumulative amount of pre-ownership change losses, including certain recognized built-in losses that may be utilized. Such pre-ownership change losses in excess of the cap may be lost. In addition, if an ownership change were to occur, it is possible that the limitations imposed on our ability to use pre-ownership change losses and certain recognized built-in losses could cause a net increase in our United States federal income tax liability and United States federal income taxes to be paid earlier than otherwise would be paid if such limitations were not in effect. Further, if for financial reporting purposes the amount or value of these deferred tax assets is reduced, such reduction could negatively impact the book value of our common stock.

We have limited experience with X-spine's product lines.

The product lines acquired in the X-spine transaction are new to us, and we have limited experience with them. The acquired X-spine business is concentrated on developing and manufacturing implants and surgical instruments for surgery of the spine, which business differs from ours. As a result, X-spine's business is comprised of different product lines with which we have limited experience.

We will depend on retaining X-spine management and employees.

We will also be highly dependent on the continued services of key members of X-spine's executive management team. The loss of any one of these individuals could disrupt X-spine's operations or strategic plans. Additionally, X-spine's future success will depend on, among other things, our ability to hire and retain the necessary qualified scientific, technical, sales, marketing and managerial personnel, for whom X-spine competes with numerous other companies, academic institutions and organizations. The loss of members of X-spine's management team, key advisors or personnel, or X-spine's inability to attract or retain other qualified personnel or advisors, could have a material adverse effect on X-spine's business, results of operations and financial condition.

Certain of X-spine's former shareholders, who now own over 10% of our common stock, own a controlling share of X-spine's largest supplier, Norwood Tool Company d/b/a Norwood Medical. In 2015, Xtant purchased from Norwood Medical approximately 12% of its operating products. X-spine's dependence on Norwood Medical exposes us to risks, including limited control over pricing, availability and delivery schedules. If Norwood Medical ceases to provide X-spine with sufficient quantities of products in a timely manner or on terms acceptable to X-spine, or ceases to manufacture products of acceptable quality, X-spine would have to seek alternate sources of supply. Because of the nature of X-spine's regulatory and quality control requirements, and the proprietary nature of its products, it may not be able to quickly engage additional or replacement suppliers. Any such disruption could harm X-spine's business, results of operations or financial condition.

The business acquired from X-spine depends, in part, on a key distributor arrangement.

The business acquired from X-spine is dependent, in part, on a key distributor arrangement. For the years ended December 31, 2015 and 2014, net sales to this one large distributor exceeded 10% of X-spine's net sales. X-spine's results of operations are directly dependent on the sales and marketing efforts of its distributors and other sales agents and employees. If X-spine's key distributor were to reduce its efforts or cease to do business with X-spine, X-spine's sales could be adversely affected. In such a situation, X-spine may need to seek alternative distributors or increase its reliance on existing direct sales employees, sales agent and other distributors, which we may be unable to do in a timely and efficient manner, if at all.

The business acquired from X-spine depends, in part, on a relationship with a key supplier, which is a related party.

The business acquired from X-spine relies on third-party suppliers to supply substantially all of its products. For X-spine to be successful, its suppliers must be able to provide it with products in substantial quantities, in compliance with regulatory requirements, in accordance with agreed-upon specifications, at acceptable costs and on a timely basis. If X-spine is unable to obtain sufficient quantities of high quality products to meet demand on a timely basis, it may lose customers, and our business and reputation may suffer.

Trends, Risks and Uncertainties Related to Federal Regulations

The impact of United States healthcare reform legislation remains uncertain.

In 2010, federal legislation, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively "PPACA"), to reform the United States healthcare system was enacted into law. Certain aspects of the law were upheld by a Supreme Court decision announced in June 2012 and in June 2015. PPACA is far-reaching and is intended to expand access to health insurance coverage, improve quality and reduce costs over time. Among other things, the PPACA imposes a 2.3 percent excise tax on medical devices, which applies to United States sales of our medical device products, including our OsteoSelect® DBM putty. X-spine products also are subject to this excise tax. Due to multi-year pricing agreements and competitive pricing pressure in our industry, there can be no assurance that we will be able to pass the cost of the device tax on to our customers. Other provisions of the law, including Medicare provisions aimed at improving quality and decreasing costs, comparative effectiveness research, an independent payment advisory board, and pilot programs to evaluate alternative payment methodologies, could meaningfully change the way healthcare is developed and delivered. We cannot predict the impact of this legislation or other healthcare programs and regulations that may ultimately be implemented at the federal or state level, the effect of any future legislation or regulation in the United States or internationally or whether any changes will have the effect of lowering prices for our products or reducing medical procedure volumes. It is important to note that recent federal legislation suspended the collection of the 2.3 percent excise tax on medical devices for two years. The tax will then resume unless the tax is permanently repealed.

We cannot predict the impact of other healthcare programs and regulations that may ultimately be implemented at the federal or state level, the effect of any future legislation or regulation in the United States or internationally or whether any changes will have the effect of lowering prices for our products or reducing medical procedure volumes.

The sale of our products is subject to regulatory clearances or approvals and our business is subject to extensive regulatory requirements. If we fail to maintain regulatory clearances and approvals, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market these products could suffer.

Our medical device products and operations are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes regulation of, among other things:

- design, development and manufacturing;
- testing, labeling, packaging, content and language of instructions for use, and storage;
- clinical trials;
- product safety;
- premarket clearance and approval;
- marketing, sales and distribution (including making product claims);

- advertising and promotion;
- product modifications;
- recordkeeping procedures;
- reports of corrections, removals, enhancements , recalls and field corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- complying with the new federal law and regulations requiring Unique Device Identifiers ("UDI") on devices and also requiring the submission of certain information about each device to FDA's Global Unique Device Identification Database ("GUDID"); and
- product import and export.

Before a new medical device, or a new use of, or claim for, an existing product can be marketed in the United States, it must first receive either premarket clearance under Section 510(k) of the U.S. Federal Food, Drug and Cosmetic Act (the "FDCA"), a de novo approval or a Premarket Approval ("PMA"), from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that the proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device. To establish substantial equivalence which allows the device to be marketed, the applicant must demonstrate the device has the: (i) the same intended use; (ii) the same technological characteristics; and (iii) to the extent the technological characteristic are different, that they do not raise different questions of safety and effectiveness. Clinical data are sometimes required to support substantial equivalence, but FDA's expectations for data are often unclear and do change. Another procedure for obtaining marketing authorization for a medical device is the "de novo classification" procedure, pursuant to which FDA may authorize the marketing of a moderate to low risk device that has no predicate. These submissions typically require more information (i.e. non-clinical and/or clinical performance data) and take longer than a 510(k), but require less data and a shorter time period than a PMA. If the FDA grants the de novo request, the device is permitted to enter commercial distribution in the same manner as if 510(k) clearance had been granted, and the device becomes a 510(k) predicate for future devices seeking to call it a "predicate." The PMA pathway requires an applicant to demonstrate reasonable assurance of safety and effectiveness of the device for its intended use based, in part, on extensive data including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k) or a PMA. The 510(k), de novo and PMA processes can be expensive, lengthy and sometimes unpredictable. The processes also entail significant user fees, unless exempt. The FDA's 510(k) clearance process usually takes from six to 18 months, but may take longer if more data are needed. The de novo process can take one to two years or longer if additional data are

needed. The PMA pathway is much more costly and uncertain than the 510(k) clearance process and it generally takes from one to five years, or even longer, from the time the application is filed with the FDA until an approval is obtained. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all.

Most of our currently commercialized products have received premarket clearances under Section 510(k) of the FDCA. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our revenue to decline. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain de novo or PMA processes. Although we do not currently market any devices under PMA and have not gone through the de novo classification for marketing clearance, we cannot assure you that the FDA will not demand that we obtain a PMA prior to marketing or that we will be able to obtain 510(k) clearances with respect to future products.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our products meet the definition of "substantial equivalence" or meet the standard for the FDA to grant a petition for de novo classification;
- we may not be able to demonstrate to the FDA's satisfaction that our products are safe and effective for their intended uses;
- the data from our pre-clinical studies (bench and/or animal) and clinical trials may be insufficient to support clearance or approval, where required;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- changes in FDA clearance or approval policies or the adoption of new regulations may require additional data.

Any delay in, or failure to receive or maintain, clearances or approvals for our products under development could prevent us from generating revenue from these products or achieving profitability. Additionally, the FDA and other governmental authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could lead governmental authorities or a court to take action against us, including but not limited to:

- issuing untitled (notice of violation) letters or public warning letters to us;
- imposing fines and penalties on us;
- obtaining an injunction or administrative detention preventing us from manufacturing or selling our products;
- seizing products to prevent sale or transport or export;
- bringing civil or criminal charges against us;
- recalling our products or engaging in a product correction;

- detaining our products at U.S. Customs;
- delaying the introduction of our products into the market;
- delaying pending requests for clearance or approval of new uses or modifications to our existing products; and/or
- withdrawing or denying approvals or clearances for our products.

If we fail to obtain and maintain regulatory clearances or approvals, our ability to sell our products and generate revenue will be materially harmed.

We are subject, directly and indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and physician payment transparency laws. Failure to comply with these laws may subject us to substantial penalties.

We are subject to federal and state healthcare laws and regulations pertaining to fraud and abuse, and physician payment transparency. Many states such as Massachusetts, Connecticut, Nevada and Vermont require different types of compliance such as having a code of conduct, as well as reporting remuneration paid to health care professionals or entities in a position to influence prescribing behavior. Many of these industry standards inevitably influence company standards of conduct. Other laws tie into these standards as well, such as compliance with the advertising and promotion regulations under the U.S. Federal Food, Drug and Cosmetic Act, the Federal Anti-Kickback Statute, the Federal False Claims Act, the Federal Physician Payments Sunshine Act and other laws. We use many distributors and independent sales representatives in certain territories and thus rely upon their compliance with applicable laws and regulations, such as with the advertising and promotion regulations under the U.S. Federal Food, Drug and Cosmetic Act, the Anti-Kickback Statute, the Federal False Claims Act, the Physician Payments Sunshine Act, similar laws under countries located outside the United States and other applicable federal, state or international laws. These laws include:

- the Federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the Federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, 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 Federal False Claims Act; this may constrain our marketing practices and those of our independent sales agencies, educational programs, pricing, bundling and rebate policies, grants for physician-initiated trials and continuing medical education, and other remunerative relationships with healthcare providers;

- federal false claims laws (such as the Federal False Claims Act) which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent; this may impact the reimbursement advice we give to our customers as it cannot be inaccurate and must relate to on-label uses of our products;

- federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters;

- the Federal Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services ("CMS"), information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners; and

- analogous state and foreign law equivalents of each of the above federal laws, such as the Anti-Kickback Statue and the Federal False Claims Act which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The Federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and its implementing regulations, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information;

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Certain laws have “safe harbors” which allow for certain activities that appear to fall within the scope of the statute to be considered lawful and safe harbored activities. For example the Anti-kickback Statute allows for payments that would technically fall under the definition of “remuneration” and be illegal, are allowed because they meet a safe harbor established by the Office of Inspector General (the “OIG”) of the Department of Health and Human Services (the “HHS”). This includes, for example, the “Discount” safe harbor which allows companies to provide discounts to their customers in many forms (such as rebates, volume discounts, etc.) as long as they meet the terms of the safe harbor. The same is true for the retention of consultants. Any remuneration paid to a physician acting as a consultant technically meets the definition of remuneration, but is not considered illegal remuneration if it is paid following the provisions of the “Personal Services” safe harbor.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our relationships with customers, physicians and other healthcare providers, some of whom have ownership interests in the company and recommend and/or use our products, could be subject to challenge under one or more of such laws. We are also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, and distributors may engage in fraudulent or other illegal activity. Misconduct by these parties could include, among other infractions or violations, intentional, reckless and/or negligent conduct or unauthorized activity that violates FDA regulations, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, laws that require the true, complete and accurate reporting of financial information or data or other commercial or regulatory laws or requirements. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Because of the nature of our business, we are involved from time to time in lawsuits, claims, audits and investigations, including whistleblower actions by private parties and subpoenas from governmental agencies such as OIG and HHS. In February 2013, we received a subpoena from the OIG seeking documents in connection with an investigation into possible false or otherwise improper claims submitted to Medicare. The subpoena requested documents related to physician referral programs operated by the Company, which we believe refers to the Company’s prior practice of compensating physicians for performing certain educational and promotional services on behalf of the Company during 2009 and 2010. We later learned that this subpoena resulted from a qui tam action that was dismissed without prejudice in November 2013 after the Department of Justice declined to intervene. If our operations are found to violate any of the laws described above or any other laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to market our products and materially adversely affect our business, results of operations and financial condition. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business.

Failure to comply with the U.S. Foreign Corrupt Practices Act could subject us to, among other things, penalties and legal expenses that could harm our reputation and have a material adverse effect on our business, financial condition and operating results.

Our United States operations, including those of our United States operating subsidiaries, are subject to the U.S. Foreign Corrupt Practices Act. We are required to comply with the FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials for the purpose of obtaining or retaining business or other benefits. In addition, the FCPA imposes accounting standards and requirements on publicly traded United States corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of “off books” slush funds from which such improper payments can be made. We also are subject to similar anticorruption legislation implemented in Europe under the Organization for Economic Co-operation and Development’s Convention on Combating Bribery of Foreign Public Officials in International Business Transactions. We either operate or plan to operate in a number of jurisdictions that pose a high risk of potential violations of the FCPA and other anticorruption laws, such as China and Brazil, and we utilize a number of third-party sales representatives for whose actions we could be held liable under the FCPA. We inform our personnel and third-party sales representatives of the requirements of the FCPA and other anticorruption laws, including, but not limited to their reporting requirements. We also have developed and will continue to develop and implement systems for formalizing contracting processes, performing due diligence on agents and improving our recordkeeping and auditing practices regarding these regulations. However, there is no guarantee that our employees, third-party sales representatives or other agents have not or will not engage in conduct undetected by our processes and for which we might be held responsible under the FCPA or other anticorruption laws.

If our employees, third-party sales representatives or other agents are found to have engaged in such practices, we could suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures, including further changes or enhancements to our procedures, policies and controls, as well as potential personnel changes and disciplinary actions. During the past few years, the SEC has increased its enforcement of violations of the FCPA against companies, including several medical device companies. Although we do not believe we are currently a target, any investigation of any potential violations of the FCPA or other anticorruption laws by United States or foreign authorities also could have an adverse impact on our business, financial condition and operating results.

Certain foreign companies, including some of our competitors, are not subject to prohibitions as strict as those under the FCPA or, even if subjected to strict prohibitions, such prohibitions may be laxly enforced in practice. If our competitors engage in corruption, extortion, bribery, pay-offs, theft or other fraudulent practices, they may receive preferential treatment from personnel of some companies, giving our competitors an advantage in securing business, or from government officials, who might give them priority in obtaining new licenses, which would put us at a disadvantage.

U.S. governmental regulation could restrict the use of our tissue products or our procurement of tissue.

In the United States, the procurement and transplantation of allograft bone tissue is 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 bone and related tissue, for "valuable consideration." NOTA permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. We provide services in all of these areas in the United States, with the exception of removal and implantation, and receive payments for all such services. We make payments to certain of our clients and tissue banks for their services related to recovering allograft bone tissue on our behalf. If NOTA is interpreted or enforced in a manner which prevents us from receiving payment for services we render or which prevents us from paying tissue banks or certain of our clients for the services they render for us, our business could be materially and adversely affected.

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

operations.

If we fail to maintain regulatory clearances and approvals, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market these products could suffer.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. Certain of our products are regulated as medical devices by the FDA while others are regulated by the FDA as tissues. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval application, or PMA, unless the device is specifically exempt from those requirements.

The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to a legally marketed device that is not subject to the PMA process, which includes devices that were legally marketed prior to May 28, 1976 (“pre-amendments devices”) for which the FDA has not called for a PMA, devices that have been reclassified from Class III to Class II or Class I, or devices that have been found substantially equivalent through the 510(k) process. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA’s satisfaction the safety and efficacy of the device for its intended use.

Our failure to comply with United States Federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

Outside of the United States, our medical devices must comply with the laws and regulations of the foreign countries in which they are marketed, and compliance may be costly and time-consuming. Failure to obtain and maintain regulatory approvals in jurisdictions outside the United States will prevent us from marketing our products in such jurisdictions.

We currently market, and intend to continue to market, our products outside the United States. To market and sell our product in countries outside the United States, we must seek and obtain regulatory approvals, certifications or registrations and comply with the laws and regulations of those countries. These laws and regulations, including the requirements for approvals, certifications or registrations and the time required for regulatory review, vary from

country to country. Obtaining and maintaining foreign regulatory approvals, certifications or registrations are expensive, and we cannot be certain that we will receive regulatory approvals, certifications or registrations in any foreign country in which we plan to market our products. The regulatory approval process outside the United States may include all of the risks associated with obtaining FDA clearance or approval in addition to other risks.

In order to market our products in the Member States of the European Economic Area ("EEA"), our devices are required to comply with the essential requirements of the EU Medical Devices Directives (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended, and Council Directive 90/385/EEC of 20 June 2009 relating to active implantable medical devices, as amended). Compliance with these requirements entitles us to affix the CE conformity mark to our medical devices, without which they cannot be commercialized in the EEA. In order to demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the Medical Devices Directives, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization accredited by a Member State of the EEA to conduct conformity assessments. The Notified Body would typically audit and examine the quality system for the manufacture, design and final inspection of our devices before issuing a certification demonstrating compliance with the essential requirements. Based on this certification we can draw up an EC Declaration of Conformity, which allows us to affix the CE mark to our products.

We may not obtain regulatory approvals or certifications outside the United States on a timely basis, if at all. Clearance or approval by the FDA does not ensure approval or certification by regulatory authorities or Notified Bodies in other countries, and approval or certification by one foreign regulatory authority or Notified Body does not ensure approval by regulatory authorities in other countries or by the FDA. We may be required to perform additional pre-clinical or clinical studies even if FDA clearance or approval, or the right to bear the CE mark, has been obtained. If we fail to obtain or maintain regulatory approvals, certifications or registrations in any foreign country in which we plan to market our products, our business, financial condition and operating results could be adversely affected.

