

Xtant Medical Holdings, Inc.
Form S-1/A
May 02, 2016

As filed with the Securities and Exchange Commission on May 2, 2016

Registration No. 333-208677

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Amendment No. 1 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 Number)

664 Cruiser Lane

Belgrade, Montana 59714

(406) 388-0480

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

John Gandolfo

Chief Financial Officer

Xtant Medical Holdings, Inc.

664 Cruiser Lane

Belgrade, Montana 59714

(406) 388-0480

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

Copies to:

Debbie Kirschman, Esq.

General Counsel

Xtant Medical Holdings, Inc.

664 Cruiser Lane

Belgrade, Montana 59714

(406) 388-0480

James R. Tanenbaum, Esq.

Morrison & Foerster LLP

250 West 55th Street

New York, New York 10019-9601

(212) 468-8000

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

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: x

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.

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered	Proposed maximum offering price per unit	Proposed maximum aggregate offering price	Amount of registration fee
6.00% Convertible Senior Notes due 2021	\$ 68,000,000.00	100 %	\$ 68,000,000.00 (1)	\$ 6,847.60
6.00% Convertible Senior Promissory Notes due 2021	\$ 2,238,166.45	100 %	\$ 2,238,166.45 (2)	\$ 225.39
Common Stock, par value \$0.000001 per share	22,396,279 (3)	N/A	N/A	— (4)

- (1) Equals the aggregate principal amount of the 6.00% Senior Convertible Notes due 2021.
- (2) Equals the aggregate principal amount of the 6.00% Senior Convertible Promissory Notes due 2021.
- (3) Represents (i) 21,451,035 shares of common stock, par value \$0.000001 per share (the “common stock”), initially potentially issuable upon conversion of the 6.00% Convertible Senior Notes due 2021 (the “initial notes”) and (ii) 945,244 shares of common stock initially potentially issuable upon conversion of the 6.00% Convertible Senior Promissory Notes due 2021 (the “promissory notes,” and together with the initial notes, the “notes”). Pursuant to Rule 416 of the Securities Act, this registration statement also covers such additional shares of common stock that may be issued from time to time upon conversion of the notes as a result of a stock split, stock dividend, recapitalization or similar event.
- (4) Pursuant to Rule 457(n) under the Securities Act, there is no additional filing fee payable with respect to the shares of common stock issuable upon conversion of the notes because no additional consideration will be received in connection with the exercise of the conversion privilege.

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 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.

The information in this prospectus is not complete and may be changed. The selling securityholders 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 securityholders are 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 MAY 2, 2016

PRELIMINARY PROSPECTUS

\$68,000,000 Aggregate Principal Amount of 6.00% Convertible Senior Notes due 2021 and Shares of Common Stock Issuable Upon Conversion Thereof

\$2,238,166.45 Aggregate Principal Amount of 6.00% Convertible Senior Promissory Notes due 2021 and Shares of Common Stock Issuable Upon Conversion Thereof

We issued (i) \$68,000,000 aggregate principal amount of our 6.00% Convertible Senior Notes due 2021 (the “initial notes”) in a private placement completed in August 2015 and (ii) 2,238,166.45 aggregate principal amount of our 6.00% Convertible Senior Promissory Notes due 2021 (the “promissory notes,” and together with the initial notes, the “notes”) in a private placement completed in April 2016. This prospectus covers resales of the notes and shares of our common stock issuable upon conversion of the notes (the “conversion shares”). We will not receive any proceeds from the sale by any selling securityholder of the notes or the conversion shares offered by this prospectus.

The notes bear interest at a rate equal to 6.00% per year. Following the first interest payment date for the notes, which will be April 15, 2016 for the initial notes and July 15, 2016 for the promissory notes, interest on the notes will be payable semiannually in arrears on January 15 and July 15 of each year. Interest accrues on the notes from the last date to which interest has been paid or duly provided for or, if no interest has been paid or duly provided for, from July 31, 2015 for the initial notes and April 14, 2016 for the promissory notes. Unless earlier converted or repurchased, the notes will mature on July 15, 2021.

