

Xtant Medical Holdings, Inc.  
Form 424B3  
September 09, 2015

Filed pursuant to Rule 424(b)(3)

Registration Statement No. 333-203492

## 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 August 24, 2015, we may receive proceeds of up to \$7,862,561 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 \$2,137,439 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 OTCQX marketplace under the ticker symbol “BONE.” On September 9, 2015, the last reported sale price per share of our common stock was \$3.70.

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 5 of 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 September 9, 2015.**

**TABLE OF CONTENTS**

	Page
<u>Summary</u>	1
<u>Risk Factors</u>	5
<u>Cautionary Note Regarding Forward-Looking Statements</u>	26
<u>The Aspire Capital Transaction</u>	27
<u>Use of Proceeds</u>	31
<u>Capitalization</u>	32
<u>Dilution</u>	33
<u>Unaudited Pro Forma Financial Data</u>	34
<u>Business</u>	40
<u>Management</u>	56
<u>Security Ownership of Certain Beneficial Owners and Management</u>	61
<u>Description of Our Common Stock</u>	63
<u>Market Price of and Dividends on Our Common Stock</u>	65
<u>Selling Stockholder</u>	66
<u>Plan of Distribution</u>	67
<u>Legal Matters</u>	69
<u>Experts</u>	69
<u>Material Changes</u>	69
<u>Incorporation of Certain Information by Reference</u>	69
<u>Where You Can Find More Information</u>	70

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.bacterin.com](http://www.bacterin.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



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. Use of proceeds 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.

OTCQX symbol BONE

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 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 30, 2015:

711,875 shares issuable upon the exercise of outstanding stock options with a weighted average exercise price of \$10.57 per share;

1,430,400 shares issuable upon the exercise of outstanding warrants with a weighted average exercise price of \$12.20 per share; and

580,000 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 30, 2015, there were 7,464,085 shares of our common stock outstanding, approximately 7,354,015 of which were 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 30, 2015, such shares would represent 23.0% of the total common stock outstanding and 23.3% of the non-affiliate shares of common stock outstanding as of June 30, 2015.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we have registered 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.

**Summary Unaudited Pro Forma Financial Data****XTANT MEDICAL HOLDINGS, INC.****Unaudited Pro Forma Combined Statements of Operations**

	For the Six Months Ended June 30,	
	2015	2014
Revenue		
Tissue and Medical Device Sales	\$ 42,885,947	\$ 38,148,136
Royalties and other	464,538	354,789
Total Revenue	43,350,485	38,502,925
Cost of sales	15,351,544	14,000,673
Gross Profit	27,998,941	24,502,252
Operating Expenses		
General and administrative	7,878,508	6,623,686
Sales and marketing	18,894,329	15,464,052
Research and development	1,826,359	1,621,333
Depreciation and amortization	2,638,838	2,319,440
Non-cash consulting expense	140,869	42,228
Total Operating Expenses	31,378,903	26,070,739
Gain (Loss) from Operations	(3,379,962 )	(1,568,487 )
Other Income (Expense)		
Interest expense	(5,992,052 )	(5,356,753 )
Change in warrant derivative liability	(476,289 )	(615,235 )
Non-cash consideration associated stock agreement	(558,185 )	0
Other income (expense)	(103,126 )	(183,839 )
Total Other Income (Expense)	(7,129,652 )	(6,155,827 )
Net Gain (Loss) from Operations Before (Provision) Benefit for Income Taxes	\$ (10,509,614 )	\$ (7,724,314 )
Benefit (Provision) for Income Taxes		
Current	(11,143 )	(77,470 )
Deferred		

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Net Income (Loss)	\$ (10,520,757	)	\$ (7,801,784	)
Net loss per share:				
Basic	\$ (0.94	)	\$ (0.81	)
Dilutive	\$ (0.94	)	\$ (0.81	)
Shares used in the computation:				
Basic	11,157,353		9,689,859	
Dilutive	11,157,353		9,689,859	

## 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 have registered 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 August 24, 2015, we have received proceeds of \$2,137,439 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 \$7,862,561 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 \$7,862,561 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.

### **Risks related to our acquisition of X-spine**

*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 after 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 the 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 U.S. 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 U.S. federal income tax liability and U.S. 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 may not be able to deduct all or a portion of the interest payments on the 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 the notes may be disallowed. If we were not entitled to deduct interest on the notes, our after-tax operating results could be adversely affected.

## **Risks Related to X-spine’s Business**

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

X-spine’s product lines are new to us, and we have limited experience with them. X-spine’s 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.

*X-spine's business depends, in part, on a key distributor arrangement.*

X-spine's business is dependent, in part, on a key distributor arrangement. For the year ended December 31, 2014, net sales to this one distributor, Zimmer, 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.

*X-spine's business depends, in part, on a relationship with a key supplier, which is a related party.*

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.

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 2013 and 2014, products purchased from Norwood Medical accounted for approximately 35% and 22% of product purchases, respectively. 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.

**Risks Related to our Business**

*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 debt 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 ROS 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, as collateral. 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.

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

Certain private investment funds for which OrbiMed Advisors LLC (“OrbiMed”) serves as the investment manager purchased \$52 million of the 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.

***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 ROS 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 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.

*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.

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.

***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. 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 False Claims Act;

federal false claims laws 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;

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 Payment 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, or 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 anti-kickback and false claims laws 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.



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 the Office of Inspector General of the Department of Health and Human Services (“OIG”). 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 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.

***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 will need to continue to innovate and develop new products to be desirable to our customers.***

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 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.

***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.

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

Although we are not currently subject to any product liability proceedings, we have no reserves for product liability disbursements, and we may incur material liabilities relating to product liability claims in the future, including product liability claims arising out of the use of our products. We currently carry product liability insurance, however, our insurance coverage and any reserves we may maintain in the future for product related liabilities may not be adequate and our business could suffer material adverse consequences.

***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, or 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 approvals and clearances, 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 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 U.S. 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.

***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.

***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, or 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.

***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 approvals that have already been granted;

refusal to grant export approval for our products; 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.