Modifications to our products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.

Modifications to our products may require new regulatory approvals or clearances, including 510(k) clearances, premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application. Where we determine that modifications to our products require a new 510(k) clearance or premarket approval, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining clearances and approvals can be a time consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Modifications to our products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.

Any modification to a 510(k)-cleared device that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, technology, materials, packaging and certain manufacturing processes, may require a new 510(k) clearance, a de novo, or possibly a PMA. Modifications to our products that have not properly followed FDA regulations and that require new regulatory clearances or approvals, may require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. To do that a manufacturer must determine if a change/modification to labeling of the device is a "major" change to the intended use statement (previously cleared by the FDA) or if a physical change/modification to the device itself "significantly affects safety or effectiveness." If the labeling change is major and/or the physical change significantly affects safety and effectiveness, the manufacturer must file for an additional 510(k) clearance or PMA for those changes before the modified device can be lawfully marketed. If the company concludes in its own self-determination that the changes do not meet either of the thresholds of "major "or "significantly affects," it may simply document those changes by way of an internal letter-to-file as part of the manufacturer's quality system recording keeping. However, the FDA can review a manufacturer's decision and may disagree. FDA will normally review a decision made by a manufacturer in a letter-to-file during a routine plant inspection, which are usually conducted every two years. In such a review the FDA may determine that a new clearance or approval was required before the device was put into commercial distribution.

We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. No assurance can be given that the FDA would agree with any of our decisions not to seek 510(k) clearance or PMA. The issue of whether a product modification is significant enough to require a 510(k), as opposed to a simple "letter-to-file" documenting the change, is in a state of flux. In 1997, FDA issued a guidance to address this issue and it is a guidance document with which FDA and industry is very familiar. FDA has announced they are about to issue a new draft guidance for public comment. We are unclear how dramatic the proposed changes may be. Until then, manufacturers may continue to adhere to the FDA's 1997 guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a device, but the practical impact of the FDA's continuing scrutiny of these issues remains unclear.

If the FDA requires us to cease marketing and recall a modified device until we obtain a new 510(k) clearance or PMA, our business, financial condition, operating results and future growth prospects could be materially adversely affected. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA. Obtaining clearances and approvals can be a time consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

In addition to the concerns stated above if FDA during a routine inspection of our plant discovers we have made modifications by way of letter-to-file, that FDA believes should have been cleared with a new 510(k), the FDA can also allege that the company has failed to file with FDA a Part 806 failure to report the correction or removal of a medical device in addition to requesting that the modified device on the market be recalled, and that a new 510(k) application must be submitted. In addition, FDA has recently proposed new draft guidance on reporting "enhancements" to medical devices under Part 806 Reports of Corrections and Removals, the practical effect of which may be to alert FDA to product modifications on an ongoing basis for which FDA may require a new 510(k). This guidance had not yet been finalized, but may be soon.

The results of our clinical studies may not support our product candidate claims or may result in the discovery of adverse effects.

Our ongoing research and development, pre-clinical testing and clinical study activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. We are currently conducting post-market clinical studies of some of our products to gather information about these products' performance or optimal use. Additionally, in the future we may conduct clinical studies to support clearance or approval of new products. Clinical studies must be conducted in compliance with FDA regulations and local regulations, and according to principles and standards collectively referred to as "Good Clinical Practices." Non-compliance could result in regulatory and legal enforcement action and also could invalidate the data. Even if our

clinical studies are completed as planned, we cannot be certain that their results will support our product candidates and/or proposed claims or that the FDA or foreign authorities and notified bodies will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical studies does not ensure that later clinical studies will be successful, and we cannot be sure that the results of the later studies will replicate those of earlier or prior studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical studies will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patient subjects enrolled in our clinical studies of our marketed products will experience adverse side effects that are not currently part of the product candidate's profile and, if so, these findings may result in lower market acceptance, which could have a material and adverse effect on our business, results of operations and financial condition.

There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

Future products may require FDA clearance of a 510(k) or approval of a PMA. In addition, future products may require clinical trials to support regulatory approval and we may not successfully complete these clinical trials. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new products. Failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

Clinical trials can be long, expensive and ultimately uncertain which could jeopardize our ability to obtain regulatory approval and market our products.

Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance. Such trials generally require an investigational device exemption application, or IDE, approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a nonsignificant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board ("IRB") for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. In addition, the commencement or completion of any clinical trial may be delayed or halted for numerous reasons, including, but not limited to patients not enrolling in clinical trials at the rate we expect, patients experiencing adverse side effects, third party contractors failing to perform in accordance with our anticipated schedule or consistent with good clinical practices, inclusive or negative interim trial results or our inability to obtain sufficient quantities of raw materials to produce our products. Clinical trials often take several years to execute. The outcome of any trial is uncertain and may have a significant impact on the success of our current and future products and future profits. Our development costs may increase if we have material delays in clinical trials or if we need to perform more or larger clinical trials than planned. If this occurs, our financial results and the commercial prospects for our products may be harmed. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the United States.

Our manufacturing operations require us to comply with the FDA's and other governmental authorities' laws and regulations regarding the manufacture and production of medical devices, which is costly and could subject us to enforcement action.

We and certain of our third-party manufacturers are required to comply with the FDA's current Good Manufacturing (cGMP) and Quality System Regulations, or QSR, which covers the methods of documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. We and certain of our suppliers also are subject to the regulations of foreign jurisdictions regarding the manufacturing process for our products marketed outside of the United States. The FDA enforces the QSR through periodic announced (routine) and unannounced ("for cause" or directed) inspections of manufacturing facilities. The inspection resulted in the issuance of a Form FDA-483 listing four inspectional observations. The FDA's observations related to our documentation of corrective and preventative actions, procedures for receiving, reviewing and evaluating complaints, procedures to control product that does not conform to specified requirements and procedures to ensure that all purchased or otherwise received product and services conform to specified requirements. Although we believe we have corrected all of these observations, the FDA could disagree with our conclusion and corrective and remedial measures. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees, disgorgement of profits, criminal and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for clearance (510(k)) or approval (de novo or PMA) of new products or modified products;
- withdrawing 510(k) clearances or PMAs that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these actions could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We also may be required to bear other costs or take other actions that may have a negative impact on our future revenue and our ability to generate profits. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

Even if our medical device products are cleared or approved by regulatory authorities, if we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product that we market, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with the FDA's current good manufacturing practice, or GMP requirements, known as the Quality System Regulation, or QSR, for medical devices, and International Standards Organization, or ISO, regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product. Regulatory bodies, such as the FDA, enforce these and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could

result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new medical device products or modified medical device products;
- operating restrictions;

- withdrawing 510(k) clearances or PMA that have already been granted;
- refusal to grant export approval for our products; and/or
- criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of certain adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

The use, misuse or off-label use of our products may harm our image in the marketplace or result in injuries that lead to product liability suits, which could be costly to our business or result in FDA sanctions if we are deemed to have engaged in improper promotion of our products.

Our products currently marketed in the United States have been cleared by the FDA's 510(k) clearance process for use under specific circumstances. Our promotional materials and training methods must comply with FDA and other

applicable laws and regulations, including the prohibition on the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside of its cleared or approved indication is known as "off-label" use. We cannot prevent a surgeon from using our products or procedure for off-label use, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials, reimbursement advice or training of sales representatives or physicians constitute promotion of an off-label use, the FDA could request that we modify our training or promotional or reimbursement materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, disgorgement of profits, a civil fine and criminal penalties. Other federal, state or foreign governmental authorities also might take action if they consider our promotion or training materials to constitute promotion of an uncleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. For example, the government may take the position that off-label promotion resulted in inappropriate reimbursement for an off-label use in violation of the Federal False Claims Act for which it might impose a civil fine and even pursue criminal action. In those possible events, our reputation could be damaged and adoption of the products would be impaired. Although we train our sales force not to promote our products for off-label uses, and our instructions for use in all markets specify that our products are not intended for use outside of those indications cleared for use, the FDA or another regulatory agency could conclude that we have engaged in off-label promotion.

Further, the advertising and promotion of our products is subject to EEA Member States laws implementing Directive 93/42/EEC concerning Medical Devices, or the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Our failure to comply with all these laws and requirements may harm our business and operating results.

In addition, there may be increased risk of injury if surgeons attempt to use our products off-label. Furthermore, the use of our products for indications other than those indications for which our products have been cleared by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among surgeons and patients. Surgeons also may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us. Any of these events could harm our business and operating results.

If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. Under the FDA's reporting regulations applicable to human cells and tissue and cellular and tissue-based products, or HCT/Ps, we are required to report all adverse reactions involving a communicable disease if it is fatal, life threatening, or results in permanent impairment of a body function or permanent damage to body structure. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

In the EEA we must comply with the EU Medical Device Vigilance System, the purpose of which is to improve the protection of health and safety of patients, users and others by reducing the likelihood of reoccurrence of incidents related to the use of a medical device. Under this system, incidents must be reported to the competent authorities of the Member States of the EEA. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious

deterioration in their state of health. Incidents are evaluated by the EEA competent authorities to whom they have been reported, and where appropriate, information is disseminated between them in the form of National Competent Authority Reports, or NCARs. The Medical Device Vigilance System is further intended to facilitate a direct, early and harmonized implementation of Field Safety Corrective Actions, or FSCAs across the Member States of the EEA where the device is in use. An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

We may implement a product recall or voluntary market withdrawal due to product defects or product enhancements and modifications, which would significantly increase our costs.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses.

Our promotional materials and training methods for physicians must comply with the FDA and other applicable laws and regulations. We believe that the specific surgical procedures for which our products are marketed fall within the general intended use of the surgical applications that have been cleared by the FDA. However, the FDA could disagree and require us to stop promoting our products for those specific indications/procedures until we obtain FDA clearance or approval for them. In addition, if the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

If we or our suppliers fail to comply with ongoing FDA or other regulatory authority requirements pertaining to Human Tissue Products, these products could be subject to restrictions or withdrawal from the market.

The FDA has statutory authority to regulate HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient, including allograft-based products. The FDA, EU and Health Canada have been working to establish more comprehensive regulatory frameworks for allograft-based, tissue-containing products, which are principally derived from cadaveric tissue. Certain of our products are regulated as HCT/Ps and are not marketed pursuant to the FDA's medical device regulatory authority, and therefore are not subject to FDA clearance or approval. Although we have not obtained premarket approval for these products, they are nonetheless subject to regulatory oversight. Human tissues intended for transplantation have been regulated by the FDA since 1993.

Section 361 of the Public Health Service Act ("PHSA") authorizes the FDA to issue regulations to prevent the introduction, transmission or spread of communicable disease. HCT/Ps regulated as 361 HCT/Ps are subject to requirements relating to: registering facilities and listing products with the FDA; screening and testing for tissue donor eligibility; Good Tissue Practice, or GTP, when processing, storing, labeling and distributing HCT/Ps, including required labeling information; stringent recordkeeping; and adverse event reporting. The FDA has also proposed extensive additional requirements that address sub-contracted tissue services, tracking to the recipient/patient, and donor records review. If a tissue-based product is considered human tissue, the FDA requirements focus on preventing the introduction, transmission and spread of communicable diseases to recipients. A product regulated solely as a 361 HCT/P is not required to undergo premarket clearance (510(k)) or approval (de novo or PMA).

The FDA may inspect facilities engaged in manufacturing 361 HCT/Ps and may issue untitled letters, warning letters, or otherwise authorize orders of retention, recall, destruction and cessation of manufacturing if the FDA has reasonable grounds to believe that an HCT/P or the facilities where it is manufactured are in violation of applicable regulations. There also are requirements relating to the import of HCT/Ps that allow the FDA to make a decision as to the HCT/Ps' admissibility into the United States.

An HCT/P is eligible for regulation solely as a 361 HCT/P if it is: (i) minimally manipulated; (ii) intended for homologous use as determined by labeling, advertising or other indications of the manufacturer's objective intent for a homologous use; (iii) the manufacture does not involve combination with another article, except for water, crystalloids or a sterilizing, preserving, or storage agent (not raising new clinical safety concerns for the HCT/P); and (iv) it does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function or, if it has such an effect, it is intended for autologous use or allogeneic use in close relatives or for reproductive use. If any of these requirements are not met, then the HCT/P is also subject to applicable biologic, device, or drug regulation under the FDCA or the PHSA. These biologic, device or drug HCT/Ps must comply both with the requirements exclusively applicable to 361 HCT/Ps and, in addition, with requirements applicable to biologics under the PHSA, or devices or drugs under the FDCA, including premarket licensure, clearance or approval.

Over the course of several years, the FDA issued comprehensive regulations that address manufacturer activities associated with HCT/Ps. The first requires that companies that produce and distribute HCT/Ps register with the FDA. This set of regulations also includes the criteria that must be met in order for the HCT/P to be eligible for marketing solely under Section 361 of the PHSA and the regulations in 21 CFR Part 1271, rather than under the drug or device provisions of the FD&C Act or the biological product licensing provisions of the PHSA. The second set of regulations 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 rule 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 these regulations are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients.

These regulations increased regulatory scrutiny within the industry in which we operate and have led to increased enforcement action which affects the conduct of our business. In addition, these regulations can increase the cost of tissue recovery activities. The FDA periodically inspects tissue processors to determine compliance with these requirements. Violations of applicable regulations noted by the FDA during facility inspections could adversely affect the continued marketing of our products. We believe we comply with all aspects of the Current Good Tissue Practices, although there can be no assurance that we will comply, or will comply on a timely basis, in the future. Entities that provide us with allograft bone tissue are responsible for performing donor recovery, donor screening and donor testing and our compliance with those aspects of the Current Good Tissue Practices regulations that regulate those functions are dependent upon the actions of these independent entities. If our suppliers fail to comply with applicable requirements, our products and our business could be negatively affected. If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions from public warning letters, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals,

seizure of our products, total or partial shutdown of our production, withdrawal of approvals, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us.

In addition, the FDA could disagree with our conclusion that some of our HCT/Ps meet the criteria for marketing solely under Section 361 of the PHSA, and therefore do not require approval or clearance of a marketing application. For our HCT/Ps that are not combined with another article, the FDA could conclude that the tissue is more than minimally manipulated, that the product is intended for a non-homologous use, or that the product has a systemic effect or is dependent on the metabolic activity of living cells for its effect. If the FDA were to draw these conclusions, it would likely require the submission and approval or clearance of a marketing application in order for us to continue to market the product. Such an action by the FDA could cause negative publicity, decreased or discontinued product sales, and significant expense in obtaining required marketing approval or clearance.

Procurement of certain human organs and tissue for transplantation, including allograft tissue we may use in future products, is subject to federal regulation under the National Organ Transplant Act, or NOTA. NOTA prohibits the acquisition, receipt, or other transfer of certain human organs, including bone and other human tissue, for valuable consideration within the meaning of NOTA. NOTA permits the payment of reasonable expenses associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human organs. For any future products implicating NOTA's requirements, we would reimburse tissue banks for their expenses associated with the recovery, storage and transportation of donated human tissue that they would provide to us. NOTA payment allowances may be interpreted to limit the amount of costs and expenses that we may recover in our pricing for our services, thereby negatively impacting our future revenue and profitability. If we were to be found to have violated NOTA's prohibition on the sale or transfer of human tissue for valuable consideration, we would potentially be subject to criminal enforcement sanctions, which could materially and adversely affect our operating results. Further, in the future, if NOTA is amended or reinterpreted, we may not be able to pass these expenses on to our customers and, as a result, our business could be adversely affected.

Other regulatory entities with authority over our products and operations include state agencies enforcing statutes and regulations covering tissue banking. Regulations issued by Florida, New York, California and Maryland will be particularly relevant to our business. Most states do not currently have tissue banking regulations. It is possible that others may make allegations against us or against donor recovery groups or tissue banks about non-compliance with applicable FDA regulations or other relevant statutes or regulations.

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

Our products may be subject to regulation in the EU as well, should we enter that market. In the European Union, or EU, regulations, if applicable, differ from one EU 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 EU, 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. Some of our products may be subject to EU 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. Some EU member states have their own tissue banking regulations.

Loss of AATB Accreditation would have a material adverse effect on us.

We are accredited with the American Association of Tissue Banks ("AATB"), a private non-profit organization that accredits tissue banks and sets industry standards. Although AATB accreditation is voluntary and not required by law, as a practical matter, many of our customers would not purchase our products if we failed to maintain our AATB

accreditation. Although we make every effort to maintain our AATB accreditation, the accreditation process is somewhat subjective and lacks regulatory oversight. There can be no assurance that we will continue to remain accredited with the AATB.

Federal regulatory reforms may adversely affect our ability to sell our products profitably.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

For example, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. For example, in 2011, the FDA initiated a review of the premarket clearance process in response to internal and external concerns regarding the 510(k) program, announcing 25 action items designed to make the process more rigorous and transparent. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-clearance or approval. The FDA has implemented, and continues to implement, these reforms, which could impose additional regulatory requirements upon us and delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. For example, the FDA recently issued guidance documents intended to explain the procedures and criteria the FDA will use in assessing whether a 510(k) submission meets a minimum threshold of acceptability and should be accepted for review. Under the "Refuse to Accept" guidance, the FDA conducts an early review against specific acceptance criteria to inform 510(k) submitters if the submission is administratively complete, or if not, to identify the missing element(s). Submitters are given the opportunity to provide the FDA with the identified information, but if the information is not provided within a defined time, the submission will not be accepted for FDA review. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

Product pricing (and, therefore, profitability) is subject to regulatory control which could impact our revenue and financial performance.