At any time prior to the close of business on the second business day immediately preceding the maturity date, (i) the initial notes may be converted into shares of our common stock (together with cash in lieu of fractional shares) at an initial conversion rate of 257.5163 shares per \$1,000 principal amount of notes (which represents an initial conversion price of approximately \$3.88 per share) and (ii) the promissory notes may be converted into shares of our common stock (together with cash in lieu of fractional shares) at an initial conversion rate of 344.8276 shares per \$1,000 principal amount of notes (which represents an initial conversion price of approximately \$2.90 per share). However, a note will not be convertible to the extent that such convertibility or conversion would result in the holder of that note or any of its affiliates being deemed to beneficially own in excess of 9.99% of the then-outstanding shares of our common stock. The conversion rate is subject to adjustment as described in this prospectus. In addition, we will, in certain circumstances, increase the conversion rate for holders who convert their notes in connection with a “make-whole fundamental change” (as defined in this prospectus).

No sinking fund is provided for the notes. We may not redeem the notes at our option prior to their maturity.

If a “fundamental change” (as defined in this prospectus) occurs at any time prior to the maturity date, holders have the right to require us to repurchase their notes at a cash price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date, subject to the right of holders of notes on a record date to receive accrued and unpaid interest.

The notes are our senior, unsecured obligations, rank equal in right of payment with our existing and future unsecured indebtedness that is not junior to the notes, are senior in right of payment to any of our existing and future indebtedness that is expressly subordinated to the notes, and are effectively subordinated to our existing and future secured indebtedness to the extent of the value of the collateral securing such indebtedness. The notes are structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent we are not a holder thereof) preferred equity, if any, of our subsidiaries.

We do not intend to apply to list the notes on any securities exchange or to include them in any automated dealer quotation system. Our common stock is listed on the NYSE MKT under the ticker symbol “XTNT.” On April 29, 2016, the closing price of our common stock was \$2.20 per share.

Pursuant to a registration rights agreement, we agreed to file this registration statement covering the resale of the notes and the conversion shares. The selling securityholders identified in this prospectus may offer from time to time up to \$68,000,000 million aggregate principal amount of the initial notes and the conversion shares thereof and up to \$2,238,166.45 aggregate principal amount of the promissory note, and the conversion shares thereof. The notes and conversion shares may be offered in market transactions, in negotiated transactions or otherwise, and at prices and on terms which will be determined by the then-prevailing market price or at negotiated prices directly or through a broker or brokers, who may act as agent or as principal, or through a combination of such methods of sale. See “Plan of Distribution” on page 132 for additional information on the methods of sale.

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 7 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 securities by the selling securityholders. 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 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 securityholders are offering to sell, and seeking offers to buy, securities 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 securities. 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 this 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 securities. For a more complete understanding of the Company and this offering, we encourage you to read and consider the more detailed information in this prospectus, including “Risk Factors” and the financial statements and related notes.

About Xtant Medical Holdings, Inc.

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

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

Recent Developments

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

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

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

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

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

The Offering

The summary below describes the principal terms of the initial notes and the promissory notes. Certain descriptions below are subject to important exceptions or limitations. The “Description of the Initial Notes” section of this prospectus contains a more detailed description of the terms of the initial notes, and the “Description of the Promissory Notes” section of this prospectus contains a more detailed description of the terms of the promissory notes.

Offering of Initial Notes

Issuer Xtant Medical Holdings, Inc., a Delaware corporation.

\$68.0 million aggregate principal amount of 6.00% Convertible Senior Notes due 2021.

Initial Notes The initial notes offered in this offering include \$52.0 million aggregate principal amount of notes that the OrbiMed purchasers have purchased from us, which we refer to as the “privately placed notes.” The privately placed initial notes constitute part of the same series as the other initial notes offered in this offering.

Maturity July 15, 2021, unless earlier converted or repurchased.

Offering Price 100% plus accrued interest, if any, from July 31, 2015.

Interest 6.00% per year. Interest accrues on the initial notes from the last date on which interest has been paid or duly provided for or, if no interest has been paid or duly provided for, from July 31, 2015. In addition to the stated interest on the initial notes, we may be required to pay additional interest on the initial notes if we fail to satisfy certain of our obligations under the registration rights agreement. See “Description of Initial Notes — Registration Rights; Additional Interest.” Furthermore, we may elect to pay special interest as the sole remedy relating to the failure to comply with our reporting requirements as described under “Description of Initial Notes — Events of Default.”

Ranking The initial notes are our senior, unsecured obligations, rank equal in right of payment with our existing and future unsecured indebtedness that is not junior to the initial notes, are senior in right of payment to any of our future indebtedness that is expressly subordinated to the initial notes, and are effectively subordinated to our existing and future secured indebtedness to the extent of the value of the collateral securing such indebtedness. The initial notes are structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent we are not a holder thereof) preferred equity, if any, of our subsidiaries.