***We face risks and uncertainties relating to an ongoing inspection and Warning Letter.***

We received two warning letters from the FDA dated January 28, 2013 following inspections in July 2012 of two of our facilities, one concerning the facility located at 600 Cruiser Lane, Belgrade, Montana (“Site 600”) and one concerning the facility located at 664 Cruise Lane, Belgrade, Montana (“Site 664”). The Site 664 warning letter has been formally closed out by the FDA, while the Site 600 warning letter remains open. The Site 600 warning letter addressed issues regarding aspects of Bacterin’s quality system with a focus on OsteoSelect DBM Putty which is both a tissue and a device, and which is marketed pursuant to a section 510(k) clearance. We responded to this warning letter on February 2, 2013, and provided periodic response updates on March 20, 2013, April 15, 2013 and May 20, 2013. We developed and implemented a corrective action strategy that we believe addressed all of the FDA’s concerns. While we have implemented a corrective action strategy that we believe addresses all of the FDA’s concerns, there is a chance that the FDA will not agree with our proposed corrective actions. If the FDA does not agree with our proposed actions, they could issue another warning letter, request that we take additional actions, or take additional enforcement actions. The FDA conducted a re-inspection of Site 600 from July 8, 2013 to July 12, 2013, which evaluated the completion of the corrective actions and resulted in the issuance of an unrelated FDA-Form 483 on July 12, 2013. We responded to the FDA-Form 483 on August 1, 2013, and provided periodic response updates on August 13, 2013, September 26, 2013, October 31, 2013 and December 4, 2013. On October 29, 2013, we received an Establishment Inspection Report (EIR) for this re-inspection. At this time, we do not know whether or when the FDA will conduct an additional follow up inspection. In addition, from July 22, 2013 to August 2, 2013, the FDA conducted a tissue-focused inspection of Site 600 which resulted in an FDA-Form 483. We responded to the FDA-Form 483 on August 22, 2013. At this time, we do not know whether this inspection will lead to an enforcement action or when the FDA will close out this inspection.

***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.

***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 scope 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 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.***

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. 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 PHS Act 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 PHS Act. 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 PHS Act, 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.

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.

***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.

***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.

***Our common stock is not listed on a stock exchange.***

In April of 2015, trading of our common stock moved from the NYSE MKT to the OTCQX marketplace due to insufficient shareholder equity. As a result, some shareholders may not wish to purchase or hold our common stock, and we may not be able to attract institutional investors in future financing transactions. In addition, because our common stock is no longer listed on a national securities exchange, we will not be eligible to utilize a Form S-3 registration statement (i) for a primary offering, if our public float is not at least \$75.0 million as of a date within 60 days prior to the date of filing the Form S-3, or a re-evaluation date, whichever is later, and (ii) to register the resale of our securities by persons other than us (*i.e.*, a resale offering). Because we are unable to utilize a Form S-3 registration statement for primary and secondary offerings of our common stock, we will be required to file a Form S-1 registration statement, which could delay our ability to raise funds in the future, may limit the type of offerings of common stock we could undertake, and could increase the expenses of any offering, as, among other things, registration statements on Form S-1 are subject to SEC review and comments whereas take downs pursuant to a previously effective Form S-3 are not. In addition, we are no longer subject to stock exchange shareholder approval requirements, which formerly required us to obtain shareholder approval before issuing 20% or more of our common stock in an acquisition or financing transaction, unless the transaction satisfied certain pricing requirements or was considered a “public offering”. Since we are no longer subject to such shareholder approval requirements, we could issue shares in excess of 20% of our outstanding shares in acquisitions or financing transactions without shareholder approval. Any such issuance would dilute the ownership of our current stockholders. In addition, we are no longer

subject to the stock exchange rules requiring us to meet certain corporate governance standards, which could decrease investor interest in 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.

***The unaudited pro forma condensed combined financial statements included in this prospectus are preliminary, and our actual financial condition and results of operations after the completion of the acquisition may materially differ.***

The pro forma financial information presented in this prospectus is subject to change and interpretation. Accordingly, this pro forma financial information has been presented for informational purposes only and is not necessarily indicative of what the combined company’s financial position or results of operations actually will be. In addition, the pro forma financial information does not purport to project the future financial position or operating results of the combined company.

## 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,” “show,” “will,” “would,” “could,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “show,” “will,” “would,” as 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 and any future business combinations or acquisitions successfully;
- our ability to obtain financing on reasonable terms and maintain sufficient liquidity to fund our operations;
- our ability to increase revenues;
- our ability to comply with the covenants in our credit facility;
- our intention to list our stock on a national securities exchange;
- the ability of our sales force to achieve expected results;
- our ability to remain competitive;
- government regulations;
- our ability to expand our production capacity;
- 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;
- government and third-party coverage and reimbursement for our products;
- our ability to obtain regulatory clearances and approvals;
- product liability claims and other litigation to which we may be subject;
- product recalls and defects;
- timing and results of clinical studies;
- our ability to obtain and protect our intellectual property and proprietary rights;
- our ability to operate our business without infringing the intellectual property rights of others; and
- infringement and ownership of intellectual property.

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 30, 2015, there were 7,464,085 shares of our common stock outstanding, approximately 7,354,015 of which were 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 30, 2015, such shares would represent 23.0% of the total common stock outstanding and 23.3% of the non-affiliate shares of common stock outstanding as of June 30, 2015.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we have registered 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;

- if 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 <sup>(1)</sup>	Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital <sup>(2)</sup>	
\$ 1.00	\$ 1,845,811	1,845,811	23.0	%
\$ 2.00	\$ 3,691,622	1,845,811	23.0	%
\$ 3.00	\$ 5,537,433	1,845,811	23.0	%
\$ 4.00	\$ 7,383,244	1,845,811	23.0	%
\$ 5.00	\$ 9,229,055	1,845,811	23.0	%
\$ 6.00	\$ 10,000,000	1,666,666	21.0	%
\$ 7.00	\$ 10,000,000	1,428,571	18.2	%

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

(2) The denominator is based on 7,464,085 shares outstanding as of June 30, 2015, which includes the Initial Purchase Shares, the Commitment Shares and 417,000 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 June 30, 2015 on:

an actual basis; and

a pro forma basis giving effect to the acquisition of X-spine, the issuance of 6.00% convertible senior unsecured notes due 2021 for an aggregate principal amount of \$68 million and our Amended and Restated Credit Agreement with ROS, as if each had occurred as of June 30, 2015.

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 June 30, 2015	
	Actual (Unaudited)	Pro Forma
Cash and cash equivalents	\$2,026,108	\$ 10,567,374
Long-term debt:		
Long-term debt (including current portion)	\$26,000,087	\$43,300,087
6.00% convertible senior notes due 2021	-	68,000,000
Total long-term debt	26,000,087	111,300,087
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; 7,464,085 shares issued and outstanding, actual, and 11,706,740 issued and outstanding, pro forma	7	12
Additional paid-in capital	66,091,741	80,941,030
Accumulated deficit	(77,940,219)	(77,797,994)
Total stockholders' (deficit) equity	(11,848,471)	3,143,047
Total capitalization	\$ 14,151,616	\$ 114,443,135

The number of outstanding shares of common stock in the table above excludes, as of June 30, 2015:



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711,875 shares issuable upon the exercise of outstanding stock options with a weighted average exercise price of \$10.57 per share;

1,430,400 shares issuable upon the exercise of outstanding warrants with a weighted average exercise price of \$12.20 per share; and

- 580,000 shares available for issuance under our Amended and Restated Equity Incentive Plan.