The pricing and profitability of our products may become subject to control by the government and other third-party payors. The continuing efforts of governmental and other third-party payors to contain or reduce the cost of healthcare through various means may adversely affect our ability to successfully commercialize our products. In most foreign markets, the pricing and/or profitability of certain diagnostics and prescription pharmaceuticals are subject to governmental control. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental control, though it is unclear which proposals will ultimately become law, if any. Changes in prices, including any mandated pricing, could impact our revenue and financial performance.

Trends, Risks and Uncertainties Relating to Our Common Stock

The market price of our common stock is extremely volatile, which may affect our ability to raise capital in the future and may subject the value of your investment to sudden decreases.

The market price for securities of biotechnology companies historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. Fluctuations in the trading price or liquidity of our common stock may harm the value of your investment in our securities.

Factors that may have a significant impact on the market price and marketability of our securities include:

- announcements of technological innovations or new commercial products by us, our collaborative partners or our present or potential competitors;
- our issuance of debt, equity or other securities, which we need to pursue to generate additional funds to cover our operating expenses;
- our quarterly operating results;
- developments or disputes concerning patent or other proprietary rights;

- developments in our relationships with employees, suppliers or collaborative partners;
- acquisitions or divestitures;
- litigation and government proceedings;
- adverse legislation, including changes in governmental regulation;
- third-party reimbursement policies;
- changes in securities analysts' recommendations;
- short selling;
- changes in health care policies and practices;
- suspension of trading of our common stock;
- economic and other external factors; and
- general market conditions.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. These lawsuits often seek unspecified damages, and as with any litigation proceeding, one cannot predict with certainty the eventual outcome of pending litigation. Furthermore, we may have to incur substantial expenses in connection with any such lawsuits and our management's attention and resources could be diverted from operating our business as we respond to any such litigation. We maintain insurance to cover these risks for us and our directors and officers, but our insurance is subject to high deductibles, and there is no guarantee that the insurance will cover any specific claim that we currently face or may face in the future, or that it will be adequate to cover all potential liabilities and damages.

If securities analysts stop publishing research or reports about us or our business, or if they downgrade our common stock, the trading volume and market price of our common stock could decline.

The market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not control these analysts. If any analyst who covers us downgrades our stock or lowers its future stock price targets or estimates of our operating results, our stock price could decline rapidly. Furthermore, if any analyst ceases to cover our company, we could lose visibility in the market. Each of these events could, in turn, cause our trading volume and the market price of our common stock to decline.

We do not anticipate, and may be prevented from, paying dividends in the foreseeable future.

We currently intend to retain our future earnings, if any, to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our common stock in the foreseeable future. In addition, our amended and restated credit facility precludes us from paying dividends.

We could issue "blank check" preferred stock without stockholder approval with the effect of diluting interests of then-current stockholders and impairing their voting rights, and provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable.

Our certificate of incorporation provides for the authorization to issue up to 5,000,000 shares of "blank check" preferred stock with designations, rights and preferences as may be determined from time to time by our board of directors. Our board of directors is empowered, without stockholder approval, to issue one or more series of preferred stock with dividend, liquidation, conversion, voting or other rights which could dilute the interest of, or impair the voting power of, our common stockholders. The issuance of a series of preferred stock could be used as a method of discouraging, delaying or preventing a change in control. For example, it would be possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company. In addition, we have a staggered board of directors and advanced notice is required prior to stockholder proposals, which might further delay a change of control.

Future sales of our common stock in the public market could lower the market price for our common stock and adversely impact the trading price of our notes.

In the future, we may sell shares of our common stock or equity-related securities to raise capital. In addition, as of March 31, 2016, 1,861,272 shares of our common stock are reserved for issuance upon the exercise of stock options and warrants and additional amounts are reserved for issuance upon conversion of the notes. At March 31, 2016, we also have reserved 1,221,629 shares of common stock for issuance pursuant to a common stock purchase agreement with Aspire Capital Fund, LLC. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance and sale of substantial amounts of common stock or equity-related securities, or the perception that such issuances and sales may occur, could adversely affect the trading price of the notes and the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

If securities analysts stop publishing research or reports about us or our business, or if they downgrade our common stock, the trading volume and market price of our common stock and, consequently, the trading price of our notes could decline.

The market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not control these analysts. If any analyst who covers us downgrades our stock, or lowers its future stock price targets or estimates of our operating results, our stock price could decline rapidly. Furthermore, if any analyst ceases to cover our company, we could lose visibility in the market. Each of these events could, in turn, cause our trading volume and the market price of our common stock and, consequently, the trading price of our notes to decline.

Trends, Risks and Uncertainties Relating to Our Indebtedness

We may not be able to deduct all or a portion of the interest payments on notes for U.S. federal income tax purposes.

The deduction for all or a portion of the interest paid or incurred on indebtedness classified as “corporate acquisition indebtedness” for U.S. federal income tax purposes may be disallowed. A convertible debt instrument may be classified as “corporate acquisition indebtedness” under the Code if the proceeds thereof are used, directly or indirectly, to finance an acquisition and certain other conditions are met. The convertible notes we issued to finance a portion of the acquisition may be treated as corporate acquisition indebtedness. Accordingly, the deduction for all or a portion of the interest paid or incurred on notes may be disallowed. If we were not entitled to deduct interest on our notes, our

after-tax operating results could be adversely affected.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to service our substantial debt obligations depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and other fixed charges, fund working capital needs and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not be able to meet financial or other covenant requirements in our credit facility, and we may not be able to successfully negotiate waivers to cure any covenant violations.

Our credit agreement with affiliates of OrbiMed contains representations, warranties, fees, affirmative and negative covenants, including a minimum cash balance, a leverage ratio and minimum revenue amounts by quarter, and default provisions, which include departures in key management, if not remedied within 90 days. A breach of any of these covenants could result in a default under these agreements. Upon the occurrence of an event of default under our debt agreements, our lender could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit. If our lender accelerates the repayment of borrowings, we may not have sufficient assets to repay our indebtedness. Also, should there be an event of default, or should we need to obtain waivers following an event of default, we may be subject to higher borrowing costs and/or more restrictive covenants in future periods. In addition, to secure the performance of our obligations under the credit facility, we pledged substantially all of our assets, including our intellectual property, to affiliates of OrbiMed. Our failure to comply with the covenants under the credit facility could result in an event of default, the acceleration of our debt and the loss of our assets.

We may need to use 50% of the net proceeds from future offerings to make a mandatory prepayment on our loan.

Subject to the discretion of our lender, our credit agreement with affiliates of OrbiMed includes an obligation on our part to use 50% of the net proceeds from equity offerings above $50 million in the aggregate to make a mandatory prepayment on our loan. This provision could reduce the net proceeds to us in future financing transactions, which may affect our ability to raise capital in the future.

We may rely on our subsidiaries for funds necessary to meet our financial obligations.

We conduct substantially all of our activities through our subsidiaries. We may depend on those subsidiaries for dividends and other payments to generate the funds necessary to meet our financial obligations, including the payment of principal and interest on notes. The ability of our subsidiaries to make payments to us may be restricted by, among other things, applicable state corporation or similar statutes and other laws and regulations. The earnings from, or other available assets of, our subsidiaries may be insufficient to enable us to pay principal or interest on notes when due.

Despite our current consolidated debt levels, we may still incur substantially more debt or take other actions which would intensify the risks discussed above.

Despite our current consolidated debt levels, we and our subsidiaries may be able to incur substantial additional debt in the future, including secured debt. The indenture governing some of our notes permits us and our subsidiaries to incur additional indebtedness or to take a number of other actions that could diminish our ability to make payments on such notes.

We may not have the ability to raise the funds necessary to pay interest on notes or to repurchase notes upon a fundamental change.

In certain circumstances, we are obligated to pay additional interest or special interest on notes. In addition, if a fundamental change occurs, holders of notes may require us to repurchase all or a portion of their notes in cash. Any of the cash payments described above could be significant, and we may not have enough available cash or be able to obtain financing so that we can make such payments when due. In addition, our ability to repurchase our notes, to pay additional interest or special interest on notes, or to pay cash upon conversions of notes may be limited by law or by agreements governing our existing or future indebtedness. For example, under the amended and restated credit facility that we entered into in connection with the initial issuance of notes, we are restricted from making any payment or distribution with respect to, or purchasing, redeeming, defeasing, retiring or acquiring, our notes, other than payments of scheduled interest on notes, issuance of conversion shares, and payment of cash in lieu of fractional shares.

An active trading market may never develop for our notes.

There has been no trading market for our notes, and we do not intend to apply to list our notes on any securities exchange or to have them quoted on any automated dealer quotation system. In addition, the liquidity of the trading market in notes, and the trading price of our notes, may be adversely affected by changes in the overall market for this type of security and by changes in our financial performance or prospects or in the prospects for companies in our industry generally. As a result, we cannot assure you that an active trading market will develop for our notes. If an active trading market does not develop or is not maintained, the trading price and the liquidity of our notes may be adversely affected. In that case, you may not be able to sell your notes at a particular time, if at all, or you may not be able to sell your notes at a favorable price.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements set forth and incorporated by reference in this prospectus that are not purely historical are forward-looking statements within the meaning of applicable securities laws. Our forward-looking statements include, but are not limited to, statements regarding our "expectations," "hopes," "beliefs," "intentions" or "strategies" regarding the future. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "shou well as similar expressions, may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward looking. Forward-looking statements set forth and incorporated by reference in this prospectus may include, for example, statements about:

- our ability to integrate the acquisition of X-spine Systems, Inc. and any other business combinations or acquisitions successfully;
- our ability to remain listed on the NYSE MKT;
- our ability to obtain financing on reasonable terms;
- our ability to increase revenue;
- our ability to comply with the covenants in our credit facility;
- our ability to maintain sufficient liquidity to fund our operations;
- the ability of our sales force to achieve expected results;
- our ability to remain competitive;
- government regulations;
- our ability to innovate and develop new products;

- our ability to obtain donor cadavers for our products;
- our ability to engage and retain qualified technical personnel and members of our management team;
- the availability of our facilities;
- government and third-party coverage and reimbursement for our products;
- our ability to obtain regulatory approvals;
- our ability to successfully integrate recent and future business combinations or acquisitions;
- our ability to use our net operating loss carry-forwards to offset future taxable income;
- our ability to deduct all or a portion of the interest payments on the notes for U.S. federal income tax purposes;
- our ability to service our debt;
- product liability claims and other litigation to which we may be subjected;
- product recalls and defects;
- timing and results of clinical studies;
- our ability to obtain and protect our intellectual property and proprietary rights;

- infringement and ownership of intellectual property;
- our ability to remain accredited with the American Association of Tissue Banks;
- influence by our management;
- our ability to pay dividends; and
- our ability to issue preferred stock.

The forward-looking statements set forth and incorporated by reference in this prospectus are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties or assumptions, many of which are beyond our control, which may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the “Risk Factors” section of this prospectus and the documents incorporated by reference. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

THE ASPIRE CAPITAL TRANSACTION

On April 17, 2015, we entered into an amendment and restatement of the Purchase Agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of our shares of common stock over the term of the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, we issued 207,182 Initial Purchase Shares and 154,189 Commitment Shares to Aspire Capital. Subsequent to the issuance of the Initial Purchase Shares and the Commitment Shares, pursuant to the Purchase Agreement, we issued to Aspire Capital 417,000 shares of our common stock for $1,387,439 in aggregate proceeds. We also entered into the Registration Rights Agreement, in which we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act the resale by Aspire Capital of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement. Aspire Capital may not assign its rights or obligations under the Purchase Agreement.

As of June 13, 2016, there were 12,135,150 shares of our common stock outstanding, all of which was held by non-affiliates. If all of the 2,000,000 shares of our common stock offered hereby were issued and outstanding as of June 13, 2016, such shares would represent 17.2% of the non-affiliate shares of common stock outstanding.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering 2,000,000 shares of our common stock under the Securities Act, which includes 207,182 Initial Purchase Shares, 154,189 Commitment Shares and 417,000 additional purchase shares that have already been issued to Aspire Capital, and 1,221,629 shares of common stock which we may issue to Aspire Capital pursuant to the terms of the Purchase Agreement. All 2,000,000 shares of common stock are being offered pursuant to this prospectus. Under the terms of the Purchase Agreement, the proceeds from the sale of our common stock to Aspire Capital may not exceed $10 million.

On any trading day on which the closing sale price of our common stock exceeds $1.00 per share, we have the right, in our sole discretion, to present Aspire Capital with a Purchase Notice directing Aspire Capital (as principal) to purchase up to 50,000 shares of our common stock per trading day, provided that the aggregate price of such purchase shall not exceed $500,000 per trading day, up to $10.0 million of our common stock in the aggregate at a Purchase Price calculated by reference to the prevailing market price of our common stock over the preceding 10-business day period (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for 50,000 shares and the closing sale price of our stock is equal to or greater than $1.00 per share of common stock, we also have the right, in our sole discretion, to present Aspire Capital with a VWAP Purchase Notice directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of our common stock on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold. The VWAP Purchase Price is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than $1.00 per share. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

Purchase Of Shares Under The Purchase Agreement

Under the Purchase Agreement, on any trading day selected by us on which the closing sale price of our common stock exceeds $1.00 per share, we may direct Aspire Capital to purchase up to 50,000 shares of our common stock per trading day. The Purchase Price of such shares is equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or

- the arithmetic average of the three lowest closing sale prices for our common stock during the 10 consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for 50,000 shares and the closing sale price of our stock is equal to or greater than $1.00 per share of common stock, we also have the right to direct Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of our common stock on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold, which is equal to the greater of (a) 80% of the closing price of our common stock on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as set forth by us in the VWAP Purchase Notice. The VWAP Purchase Price of such shares is the lower of:

- the closing sale price on the VWAP Purchase Date; or

- 97% of the volume-weighted average price for our common stock traded on the principal market where the common stock is listed or traded:

  - on the VWAP Purchase Date, if the aggregate shares to be purchased on that date have not exceeded the VWAP Purchase Share Volume Maximum; or

  - during that portion of the VWAP Purchase Date until such time as the sooner to occur of (i) the time at which the aggregate shares traded exceed the VWAP Purchase Share Volume Maximum or (ii) the time at which the sale price of our common stock falls below the VWAP Minimum Price Threshold.

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction occurring during the trading day(s) used to compute the Purchase Price. We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

Minimum Share Price

Under the Purchase Agreement, we and Aspire Capital may not effect any sales of shares of our common stock under the Purchase Agreement on any trading day that the closing sale price of our common stock is less than $1.00 per share.

Events of Default

Generally, Aspire Capital may terminate the Purchase Agreement upon the occurrence of any of the following events of default:

- while any registration statement is required to be maintained effective pursuant to the terms of the Registration Rights Agreement, the effectiveness of such registration statement lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Aspire Capital, and such lapse or unavailability continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement or the filing of a new registration statement; provided, however, that in connection with any post-effective amendment to such registration statement or filing of a new registration statement that is required to be declared effective by the Securities and Exchange Commission (the "SEC"), such lapse or unavailability may continue for a period of no more than 30 consecutive business days, which such period shall be extended for up to an additional 30 business days if the Company receives a comment letter from the SEC in connection therewith;

- the suspension from trading or failure of the common stock to be listed on a principal market for a period of three consecutive business days;

- in the event of a delisting of the common stock from the principal market, if the common stock is not immediately thereafter trading on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market, the OTC Bulletin Board or the OTCQB marketplace of the OTC Market Group;

- the failure for any reason by our transfer agent to issue shares to Aspire Capital within five business days after the applicable purchase date that Aspire Capital is entitled to receive under the Purchase Agreement;

- our breach of any representation, warranty, covenant or other term or condition under any transaction document with Aspire Capital, if such breach could reasonably be expected to have a material adverse effect and except, in the case of a breach of a covenant which is reasonably curable, only if such breach continues uncured for a period of at least five business days;

- of any person commences a proceeding against us pursuant to or within the meaning of any bankruptcy law;

- if we, pursuant to or within the meaning of any bankruptcy law: (A) commence a voluntary case, (B) consent to the entry of an order for relief against us in an involuntary case, (C) consent to the appointment of a custodian over us or for all or substantially all of our property, (D) make a general assignment for the benefit of our creditors or (E) become insolvent; or

- a court of competent jurisdiction enters an order or decree under any bankruptcy law that: (A) is for relief against us in an involuntary case, (B) appoints a custodian over us or for all or substantially all of our property, or (C) orders our liquidation or of any of our subsidiaries.

The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

No Short-Selling or Hedging by Aspire Capital

Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

Effect of Performance of the Purchase Agreement on Our Stockholders

The Purchase Agreement does not limit the ability of Aspire Capital to sell any or all of the 2,000,000 shares of our common stock registered in this offering. The sale by Aspire Capital of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and/or to be highly volatile. Aspire Capital may ultimately purchase all, some or none of the 1,221,629 shares of common stock not yet issued but registered in this offering. After it has acquired such shares, it may sell all, some or none of such shares. Sales to Aspire Capital by us pursuant to the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. However, we have the right to control the timing and amount of any sales of our shares to Aspire Capital and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital

In connection with entering into the Purchase Agreement, we authorized the sale to Aspire Capital of up to $10.0 million of our shares of common stock. In the event we elect to issue more than 2,000,000 shares under the Purchase Agreement, we will be required to file a new registration statement and have it declared effective by the SEC. The number of shares ultimately offered for sale by Aspire Capital in this offering is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement. The following table sets forth the number and percentage of outstanding shares to be held by Aspire Capital after giving effect to the sale of shares of common stock issued to Aspire Capital at varying Purchase Prices:

Assumed Average Purchase Price	Proceeds from the Sale of Shares to Aspire Capital Under the Purchase Agreement Registered in this Offering	**Number of Shares to be Issued in this Offering at the Assumed Average Purchase Price[1]**	**Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital[2]**
$ 1.00	$ 1,845,811	1,845,811	15.2 %
$ 2.00	$ 3,691,622	1,845,811	15.2 %
$ 3.00	$ 5,537,433	1,845,811	15.2 %
$ 4.00	$ 7,383,244	1,845,811	15.2 %
$ 5.00	$ 9,229,055	1,845,811	15.2 %
$ 6.00	$ 10,000,000	1,666,666	13.7 %
$ 7.00	$ 10,000,000	1,428,571	11.8 %

(1) Excludes the Commitment Shares issued under the Purchase Agreement.