As of December 31, 2015, on a consolidated basis, we had \$112.7 million of debt outstanding, \$44.7 million of which was indebtedness of our operating subsidiaries that was guaranteed by us and secured by a lien on substantially all of our and our subsidiaries' assets. Our subsidiaries had indebtedness and other liabilities (including trade payables) of \$134.2 million, excluding intercompany liabilities, as of December 31, 2015.

Conversion
Rights

At any time prior to the close of business on the second business day immediately preceding the maturity date, the initial notes may be converted into shares of our common stock (together with cash in lieu of fractional shares) at an initial conversion rate of 257.5163 shares per \$1,000 principal amount of initial notes (which represents an initial conversion price of approximately \$3.88 per share). However, an initial note will not be convertible to the extent that such convertibility or conversion would result in the holder of that initial note or any of its affiliates being deemed to beneficially own in excess of 9.99% of the then-outstanding shares of our common stock.

The conversion rate is subject to adjustment as described in this prospectus. See “Description of the Initial Notes — Conversion Rights.” In addition, we will, in certain circumstances, increase the conversion rate for holders who convert their initial notes in connection with a “make-whole fundamental change.” See “Description of the Initial Notes — Increase in

the Conversion Rate for Conversions in Connection with a Make-Whole Fundamental Change.”

No Redemption at
Our Option

We may not redeem the initial notes at our option prior to their maturity.

Fundamental
Change

If a fundamental change occurs at any time prior to the maturity date, holders have the right to require us to repurchase their initial notes at a cash price equal to 100% of the principal amount of the initial notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date, subject to the right of holders of initial notes on a record date to receive accrued and unpaid interest. See “Description of the Initial Notes — Fundamental Change Permits Holders to Require Us to Repurchase Notes.”

In addition, every fundamental change is a make-whole fundamental change. As a result, we will, in certain circumstances, increase the conversion rate for holders who convert their initial notes in connection with such fundamental change. See “Description of the Initial Notes — Increase in the Conversion Rate for Conversions in Connection with a Make-Whole Fundamental Change.”

Use of Proceeds

The selling securityholders will receive all of the proceeds from the sale of the initial notes or the conversion shares offered by this prospectus. We will not receive any proceeds from the sale by any selling securityholder of the initial notes or the conversion shares offered by this prospectus.

Book-entry Form

The initial notes are issued in book-entry form and are represented by global notes deposited with, or on behalf of, The Depository Trust Company (“DTC”) and registered in the name of Cede & Co., as the nominee of DTC. Beneficial interests in the global notes are shown on, and transfers will be effected only through, records maintained by DTC or its nominee, and such beneficial interests may be exchanged for certificated securities only in limited circumstances.

Absence of a
Public Market for
the Initial Notes

The initial notes are a new class of securities, and there is currently no established market for the initial notes. We do not intend to apply to list the initial notes on any securities exchange or to include them in any automated dealer quotation system. Accordingly, a liquid market for the initial notes may never develop.

Registration
Rights

We entered into a registration rights agreement with the initial purchaser and the OrbiMed purchasers, pursuant to which we agreed to:

- file with the Securities and Exchange Commission (the “SEC”) a shelf registration statement (which, initially, will be on Form S-1 and, as soon as we are eligible, will be on Form S-3) covering the resale, from time to time, of the initial notes and the conversion shares;
- use our best efforts to cause the shelf registration statement to become effective under the Securities Act no later than the 180th day after the original issuance date of the initial notes; and
- use our best efforts to keep the shelf registration statement continuously effective under the Securities Act until the earlier of (1) the 60th trading day immediately following the maturity date (subject to extension for any suspension of the effectiveness of the shelf registration statement during the 60 trading days immediately following the maturity date) and (2) the date on which no initial notes or conversion shares are outstanding and constitute “restricted securities” (as defined in Rule 144 under the Securities Act).

If we fail to satisfy certain of our obligations under the registration rights agreement, we will be required to pay additional interest to holders of the initial notes. If holders convert some or all of their initial notes into shares of our common stock, they will not be entitled to additional interest with respect to those shares of common stock. However, if a registration default exists on the maturity date for the initial notes, then, in addition to any additional interest otherwise payable, we will make a cash payment to each holder of initial notes in an amount equal to 5% of the principal amount of initial notes outstanding and held by such holder as of the close of business on the business day immediately before the maturity date. For purposes of the preceding sentence, initial notes that have been converted with a conversion date that is on or after January 15, 2021 and on or before the second business day immediately preceding the maturity date will be considered to be outstanding. See “Description of the Initial Notes — Registration Rights; Additional Interest.”