## DILUTION

If you acquire shares of our common stock from Aspire Capital 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. Our historical net tangible book value of common stock as of June 30, 2015 was negative \$12.5 million, or \$(1.67) per share of common stock. Historical 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 pro forma net tangible book value as of June 30, 2015 was negative \$63.5 million, or \$(5.42) 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 June 30, 2015: (i) the acquisition of X-spine, (ii) the issuance of 6.00% convertible senior unsecured notes due 2021 for an aggregate principal amount of \$68 million, and (iii) the entry of an amended and restated credit agreement with ROS.

After giving effect to the sale of 1,221,629 shares of common stock to Aspire Capital at an assumed offering price of \$3.70 per share (the closing price of our common stock on August 21, 2015), after deducting estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2015 would have been negative \$59.0 million, or \$(4.56) per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of \$0.86 per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of \$8.26 per share to investors participating in this offering. The following table illustrates this per share dilution:

Assumed offering price per share	\$3.70
Historical net tangible book value per share as of June 30, 2015	\$(1.67)
Pro forma decrease in net tangible book value per share attributable to pro forma transactions and other adjustments described above	(3.75)
Pro forma net tangible book value per share before this offering	(5.42)
Pro forma increase in net tangible book value per share attributable to this offering	0.86
Pro forma as adjusted net tangible book value per share after this offering	(4.56)
Dilution in pro forma as adjusted net tangible book value per share to investors participating in this offering	\$8.26

The shares sold in this offering, if any, in addition to the Commitment Shares, may be sold from time to time at various prices.

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Each \$1.00 increase (decrease) in the assumed offering price of \$3.70 per share would increase (decrease) our pro forma as adjusted net tangible book value by \$1.2 million, or by \$0.09 per share, and the dilution per share to new investors purchasing shares of common stock in this offering by \$0.09, assuming that the number of shares of common stock offered, as set forth on the cover page of this prospectus, 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 June 30, 2015 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.

## UNAUDITED PRO FORMA FINANCIAL DATA

The following unaudited pro forma financial data has been prepared in accordance with guidelines specified by Article 11 of Regulation S-X. Specifically, the unaudited pro forma condensed combined statements of operations for the year ended December 31, 2014 and the six months ended June 30, 2015 have been prepared as if our acquisition of X-spine and related financing transactions occurred on January 1, 2014, and include all adjustments that (i) are deemed to be directly attributable to the acquisition and (ii) are factually supportable. The unaudited pro forma condensed combined balance sheet as of June 30, 2015 has been prepared as if the acquisition and related financing transactions occurred as of June 30, 2015 and include all adjustments that (a) are deemed to be directly attributable to the acquisition, (b) have a continuing impact on our financial statements and (c) are factually supportable.

The pro forma adjustments are based on various estimates and assumptions that our management believes are reasonable and appropriate given the currently available information. Use of different estimates and judgments could yield different results.

The unaudited pro forma financial data does not reflect any future operating efficiencies, associated cost savings or possible integration costs that may occur related to the acquisition of X-spine.

The unaudited pro forma financial data is included for informational purposes only and does not purport to reflect our results of operations or financial position that would have occurred had we operated as a combined company during the periods presented. The unaudited pro forma financial data should not be relied upon as being indicative of our financial condition or results of operations had the acquisition occurred on the date assumed nor as a projection of our results of operations or financial position for any future period or date.

The unaudited pro forma financial data should be read in conjunction with our historical financial statements and related notes, appearing in our public filings available on [www.sec.gov](http://www.sec.gov), and X-spine's historical financial statements and related notes, appearing elsewhere in this prospectus.

**XTANT MEDICAL INTERNATIONAL HOLDINGS, INC.****Unaudited Pro Forma Combined Statements of Operations**

	For the Twelve Months Ended December 31, 2014			
	Bacterin	X-Spine Systems Inc.	Pro Forma Adj's	Pro Forma
Revenue				
Tissue and Medical Device Sales	\$34,569,160	\$ 42,144,675	\$	\$76,713,835
Royalties and other	762,652	68,343		830,995
Total Revenue	35,331,812	42,213,018	0	77,544,830
Cost of sales	13,034,314	14,488,855		27,523,169
Gross Profit	22,297,498	27,724,163	0	50,021,661
Operating Expenses				
General and administrative	8,886,972	4,731,252	(395,450 )	(a) 13,222,774
Sales and marketing	16,912,865	15,865,370		32,778,235
Research and development	1,443,018	2,140,450		3,583,468
Depreciation and amortization	271,748		395,450 (a)	4,630,917
			3,963,719 (b)	
Impairment of Assets	912,549			912,549
Non-cash consulting expense	135,075		-	135,075
Total Operating Expenses	28,562,227	22,737,072	3,963,719	55,263,018
Income (Loss) from Operations	(6,264,729 )	4,987,091	(3,963,719 )	(5,241,357 )
Other Income (Expense)				
Interest expense	(5,660,357 )	(593,593 )	(10,920,554)(c)	(10,920,554)
			6,253,950 (d)	
Change in warrant derivative liability	1,736,053		-	1,736,053
Other income (expense)	(318,836 )			(318,836 )
Total Other Income (Expense)	(4,243,140 )	(593,593 )	(4,666,604 )	(9,503,337 )
Net Gain (Loss) from Operations Before (Provision) Benefit for Income Taxes	\$(10,507,869)	\$ 4,393,498	\$(8,630,323 )	\$(14,744,694)
Current		(112,337 )		(112,337 )
Deferred				
Net Income (Loss)	\$(10,507,869)	\$ 4,281,161	\$(8,630,323 )	\$(14,857,031)

Net loss per share:

Basic	\$ (1.76 )		\$ (1.46 )
Dilutive	\$ (1.76 )		\$ (1.46 )

Shares used in the computation:

Basic	5,954,195	4,242,655 (e)	10,196,850
Dilutive	5,954,195	4,242,655 (e)	10,196,850