(2) The denominator is based on 12,135,150 shares outstanding as of June 13, 2016, which includes the Initial Purchase Shares, the Commitment Shares and 717,000 additional purchase shares previously issued to Aspire Capital, as well as the number of shares set forth in the adjacent column which we would have sold to Aspire Capital at the corresponding assumed Purchase Price set forth in the adjacent column. The numerator is based on the number of shares which we may issue to Aspire Capital under the Purchase Agreement at the corresponding assumed Purchase Price set forth in the adjacent column.

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Aspire Capital. We will not receive any proceeds upon the sale of shares by Aspire Capital. However, we may receive proceeds up to $10.0 million under the Purchase Agreement with Aspire Capital. The proceeds received from the sale of the shares under the Purchase Agreement will be used for working capital and general corporate purposes. This anticipated use of net proceeds from the sale of our common stock to Aspire Capital under the Purchase Agreement represents our intentions based on our current plans and business conditions.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2016:

You should read this table in conjunction with the information contained in our consolidated financial statements and accompanying notes incorporated by reference into this prospectus.

	As of March 31, 2016 (Unaudited)
Cash and cash equivalents	$ 4,668,355
Long-term debt:	
Total lease obligations (less current portion)	$ 4,804
Long-term debt (less issuance costs)	44,441,737
6.00% convertible senior notes due 2021	68,000,000
Total long-term debt	112,446,541
Stockholders' equity	
Preferred stock, $0.000001 par value per share; 5,000,000 shares authorized; no shares issued and outstanding, actual and pro forma	—
Common stock, $0.000001 par value per share; 95,000,000 shares authorized; 11,897,601 issued and outstanding	11
Additional paid-in capital	81,998,270
Accumulated deficit	(78,637,044)
Total stockholders' (deficit) equity	3,361,237
Total capitalization	$ 115,807,778

The number of outstanding shares of common stock in the table above excludes, as of March 31, 2016:

- 582,706 shares issuable upon the exercise of outstanding stock options with a weighted average exercise price of $10.88 per share;
- 1,278,566 shares issuable upon the exercise of outstanding warrants with a weighted average exercise price of $8.45 per share;

- Approximately 470,000 shares available for issuance under our Amended and Restated Equity Incentive Plan;

- 1,221,629 shares reserved for issuance pursuant to a common stock purchase agreement with Aspire Capital Fund, LLC; and

- 21,451,035 shares reserved for issuance upon conversion of the notes.

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DILUTION

If you acquire shares of our common stock from the selling securityholders in this offering, your ownership interest will be diluted to the extent of the difference between the assumed public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering. Net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the total number of shares of common stock outstanding. Our historical net tangible book value of common stock as of March 31, 2016 was negative $35.6 million, or $(3.01) per share of common stock.

Our pro forma net tangible book value as of March 31, 2016 was negative $35.6 million, or $(3.01) per share of common stock. Our pro forma net tangible book value per share gives effect to the following as if each had occurred as of March 31, 2016: (i) the acquisition of X-spine, (ii) the issuance of the initial notes to the initial purchaser and the OrbiMed purchasers for an aggregate principal amount of $68,000,000, (iii) the issuance of the promissory notes to the OrbiMed purchasers for an aggregate principal amount of $2,238,166.45 and (iii) the entry of an amended and restated credit agreement with ROS.

After giving effect to (i) the sale of 17,511,108 shares of common stock in this offering at the conversion price of $3.88 per share and (ii) the sale of 771,781 shares of common stock in this offering at the conversion price of $2.90 per share, after deducting estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2016 would have been $34.4 million, or $1.14 per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $4.15 per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of $3.01 per share to investors participating in this offering. The following table illustrates this per share dilution:

Assumed weighted average public offering price per share		$3.84
Historical net tangible book value per share as of March 31, 2016	$(3.01)	
Pro forma change in net tangible book value per share attributable to pro forma transactions and other adjustments described above	-	
Pro forma net tangible book value per share before this offering	(3.01)	
Pro forma increase in net tangible book value per share attributable to this offering	4.15	
Pro forma as adjusted net tangible book value per share after this offering		1.14
Dilution in pro forma as adjusted net tangible book value per share to investors participating in this offering		$2.70

The shares of common stock sold in this offering, if any, may be sold from time to time at various prices.

Each $1.00 increase (decrease) in the $3.84 assumed weighted average public offering price of (i) $3.88 per share with respect to 17,511,108 shares of common stock in this offering and (ii) $2.90 per share with respect to 771,781 shares of common stock in this offering would increase (decrease) our pro forma as adjusted net tangible book value by $18.3 million, or by $0.65 per share, and the dilution per share to new investors purchasing shares of common stock in this offering by $0.61, assuming that the number of shares of common stock offered remains the same and after deducting estimated aggregate offering expenses payable by us. This information is supplied for illustrative purposes only.

The table and calculations set forth above are based on the number of shares of common stock outstanding as of March 31, 2016 and assumes no exercise of any outstanding options or warrants. To the extent that options or warrants are exercised, there will be further dilution to new investors. The table and calculations set forth above also do not take into account the number of additional shares that may be issued upon the conversion of notes at an increased conversion rate “in connection with” a make-whole fundamental change (as defined below under “Description of the Initial Notes — Increase in the Conversion Rate for Conversions in Connection with a Make-Whole Fundamental Change” and “Description of the Promissory Notes — Increase in the Conversion Rate for Conversions in Connection with a Make-Whole Fundamental Change”). The number of additional shares, if any, by which the conversion rate will be increased for a holder that converts its notes in connection with a make-whole fundamental change will be determined by reference to the applicable make-whole table set forth below under “Description of the Initial Notes — Increase in the Conversion Rate for Conversions in Connection with a Make-Whole Fundamental Change” or “Description of the Promissory Notes — Increase in the Conversion Rate for Conversions in Connection with a Make-Whole Fundamental Change.”

BUSINESS

The following description of our business should be read in conjunction with the section titled "Business" in Item 1, Part I of our Annual Report on Form 10-K for the year ended December 31, 2015, which is incorporated by reference into this prospectus.

The Acquisition of X-spine

On July 31, 2015, we acquired all of the outstanding capital stock of X-spine for approximately $60.0 million in cash, repayment of all outstanding indebtedness of X-spine to U.S. Bank, National Association, which was approximately $13.0 million, and approximately 4.24 million shares of our common stock. An escrow was established at the closing with Wells Fargo Bank, N.A., as escrow agent. The escrow account was funded with $6.0 million of cash and all of the shares of our common stock issued in the transaction. The term of the escrow will be 27 months following the closing. Subject to any claims then outstanding, the cash portion of the escrow will be released 15 months following the closing, and 25% of the shares will be released on each of the dates that are 18, 21, 24 and 27 months following the closing.

The stock purchase agreement contains customary representations and warranties by the individual Sellers relating to themselves and by the individual Sellers relating to X-spine. The agreement provides for indemnification for breaches of representations and warranties, non-fulfillment of covenants, any unpaid indebtedness and transaction costs, taxes and pre-closing product liability claims. Indemnity for breaches of representations and warranties is generally subject to a $100,000 deductible basket and a cap of $6.0 million for basic representations, the full escrow amount for intermediate representations, and the full purchase price for fundamental representations. All claims must first be asserted against the escrowed cash, then the escrowed shares valued at $4.00 per share.

Dr. David L. Kirschman, President of X-spine prior to the acquisition, remains in that role and is now also a member of our board of directors and is our Executive Vice President and Chief Scientific Officer. Dr. Kirschman's annual base salary is $500,000, with bonus compensation targeted at 50% of base salary. In connection with his continued service after the acquisition, Dr. Kirschman also received a restricted stock grant of 40,000 shares of our common stock, vesting over four years. Dr. Kirschman has agreed to customary proprietary information provisions and restrictive covenants, including non-solicitation and non-competition covenants, and his agreement provides for 12 months' severance if he is terminated in connection with a change of control.

The X-spine Business

Overview

X-spine is a global developer, manufacturer and marketer of implants and instruments for surgery of the spine and sacroiliac joint. X-spine's product emphasis is the minimally invasive approach to the treatment of degenerative spine disorders.

X-spine's global strategy is to advance minimally invasive technologies for the treatment of degenerative spinal disorders, while supporting established spinal fusion markets. By leveraging its vertically-integrated product development resources, X-spine believes it can rapidly respond to the evolving demands of the spinal marketplace. X-spine has developed two product tracks, consisting of core fusion products and minimally-invasive surgery ("MIS") products. Core products address the traditional spinal fusion market, while MIS products include devices implanted in the facet joint, the sacroiliac joint, and interspinous space. X-spine internationally markets the Zyfix®, Fixcet®, H-Graft®, Silex®, and Axle® spinal implant systems in these respective segments. Additional X-spine MIS products include cannulated pedicle screw systems Fortex® and Xpress®. These MIS products are designed to allow for less invasive access to the spine as compared to traditional open access surgical approaches.

X-spine currently markets and sells products in the United States and several other countries. For the year ended December 31, 2015, international sales represented approximately 3% of X-spine's revenue. X-spine has made significant investments in building a managed independent sales organization consisting of direct sales managers, independent sales agencies and distributor partners. As of December 31, 2015, the X-spine global sales force consisted of multiple independent sales agencies and medical device distributorships.

X-spine was founded and incorporated in 2004 by neurosurgeon, Dr. Kirschman, in the Dayton, Ohio region.

Competitive Strengths

X-spine believes the following competitive strengths have been instrumental to X-spine's success:

Emphasis on MIS Technologies: X-spine's strategic focus and core competencies are the design, development and commercialization of MIS technologies and techniques. MIS techniques are rapidly becoming the standard of care in the spinal industry and will continue to evolve over the next decade.

Portfolio of Proprietary Technologies: X-spine has developed a comprehensive portfolio of products that address a broad array of spinal pathologies, anatomies and surgical approaches in the complex spine and MIS markets. To protect company innovative technologies and techniques, X-spine maintains and continues to grow its intellectual property portfolio, with over 50 issued patents globally and over 30 patent applications pending.

Lean Product Development Process: Responding quickly and efficiently to the needs of patients, surgeons and hospitals is central to corporate culture and critical to success. Through a vertically integrated process, X-spine can take a product from concept to market using close internal teams and resources.

Multi-channel Distribution Network: X-spine has approximately 150 contracted sales agents and independent distributors in its global distribution channel. The distribution channel consists of multiple sub-channels including direct sales, consignment agents, reseller distributors, and private label distributors and technology licensees.

Products and Services

X-spine's customers are hospitals, medical device distributors, physicians and payors, to whom X-spine delivers best-in-class products, customer-critical services and economic sustainability. During X-spine's 11-year history, it has commercialized approximately 22 product families that are used to treat a variety of spinal and sacroiliac conditions, including trauma, degeneration, deformity and tumor, with an emphasis on MIS. Some of X-spine's key product lines include:

- Launched in early 2011, the Axle® Interspinous Fusion System is a fully modular interspinous device. Available in multiple implantable configurations, the Axle® can be ideally matched to each patient's individual anatomy.

- Launched in late 2013, the Silex® Sacroiliac Joint Fusion System is a sacroiliac fixation system which actively compresses across the SI joint. Sacroiliac dysfunction is increasingly recognized as a frequent contributor to chronic low back pain.

- Launched in 2014, the Xpress™ Minimally Invasive Pedicle Screw System combines minimally invasive functionality to the most common lumbar fixation procedures — pedicle screw fixation.

- The Certex™ Spinal Fixation System consists of screws, hooks, rods, and cross connectors. Various sizes of these implants are available so that adaptations can be made to take into account pathology and individual patient anatomy. It is intended to promote fusion of the subaxial cervical spine and cervico-thoracic junction (C3 – T3 inclusive).

- The Butrex® Anterior Lumbar Buttress Plating System utilizes the patented Resilient Locking Arm Technology to prevent screw back out, while providing repeatable and reliable results. The low profile design, and two point fixation ensures minimal disruption to the local anatomy and high cantilever expulsion resistance. The Butrex® System also features an all-in-one drill guide with a plate retaining feature to allow for greater control during plate placement, and to protect adjacent structures.

- CalixPC™ combines the osteo-equivalent modules of PEEK with the bone contact qualities of titanium. Frictional titanium plasma-coated PEEK implants provide additional biomechanical performance and end-plate visualization.

- The Calix A Peek Lumbar System is an anterior PEEK lumbar system.

- The Calix ATP™ Peek Lumbar System consists of PEEK implants and complementary instrumentations systems.

- Spider® Cervical Plating System.

- The Calix® Cervical Interbody Spacer is comprised of precision instruments and implants to aid in cervical fusion. The combination of PEEK and tantalum markers facilitate radiographic identification of implant placement and fusion.

- The Zyfix™ Facet Fusion System is a minimally invasive facet fusion system featuring a hollow fenestrated titanium compression screw for bone graft introduction. It is intended for bilateral, transfacet fixation of the facet joint in order to provide stability for fusion.

- The Fixcet® Spinal Facet Screw System is a percutaneous facet screw system offering dual-compression thread and single-thread screws. It is intended for posterior fixation to the lumbar spine (L1 to S1 inclusive). It enables a bilateral, transfacet fixation of the facet joint in order to provide stability for fusion.

- The Fortex® Pedicle Screw System consists of titanium alloy bone screws, rods, cross-connectors and associated instruments. The system is indicated for attachment to the pedicles of the thoracic, lumbar, and sacral spine.

- The X90® Pedicle Screw System combines unique rotary locking technology and maximum biomechanical performance allowing for simple rod locking without a separate locking cap or set screw. Through its unified design, the X90® Pedicle Screw System is designed to avoid the problems of cross threading, head splay, and cap loosening, endemic to cap type pedicle screw systems.

- The Irix-A™ Lumbar Integrated Fusion System consists of an integrated titanium ring, surrounded by an outer PEEK ring and three screws. It is intended for spinal fusion procedures at one or two contiguous levels of the lumbosacral spine (L2 – S1 inclusive) in skeletally mature patients for the treatment of degenerative disc disease.

- The Irix-C™ Cervical Integrated Fusion System consists of an integrated titanium ring, surrounded by an outer PEEK ring and two screws. It is intended for spinal fusion procedures at one level (C3 – T1 inclusive) in skeletally mature patients for the treatment of degenerative disc disease.

- The Axle-X™ Interspinous Fusion System is an internal fixation device for spinal surgery in the non-cervical spine (T1 – S1 inclusive). It is a minimally invasive, modular interspinous fusion system with angled spikes that allows for adequate L5 – S1 engagement and other variations in patient anatomy. The Axle-X™ Interspinous Fusion System is designed to provide spinal stability for lumbar fusion procedures, including the treatment of degenerative disc disease, spinal tumors and trauma.

- The X-PORT™ tissue-sparing instrumentation system was designed to maximize surgical access and visualization while minimizing tissue disruption. An ideal partner to the X-spine Fortex pedicle screw system, the radiolucent X-PORT™ retractor component is integrated with a siderail mounted flexible arm for accurate localization and stability. The X-PORT™ system includes integral tissue-sparing instrumentation to allow for compression, distraction and rod placement while maintaining anatomic visualization through the retractor component.

Technology and Intellectual Property

X-spine has developed and maintains an expanding portfolio of intellectual property, which includes over 50 issued patents globally and over 30 patent applications pending. In addition to current product offerings, X-spine continues to invest in the research and development necessary to design, develop and commercialize new surgical solutions for unmet clinical needs. X-spine's product development process utilizes a lean vertically-integrated approach among small teams of product experts to develop class-leading and differentiated products. X-spine has spent $2,140,450 and $ in 2014 and 2015, respectively, in research and development expenses. Since early 2010, X-spine has introduced multiple product lines, including products driven by an MIS product focus such as Axle® modular interspinous and Silex® sacroiliac platforms.

X-spine believes in the superiority of its technology and products. As a result, X-spine has invested in the development of the names of its products in order to drive consumer awareness and loyalty to the brand. To protect this investment, X-spine has registered, and continues to seek registration, of these trademarks and monitors and pursues users of names and marks that potentially infringe upon its registered trademarks. X-spine currently owns the following registered trademarks: SILEX®, X-SPINE®, IRIX®, CAPLESS®, CERTEX®, CALIX®, H-GRAFT®, SPIDER, X90®, HYDRAGRAFT®, BUTREX®, FORTEX®, AXLE®, FIXCET®, Capless® and X-spine's square design logo.

To safeguard its proprietary knowledge and technology, X-spine relies upon trade secret protection and non-disclosure/confidentiality agreements with employees, consultants and third party collaboration partners with access to its confidential information. There can be no assurance, however, that these measures will adequately protect against the unauthorized disclosure or use of confidential information, or that third parties will not be able to independently develop similar technology. Additionally, there can be no assurance that any agreements concerning confidentiality and non-disclosure will not be breached, or if breached, that X-spine will have an adequate remedy to protect it against losses. X-spine believes that the intrinsic knowledge and experience of management, advisory board, consultants and personnel and their ability to identify unmet market needs and to create, invent, develop and market innovative and differentiated products are keys to its future success.

Sales and Marketing

X-spine promotes, markets and sells products through a global sales organization comprised of direct sales managers, product specialists, independent sales agents and distributor partners. The global sales organization consists of independent sales agencies and distributors. Each sales manager is assigned a defined territory.

X-spine currently generates revenues from several countries internationally, in addition to the United States. For the year ended December 31, 2014, international sales represented approximately 4% of revenue. The global sales organization provides geographic coverage in regions where X-spine products are sold, including North America, Europe, Middle East, South Africa and Australia. X-spine continually evaluates new market opportunities and expects to expand the number of international markets served.