Certain U.S.
Federal Income
Tax
Considerations

For certain U.S. federal income tax consequences of the holding, disposition and conversion of the initial notes, and the holding and disposition of any conversion shares, see “Certain U.S. Federal Income Tax Considerations.”

NYSE MKT
Ticker Symbol

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

Trustee, Paying
Agent and
Conversion Agent

Wilmington Trust, National Association.

Risk Factors

Before deciding whether to invest in the initial notes, you should carefully consider the risks described under “Risk Factors” beginning on page 7 of this prospectus, as well as the other information included or incorporated by reference into this prospectus, including our financial

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statements and the notes thereto.

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Offering of Promissory Notes

Issuer	Xtant Medical Holdings, Inc., a Delaware corporation.
Promissory Notes	\$2,238,166.45 aggregate principal amount of 6.00% Convertible Senior Promissory Notes due 2021.
Maturity	July 15, 2021, unless earlier converted or repurchased.
Interest	<p>6.00% per year. Interest accrues on the promissory notes from the last date on which interest has been paid or duly provided for or, if no interest has been paid or duly provided for, from April 14, 2016. In addition to the stated interest on the promissory notes, we may be required to pay additional interest on the promissory notes if we fail to satisfy certain of our obligations under the registration rights agreement. See “Description of the Promissory Notes — Registration Rights; Additional Interest.” Furthermore, we may elect to pay special interest as the sole remedy relating to the failure to comply with our reporting requirements as described under “Description of the Promissory Notes — Events of Default.”</p> <p>The promissory notes are our senior, unsecured obligations, rank equal in right of payment with our existing and future unsecured indebtedness that is not junior to the promissory notes, are senior in right of payment to any of our future indebtedness that is expressly subordinated to the notes, and are effectively subordinated to our existing and future secured indebtedness to the extent of the value of the collateral securing such indebtedness. The promissory notes are structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent we are not a holder thereof) preferred equity, if any, of our subsidiaries.</p>
Ranking	<p>As of December 31, 2015, on a consolidated basis, we had \$112.7 million of debt outstanding, \$44.7 million of which was indebtedness of our operating subsidiaries that was guaranteed by us and secured by a lien on substantially all of our and our subsidiaries’ assets. Our subsidiaries had indebtedness and other liabilities (including trade payables) of \$134.2 million, excluding intercompany liabilities, as of December 31, 2015.</p>
Conversion Rights	<p>At any time prior to the close of business on the second business day immediately preceding the maturity date, the promissory notes may be converted into shares of our common stock (together with cash in lieu of fractional shares) at an initial conversion rate of 344.8276 shares per \$1,000 principal amount of notes (which represents an initial conversion price of approximately \$2.90 per share). However, a promissory note will not be convertible to the extent that such convertibility or conversion would result in the holder of that promissory note or any of its affiliates being deemed to beneficially own in excess of 9.99% of the then-outstanding shares of our common stock.</p>

The conversion rate is subject to adjustment as described in this prospectus. See “Description of the Promissory Notes — Conversion Rights.” In addition, we will, in certain circumstances, increase the conversion rate for holders who convert their promissory notes in connection with a “make-whole fundamental change.” See “Description of the Promissory Notes — Increase in the Conversion Rate for Conversions in Connection with a Make-Whole Fundamental Change.”

No

Redemption at Our Option We may not redeem the promissory notes at our option prior to their maturity.

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If a fundamental change occurs at any time prior to the maturity date, holders have the right to require us to repurchase their promissory notes at a cash price equal to 100% of the principal amount of the promissory notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date, subject to the right of holders of promissory notes on a record date to receive accrued and unpaid interest. See “Description of the Promissory Notes — Fundamental Change Permits Holders to Require Us to Repurchase Promissory Notes.”

Fundamental
Change

In addition, every fundamental change is a make-whole fundamental change. As a result, we will, in certain circumstances, increase the conversion rate for holders who convert their promissory notes in connection with such fundamental change. See “Description of the Promissory Notes — Increase in the Conversion Rate for Conversions in Connection with a Make-Whole Fundamental Change.”

Use of Proceeds

The selling securityholders will receive all of the proceeds from the sale of the promissory notes or the conversion shares offered by this prospectus. We will not receive any proceeds from the sale by any selling securityholder of the promissory notes or the conversion shares offered by this prospectus.

Absence of a
Public Market for
the Promissory
Notes

The promissory notes are a new class of securities, and there is currently no established market for the promissory notes.