**XTANT MEDICAL INTERNATIONAL HOLDINGS, INC.****Unaudited Pro Forma Combined Statements of Operations**

	For the Six Months Ended June 30, 2015			
	Bacterin	X-Spine Systems Inc.	Pro Forma Adj's	Pro Forma
Revenue				
Tissue and Medical Device Sales	\$ 19,009,956	\$ 23,875,991	\$	\$42,885,947
Royalties and other	385,773	78,765		464,538
Total Revenue	19,395,729	23,954,756		43,350,485
Cost of sales	6,847,766	8,503,778		15,351,544
Gross Profit	12,547,963	15,450,978		27,998,941
Operating Expenses				
General and administrative	4,824,300	3,236,646	(182,438 ) (a)	7,878,508
Sales and marketing	9,749,249	9,145,080		18,894,329
Research and development	724,732	1,101,627		1,826,359
Depreciation and amortization	224,774	-	182,438 (a)	2,638,838
			2,231,626 (b)	
Non-cash consulting expense	140,869	-	-	140,869
Total Operating Expenses	15,663,924	13,483,353	2,231,626	31,378,903
Gain (Loss) from Operations	(3,115,961 )	1,967,625	(2,231,626)	(3,379,962 )
Other Income (Expense)				
Interest expense	(2,819,220 )	(166,459 )	(5,992,052)(c)	(5,992,052 )
			2,985,679 (d)	
Change in warrant derivative liability	(476,289 )	-	-	(476,289 )
Non-cash consideration associated stock agreement	(558,185 )	-	-	(558,185 )
Other income (expense)	(103,126 )			(103,126 )
Total Other Income (Expense)	(3,956,820 )	(166,459 )	(3,006,373)	(7,129,652 )
Net Gain (Loss) from Operations Before (Provision) Benefit for Income Taxes	\$(7,072,781 )	\$ 1,801,166	\$(5,237,999)	\$(10,509,614)
Benefit (Provision) for Income Taxes				
Current		(11,143 )	-	(11,143 )
Deferred			-	-
Net Income (Loss)	\$(7,072,781 )	\$ 1,790,023	\$(5,237,999)	\$(10,520,757)
Net loss per share:				

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Basic	\$ (1.02 )		\$ (0.94 )
Dilutive	\$ (1.02 )		\$ (0.94 )

Shares used in the computation:

Basic	6,914,698	4,242,655 (e)	11,157,353
Dilutive	6,914,698	4,242,655 (e)	11,157,353



**XTANT MEDICAL INTERNATIONAL HOLDINGS, INC.****Unaudited Pro Forma Combined Balance Sheet**

	As of June 30, 2015			Pro Forma Adj's	Pro Forma
	Bacterin	X-Spine Systems Inc.	Combined before Adj's		
<b>Current Assets:</b>					
Cash and cash equivalents	2,026,108	3,000	2,029,108	5,651,766 (a)	7,680,874
Trade accounts receivable	5,574,285	6,972,764	12,547,049		12,547,049
Inventories, net	9,392,150	12,861,550	22,253,700		22,253,700
Prepaid and other current assets	1,033,605	204,167	1,237,772	(223,410) (b) 120,663 (c) 329,663 (d)	1,464,688
<b>Total Current Assets</b>	<b>18,026,148</b>	<b>20,041,481</b>	<b>38,067,629</b>	<b>5,878,681</b>	<b>43,946,310</b>
Non-current inventories	1,839,971	0	1,839,971		1,839,971
Property and equipment, net	4,430,038	7,533,106	11,963,144		11,963,144
Intangible assets, net	609,348	648,882	1,258,230	(648,882) (e) 43,193,500 (f)	43,802,848
Goodwill	0	0	0	22,816,088 (f)	22,816,088
Other Assets	1,446,515	0	1,446,515	(744,698) (b) (300,000) (n) 482,651 (c) 1,318,651 (d)	2,203,118
<b>Total Assets</b>	<b>\$26,352,020</b>	<b>\$28,223,469</b>	<b>\$54,575,489</b>	<b>71,995,990</b>	<b>\$126,571,479</b>
<b>Liabilities + Equity</b>					
Accounts payable	4,577,488	3,435,848	8,013,336		8,013,336
Accounts payable - related party	293,565	267,249	560,814		560,814
Accrued liabilities	2,399,599	2,164,179	4,563,778		4,563,778
Warrant derivative liability	1,796,660	0	1,796,660		1,796,660
Current portion of capital lease obligations	42,761	0	42,761		42,761
Current portion of royalty liability	1,169,500	0	1,169,500	(1,169,500) (b)	0
Current portion of long-term debt	52,374	0	52,374		52,374
<b>Current Liabilities</b>	<b>10,331,947</b>	<b>5,867,276</b>	<b>16,199,223</b>	<b>(1,169,500) (b)</b>	<b>15,029,723</b>
Capital lease obligation, less current portion	37,496	0	37,496		37,496
Long term royalty liability, less current portion	6,139,374	0	6,139,374	(6,139,374) (b)	0
Long-term debt, less current portion	21,691,674	0	21,691,674	42,000,000 (h) (24,000,000)(h)	43,247,713

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				(700,000 )	(b)	
				4,256,039	(b)	
Revolving Line of Credit	0	12,867,606	12,867,606	(12,867,606)	(g)	0
Convertible Long Term Debt	0	0	0	65,000,000	(i)	65,000,000
Long Term Liabilities	27,868,544	12,867,606	40,736,150	67,549,060		108,285,210
Total Liabilities	\$38,200,491	\$18,734,882	\$56,935,373	66,379,560		\$123,314,933
Preferred stock, par value	-		0	0	(j)	0
Common stock, par value	7	1,100,000	1,100,007	4	(k)	11
				(1,100,000)	(j)	
Additional paid-in capital	66,091,741	350,000	66,441,741	14,849,289	(k)	80,941,030
				(350,000)	(j)	
Accumulated deficit	(77,940,219)	8,038,587	(69,901,632)	(8,038,587)	(j)	(77,684,494 )
				2,784,726	(l)	
				(2,529,001)	(m)	
Total Stockholders' Equity	(11,848,471)	9,488,587	(2,359,884 )	5,616,430		3,256,546
Total Liabilities and Equity	\$26,352,020	\$28,223,469	\$54,575,489	71,995,990		\$126,571,479

**Note 1 – Basis of Pro Forma Presentation**

For purposes of pro forma presentation, the acquisition date of X-spine Systems, Inc. is assumed to be the following for each of the respective financial statements.