Relationship with Zimmer Holdings, Inc.

In January 2014, X-spine entered into a license agreement with Zimmer, under which Zimmer granted to X-spine a royalty-bearing, non-exclusive license under certain Zimmer patents to make, have made, use, practice, offer for sale, sell, export and import certain spinal screw, anchor and rod implants. X-spine is required to pay a royalty in the mid-single digits on gross sales of products covered by the in-licensed patents. X-spine’s license agreement with Zimmer continues so long as there is an enforceable claim in the in-licensed patents. Either X-spine or Zimmer may terminate the agreement for any material breach by the other party that is not cured within a specified time period or in the event of the other party’s insolvency.

Also, in January 2014, X-spine entered into a distribution agreement with Zimmer, under which X-spine granted Zimmer a co-exclusive right to distribute certain X-spine products worldwide. X-spine is entitled to receive a royalty in the low-single digits on net sales of products. X-spine also obtained a non-exclusive, perpetual, worldwide license under certain Zimmer patents to distribute certain of X-spine's products. In consideration for the rights granted to X-spine under the agreement, X-spine will be required to pay a royalty on net sales of certain products in the low-single digits.

Absent earlier termination, the distribution agreement with Zimmer will expire 10 years from the effective date, subject to automatic two-year extensions unless either party notifies the other party in writing that it desires not to renew the agreement. The agreement may be terminated by either party upon the occurrence of a material breach, a force majeure event, or a bankruptcy event. Zimmer may terminate the agreement if X-spine is subject to a change in control event involving a Zimmer competitor or if X-spine breaches a specific regulatory warranty.

Competition

X-spine's currently marketed products are, and any future products commercialized will be, subject to intense competition. Several companies compete or are developing technologies in current and future product areas. As a result, competition will remain intense. Principal competitors include Medtronic Spine and Biologics, DePuy Synthes, Stryker, Globus Medical and NuVasive, which together represent a significant portion of the spine market. X-spine also competes with smaller spine market participants such as Alphatec Spine, LDR Holding Corporation, Orthofix, SeaSpine, and K2 Medical, who generally have a smaller market share than the principal competitors listed above.

Related Party Transactions

Certain former X-spine shareholders, who now own over 10% of our common stock, own a controlling interest in Norwood Tool Company d/b/a Norwood Medical, X-spine's largest supplier. In 2015, Xtant purchased from Norwood Medical approximately 12% of its operating products.

David Kirschman's sister, Deborah Kirschman, serves as the Company's Corporate Counsel and Director of Corporate Compliance. Compensation paid to Ms. Kirschman since the acquisition date was $50,327 in 2015. Ms. Kirschman also received 1,005 of the restricted stock units at $3.19 a share for a total cost of approximately $3,000 to be expensed ratably over the vesting period as general and administrative expense.

Unless delegated to the compensation committee by the board of directors, the audit committee or the disinterested members of the full board of directors reviews and approves all related party transactions.

Governmental Regulation

X-spine markets products that are regulated as medical devices and tissues and therefore is subject to extensive regulation by the FDA, as well as by other domestic and international regulatory bodies. These regulations govern multiple activities that X-spine and suppliers, licensors and partners perform and will continue to perform. These regulated activities include product design and development, testing, manufacturing, labeling, storage, safety, premarket clearance, advertising and promotion, product marketing, sales and distribution, postmarket surveillance and postmarket adverse event reporting.

Regulatory Clearances and Approvals of Medical Devices

Unless an exemption applies, each medical device X-spine wishes to commercially distribute in the United States requires either prior 510(k) clearance or PMA approval from the FDA. The FDA classifies all medical devices into one of three classes. Devices deemed to pose lower risk are categorized as either Class I or II, which requires the manufacturer to submit to the FDA a 510(k) premarket notification requesting clearance of the device for commercial distribution in the United States. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k)-cleared device, are categorized as Class III, requiring premarket approval. All commercially-marketed X-spine medical device products to date have been cleared for marketing and distribution through the 510(k) pathway, unless exempt.

To obtain 510(k) clearance, we must submit a premarket notification to the FDA demonstrating the proposed device to be substantially equivalent to a previously cleared 510(k) device, a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMAs, or is a device that has been reclassified from Class III to either Class II or I. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the notification is submitted, but it can take considerably longer, depending on the extent of requests for additional information from the FDA and the amount of time a sponsor takes to fulfill them, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a premarket notification, the FDA may request additional information, including clinical data, which may significantly prolong the review process.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require premarket approval. The FDA requires each manufacturer to make this decision initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. X-spine has made, and plans to continue to make, product enhancements that it believes do not require new 510(k) clearances. If the FDA requires X-spine to seek 510(k) clearance or premarket approval for any such modifications to previously cleared products, X-spine may be required to cease marketing or recall the modified device until this clearance is obtained, and significant regulatory fines or penalties could result.

A PMA must be submitted if a device is in Class III (although the FDA has the discretion to continue to allow certain pre-amendment Class III devices to use the 510(k) process) or cannot be cleared through the 510(k) clearance process. A PMA must be supported by extensive data, including, but not limited to, technical information, preclinical data, clinical trial data, manufacturing data and labeling to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. After a PMA is submitted and filed, the FDA begins an in-depth review of the submitted information, which typically takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA will usually be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with QSR, which imposes elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMAs or PMA supplements are required for significant modifications to the manufacturing process, labeling of the product and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA, and may not require as extensive clinical data or the convening of an advisory panel.

No X-spine existing products are currently approved under a PMA. In the future, X-spine may decide to strategically commercialize products in the United States that would require a PMA, but there are no plans to do so at the present time. Clinical trials are almost always required to support a PMA and are sometimes required for a 510(k) premarket notification.

Ongoing FDA Regulation

After a device is placed on the market, numerous FDA and other regulatory requirements continue to apply. These include: establishment registration and device listing with the FDA; the QSR, which requires manufacturers to follow stringent design, testing, process control, documentation and other quality assurance procedures; labeling regulations, which prohibit the promotion of products for unapproved, i.e. "off-label," uses and impose other restrictions on labeling; Medical Devise Reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act (the "FDCA") that may present a risk to health; and requirements to conduct postmarket surveillance studies to establish continued safety data.

The FDA enforces these requirements by inspection and market surveillance. Failure to comply with applicable regulatory requirements may result in enforcement action by the FDA, which may include one or more of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions and civil penalties;
- mandatory recall or seizure of our products;
- administrative detention or banning of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) clearance or PMA of new product versions;
- revocation of 510(k) clearance or PMAs previously granted; and
- criminal prosecution and penalties.

International Regulation

Many foreign countries have regulatory bodies and restrictions similar to the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval in a foreign country or to obtain a CE Certificate of Conformity may be longer or shorter than that required for FDA approval and the related requirements may differ. Some third-world countries accept CE Certificates of Conformity or FDA clearance or approval as part of applications of approval for marketing of medical devices in their territory. Other countries, including Brazil, Canada, Australia and Japan, require separate regulatory filings.

Tissue, Cellular and Tissue Based Product

X-spine currently distributes Axograft™, HGraft™, and HydraGraft™ allograft products, which are manufactured by third-party suppliers. Tissue-only products are regulated by the FDA as HCT/Ps. FDA regulations do not currently require clearance or approval of a marketing application before marketing these products. Tissue banks must register their establishments, list products with the FDA and comply with Current Good Tissue Practices for HCT/P Establishments.

The FDA periodically inspects tissue processors to determine compliance with these requirements. Violations of applicable FDA regulations could adversely affect the continued marketing of these products and could result in untitled letters and warning letters; fines, injunctions and civil penalties; mandatory recall or seizure of our products; administrative detention or banning of our products; operating restrictions, partial suspension or total shutdown of production; and/or criminal prosecution and penalties. Entities that provide X-spine with allograft bone tissue are responsible for performing donor recovery, donor screening and donor testing and compliance with those aspects of the Current Good Tissue Practices regulations that regulate those functions are dependent upon the actions of these independent entities.

Healthcare Fraud and Abuse

Healthcare fraud and abuse laws apply to X-spine business when a customer submits a claim for an item or service that is reimbursed under Medicare, Medicaid or most other federally-funded healthcare programs. The federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under federal health care programs, such as by Medicare or Medicaid. The federal Anti-Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. For example, the federal government has enforced the Anti-Kickback Statute to reach large settlements with device manufacturers based on allegedly sham consultant arrangements with physicians. A number of states also have anti-kickback laws that establish similar prohibitions that may apply to items or services reimbursed by government programs as well as any third-party payors, including commercial insurers.

The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Further, the recently enacted PPACA, among other things, clarified the intent requirements of the federal Anti-Kickback Statute and the federal criminal statutes governing healthcare fraud. Specifically, a person or entity can be found to have violated the statutes without actual knowledge of these statutes or specific intent to violate them. In addition, the PPACA amended the Social Security Act to provide 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 federal False Claims Act or federal civil money penalties statute. Recent amendments to the federal False Claims Act provide that a violation of the federal Anti-Kickback Statute is also a violation of the federal False Claims Act, subjecting healthcare entities to treble damages and mandatory penalties for each false claim or statement.

Additionally, the civil False Claims Act prohibits, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment of federal funds, or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Actions under the federal False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the federal False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigations of healthcare companies

throughout the country for a wide variety of Medicare billing practices, as well as federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, and has obtained multi-million and multi-billion dollar settlements under the federal False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and suppliers' compliance with the healthcare reimbursement rules and fraud and abuse laws.

The federal False Claims Act amendments in 2009 and 2010 expanded the scope of the liability for health care entities generally to potentially reach violations of regulatory duties, such as good manufacturing practices. There have been large settlements in the life sciences arena related to FDA regulatory violations for promotional activities and good manufacturing practices.

Even in instances where a company may have no actual liability, the federal False Claims Act private citizen provisions (qui tam) allow the filing of federal False Claims Act actions under seal and impose a mandatory duty on the U.S. Department of Justice to investigate such allegations. Most private citizen actions are declined by the Department of Justice or dismissed by federal courts. However, the investigation costs for a company can be significant and material even if the allegations are without merit.

Federal False Claims Act liability is potentially significant in the health industry because the statute provides for treble damages and mandatory minimum penalties of $5,500 to $11,000 per false claim or statement. Because of the potential for large monetary exposure, health care companies resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages that may awarded in litigation proceedings. They may be required, however, to enter into corporate integrity agreements with the government, which may impose substantial costs to companies to ensure compliance. There has also been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. The Physician Payment Sunshine Act imposes annual reporting requirements on device manufacturers for payments and other transfers of value provided by them, directly or indirectly, to physicians (including physician family members) and teaching hospitals, as well as ownership and investment interests held by physicians. A manufacturer’s failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year, and up to an aggregate of $1.0 million per year for “knowing failures.” Manufacturers must submit reports by the 90th day of each calendar year. Certain states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements.

If a governmental authority were to conclude that X-spine is not in compliance with applicable laws and regulations, X-spine and its officers and employees could be subject to severe criminal and civil penalties, including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare, Medicaid and other federal health care programs.

Coverage and Reimbursement

X-spine’s currently approved products are commonly treated as general supplies utilized in spinal and orthopedic surgery and if covered by third-party payors, are paid for as part of the surgical procedure. Accordingly, healthcare providers in the United States generally rely on third-party payors, principally private insurers and governmental payors such as Medicare and Medicaid, to cover and reimburse all or part of the cost of a spine surgery in which X-spine products are used. Sales volumes and prices of X-spine products will continue to depend in large part on the availability of coverage and reimbursement from such third-party payors. Third-party payors perform analyses on new

technologies to determine if they are medically necessary before providing coverage for them. These third-party payors may still deny reimbursement on covered technologies if they determine that a device used in a procedure was not used in accordance with the payor's coverage policy. Particularly in the United States, third-party payors continue to carefully review, and increasingly challenge, the prices charged for procedures and medical products.

In the United States, a large percentage of insured individuals receive their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs pay their providers on a per capita basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month and, consequently, may limit the willingness of these providers to use X-spine products.

The overall escalating cost of medical products and services has led to, and will likely continue to lead to increased pressures on the healthcare industry to reduce the costs of products and services. Government or private third-party payors cannot be guaranteed to cover and reimburse the procedures using X-spine products in whole or in part in the future or that payment rates will be adequate. In addition, it is possible that future legislation, regulation or coverage and reimbursement policies of third-party payors will adversely affect the demand for X-spine products or the ability to sell them on a profitable basis.

Internationally, reimbursement and healthcare payment systems vary substantially from country to country and include single-payor, government-managed systems as well as systems in which private payors and government managed systems exist side-by-side. X-spine's ability to achieve market acceptance or significant sales volume in international markets will be dependent in large part on the availability of reimbursement for procedures performed using company products under the healthcare payment systems in such markets. A number of countries may require X-spine to gather additional clinical data before recognizing coverage and reimbursement for its products.

Employees

As of December 7, 2015, X-spine had 90 full-time employees and 93 total employees, of whom 22 were in operations, 12 were in sales, 7 were in marketing, 17 were in regulatory compliance, 11 were in research and development, 6 were in manufacturing, 8 were in customer service and 10 were in administrative functions. In addition, X-spine makes use of a varying number of outsourced services to manage normal business cycles. None of X-spine's employees are covered by a collective bargaining agreement and X-spine management considers relations with employees and service partners to be good.

Facilities

X-spine leases its headquarters and facilities, which are located at 452 and 444 Alexandersville Road, Miamisburg, Ohio 45342. The leased property contains approximately 31,600 square feet, of which approximately 19,260 square feet are office space and approximately 4,740 square feet are warehouse space. The space includes a manufacturing facility with multi-axis CNC machining capacity. The facility specializes in the manufacturing of prototypes, custom instrumentation, test fixtures and key production items. The space includes an advanced biomechanical laboratory and a full bioskills lab for cadaver surgery and clinician training. The facilities are leased under a five-year lease which runs through November 2016 and has a monthly lease payment of $21,379 plus CAM charges and taxes. The lease has a three-year renewal option.

Litigation

The medical device industry is characterized by frequent claims and litigation, including product liability claims and claims regarding patent and other intellectual property rights as well as improper hiring practices. X-spine is not aware of any pending or threatened legal proceeding against X-spine that is expected to have a material adverse effect on X-spine business, operating results or financial condition. However, X-spine is a party in multiple legal actions, including product liability claims, involving claimants seeking various remedies, including monetary damages, and none of the outcomes are certain or entirely within X-spine's control.

Government Regulation

Food and Drug Administration

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to the FDCA and the Public Health Service Act (the "PHSA"), as implemented and enforced by the FDA. Certain of our products sold in the United States require FDA clearance to market under Section 510(k) of the FDCA. Foreign countries may require similar or more onerous approvals to manufacture or market these products. Many of our products are marketed as HCT/Ps solely under Section 361 of the PHSA.

The FDA governs the following activities that we perform or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

· product design, development and manufacture;

- product safety, testing, labeling and storage;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

There are numerous FDA regulatory requirements governing the approval or clearance and marketing of our products. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of a cleared product;
- approval of product modifications that affect the safety or effectiveness of an approved product;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and

- notices of correction or removal and recall regulations.

We have registered our facilities with the FDA as a medical device manufacturer. The FDA has broad post-market and regulatory enforcement powers. We are subject to announced and unannounced inspections by the FDA to determine our compliance with the QSR and other regulations and these inspections may include the manufacturing facilities of our suppliers. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- operating restrictions;
- withdrawing clearances or approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice.

FDA's Premarket Clearance and Approval Requirements

Unless an exemption applies, before we can commercially distribute medical devices in the United States, depending on the type of device, we must obtain either prior 510(k) clearance or premarket approval from the FDA. The FDA classifies medical devices into one of three classes:

- Class I devices, which are subject to only general controls (e.g., labeling, medical devices reporting, and prohibitions against adulteration and misbranding) and, in some cases, to the 510(k) premarket clearance requirements;
- Class II devices, generally requiring 510(k) premarket clearance before they may be commercially marketed in the United States; and
- Class III devices, consisting of devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device, generally requiring submission of a PMA supported by clinical trial data.

510(k) Clearance Pathway

When a 510(k) clearance is required, we must submit a premarket notification demonstrating that our proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMAs. By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance may take longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. Our OsteoSelect DBM Putty and our Elutia coated wound drains are currently cleared under a 510(k).

Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device, requires a new 510(k) clearance and may even, in some circumstances, require a PMA, if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer’s decision. We have modified our devices since they received the FDA clearance. If the FDA were to disagree with any of our determinations that changes did not require a new 510(k), it could require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or PMA approval is obtained. If the FDA requires us to seek 510(k) clearance or PMA approval for any modifications, we may be required to cease marketing and/or recall the modified device, if already in distribution, until 510(k) clearance or PMA approval is obtained and we could be subject to significant regulatory fines or penalties.

There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business. Delays in receipt or failure to receive clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects.

Premarket Approval Pathway

A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process. A PMA must be supported by extensive data, including but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. No device that we are marketing to date has required premarket approval. During the review period, the FDA will typically request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the QSRs. To date, none of our products have required approval of a PMA.

New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. There is no guarantee that the FDA will grant PMA approval of our future products and failure to obtain necessary approvals for our future products would adversely affect our ability to grow our business. Delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects.

Clinical Trials

Clinical trials are generally required to support a PMA and are sometimes required for 510(k) clearance. Such trials generally require an IDE approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed an nonsignificant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal

privacy and human subject protection regulations. We, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the United States.

FDA Regulation of Human Tissue Products

The FDA regulates the manufacture of human tissue products under the authority of the PHSA and, in some cases, under the FDCA as well. Human tissues are subject to the FDA's HCT/P regulations, or may also be subject to FDA's drug, biological product, or medical device regulations.

Under Section 361 of the PHSA, the FDA issued specific regulations governing the use of HCT/Ps in humans. Pursuant to Part 1271 of Title 21 of the Code of Federal Regulations, the FDA established a unified registration and listing system for establishments that manufacture and process HCT/Ps. The regulations also include provisions pertaining to donor eligibility determinations; current good tissue practices covering all stages of production, including harvesting, processing, manufacture, storage, labeling, packaging, and distribution; and other procedures to prevent the introduction, transmission, and spread of communicable diseases.

