Xtant Medical Holdings, Inc.
Form POS AM
April 29, 2016

As filed with the Securities and Exchange Commission April 29, 2016

Registration Statement No. 333-203492

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 2 TO

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

XTANT MEDICAL HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

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

664 Cruiser Lane

Belgrade, Montana 59714

(406) 388-0480

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

John Gandolfo

Chief Financial Officer

Xtant Medical Holdings, Inc.

664 Cruiser Lane

Belgrade, Montana 59714

(406) 388-0480

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

Copies to:

Travis Leach

Ballard Spahr LLP

One East Washington Street, Suite 2300

Phoenix, Arizona 85004

(602) 798-5444

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

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

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

registration statement for the same offering. ¨

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

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

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

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

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

This Post-Effective Amendment No. 2 to the registration statement on Form S-1 (File No. 333-203492) (the "Registration Statement"), which was amended by Post-Effective Amendment No. 1 filed with the Securities and Exchange Commission on August 25, 2015, is being filed by Xtant Medical Holdings, Inc. (the "Company") pursuant to (i) Section 10(a)(3) of the Securities Act of 1933, as amended, to update the Registration Statement, which was previously declared effective by the Securities and Exchange Commission on September 8, 2015, and (ii) the undertakings in Item 17 of the Registration Statement for the purpose of superseding and replacing the sections entitled "Incorporation of Certain Information By Reference" and "Undertakings" in the Registration Statement. No additional securities are being registered under this Post-Effective Amendment No. 2.

Other than the changes identified above, and updates to the cover page, the exhibit index, and signature page associated with filing this Post-Effective Amendment No. 2, the remainder of the filing is unchanged from Post-Effective Amendment No.1. All applicable registration fees were paid at the time of the initial filing of the Registration Statement.

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

SUBJECT TO COMPLETION, DATED APRIL 29, 2016

PRELIMINARY PROSPECTUS

2,000,000 Shares

Common Stock

This prospectus relates to the sale of up to 2,000,000 shares of our common stock by Aspire Capital Fund, LLC. Aspire Capital Fund, LLC is also referred to in this prospectus as Aspire Capital or the selling stockholder. The prices at which the selling stockholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the selling stockholder. However, as of April 29, 2016, 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 NYSE MKT under the ticker symbol “XTNT.” On April 25, 2016, the last reported sale price per share of our common stock was $2.47 per share.

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

Investing in our securities involves a high degree of risk. See “Risk Factors” on page 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 , 2016.

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

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

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

Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and tradenames.

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

SUMMARY

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

About Xtant Medical Holdings, Inc.

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

We are a Delaware corporation. Our principal executive offices are located at 664 Cruiser Lane, Belgrade, Montana 59714. Our telephone number is (406) 388-0480 and our website address is www.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 name on July 31, 2015 was known as Bacterin International Holdings, Inc. The acquisition was financed through cash and stock with a purchase price of approximately $90 million, consisting of approximately $60 million in cash,

approximately $13 million in debt repayment and approximately $17 million in shares of our common stock. Based on an agreed upon fixed price per share of $4.00, approximately 4.24 million shares of our common stock were issued to the Sellers at the closing of the acquisition. All of the shares of common stock issued to the Sellers were issued in a private offering and are subject to securities law and contractual restrictions on transferability. The shares issued to the Sellers, along with $6 million of the cash portion of the acquisition consideration, are also subject to an escrow agreement to satisfy indemnification claims that may arise pursuant to the stock purchase agreement. For additional information on the acquisition, see “Business – The Acquisition.” Concurrently with the acquisition, we also issued $65.0 million aggregate principal amount of 6.00% convertible senior unsecured notes due 2021 (the “Notes”) and borrowed an additional $18 million under an Amended and Restated Credit Agreement with ROS Acquisition Offshore LP (“ROS”).

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The Offering

Common stock offered by the selling stockholder	Up to 2,000,000 shares
Common stock outstanding	7,464,085 shares (as of June 30, 2015)
Use of proceeds	The selling stockholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive up to $10 million in proceeds from the sale of our common stock to the selling stockholder under the Purchase Agreement (as defined below). Any proceeds from the selling stockholder that we receive under the Purchase Agreement are expected to be used for working capital and general corporate purposes.
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 are registering 2,000,000 shares of our common stock under the Securities Act, which includes 207,182 Initial Purchase Shares, 154,189 Commitment Shares that have already been issued to Aspire Capital, an additional 417,000 shares of common stock that we have issued to Aspire Capital as of August 24, 2015 pursuant to the terms of the Purchase Agreement, and 1,221,629 shares of common stock which we may issue to Aspire Capital. All 2,000,000 shares of common stock are being offered pursuant to this prospectus. Under the terms of the Purchase Agreement, the proceeds from the sale of our common stock to Aspire Capital may not exceed $10 million.

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

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

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

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

As of 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.

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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," "shou well as similar expressions, may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward looking. Forward-looking statements set forth and incorporated by reference in this prospectus may include, for example, statements about:

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

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

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

calculated by reference to the prevailing market price of our common stock (as more specifically described below).

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

Purchase Of Shares Under The Purchase Agreement

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

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

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

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

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

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

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

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

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

Minimum Share Price

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

Events of Default

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

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

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

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

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

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

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

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

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

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

No Short-Selling or Hedging by Aspire Capital

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

Effect of Performance of the Purchase Agreement on Our Stockholders

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

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

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

Assumed Average Purchase Price		Proceeds from the Sale of Shares to Aspire Capital Under the Purchase Agreement Registered in this Offering	Number of Shares to be Issued in this Offering at the Assumed Average Purchase Price[1]	Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital[2]	
$	1.00	$ 1,845,811	1,845,811	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
June 30, 2015 Shares	7,464,085	
Acquisition shares issued	4,242,655	
	11,706,740	

The number of outstanding shares of common stock in the table above 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.

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.

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, 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

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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) 2,231,626 (b)	2,638,838
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) 2,985,679 (d)	(5,992,052)
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:				

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				
	Bacterin	X-Spine Systems Inc.	Combined before Adj's	Pro Forma Adj's	Pro Forma
Current Assets:					
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		