Unaudited Condensed Combined Statement of Operations for the twelve months ended December 31, 2014 and the six months ended June 30, 2015 – Acquisition Date January 1, 2014

- Unaudited Condensed Combined Balance sheet as of June 30, 2015 – Acquisition Date June 30, 2015

In conjunction with the acquisition of X-spine, the following equity and debt instruments were issued:

- 4,242,655 common shares of Bacterin International Holdings, Inc.
- \$42,000,000 in long term debt; maturity July 2020, interest rate of 14% plus LIBOR (minimum 1%)
- \$65,000,000 in convertible debt; maturity July 2021, interest rate of 6%

Note: The issuance of the \$42,000,000 in long term debt replaces the Company's existing long term debt of \$24,000,000 for an incremental increase of \$18,000,000.

For purposes of these unaudited pro forma condensed combined financial statements, it has been assumed that the proceeds associated with Long Term Debt and Convertible Long Term Debt instruments have been received as of the Acquisition Date(s).

The unaudited pro forma condensed combined financial statements have been prepared assuming that the acquisition is accounted for using the acquisition method of accounting. Accordingly, the assets acquired and liabilities of the Seller have been adjusted to their fair values as of June 30, 2015.

Fair Values as of June 30,2015

X-spine Tangible Assets		\$27,574,587	
X-spine Tangible Liabilities		(5,867,276 )	
Net Tangible Assets		21,707,311	
Goodwill		22,816,088	
Identifiable intangible assets			
Tradename	4,543,300		
Technology	28,698,700		
Non-Compete	40,500		
Customer Relationship	9,911,000	43,193,500	
Cash	72,867,606		
Stock	14,849,293		
Consideration - Stock and Cash		\$87,716,899	

A fair market value of \$21.7 million has been assigned to net tangible assets acquired. The difference between the fair market value of the net tangible assets and the consideration given have been allocated between Identifiable intangible assets (technology, trademarks, customer relationships and non-compete agreements) which will be amortized over three (3) to fourteen (14) years and Goodwill which in accordance with the ASC No. 805 Business Combinations will not be amortized but instead will be tested for impairment at least annually and whenever events or circumstances have occurred that may indicate a possible impairment.

Acquisition-related costs are estimated to be \$2.5 million for the period ended June 30, 2015.

## **Note 2 – Pro Forma Presentation Adjustments and Assumptions**

The adjustments included in the column under the heading “Pro Forma Adjustments” in the unaudited pro forma condensed combined financial statements are as follows:

### **Pro Forma Adjustments to the Condensed Combined Balance Sheet**

- a) To record cash and cash equivalents which is the excess of consideration given less net term debt, convertible debt and equity instruments issued.
  - b) To eliminate the Long term debt discount, royalty liability and debt penalty fee associated with the extinguishment of the prior long term debt instrument.
- c) To record that portion of the third party fees incurred in conjunction with the acquisition of X-spine associated with the issuance with the modification and amendment of the existing long term debt instrument.
- d) To record that portion of the third party fees incurred in conjunction with the acquisition of X-spine associated with the convertible debt instrument classified as part of long term debt.
  - e) To eliminate the historical intangible assets of the Seller.
  - f) To record the Identifiable intangible assets and Goodwill associated with the acquisition of X-spine.
- g) To record the extinguishment of the Revolving Line of Credit which will be paid off with the issuance of new debt associated with the acquisition of X-spine.
- h) To record the issuance of the extinguishment and issuance of the modification and amendment of the existing long term debt instrument associated with the acquisition of X-spine.
  - i) To record the issuance of the convertible long term debt instrument classified as part of long term debt.
  - j) To eliminate the Seller’s portion of Stockholders’ equity.
- k) To record the values associated with common stock and additional paid in capital associated with the 4,242,655 shares of common stock issued to the Seller as part of the consideration for X-spine.
- l) To record the gain associated with the extinguishment of the long term debt instrument associated with the modification and amendment of the existing long term debt instrument
  - m) To record that portion of the third party fees incurred in conjunction with the acquisition of X-spine a portion of which had been recorded as part of prepaid expenses.
- n) To eliminate those prepaid expenses related to the third party fees incurred in conjunction with the acquisition of X-spine.

### **Pro Forma Adjustments to the Condensed Combined Statements of Operations**

- To reclassify amortization and depreciation from General and administrative expense to Depreciation and
- a) amortization expense which is the financial reporting presentation used by Bacterin for the six months ending June 30, 2015 and for the twelve months ending December 31, 2014.
  - b) To record the amortization of Identifiable intangible assets expense for the six months ending June 30, 2015 and for the twelve months ending December 31, 2014.  
To record the interest expense associated with the issuance of modified and amended existing debt and of the
  - c) convertible debt instruments associated with the acquisition of X-spine for the six months ending June 30, 2015 and for the twelve months ending December 31, 2014.  
To reverse out the interest expense associated with the prior term debt instrument and revolving line of credit which
  - d) has been extinguished with the issuance of the modified and amended existing long term debt and of the new convertible debt instruments associated with the acquisition of X-spine for the six months ending June 30, 2015 and for the twelve months ending December 31, 2014.
  - e) To reflect the common stock shares issued as consideration for the acquisition.

## 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, 2014, 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 million in cash, repayment of all outstanding indebtedness of X-spine to U.S. Bank, National Association, which was approximately \$13 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 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 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 will be \$500,000, with bonus compensation targeted at 50% of base salary. Dr. Kirschman will also receive 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, 2014, international sales represented approximately 4% 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, 2014, 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 \$1,911,268 and \$2,140,450 in 2013 and 2014, 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 Xtant's common stock own a controlling interest in Norwood Tool Company d/b/a Norwood Medical, X-spine's largest supplier. Products purchased from Norwood Medical accounted for approximately 35% and 22% of products purchased by X-spine in 2013 and 2014, respectively. Aggregate payments to Norwood Medical were \$4,709,000 in 2013 and \$4,654,384 in 2014.

Former X-spine shareholders who now own over 10% of Xtant's common stock also own a controlling interest in Aerobiotix, Inc., a sub-lessor of X-spine's leased facilities until February 1, 2015.

Certain former X-spine shareholders who now own over 10% of Xtant's common stock were the senior secured debt holders of X-spine until December 2014, when X-spine obtained a line of credit from U.S. Bank, National Association. The line of credit with U.S. Bank was paid in full in connection with Xtant's acquisition of X-spine.

### ***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 Device 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 be 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 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 May 1, 2015, X-spine had 77 full-time employees and 82 total employees, of whom 32 were in operations, 10 were in sales, 7 were in marketing, 10 were in engineering, and 23 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 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 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 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 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 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.