The HCT/P regulations strictly constrain the types of products that may be regulated solely under these regulations. Factors considered include the degree of manipulation, whether the product is intended for a homologous function, whether the product has been combined with another article, and the product's effect or dependence on the body's metabolic function. In those instances where cells, tissues, and cellular and tissue- based products have been only minimally manipulated, are intended strictly for homologous use, have not been combined with noncellular or nontissue substances, and do not depend on or have any effect on the body's metabolism, the manufacturer is only required to register with the FDA, submit a list of manufactured products, adopt and implement procedures for the control of communicable diseases and comply with Good Tissue Practices and other provisions of 21 CFR Part 1271. If one or more of the above factors (minimal manipulation, homologous use, etc.) has been exceeded, the product would be regulated as a drug, biological product, or medical device rather than an HCT/P. There is no requirement that manufacturers of human tissue products confirm with FDA that their products are eligible for marketing without FDA review and approval or clearance of a marketing application. However, after a human tissue product is marketed without approval or clearance of a marketing application, FDA may inform a company that the product does not meet all the criteria, and that a medical device or biological product marketing application is required.

Healthcare Fraud and Abuse

Federal healthcare fraud and abuse laws apply to our business when a customer submits a claim for an item or service that is reimbursed under Medicare, Medicaid or most other federally-funded healthcare programs. The federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under federal healthcare programs, such as by Medicare or Medicaid. The Anti-Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. For example, the federal government has enforced the Anti-Kickback Statute to reach large settlements with device manufacturers based on allegedly sham consultant arrangements with physicians. A number of states also have anti-kickback laws that establish similar prohibitions that may apply to items or services reimbursed by government programs, as well as any third-party payors, including commercial insurers.

HIPAA created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors,

knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Further, the recently enacted PPACA, among other things, clarified the intent requirements of the Anti-Kickback Statute and the federal criminal statutes governing healthcare fraud. Specifically, a person or entity can be found to have violated the statutes without actual knowledge of these statutes or specific intent to violate them. In addition, the PPACA amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act or the federal civil money penalties statute. Recent amendments to the False Claims Act further provide that a violation of the Anti-Kickback Statute also is a violation of the False Claims Act, subjecting healthcare entities to treble damages and mandatory penalties for each false claim or statement.

Additionally, the False Claims Act prohibits, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment of federal funds, or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigations of healthcare companies throughout the country for a wide variety of Medicare billing practices, as well as Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, and has obtained multi-million and, in some cases, multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating compliance with the healthcare fraud and abuse laws.

The False Claims Act amendments in 2009 and 2010 expanded the scope of liability for healthcare entities generally to potentially reach violations of regulatory duties, such as good manufacturing practices. There have been large settlements in the life sciences arena related to FDA regulatory violations for promotional activities and good manufacturing practices.

Even in instances where a company may have no actual liability, the False Claims Act private citizen provisions (qui tam) allow the filing of False Claims Act actions under seal and impose a mandatory duty on the U.S. Department of Justice to investigate such allegations. Most private citizen actions are declined by the Department of Justice or dismissed by federal courts. However, the investigation costs for a company can be significant and material even if the allegations are without merit.

False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory minimum penalties of $5,500 to $11,000 per false claim or statement. Because of the potential for large monetary exposure, healthcare companies resolve allegations without admissions of liability oftentimes for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may awarded in litigation proceedings. They may be required, however, to enter into corporate integrity agreements with the government, which may impose substantial costs to companies to ensure compliance.

There also has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. The Physician Payment Sunshine Act imposes annual reporting requirements on device manufacturers for payments and other transfers of value provided by them, directly or indirectly, to physicians (including physician family members) and teaching hospitals, as well as ownership and investment interests held by physicians. A manufacturer’s failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year, and up to an aggregate of $1.0 million per year for “knowing failures.” Manufacturers must submit reports by the 90th day of each calendar year. Certain states also

mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements.

If a governmental authority were to conclude that we were not in compliance with applicable laws and regulations, the Company and our officers and employees could be subject to severe criminal and civil penalties, including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare, Medicaid and other federal healthcare programs.

Coverage and Reimbursement

Our currently approved products are commonly treated as general supplies utilized in surgical procedures and if covered by third-party payors, are paid for as part of the surgical procedure. Accordingly, healthcare providers in the United States generally rely on third-party payors, principally private insurers and governmental payors, such as Medicare and Medicaid, to cover and reimburse all or part of the cost of a surgery in which our products are used. Sales volumes and prices of our products will continue to depend in large part on the availability of coverage and reimbursement from such third-party payors.

Some third-party payors perform analyses on new technologies to determine if they are medically necessary before providing coverage for them. These third-party payors potentially could deny reimbursement on covered technologies if they determine that a product used in a procedure was not used in accordance with the payor's coverage policy. Particularly in the United States, third-party payors continue to carefully review, and increasingly challenge, the prices charged for procedures and medical products.

In the United States, a large percentage of insured individuals receive their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs pay their providers on a per capita basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month and, consequently, may limit the willingness of these providers to use our products.

The overall escalating cost of medical products and services has led to, and will likely continue to lead to increased pressures on the healthcare industry to reduce the costs of products and services. Government or private third-party payors cannot be guaranteed to cover and reimburse the procedures using our products in whole or in part in the future or to provide payment rates that will be considered adequate by our customers. In addition, it is possible that future legislation, regulation or coverage and reimbursement policies of third-party payors will adversely affect the demand for our products or the ability to sell them on a profitable basis.

Internationally, reimbursement and healthcare payment systems vary substantially from country to country and include single-payor and government-managed systems, as well as systems in which private payors and government managed systems exist side-by-side. Our ability to achieve market acceptance or significant sales volume in international markets will be dependent in large part on the availability of reimbursement for procedures performed using our products under the healthcare payment systems in such markets. A number of countries may require us to gather additional clinical data before recognizing coverage and reimbursement for our products.

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MANAGEMENT

Directors and Executive Officers

The names, ages and positions of our directors and executive officers are as follows:

Name	Age	Position
Daniel Goldberger	57	Director, Chief Executive Officer
Kent Swanson	71	Chairman of the board
Michael Lopach	67	Director
Jon Wickwire	73	Director*
John Deedrick	53	Director
David Goodman, M.D.	61	Director*
David L. Kirschman, M.D.	45	Director, Executive Vice President and Chief Scientific Officer**
Paul R. Buckman	60	Director Nominee***
Eric B. Timko	50	Director Nominee***
Rudy A. Mazzocchi	57	Director Nominee***
John P. Gandolfo	55	Chief Financial Officer

* Will resign, effective July 2, 2015 (see Form 8-K, filed as of June 17, 2015, and incorporated by reference herein).
** Will resign from the position of Executive Vice President and Chief Scientific Officer, effective July 2, 2015; however, Dr. Kirschman will remain a director of the Company (see Form 8-K, filed as of June 17, 2015, and incorporated by reference herein).
*** Appointment effective July 2, 2015 (see Form 8-K, filed as of June 17, 2015, and incorporated by reference herein).

The principal occupations for the past five years (and, in some instances, for prior years) of each of our directors and executive officers are as follows.

Daniel Goldberger, Director, Chief Executive Officer, has more than 25 years of experience as a leader of both publicly traded and privately held medical technology companies, with a proven track record of building revenue and profits through the introduction of market changing product innovations. He was most recently Chief Executive Officer and a director of Sound Surgical Technologies from April 2007 through its merger with Solta Medical (Nasdaq: SLTM) in February 2013. Previously, he was President/Chief Executive Officer and a director of Xcorporeal (Amex XCR) an innovator in portable dialysis and Glucon (private) a developer of glucose measurement technology and several other successful enterprises. Mr. Goldberger is a named inventor on more than 60 US patents. He holds a B.S. in Mechanical Engineering from the Massachusetts Institute of Technology and an MS in Mechanical Engineering from Stanford University. Mr. Goldberger contributes medical industry and management experience to

the board of directors.

Kent Swanson, Chairman of the board, was with Accenture for over 32 years, retiring from the firm in 2001 as a Senior Partner. He held global leadership and management positions in a wide range of industries and geographies. From 2001 to 2008, he was the board chair of ALN Medical Management; providing outsourced services for clinic-based physician practices. Also from 2001 to 2008, he was board chair for Boys Hope Girls Hope of Colorado, a charitable organization providing a home and scholarship education for disadvantaged children with significant capabilities and promise. From 2002 to 2009, he was a board member, audit committee member and compensation committee chair for MPC Computers. Mr. Swanson graduated with distinction from the University of Minnesota earning an M.S. in Business and received an M.B.A. from the University of Chicago in 1969. Mr. Swanson contributes significant management experience to the board of directors.

Michael Lopach, Director, is a certified public accountant with over 40 years of accounting experience. Mr. Lopach spent 27 years of his career with Galusha, Higgins, Galusha & Co., the largest privately held accounting firm in Montana and northern Idaho, where he served as president and Chief Executive Officer. In 1999, Mr. Lopach founded Lopach & Carparelli PC, an accounting firm that focuses on medical practitioners. Mr. Lopach received his MBA from the University of Notre Dame. Mr. Lopach serves as chairman of the audit committee. Mr. Lopach contributes significant accounting experience to the board of directors.

Jon Wickwire, Director, is an attorney and founding shareholder of Wickwire Gavin, P.C., a national construction law firm which merged with Akerman Senterfitt, one of the top 100 law firms in the United States. Mr. Wickwire served as lead counsel on major infrastructure litigation and alternative dispute resolutions, both domestically and internationally, throughout his 35 year career, and was the founding fellow of the American College of Construction Lawyers. Mr. Wickwire also served as the founding chairman of the College of Scheduling, an organization dedicated to advancing the techniques, practice and profession of project scheduling, and has authored several books and articles on construction and public contract law, including *Construction Management: Law and Practice* and *The Construction Subcontracting Manual: Practice Guide with Forms* . Mr. Wickwire currently serves on the advisory board for Crunchies Food Company. Mr. Wickwire is a graduate of the University of Maryland and Georgetown University Law Center. Mr. Wickwire serves as chairman of the nominations and corporate governance committee. Mr. Wickwire contributes legal experience to the board of directors.

John Deedrick, Director, is an experienced senior executive with 30 years of experience in healthcare, defense, and business consulting. He was a co-founder and managing director for Accuitive Medical Ventures and a corporate venture capitalist for Mayo Clinic. Mr. Deedrick currently serves as President and Chief Executive Officer of CHIP Solutions and is founder and chairman of GreatDeeds, a Minnesota non-profit organization. Mr. Deedrick has served on the board of numerous early, mid and growth stage healthcare companies over the last 17 years, including GreatDeeds and Ironwood Springs Ranch. Mr. Deedrick received his undergraduate degree from the University of Northwestern St. Paul (Roseville, MN) and his MBA from St. Thomas University (St. Paul, MN). Mr. Deedrick contributes significant financial, management and industry experience to the board of directors.

David Goodman, M.D., Director, has devoted his career to improving health through the development and integration of innovative technologies into clinical practice. Dr. Goodman currently serves as co-founder and Chief Medical Officer of FirstVitals Health & Wellness, a technology-enabled service company focused on preventing complications such as foot ulcers and lower extremity amputations in people with diabetes. Dr. Goodman also serves on the board of directors of NEUROMetrix (Nasdaq: NURO), a neurotechnology company focused on the early detection of diabetic peripheral neuropathy (DPN) and treatment of painful diabetic neuropathy (PDN). In addition, Dr. Goodman served as a director of Sound Surgical Technologies LLC, a private manufacturer of aesthetic surgical tools until its successful acquisition by Solta Medical (Nasdaq: SLTM) in 2013. Dr. Goodman has a long track record of accomplishment in executive management as well as through his own entrepreneurial efforts. As an executive, Dr. Goodman served as Chief Executive Officer of SEDLine, an EEG-based brain monitoring company as well as the EVP of Business Development for Masimo (Nasdaq: MASI), a leading company in non-invasive patient monitoring. As an entrepreneur, Dr. Goodman was the founding Chief Executive Officer of LifeMasters Supported SelfCare, a pioneering disease management company, and Aradigm, a developer of electronic aerosol drug delivery systems. Dr. Goodman began his career as the first engineer at Nellcor, the company that developed modern pulse oximetry. He holds a B.A.S. in applied science and bioengineering and a M.S.E. in bioengineering from the University of Pennsylvania. Dr. Goodman also received an M.D. cum laude from Harvard Medical School and the Harvard-M.I.T. Division of Health Sciences and Technology. Dr. Goodman completed his internship at the University of California, San Francisco (UCSF) in the Department of Medicine. He holds 18 issued and 4 pending US patents and maintains clinical practices in California and Hawaii. Dr. Goodman contributes medical and industry experience to the board of directors.

David L. Kirschman, M.D., Director, Executive Vice President and Chief Scientific Officer, is an inventor and entrepreneur with a background in the medical device industry. He completed training in neurosurgery with a specialization in instrumented spinal surgery. Dr. Kirschman retired from the practice of medicine in 2006. Dr. Kirschman has issued and pending patents for a wide range of spinal devices and has been the President of X-spine since 2004. In connection with the acquisition of X-spine by the Company on July 31, 2015, Dr. Kirschman became a member of our board of directors and our Executive Vice President and Chief Scientific Officer. Dr. Kirschman also serves on the board of directors of Aerobiotix, Inc. He received his B.S. in Biological Science cum laude from Colorado State University and M.D. from the University of Colorado School of Medicine. Dr. Kirschman contributes medical, management and industry experience to the board of directors, as well as an in-depth understanding of the X-spine business. Effective July 2, 2016, Dr. Kirschman will resign from his officer position of Executive Vice President and Chief Scientific Officer, but will remain as a director of the Company.

John P. Gandolfo, Chief Financial Officer, joined us as our interim Chief Financial Officer on a part-time basis, effective June 4, 2010, and filled this position full time commencing on July 6, 2010. Mr. Gandolfo also served as Interim Co-Chief Executive Officer from April 5, 2013 to August 14, 2013, and as a Director from July 9, 2013 to August 14, 2013. Mr. Gandolfo has 25 years of experience as chief financial officer of rapidly growing private and publicly held companies with a primary focus in the life sciences, healthcare and medical device areas. Mr. Gandolfo has had direct responsibility over capital raising, including four public offerings, financial management, mergers and acquisition transactions and SEC reporting throughout his professional career. Prior to joining us, Mr. Gandolfo served as the Chief Financial Officer for Progenitor Cell Therapy LLC, a leading manufacturer of stem cell therapies. Prior to joining Progenitor, Mr. Gandolfo served as the Chief Financial Officer for Power Medical Interventions, Inc., a publicly held developer and manufacturer of computerized surgical stapling and cutter systems, from January 2007 to January 2009. Prior to joining PMI, Mr. Gandolfo was the Chief Financial Officer of Bioject Medical Technologies, Inc., a publicly held supplier of needle-free drug delivery systems to the pharmaceutical and biotechnology industries, from September 2001 to May 2006, and served on the Bioject's board of directors from September 2006 through May 2007. Prior to joining Bioject, Mr. Gandolfo was the Chief Financial Officer of Capital Access Network, Inc., a privately held specialty finance company, from 2000 through September 2001, and Xceed, Inc., a publicly held Internet consulting firm, from 1999 to 2000. From 1994 to 1999, Mr. Gandolfo was Chief Financial Officer and Chief Operating Officer of Impath, Inc., a publicly held, cancer-focused healthcare information company. From 1987 through 1994, he was Chief Financial Officer of Medical Resources, Inc., a publicly held manager of diagnostic imaging centers throughout the United States. A graduate of Rutgers University, Mr. Gandolfo is a certified public accountant (inactive status) who began his professional career at Price Waterhouse.

Paul R. Buckman, age 60, will become a member of our Board, effective July 2, 2015. He has served as chief executive officer of Conventus Orthopaedics, a Minnesota-based company specializing in peri-articular bone fracture fixation, since September 2013. Mr. Buckman was chief executive officer of Sentreheart, Inc., a medical technology company focused on closure of various anatomic structures, from February 2012 to September 2013. Previously, Mr. Buckman served as chief executive officer of Pathway Medical Technologies, Inc., a medical device company focused on treatment of peripheral arterial disease, from September 2008 to February 2012; as chief executive officer of Devax, Inc., a developer and manufacturer of drug eluting stents, from December 2006 to September 2008; as president of the cardiology division of St. Jude Medical, Inc., a diversified medical products company, from August 2004 to December 2006; and as chairman of the board of directors and chief executive officer of ev3, LLC, a Minnesota-based medical device company focused on endovascular therapies that Mr. Buckman founded and developed into an $80 million business, from January 2001 to January 2004. Mr. Buckman has worked in the medical device industry for over 30 years, including 10 years at Scimed Life Systems, Inc. and Boston Scientific Corporation, where he held several executive positions before becoming president of the cardiology division of Boston Scientific in January 2000. Mr. Buckman also currently serves as a business advisory board member for Bio Star Ventures, and as a director for Conventus Orthopaedics, Ablative Solutions, Inc., Pathway Medical Technologies (where he also served as chairman of the board of directors from December 2006 to September 2008) and Caisson Interventional, LLC. Since February 2011, Mr. Buckman has served as a director of Sunshine Heart, Inc. He previously served as a director of Velocimed, Inc., where he was a co-founder, EndiCor, Inc., Microvena, Inc., and Micro Therapeutics, Inc. Mr. Buckman received his B.A. and M.B.A from Western Michigan University. Mr. Buckman's qualifications to serve on the Board include his extensive experience in the management of medical device companies, including his collective 13 years of experience in chief executive officer roles and four years of experience in divisional president roles.