## MANAGEMENT

**Executive Officers and Directors**

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

<b>Name</b>	<b>Age</b>	<b>Position</b>
Daniel Goldberger	56	Director, Chief Executive Officer
Kent Swanson	70	Chairman of the Board
Michael Lopach	66	Director
Jon Wickwire	71	Director
John Deedrick	52	Director
David Goodman, M.D.	59	Director
David L. Kirschman, M.D.	44	Director, Executive Vice President and Chief Scientific Officer
John Gandolfo	54	Chief Financial Officer
Robert Di Silvio	61	President
Darrel Holmes	62	Chief Operating Officer

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

**John 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.

**Robert Di Silvio, President**, has over 30 years of experience serving in executive management positions in the medical industry, overseeing sales and marketing efforts in the management of medical sales operations. Prior to joining us as a consultant in January of 2014, Mr. Di Silvio served as Senior Vice President and General Manager of the Americas region for Lumenis since January 2012, and prior to that role, beginning in October 2010, as Senior Vice President and General Manager, Lumenis North America Region. Mr. Di Silvio previously served as President and Chief Executive Officer of Pyng Medical Inc. from February 2009 to September 2010; as Vice President Global Sales and Marketing of Safe Life from May 2007 to September 2008; as Vice President of US Field Operations Physio-Control Division of Medtronic, Inc. from May 2002 to April 2007; and as Vice President, US Field Operations of Coherent Medical Group from February 1999 to January 2002. Mr. Di Silvio currently serves as a member of the board of directors of Pyng Medical Corp. He holds a bachelor's degree in economics and organic chemistry and a master's degree in biochemistry from the University of Connecticut, and he also completed three years at the University of Rome School of Medicine in Italy.

**Darrel Holmes, Chief Operating Officer**, Mr. Holmes has over 25 years of experience in the medical device, biologics, and diagnostic industries. He previously served as Operations Executive for American Qualex, HYCOR Biomedical and Stratagene, and as Executive Vice President and COO of Big Spring Water Company. Since joining us in 2003, Mr. Holmes has assumed responsibilities for all aspects of medical device and biologic product design and development, process scale-up, and production, and Mr. Holmes also served as Interim Co-Chief Executive Officer from April 5, 2013 to August 14, 2013. Mr. Holmes has worked with numerous regulatory agencies at the federal, state, and local level and coordinates our ISO 13485 compliance and environmental health and safety programs. He oversees our operations and production, facility management, engineering and information technology to produce our medical devices and biologic products, and to accommodate business growth. He directs the design, purchase,

validation and implementation of capital assets and facility expansions for us, and is responsible for strategic planning as well as the development and administration of division-level budgets. Currently, Mr. Holmes serves as the Tissue Bank Director and on our Medical Advisory Committee, as a member of Montana State University's Employer Advisory Board, as a Scientific Advisory Board Member for Montana Molecular in Bozeman, Montana, and as member of the board of directors of American Donor Services. Mr. Holmes graduated from California State University at Long Beach with a degree in Biological Science.

### **Board Composition and Terms of Office**

A majority of our board members and all of our board committee members are independent directors. Our independent board members are Messrs. Swanson, Lopach, Wickwire, Deedrick and Goodman. 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, and a business development committee. The charters of our audit committee, compensation committee and nominations and corporate governance committee have been posted on our website at [www.bacterin.com](http://www.bacterin.com).

### ***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, Wickwire and Goodman, each an independent director under rules adopted by the SEC pursuant to the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley"). Mr. Lopach serves as the chairman of the audit committee. The board of directors has determined that Messrs. Lopach and Swanson (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 serves 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 serves as the chairman of the nominations and corporate governance committee.

***Business Development Committee***

In September 2014, the board formed a business development committee to advise the board on strategic direction and growth strategies. With our recent acquisition of X-spine, the board expanded the scope of the business development committee to include integration activities. The business development committee currently consists of Messrs. Deedrick and Goodman, and Mr. Deedrick serves 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.

### **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.

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership of our common stock as of August 18, 2015 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 <sup>(2)</sup>	Percentage of Shares Beneficially Owned <sup>(3)</sup>	
<b><i>Directors and Named Executive Officers<sup>(1)</sup>:</i></b>			
Daniel Goldberger	99,172	(4)	*
Kent Swanson	80,828	(5)	*
Michael Lopach	32,943	(6)	*
Jon Wickwire	65,201	(7)	*
John Deedrick	19,828	(8)	*
David Goodman, M.D.	5,000	(9)	*
David L. Kirschman, M.D.	1,697,063	(10)	14.4 %
John P. Gandolfo	21,287	(11)	*
Robert Di Silvio	14,949	(12)	*
All executive officers and directors as a group (10 persons)	2,046,386		17.4 %
<b>Five Percent Stockholders:</b>			
OrbiMed Advisors LLC 601 Lexington Ave., 54 <sup>th</sup> Floor New York, NY 10022	1,173,430	(13)	9.99 %
Kenneth J. Hemmelgarn, Jr. Revocable Living Trust dated February 9, 1998 9485 Gulfshore Drive, B-201 Naples, FL 34108	1,272,796	(14)	10.8 %
Brian J. Hemmelgarn Revocable Living Trust dated February 9, 1998 PO Box 421 15643 Captive Drive Captive, FL 33924	1,272,796	(15)	10.8 %

\*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.

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

(2) the right to acquire within 60 days after August 18, 2015, 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.

(3)



The calculation in this column is based on 11,746,051 shares of common stock outstanding on August 18, 2015. 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) Includes (a) 12,510 shares of our common stock, and (b) options to purchase 86,662 shares of our common stock. Includes (a) 44,828 shares of our common stock held directly, (b) 20,000 shares held by a family limited
- (5) 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) Includes (a) 11,522 shares of our common stock held directly, (b) 3,389 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.  
Includes (a) 20,378 shares of our common stock held directly, (b) 25,762 shares of common stock held by trusts,
- (7)(c) warrants to purchase 3,061 shares of our common stock, and (d) options to purchase 16,000 shares of our common stock.
- (8) Includes (a) 9,828 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.  
Based on Schedule 13D filed with the SEC on August 13, 2015. Consists of 1,697,063 shares of our common
- (10) stock acquired in connection with our acquisition of X-spine which are subject to a Lock-Up Agreement and Escrow Agreement.  
Includes (a) 6,396 shares of our common stock held directly, (b) 994 shares of our common stock held by an IRA,
- (11)(c) warrants to purchase 397 shares of our common stock, and (d) options to purchase 13,500 shares of our common stock.
- (12) Includes (a) 1,198 shares of common stock, and (b) options to purchase 13,751 shares of common stock.  
Based on Schedule 13G filed with the SEC on February 17, 2015, as well as the Company's knowledge regarding recent purchases of the Company's 6.00% convertible senior notes due 2021 (the "Notes") by affiliates of OrbiMed. Includes 475,439 shares of our common stock and warrants to purchase 87,719 shares of common stock held by Royalty Opportunities S.à.r.l., an entity managed by OrbiMed Advisors LLC. Affiliates of OrbiMed also recently
- (13) purchased \$52 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 Advisors LLC, 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 held by Royalty Opportunities S.à.r.l.  
Based on Schedule 13D filed with the SEC on August 10, 2015. Consists of 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
- (14) 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 Securities Exchange Act of 1934, though they have disclaimed any express agreement to act as a group, other than as described in their jointly filed Schedule 13D.  
Based on Schedule 13D filed with the SEC on August 10, 2015. Consists of 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
- (15) 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 Securities Exchange Act of 1934, though they have disclaimed any express agreement to act as a group, other than as described in their jointly filed Schedule 13D.