Eric B. Timko, age 50, will become a member of our Board, effective July 2, 2015. He has over 25 years in the medical industry, most recently serving as Chief Executive Officer of Blue Belt Technologies, a company that was acquired by Smith & Nephew earlier this year. Prior to joining Blue Belt, Mr. Timko was the President and Chief Executive Officer of NeuroVasx, Inc., a Minneapolis-based company developing a unique therapeutic device to treat hemorrhagic stroke. Previously, he served as President of Carl Zeiss Surgical, Inc., and as Vice President of Siemens Medical Systems, Inc. Mr. Timko possesses a proven track record in building an effective and profitable sales and distribution organization and he brings vast experience in medical technologies at both the start-up and commercial stages.

Rudy A. Mazzocchi, age 57, will become a member of our Board, effective July 2, 2015. He is Chief Executive Officer of ELENZA, Inc., a company developing the world's first electronic "AutoFocal" Intraocular Lens, a position he has held since 2010, and currently serves as Executive Chairman of Establishment Labs, a leading manufacturer of implantable medical devices in San Jose, Costa Rica. From 2008 to 2010, he was President and Chief Executive Officer of NovaVision, Inc., a neuro-ophthalmology device company specializing in non-invasive photic neurostimulation to restore vision. From 2005 to 2008, Mr. Mazzocchi served as Managing Director of Accuitive Medical Ventures, a venture capital fund established to finance and develop early and expansion stage medical device and technology companies. He also served as President and Chief Executive Officer of Image-Guided NEUROLOGICS from 1998 to 2005. Prior to that, Mr. Mazzocchi was the co-founder and Director of Vascular Science and founding-Chief Executive Officer of MICROVENA Corporation, eventually known as eV3, and served in numerous management and operations roles at Cook Critical Care, an operating division of COOK, Inc. He also previously served as Chairman of Cytogenesis in 2000 to 2003, as well as director of Greatbatch, Inc. from 2012 to 2014. Mr. Mazzocchi received his B.S. in Life Sciences/Biochemistry from the University of Pittsburgh, and completed graduate studies in biophysics at the University of California, Los Angeles. Mazzocchi brings 27 years of experience in the medical device industry in operations and general management roles and has extensive background and experience in the medical device industry.

Board Composition and Terms of Office

The composition of our board of directors, audit committee, compensation committee, and nominations and governance committee, is subject to the corporate governance provisions of the NYSE MKT, including rules relating to the independence of directors. A majority of our board members and all of our board committee members are independent directors. Currently, our independent board members are Messrs. Swanson, Lopach, Wickwire, Deedrick and Goodman. As of July 2, 2016, our independent board members will be Messrs. Swanson, Lopach, Deedrick, Timko, Mazzocchi and Buckman. All directors hold office for staggered three-year terms and until the election and qualification of their successors. Officers are elected by, and serve at the discretion of, the board of directors.

Board Committees

We have established an audit committee, compensation committee, nominations and corporate governance committee, in compliance with applicable corporate governance requirements, and the board of directors also formed a business development committee in 2014. The charters of our audit committee, compensation committee and nominations and corporate governance committee have been posted on our website at www.xtantmedical.com. The contents of our website are not incorporated by reference into this prospectus.

Audit Committee

The purpose of the audit committee is to assist the oversight of our board of directors with the integrity of our financial statements, our compliance with legal and regulatory matters, our internal audit function, and our independent auditor's qualifications, independence, and performance. The primary responsibilities of the audit committee are set forth in its charter and include various matters with respect to the oversight of our accounting and financial reporting process and audits of our financial statements. The audit committee also selects the independent auditor, reviews the proposed scope of the audit, reviews our accounting and financial controls with the independent auditor and financial accounting staff, and reviews and approves transactions between us and our directors, officers, and their affiliates.

The audit committee currently consists of Messrs. Lopach, Swanson and Wickwire, each an independent director under rules adopted by the SEC pursuant to the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley"). As of July 2, 2016, our audit committee will consist of Messrs. Lopach, Buckman and Mazzocchi, each an independent director under rules adopted by the SEC pursuant to Sarbanes-Oxley. Mr. Lopach serves as the chairman of the audit committee. The board of directors has determined that Messrs. Lopach, Swanson, Buckman and Mazzocchi (whose backgrounds are detailed above) each qualify as an "audit committee financial expert" in accordance with applicable rules and regulations of the SEC.

Compensation Committee

The primary purposes of the compensation committee are to determine or recommend the compensation of our Chief Executive Officer and other executive officers, and to oversee our Amended and Restated Equity Incentive Plan. Our compensation committee currently consists of Messrs. Deedrick, Lopach and Goodman, each an independent director under rules adopted by the SEC pursuant to Sarbanes-Oxley. Mr. Deedrick currently serves as the chairman of the compensation committee. As of July 2, 2016, our compensation committee will consist of Messrs. Buckman, Lopach and Timko, each an independent director under rules adopted by the SEC pursuant to Sarbanes-Oxley. As of July 2, 2016, Mr. Buckman will serve as the chairman of the compensation committee.

Nominations and Corporate Governance Committee

The purposes of the nominations and corporate governance committee include the selection or recommendation to our board of directors of nominees to stand for election as directors, the oversight of the selection and composition of the committees of our board of directors, the oversight of the evaluations of our board of directors and management, and the development and recommendation to our board of directors of a set of corporate governance principles applicable to us. The nominations and corporate governance committee currently consists of Messrs. Wickwire, Deedrick and Goodman, each an independent director under rules adopted by the SEC pursuant to Sarbanes-Oxley. Mr. Wickwire currently serves as the chairman of the nominations and corporate governance committee. As of July 2, 2016, the nominations and corporate governance committee will consist of Messrs. Deedrick, Mazzocchi and Timko, each an independent director under rules adopted by the SEC pursuant to Sarbanes-Oxley. As of July 2, 2016, Mr. Deedrick will serve as the chairman of the nominations and corporate governance committee.

Business Development Committee

In September 2014, the board of directors formed a business development committee to advise the board on strategic direction and growth strategies. The business development committee currently consists of Messrs. Deedrick, Swanson and Goodman, and Mr. Deedrick serves as the chairman of the committee. As of July 2, 2016, the business development committee will consist of Messrs. Deedrick, Mazzocchi, Timko and Buckman, and Mr. Deedrick will continue to serve as the chairman of the committee.

Nominations to the Board of Directors

Our directors take a critical role in guiding our strategic direction and overseeing the management of the Company. Board candidates are considered based on various criteria, such as their broad-based business and professional skills and experiences, a global business and social perspective, concern for the long-term interests of the stockholders, diversity, personal integrity and judgment.

In addition, directors must have time available to devote to board activities and to enhance their knowledge in the growing business. Accordingly, we seek to attract and retain highly qualified directors who have sufficient time to attend to their substantial duties and responsibilities.

Family Relationships

There are no family relationships among our directors and executive officers.

Compliance with Section 16(a) of the Exchange Act

Section 16(a) requires directors, executive officers and holders of more than 10% of an equity security registered pursuant to Section 12 of the Exchange Act to file various reports with the SEC.

To our knowledge, based solely on our review of the Section 16 reports furnished to us with respect to 2015, we believe all reports required pursuant to Section 16(a) were filed on a timely basis.

Code of Ethics

We have adopted a code of conduct and a code of ethics for our Chief Executive Officer and senior financial officers, both of which are posted on our website at www.xtantmedical.com. We intend to disclose any changes in, or waivers from, these codes by posting such information on the same website or by filing a Form 8-K. The contents of our website are not incorporated by reference into this prospectus.

Procedures for Stockholder Recommendation of Nominees to the Board of Directors

The procedures by which stockholders may recommend nominees to the board of directors are contained in our Amended and Restated Bylaws.

EXECUTIVE COMPENSATION

The table below summarizes the compensation earned for services rendered to the Company for the fiscal years indicated, by our Chief Executive Officer and two most highly-compensated named executive officers other than our Chief Executive Officer.

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards (1)	Option Awards (1)	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Daniel Goldberger	2015	404,000	245,000	-	-	-	-	-	649,000
Chief Executive Officer	2014	400,000	100,154	-	-	-	-	143,422 (2)	643,576
David Kirschman									
Executive Vice President and Chief Scientific Officer (from July 31, 2015 to present)	2015	209,615	62,500	-	76,868	-	-	-	348,983
John Gandolfo	2015	330,000	153,000	-	-	-	-	-	483,000
Chief Financial Officer	2014	330,000	20,000	-	90,841	-	-	-	440,841
Robert Di Silvio[4]	2015	325,000	-	-	-	-	-	-	325,000
President (from July 1, 2014 to January 8, 2016)	2014	153,750	-	-	150,990	-	-	129,300 (3)	433,140

From July 1, 2014 to January 8, 2016.

(1) Key assumptions used to estimate the grant date fair value of restricted stock and option awards are contained in Note 10 to the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2015.

(2) Relocation reimbursement.

(3) Consulting fees paid to Mr. Di Silvio for services provided prior to his employment.

(4) Effective January 8, 2016, Mr. Di Silvio ceased to be our President and a named executive officer of the Company; however, Mr. Di Silvio continues to work with the Company as a consultant.

Employment Agreements

Employment agreements for our current executive officers are set forth as exhibits to the registration statement that includes this prospectus. The employment agreements require each of the executives to perform such duties as are customarily performed by one holding their positions and provide for a fixed annual base salary. In addition, each executive is entitled to receive certain cash bonuses and grants under our equity incentive plan as may be determined by the compensation committee of our board of directors.

The employment agreements contain covenants (a) restricting the executives from engaging in any activity competitive with our business, (b) prohibiting the executive from disclosing confidential information regarding our company, and (c) requiring that all intellectual property developed by the executive and relating to our business constitutes our sole and exclusive property. The employment agreements also contain severance provisions in the event of termination without cause, resignation for good reason, or termination in connection with a change of control.

Amended and Restated Xtant Medical Equity Incentive Plan and Inducement Grants

The following is a summary of the material terms of the Amended and Restated Xtant Medical Equity Incentive Plan (the “Plan”):

The purpose of the Plan is to enable us to attract, retain and motivate key employees, directors and independent consultants, by providing them with stock options and restricted stock grants. Stock options granted under the Plan may be either incentive stock options to employees, as defined in Section 422A of the Internal Revenue Code of 1986, or non-qualified stock options. The Plan is administered by the compensation committee of the board of directors. The administrator of the Plan has the power to determine the terms of any stock options granted under the Plan, including the exercise price, the number of shares subject to the stock option and conditions of exercise. Stock options granted under the Plan are generally not transferable, vest in installments and are exercisable during the lifetime of the optionee only by such optionee. The exercise price of all incentive stock options granted under the Plan must be at least equal to the fair market value of the shares of common stock on the date of the grant.

There are 1,400,000 shares of our common stock authorized to be issued under the Plan. As of March 31, 2016, we had outstanding options to purchase 366,003 shares and 157,330 shares of restricted stock issued, to directors, executives, employees and consultants, leaving approximately 470,000 shares available for issuance thereunder.

We also granted stock options to our Chief Executive Officer (Daniel Goldberger) and former President (Robert Di Silvio) outside of our Plan as inducements material to entering into employment with the company pursuant to Section 711(a) of the NYSE MKT Company Guide. The inducement grants to our Chief Executive Officer and former President were approved by the Compensation Committee of our Board of Directors. The inducement grant to our Chief Executive Officer consists of a stock option to purchase up to 200,000 shares of our common stock, with a per share exercise price of $6.00, which was the adjusted closing price of the Company's common stock on the August 14, 2013 grant date. Our Chief Executive Officer's inducement grant stock option vests over five years, with 20% of the underlying shares vesting after one year and the remaining 80% vesting in forty-seven (47) equal monthly installments as to 3,333 underlying shares, beginning September 15, 2014, and one final installment as to 3,330 underlying shares. The inducement grant to our former President consists of a stock option to purchase up to 55,000 shares of our common stock, with a per share exercise price of $6.80, which was the adjusted closing price of our common stock on the July 1, 2014 grant date. Our former President's inducement grant stock option vested over five years, with 20% of the underlying shares vesting after one year and the remaining 80% vesting in forty-seven (47) equal monthly installments as to 917 underlying shares, beginning on August 1, 2015, and one final installment as to 901 underlying shares. Per the terms of his stock option agreement, Mr. Di Silvio has ninety days from January 8, 2016 to exercise his vested stock options.

Except for the Amended and Restated Xtant Medical Equity Incentive Plan and the inducement grants to our Chief Executive Officer and former President discussed above, we do not have any other stock option plans or other similar incentive compensation plans for officers, directors and employees.

Outstanding Equity Awards to Our Named Executive Officers at Fiscal Year-End (December 31, 2015).

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options Exercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date	Number of shares or units of stock that have not vested	Market value of shares or units of stock that have not vested
Daniel Goldberger	93,328	106,653	$ 6.00	8/14/23	-	-
John Gandolfo	7,500	22,500	5.01	9/4/24	-	-
	7,000	-	6.80	5/24/23	-	-
Robert Di Silvio	15,585	39,415	6.80	7/1/24	-	-

Potential Payments Upon Termination or Change-in-Control

All of our named executive officers have employment agreements that provide for severance payments for termination in connection with a change in control.

Under Mr. Goldberger's employment agreement, Mr. Goldberger currently receives an annual base salary of $520,000, which is subject to annual increases based on periodic reviews, along with other incentive compensation as determined by the Board of Directors, with a bonus target of 50% of Mr. Goldberger's annual base salary. Mr. Goldberger's employment agreement contains customary intellectual property provisions and restrictive covenants and provides for six (6) months of severance for termination without cause or resignation with good reason and twelve (12) months of severance for termination in connection with a change in control.

Dr. David L. Kirschman's employment agreement provides for an annual base salary of $500,000, along with other incentive compensation as determined by the Board of Directors, with a bonus target of 50% of his annual base salary. Dr. Kirschman also received a restricted stock grant of 40,000 shares of our common stock in 2015, vesting over four years. Dr. Kirschman's employment agreement contains customary proprietary information provisions and restrictive covenants, including non-solicitation and non-competition covenants, and his agreement provides for 12 months' severance for termination in connection with a change of control.

Mr. Gandolfo's employment agreement provides for an annual base salary of $360,000, along with other incentive compensation as determined by the Compensation Committee of the Board of Directors, with a bonus target of 50% of Mr. Gandolfo's annual base salary. Mr. Gandolfo's employment agreement contains customary intellectual property provisions and restrictive covenants and provides for twelve (12) months of severance for termination without cause, resignation with good reason, or termination in connection with a change in control.

Mr. Di Silvio's employment agreement provided for an annual base salary of $325,000, along with other incentive compensation as determined by the Compensation Committee of the Board of Directors, with a bonus target of 50% of Mr. Di Silvio's annual base salary. Mr. Di Silvio's employment agreement contained customary intellectual property provisions and restrictive covenants and provides for six (6) months of severance for termination without cause or resignation with good reason and twelve (12) months of severance for termination in connection with a change in control. We are currently paying severance to Mr. Di Silvio pursuant to the term of his agreement. Per the terms of his stock option agreement, Mr. Di Silvio had ninety days from January 8, 2016 to exercise his vested stock options, and did not exercise his options within such time period.

Retirement Plans

The Company currently has two 401(k) retirement plans for its employees. Under both plans, the employee becomes qualified after six months of employment. The Company is in the process of integrating the two plans. Terms for the two plans are as follows:

	Bacterin	X-Spine
Matching:	2%	None
Contribution Limit:	$18,000 or the statutorily prescribed limit	$18,000 or $24,000 if over the age of 50
Enrollment Period:	Twice a year	Four times a year

Director Compensation Earned by Our Independent Board Members During Fiscal 2015

Name	Fees Earned or Paid in Cash (1)	Stock Awards (2)	Option Awards (2)	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Kent Swanson	$ 97,500	$ 40,000	$ -	$ -	$ -	$ -	$137,500
Michael Lopach	$ 56,500	$ 40,000	$ -	$ -	$ -	$ -	$96,500
Jon Wickwire	$ 55,000	$ 40,000	$ -	$ -	$ -	$ -	$95,000
John Deedrick	$ 150,250	$ 40,000	$ -	$ -	$ -	$ -	$190,250
David Goodman	$ 51,750	$ 40,000	$ -	$ -	$ -	$ -	$91,750

(1) Effective September 4, 2014, compensation for our independent board members was revised as follows: independent directors receive an annual retainer of $40,000 per year, the independent chairman of our board of directors receives an additional $20,000 per year, the audit committee chair receives $12,500 per year, other committee chairs receive $10,000 per year, audit committee members receive $5,000 per year, other committee members receive $4,000 per year and all independent directors receive an annual equity grant valued at $40,000. In addition, the chair of our business development committee earned $90,000 for the first six months of 2015, the other members of the business development committee earned $30,000 for the first six months of 2015, and thereafter, beginning July 1, 2015, the annual compensation for the business development committee was set at $12,500 per year for the committee chair and $5,000 per year for the other members..

(2) Key assumptions used to estimate the grant date fair value of stock and option awards are contained in Note 10 to the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2015.

Compensation Committee Interlocks and Insider Participation

No interlocking relationship exists between our board of directors and the board of directors or compensation committee of any other company, nor has any interlocking relationship existed in the past.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership of our common stock as of June 13, 2016 by (a) each of our directors and named executive officers, (b) all of our current directors and executive officers as a group, and (c) each person who is known by us to beneficially own more than 5% of our common stock.

Name and Address of Beneficial Owner	**Number of Shares Beneficially Owned[2]**		**Percentage of Shares Beneficially Owned[3]**	
Directors and Named Executive Officers[1]:				
Daniel Goldberger	213,691	(4)	1.8	%
Kent Swanson	120,828	(5)	1.0	%
Michael Lopach	43,812	(6)	*	
Jon Wickwire	74,509	(7)	*	
John Deedrick	26,621	(8)	*	
David Goodman, M.D.	5,000	(9)	*	
David L. Kirschman, M.D.	1,701,063	(10)	14.0	%
John P. Gandolfo	25,390	(11)	*	
All executive officers and directors as a group (8 persons)	2,210,914		18.2	%
Five Percent Stockholders:				
OrbiMed Advisors LLC 601 Lexington Ave., 54th Floor New York, NY 10022	1,212,301	(12)	10.0	%
Kenneth J. Hemmelgarn, Jr. Revocable Living Trust dated February 9, 1998 9485 Gulf Shore Drive, B-201 Naples, FL 34108	1,272,796	(13)	10.5	%
Brian J. Hemmelgarn Revocable Living Trust dated February 9, 1998 P.O. Box 421 15643 Captive Drive Captiva, FL 33924	1,272,796	(14)	10.5	%

* Less than 1% of outstanding shares of common stock.

(1) The address for directors and named executive officers is c/o Xtant Medical Holdings, Inc., 664 Cruiser Lane, Belgrade, Montana 59714.

(2) Unless otherwise indicated, includes shares owned by a spouse, minor children and relatives sharing the same home, as well as entities owned or controlled by the named person. Also includes shares that the named person has the right to acquire within 60 days after June 13, 2016, by the exercise or conversion of any warrant, stock option or convertible preferred stock. Unless otherwise noted, shares are owned of record and beneficially by the named person and the persons named in the table have sole voting and investment power with respect to the shares beneficially owned by them as set forth opposite their respective names.

(3) The calculation in this column is based on 12,135,150 shares of common stock outstanding on June 13, 2016. The shares of common stock underlying warrants and stock options are deemed outstanding for purposes of computing the percentage of the person holding them, but are not deemed outstanding for the purpose of computing the percentage of any other person.

(4) Consists of (a) 15,510 shares of our common stock held directly, (b) 81,522 shares of our common stock held by an IRA, and (c) options to purchase 116,659 shares of our common stock.

(5) Consists of (a) 84,828 shares of our common stock held directly, (b) 20,000 shares held by a family limited partnership, (c) warrants to purchase 5,000 shares of our common stock, and (d) options to purchase 11,000 shares of our common stock.

(6) Consists of (a) 11,522 shares of our common stock held directly, (b) 14,258 shares held by a 401(k) plan, (c) warrants to purchase 2,032 shares of our common stock, and (d) options to purchase 16,000 shares of our common stock.

(7) Consists of (a) 31,247 shares of our common stock held directly, (b) 25,762 shares of common stock held by trusts, (c) warrants to purchase 1,500 shares of our common stock, and (d) options to purchase 16,000 shares of our common stock.

(8) Consists of (a) 16,621 shares of our common stock, and (b) options to purchase 10,000 shares of our common stock.

(9) Consists of an option to purchase 5,000 shares of our common stock not yet exercised.

(10) Consists of (a) 4,000 shares of our common stock held directly, and (b) 1,697,063 shares of our common stock acquired in connection with our acquisition of X-spine, which are subject to a lock-up agreement and escrow agreement.

(11) Consists of (a) 6,396 shares of our common stock held directly, (b) 994 shares of our common stock held by an IRA, and (c) options to purchase 18,000 shares of our common stock.

(12) Based on Schedule 13G/A filed with the SEC on February 17, 2015, as well as our knowledge regarding recent purchases of the Notes by affiliates of OrbiMed. Includes 475,438 shares of our common stock and warrants to purchase 87,719 shares of our common stock held by Royalty Opportunities S.àr.l., an entity managed by OrbiMed. Affiliates of OrbiMed also purchased $52.0 million aggregate principal amount of the Notes, which are convertible into shares of our common stock. However, the indenture prevents note holders from converting their Notes to the extent that such conversion would result in beneficial ownership by the note holder or any of its affiliates in excess of 9.99% of the then-outstanding shares of our common stock. OrbiMed, an investment advisor, and Samuel D. Isaly, its managing member and a control person, each have shared voting and dispositive power with respect to shares of our common stock and notes held by Royalty Opportunities S.àr.l. and Royalty Opportunities II, LP.

(13) Based on Schedule 13D filed with the SEC on August 10, 2015. Consists of 1,272,796 shares of our common stock acquired in connection with our acquisition of X-spine, which are subject to a lock-up agreement and escrow agreement. Kenneth J. Hemmelgarn, Jr. is a beneficiary of and the sole trustee of the Kenneth J. Hemmelgarn, Jr. Revocable Living Trust dated February 9, 1998, which may be revoked by Kenneth J. Hemmelgarn, Jr. Kenneth J. Hemmelgarn, Jr. and Brian J. Hemmelgarn are brothers and may be deemed to be members of a "group" for purposes of Section 13(d)(3) of the Exchange Act, though they have disclaimed any express agreement to act as a group, other than as described in their jointly filed Schedule 13D.

(14) Based on Schedule 13D filed with the SEC on August 10, 2015. Consists of 1,272,796 shares of our common stock acquired in connection with our acquisition of X-spine, which are subject to a lock-up agreement and escrow agreement. Brian J. Hemmelgarn is a beneficiary of and the sole trustee of the Brian J. Hemmelgarn Revocable Living Trust dated February 9, 1998, which may be revoked by Brian J. Hemmelgarn. Kenneth J. Hemmelgarn, Jr. and Brian J. Hemmelgarn are brothers and may be deemed to be members of a "group" for purposes of Section 13(d)(3) of the Exchange Act, though they have disclaimed any express agreement to act as a group, other than as described in their jointly filed Schedule 13D.

Economic Ownership; Stock Ownership Guidelines

Because the table above is limited to shares that are owned or which the person has the right to acquire within 60 days, it does not present a complete view of the economic exposure our directors and executive officers have to our common stock. Excluded from the table above are unvested stock options, unvested restricted stock units and unvested warrants which will become vested more than 60 days from June 13, 2016.

DESCRIPTION OF OUR COMMON STOCK

The following description, together with the additional information we include in any applicable prospectus supplement, summarizes the material terms and provisions of our common stock and preferred stock. For the complete terms of our common stock and preferred stock, please refer to our Restated Certificate of Incorporation and Amended and Restated Bylaws that are filed as exhibits to our reports incorporated by reference into the registration statement that includes this prospectus. The Delaware General Corporation Law may also affect the terms of our common stock and preferred stock.

Authorized and Outstanding Capital Stock

Our Restated Certificate of Incorporation provides that we have authority to issue (i) 95,000,000 shares of common stock, par value $0.000001 per share, 11,897,601 of which are issued and outstanding as of March 31, 2016, and (ii) 5,000,000 shares of preferred stock, par value $0.000001 per share, none of which are issued and outstanding as of the date of this prospectus. As of March 31, 2016, we also had outstanding warrants to purchase approximately 1,278,566 shares of our common stock and 1,400,000 shares authorized for issuance under our Amended and Restated Equity Incentive Plan.

Common Stock

Principal Market for our Common Stock

Our common stock is listed on the NYSE MKT under the symbol “XTNT.”

Dividends

Our board of directors may authorize, and we may make, distributions to our common stockholders, subject to any restriction in our Restated Certificate of Incorporation and to those limitations prescribed by law and contractual restrictions. Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock will be entitled to share equally, identically and ratably in any dividends that our board of directors may determine to issue from time to time. However, we have never paid cash dividends on our common

stock or any other securities. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying any cash dividends in the foreseeable future.

Fully Paid and Non-Assessable

All shares of our outstanding common stock are fully paid and non-assessable.

Voting Rights

Each share of our common stock is entitled to one vote in each matter submitted to a vote at a meeting of stockholders, including in all elections for directors. Stockholders are not entitled to cumulative voting in the election for directors. Our stockholders may vote either in person or by proxy. Except in respect of matters relating to the election of directors and as otherwise provided in our Restated Certificate of Incorporation or required by law, all matters to be voted on by our stockholders must be approved by holders of a majority of the shares present in person or by proxy at the meeting and entitled to vote on the subject matter. In the case of election of directors, all matters to be voted on by our stockholders must be approved by a plurality of the votes entitled to be cast by holders of all outstanding shares of common stock.

Preemptive and Other Rights

Holders of our common stock have no preemptive rights and have no other rights to subscribe for additional securities of ours under Delaware law, nor does our common stock have any conversion rights or rights of redemption. Upon liquidation, all holders of our common stock are entitled to participate pro rata in our assets available for distribution, subject to the rights of any class of preferred stock then outstanding.

Preferred Stock

Though we currently have no plans to issue any shares of preferred stock, our board of directors has the authority, without further action by our stockholders, to designate and issue up to 5,000,000 shares of preferred stock in one or more series. Our board of directors may also designate the rights, preferences and privileges of the holders of each such series of preferred stock, any or all of which may be greater than or senior to those granted to the holders of common stock. Though the actual effect of any such issuance on the rights of the holders of common stock will not be known until our board of directors determines the specific rights of the holders of preferred stock, the potential effects of such an issuance include:

- diluting the voting power of the holders of common stock;
- reducing the likelihood that holders of common stock will receive dividend payments;
- reducing the likelihood that holders of common stock will receive payments in the event of our liquidation, dissolution or winding up; and

	(44,349)	2.65
Outstanding at December 31, 2003	878,189	
Options granted at market price	77,396	9.16
Options exercised	(72,356)	2.31
Options canceled or expired	(16,125)	3.60
Outstanding at December 31, 2004	867,104	
Options granted at market price	233,228	15.35
Options exercised	(174,978)	2.67
Outstanding at December 31, 2005	925,354	
Available for grant at December 31, 2005	93,877	

14. Stock Incentive Plans (Continued)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model, with the following weighted-average assumptions used for grants in 2005, 2004 and 2003:

	2005	2004	2003
Expected volatility	59%	61%	62%
Risk free rate of return	4.18%	3.63%	3.22%
Expected dividend yield	0%	0%	0%
Expected life (years)	4.8	5.0	5.0

Total fair value of options granted at market price was computed to be $1.9 million, $379,000 and $369,000 for the years ended December 31, 2005, 2004 and 2003, respectively. There were no options granted during 2005, 2004 and 2003 below market price. The weighted average fair value per share of all options granted in 2005, 2004 and 2003 was $8.20, $4.90 and $1.44, respectively.

The following table summarizes information about stock options outstanding at December 31, 2005:

Options outstanding				Options exercisable	
Exercise price range	Number of shares	Weighted-average exercise price	Weighted-average remaining contractual life (years)	Exercisable at December 31, 2005	Weighted-average exercise price
$ .97 - $ 2.20	512,274	$ 2.07	6.9	512,274	$ 2.07
2.42 - 5.17	87,049	2.74	5.2	87,049	2.74
8.33 - 17.50	326,031	13.63	9.1	326,031	13.63
	925,354			925,354	

At December 31, 2005, 2004 and 2003, 925,354, 320,109 and 155,292 options were exercisable at weighted average per share exercise prices of $6.20, $2.99 and $2.88, respectively.

15. Stockholders Equity

In August 2005, the Company completed a follow-on offering of its common stock. The Company sold a total of 2,184,850 shares of common stock in the offering and received total net proceeds of $33.0 million after deducting underwriting discounts, commissions and offering expenses.

During 2005, 2004 and 2003, the Company recognized a tax benefit of $1.0 million, $187,000 and $137,000, respectively, resulting from disqualifying dispositions of stock acquired in option exercises. The Company recorded this tax benefit in additional paid-in capital.

16. Stock Repurchase Program

The Company has made no share repurchases since August 2003. During 2003, the Company repurchased 169,050 shares at an aggregate price of $446,000. Since inception of the repurchase program in 1999, the Company has repurchased 3.1 million shares for a weighted average price of $2.98 per share. In accordance with Maryland corporation law, all repurchased shares were immediately cancelled. In July 2005, the Board terminated the repurchase program.

17. Litigation

The Company is subject to legal proceedings and claims, which arise in the ordinary course of its business. In the opinion of management, the amount of ultimate liability with respect to currently pending or threatened actions is not expected to materially affect the financial position or results of operations of the Company.

Barrett Business Services, Inc.
Notes to Consolidated Financial Statements (Continued)

18. Quarterly Financial Information (Unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year ended December 31, 2003				
Revenues	$ 23,397	$ 27,902	$ 34,773	$ 36,649
Cost of revenues	20,028	23,446	28,543	29,707
Net (loss) income	(343)	167	943	1,318
Basic (loss) earnings per share	(.04)	.02	.11	.16
Diluted (loss) earnings per share	(.04)	.02	.11	.14
Common stock market prices:				
High	$ 2.50	$ 2.43	$ 4.94	$ 10.09
Low	1.54	1.76	2.00	4.67
Year ended December 31, 2004				
Revenues	$ 40,610	$ 47,704	$ 54,679	$ 51,968
Cost of revenues	34,205	39,178	44,317	42,105
Net income	606	1,840	2,448	2,477
Basic earnings per share	.07	.21	.28	.29
Diluted earnings per share	.07	.20	.26	.27
Common stock market prices:				
High	$ 11.84	$ 10.14	$ 11.79	$ 11.00
Low	7.66	8.17	8.66	8.83
Year ended December 31, 2005				
Revenues	$ 49,244	$ 59,631	$ 64,551	$ 57,963
Cost of revenues	41,644	48,196	50,842	44,404
Net income	931	2,905	4,340	4,314
Basic earnings per share	.11	.33	.43	.39
Diluted earnings per share	.10	.31	.40	.37
Common stock market prices:				
High	$ 16.59	$ 16.45	$ 23.50	$ 29.00
Low	8.99	12.27	14.65	21.00

19. Subsequent Events

Subsequent to year end, effective January 1, 2006, the Company acquired certain assets of Pro HR, LLC, a privately-held PEO company with three offices in Idaho and Western Colorado. The Company paid $4.0 million in cash for the assets of Pro HR and the selling shareholders noncompete agreements and agreed to pay an additional $1.5 million in cash contingent upon 2006 financial performance.

Subsequent to year end, effective February 16, 2006, the Company issued an additional 19,971 Earnout Shares to SRTC (see Note 2 above) in full satisfaction of the contingent consideration of this acquisition, which will result in the recognition of an additional $167,000 of goodwill in the first quarter of 2006.

SIGNATURES

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

BARRETT BUSINESS SERVICES, INC.
Registrant

Date: March 30, 2006

By: /s/ Michael D. Mulholland
Michael D. Mulholland
Vice President-Finance and Secretary

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on the 30th day of March, 2006.

Principal Executive Officer and Director:

/s/ William W. Sherertz
William W. Sherertz — President and Chief Executive Officer and Director

Principal Financial Officer:

/s/ Michael D. Mulholland
Michael D. Mulholland — Vice President-Finance and Secretary

Principal Accounting Officer:

/s/ James D. Miller
James D. Miller — Controller and Assistant Secretary

Majority of Directors:

/s/ Thomas J. Carley
Thomas J. Carley — Director

_____
James B. Hicks. Ph.D. — Director

/s/ Jon L. Justesen
Jon L. Justesen — Director

/s/ Anthony Meeker
Anthony Meeker — Director

EXHIBIT INDEX

3.1 Charter of the Registrant, as amended. Incorporated by reference to Exhibit 3 to the Registrant s Quarterly Report on Form 10 Q for the quarter ended June 30, 1994.

3.2 Bylaws of the Registrant, as amended through August 9, 2005. Incorporated by reference to Exhibit 3.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2005.

The Registrant has incurred long-term indebtedness as to which the amount involved is less than 10 percent of the Registrant s total assets. The Registrant agrees to furnish copies of the instruments relating to such indebtedness to the Commission upon request.

10.1 Second Amended and Restated 1993 Stock Incentive Plan of the Registrant. Incorporated by reference to Exhibit 10.1 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2001.*

10.2 Form of Indemnification Agreement with each director of the Registrant. Incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (No. 33-61804).*

10.3 Summary of annual cash incentive bonus award program for executive officers of the Registrant. Incorporated by reference to Exhibit 10.3 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2004 (the 2004 10-K).*

10.4 Employment Agreement between the Registrant and Michael D. Mulholland, dated January 26, 1999. Incorporated by reference to Exhibit 10.4 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 1998.*

10.5 Summary of compensation arrangements for non-employee directors of the Registrant. Incorporated by reference to Exhibit 10.5 to the 2004 10-K.*

10.6 Credit Agreement dated as of July 1, 2005, between the Registrant and Wells Fargo Bank, N.A. Incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed July 7, 2005 (the 2005 8-K).

10.7 Revolving Line of Credit Note dated as of July 1, 2005, in the amount of $4,000,000 issued to Wells Fargo Bank, N.A. Incorporated by reference to Exhibit 10.2 to the 2005 8-K.

10.8	2003 Stock Incentive Plan of the Registrant (the 2003 Plan). Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2003.*
10.9	Form of Incentive Stock Option Agreement under the 2003 Plan. Incorporated by reference to Exhibit 10.11 to the 2003 10-K.*
10.10	Form of Nonqualified Stock Option Agreement under the 2003 Plan. Incorporated by reference to Exhibit 10.12 to the 2003 10 K.*
10.11	Form of Incentive Stock Option Agreement relating to July 2005 option grants under the 2003 Plan.*
10.12	Form of Nonqualified Stock Option Agreement relating to July 2005 option grants under the 2003 Plan.*
10.13	Form of Annual Director Option Agreement under the 2003 Plan. Incorporated by reference to Exhibit 10.13 to the 2003 10-K.*
10.14	Form of Annual Director Option Agreement for July 2005 option grants under the 2003 Plan.*
10.15	Summary of Compensatory Arrangement with William W. Sherertz. Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.*
10.16	Employment Agreement between the Registrant and Michael L. Elich, dated September 25, 2001. Incorporated by reference to Exhibit 10.17 to the Registrant s Registration Statement on Form S-2 (Registration No. 333-126496) filed July 11, 2005.*
14	Code of Business Conduct. Incorporated by reference to Exhibit 14 to the 2003 10-K.
23.1	Consent of Moss Adams LLP, Independent Registered Public Accounting Firm.
23.2	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32	Certification pursuant to 18 U.S.C. Section 1350.

* Denotes a management contract or a compensatory plan or arrangement.