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 and unvested warrants which will become vested more than 60 days from August 18, 2015.



## DESCRIPTION OF OUR COMMON STOCK

The following description of our common stock, together with the additional information we include in any applicable prospectus supplement, summarizes the material terms and provisions of the common stock that we may offer under this prospectus. For the complete terms of our common stock, please refer to our Amended and 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 General Corporation Law of the State of Delaware may also affect the terms of our common stock.

### **Authorized and Outstanding Common Stock**

Our Amended and 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, 7,464,085 of which are issued and outstanding as of June 30, 2015, 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 June 30, 2015, we also had outstanding warrants to purchase approximately 1,430,400 shares of our common stock and 580,000 shares authorized for issuance under our Amended and Restated Equity Incentive Plan.

### **Principal Market for our Common Stock**

Our common stock is traded on the OTCQX marketplace under the symbol “BONE”.

### **Dividends**

Our board of directors may authorize, and we may make, distributions to our common stockholders, subject to any restriction in our Amended and Restated Certificate of Incorporation and to those limitations prescribed by law. 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.

### **Preemptive and Other Rights**

Holders of our common stock have no preemptive rights and have no other rights to subscribe for additional securities of the Company 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.

### **Staggered Board of Directors**

Our board of directors is divided into three classes, the members of each of which serve for staggered three-year terms. Our stockholders may elect only one-third of the directors each year. Therefore, it is more difficult for a third party to gain control of our board of directors than if our board was not staggered.

### **Transfer Agent**

The transfer agent for our common stock is Corporate Stock Transfer.

### **Limitations of Director Liability**

Delaware law authorizes corporations to limit or eliminate the personal liability of directors to corporations and their stockholders for monetary damages for breach of directors' fiduciary duty of care. Our Amended and Restated Certificate of Incorporation limits the liability of directors to the fullest extent permitted by Delaware law.

### **Indemnification**

Our Amended and Restated Bylaws provide for mandatory indemnification of directors and officers to the maximum extent allowed by applicable law. In addition, we have also entered into indemnification agreements with our directors and officers, and we must advance or reimburse directors and officers for expenses they incur in connection with indemnifiable claims. We also maintain directors' and officers' liability insurance.

## MARKET PRICE OF AND DIVIDENDS ON OUR COMMON STOCK

**Market Information**

Our common stock is currently traded on the OTCQX marketplace under the ticker symbol “BONE.” Our common stock previously traded on the NYSE MKT and commenced trading on the OTCQX marketplace on April 9, 2015. The following table sets forth the range of high and low prices per share of our common stock for each quarter, as reported by the OTCQX marketplace or the NYSE MKT, as applicable, for the periods indicated below. Prices have been adjusted to reflect the Company’s July 25, 2014 1:10 reverse stock split.

	High	Low
First Quarter 2013 (January 1, 2013 – March 31, 2013)	\$14.80	\$8.10
Second Quarter 2013 (April 1, 2013 – June 30, 2013)	\$9.80	\$4.50
Third Quarter 2013 (July 1, 2013 – September 30, 2013)	\$8.00	\$4.70
Fourth Quarter 2013 (October 1, 2013 – December 31, 2013)	\$8.20	\$3.70
First Quarter 2014 (January 1, 2014 – March 31, 2014)	\$14.10	\$4.80
Second Quarter 2014 (April 1, 2014 – June 30, 2014)	\$8.50	\$6.30
Third Quarter 2014 (July 1, 2014 – September 30, 2014)	\$7.40	\$4.07
Fourth Quarter 2014 (October 1, 2014 – December 31, 2014)	\$4.75	\$2.19
First Quarter 2015 (January 1, 2015 – March 31, 2015)	\$4.50	\$2.75
Second Quarter 2015 (April 1, 2015 – June 30, 2015)	\$4.49	\$2.55
Third Quarter 2015 (July 1, 2015 – August 24, 2015)	\$4.49	\$2.70

**Holders of Record**

As of August 18, 2015, we had 218 holders of record.

**Dividends**

We have not paid any cash dividends and do not expect to do so in the foreseeable future. In addition, our amended and restated credit agreement with ROS precludes us from paying dividends.





## SELLING STOCKHOLDER

The selling stockholder may from time to time offer and sell any or all of the shares of our common stock set forth below pursuant to this prospectus. When we refer to the “selling stockholder” in this prospectus, we mean the entity listed in the table below, and its respective pledgees, donees, permitted transferees, assignees, successors and others who later come to hold any of the selling stockholder’s interests in shares of our common stock other than through a public sale.

The following table sets forth, as of the date of this prospectus, the name of the selling stockholder for whom we have registered shares for sale to the public, the number of shares of common stock beneficially owned by the selling stockholder prior to this offering, the total number of shares of common stock that the selling stockholder may offer pursuant to this prospectus and the number of shares of common stock that the selling stockholder will beneficially own after this offering. Except as noted below, the selling stockholder does not have, or within the past three years has not had, any material relationship with us or any of our predecessors or affiliates and the selling stockholder is not or was not affiliated with registered broker-dealers.

Based on the information provided to us by the selling stockholder, assuming that the selling stockholder sells all of the shares of our common stock beneficially owned by it that have been registered by us and does not acquire any additional shares during the offering, the selling stockholder will not own any shares other than those appearing in the column entitled “Beneficial Ownership After This Offering.” We cannot advise you as to whether the selling stockholder will in fact sell any or all of such shares of common stock. In addition, the selling stockholder may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, the shares of our common stock in transactions exempt from the registration requirements of the Securities Act after the date on which it provided the information set forth in the table below.

Name	Shares of Common Stock Owned Prior to this Offering	Shares of Common Stock Being Offered	Beneficial Ownership After this Offering <sup>(1)</sup>	
			Number of Shares	%
Aspire Capital Fund, LLC <sup>(2)</sup>	361,371	2,000,000	0	0

(1) Assumes the sale of all shares of common stock registered pursuant to this prospectus, although the selling stockholder is under no obligation known to us to sell any shares of common stock at this time.

Aspire Capital Partners LLC (“Aspire Partners”) is the Managing Member of Aspire Capital Fund LLC (“Aspire Capital”). SGM Holdings Corp (“SGM”) is the Managing Member of Aspire Partners. Mr. Steven G. Martin is the president and sole stockholder of SGM, as well as a principal of Aspire Partners. Mr. Erik J. Brown is the president and sole stockholder of Red Cedar Capital Corp (“Red Cedar”), which is a principal of Aspire Partners. Mr. Christos Komissopoulos is president and sole stockholder of Chrisko Investors Inc. (“Chrisko”), which is a principal of Aspire Partners. Each of Aspire Partners, SGM, Red Cedar, Chrisko, Mr. Martin, Mr. Brown and Mr. Komissopoulos may be deemed to be a beneficial owner of common stock held by Aspire Capital. Each of Aspire Partners, SGM, Red Cedar, Chrisko, Mr. Martin, Mr. Brown and Mr. Komissopoulos disclaims beneficial ownership of the common stock held by Aspire Capital. Aspire Capital is not a licensed broker dealer nor are any of its affiliates a licensed broker dealer.

## PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by Aspire Capital, the selling stockholder. The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

· ordinary brokers' transactions;

· transactions involving cross or block trades;

· through brokers, dealers or underwriters who may act solely as agents;

· "at the market" into an existing market for the common stock;

· in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;

· in privately negotiated transactions; or

· any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

The selling stockholder may also sell shares of common stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the selling stockholder may transfer the shares of common stock by other means not described in this prospectus.

Brokers, dealers, underwriters or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. Aspire Capital has informed us that each such broker-dealer will receive commissions from Aspire Capital which will not exceed customary brokerage commissions.

Aspire Capital is an “underwriter” within the meaning of the Securities Act.

Neither we nor Aspire Capital can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between Aspire Capital, any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholder, and any other required information. Pursuant to a requirement of the Financial Industry Regulatory Authority (“FINRA”), the maximum commission or discount and other compensation to be received by any FINRA member or independent broker-dealer shall not be greater than 8% of the gross proceeds received by us for the sale of any securities being registered pursuant to Rule 415 under the Securities Act.

We will pay all of the expenses incident to the registration, offering and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers or agents. We have agreed to indemnify Aspire Capital and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Aspire Capital has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Aspire Capital specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Aspire Capital and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the Purchase Agreement.

We have advised Aspire Capital that while it is engaged in a distribution of the shares included in this prospectus, it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase, any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered by this prospectus.

We may suspend the sale of shares by Aspire Capital pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Aspire Capital.

## LEGAL MATTERS

The validity of the issuance of the common stock offered in this offering was passed upon for us by Ballard Spahr LLP.

## EXPERTS

The financial statements incorporated by reference into this prospectus have been audited by EKS&H LLLP, an independent registered public accounting firm, as set forth in their report thereon appearing in our Annual Report on Form 10-K for the year ended December 31, 2014 and incorporated by reference into this prospectus, and such report is included in reliance upon the authority of such firm as experts in accounting and auditing.

The consolidated financial statements of X-spine incorporated by reference into this prospectus for the year ended December 31, 2014 have been audited by McGladrey LLP, independent auditors, as set forth in their report thereon appearing in our Current Report on Form 8-K filed with the SEC on July 28, 2015 and incorporated by reference into this prospectus, and such report is included in reliance upon the authority of such firm as experts in accounting and auditing.

The consolidated financial statements of X-spine incorporated by reference into this prospectus for the year ended December 31, 2013 have been audited by Battelle Rippe Kingston LLP, independent auditors, as set forth in their report thereon appearing in our Current Report on Form 8-K filed with the SEC on July 28, 2015 and incorporated by reference into this prospectus, and such report is included in reliance upon the authority of such firm as experts in accounting and auditing.

## MATERIAL CHANGES

In addition to the disclosures contained in this prospectus, material changes since the end of our last fiscal year are described in the Company's Quarterly Reports on Form 10-Q and Current Reports on Form 8-K incorporated by reference into this prospectus.

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference certain information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of the prospectus. This prospectus incorporates by reference the documents listed below that we previously have filed with the SEC. These documents contain important information about us.

·Our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 18, 2015;

· Our definitive proxy statement on Schedule 14A, filed with the SEC on May 22, 2015;

· Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015, filed with the SEC on May 6, 2015 and August 14, 2015; and

· Our Current Reports on Form 8-K (other than portions thereof furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits accompanying such reports that are related to such items) filed with the SEC on March 17, 2015, April 9, 2015, May 12, 2015, June 26, 2015, July 28, 2015, August 3, 2015 and August 14, 2015.

We are not, however, incorporating by reference any documents, or portions of documents, which are not deemed “filed” with the SEC.

You can obtain a copy of any or all of the documents incorporated by reference in this prospectus (other than an exhibit to a document unless that exhibit is specifically incorporated by reference into that document) from the SEC on its website at [www.sec.gov](http://www.sec.gov). You may also obtain these documents from us, free of charge, by visiting our internet website [www.bacterin.com](http://www.bacterin.com) or by writing to us or calling us at the following address and phone number:

Xtant Medical Holdings, Inc.

600 Cruiser Lane

Belgrade, Montana 59714

Attn: Corporate Secretary

(406) 388-0480

#### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement under the Securities Act that registers the distribution of the securities offered under this prospectus. The registration statement, including the attached exhibits and schedules and the information incorporated by reference, contains additional relevant information about us and the securities. The rules and regulations of the SEC allow us to omit from this prospectus certain information included in the registration statement. In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy this information and the registration statement at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room.

You may also obtain the documents that we file electronically on the SEC's website at [www.sec.gov](http://www.sec.gov) or on our website at [www.bacterin.com](http://www.bacterin.com). Information contained on our website is not incorporated by reference herein and does not constitute part of this prospectus.



**2,000,000 Shares**

**Common Stock**

**PROSPECTUS**

September 9, 2015