We do not intend to apply to list the promissory notes on any securities exchange or to include them in any automated dealer quotation system. Accordingly, a liquid market for the promissory notes may never develop.

Registration
Rights

We entered into a registration rights agreement with the the OrbiMed purchasers, pursuant to which we agreed to:

- file with the SEC a shelf registration statement (which, initially, will be on Form S-1 and, as soon as we are eligible, will be on Form S-3) covering the resale, from time to time, of the promissory notes and the conversion shares;
- use our best efforts to cause the shelf registration statement to become effective under the Securities Act no later than the 180th day after the original issuance date of the promissory notes; and

· use our best efforts to keep the shelf registration statement continuously effective under the Securities Act until the earlier of (1) the 60th trading day immediately following the maturity date (subject to extension for any suspension of the effectiveness of the shelf registration statement during the 60 trading days immediately following the maturity date) and (2) the date on which no promissory notes or conversion shares are outstanding and constitute “restricted securities” (as defined in Rule 144 under the Securities Act).

If we fail to satisfy certain of our obligations under the registration rights agreement, we will be required to pay additional interest to holders of the promissory notes. If holders convert some or all of their promissory notes into shares of our common stock, they will not be entitled to additional interest with respect to those shares of common stock. However, if a registration default exists on the maturity date for the promissory notes, then, in addition to any additional interest otherwise payable, we will make a cash payment to each holder of promissory notes in an amount equal to 5% of the principal amount of promissory notes outstanding and held by such holder as of the close of business on the business day immediately before the maturity date. For purposes of the preceding sentence, promissory notes that have been converted with a conversion date that is on or after January 15, 2021 and on or before the second business day immediately preceding the maturity date will be considered to be outstanding. See “Description of the Promissory Notes — Registration Rights; Additional Interest.”

Certain U.S.
Federal Income
Tax
Considerations

For certain U.S. federal income tax consequences of the holding, disposition and conversion of the promissory notes, and the holding and disposition of any conversion shares, see “Certain U.S. Federal Income Tax Considerations.”

NYSE MKT
Ticker Symbol

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

Risk Factors

Before deciding whether to invest in the promissory notes, you should carefully consider the risks described under “Risk Factors” beginning on page 7 of this prospectus, as well as the other information included or incorporated by reference into this prospectus, including our financial statements and the notes thereto.

Risk Factors

An investment in the notes and the underlying common stock involves a high degree of risk. You should carefully consider the risks described below, and the other information included or incorporated by reference in this prospectus, before making an investment decision. Our business, financial condition, results of operations and cash flows could be materially adversely affected by any of these risks. The market or trading price of our securities could decline due to any of these risks. In addition, please read “Cautionary Note Regarding Forward-Looking Statements” in this prospectus, where we describe additional uncertainties associated with our business, and the forward-looking statements included or incorporated by reference in this prospectus. Please note that additional risks not presently known to us or that we currently deem immaterial may also impair our business and operations.

Risks Related to this Offering

We expect that the trading price of the notes will be significantly affected by the market price of our common stock, the general level of interest rates and our credit quality, each of which may be volatile.

The market price of our common stock, as well as the general level of interest rates and our credit quality, will likely significantly affect the trading price of the notes. Each may be volatile and could fluctuate in a way that adversely affects the trading price of the notes and our stock.

We cannot predict whether the market price of our common stock will rise or fall. The market price of our common stock will be influenced by a number of factors, including general market conditions, our operating results, leverage, ability to raise additional capital, product announcements and the successful integration of the acquisition. The market price of our common stock also could be affected by possible sales of common stock by investors who view the notes as an attractive means of equity participation in us and by hedging or arbitrage activity involving our common stock that we expect to develop as a result of the issuance of the notes. The hedging or arbitrage activity could, in turn, affect the trading prices of the notes.

We also cannot predict whether interest rates will rise or fall. During the term of the notes, interest rates will be influenced by a number of factors, most of which are beyond our control. However, if interest rates increase, the trading price of the notes will decrease, and if interest rates decrease, the trading price of the notes will increase.

In addition, our credit quality may vary substantially during the term of the notes and will be influenced by a number of factors, including variations in our cash flows and the amount of indebtedness we have outstanding. Any decrease in our credit quality is likely to negatively impact the trading price of the notes.

The notes are effectively subordinated to our secured indebtedness to the extent of the value of the collateral securing such secured indebtedness and any liabilities of our subsidiaries.

The notes are our senior, unsecured obligations, rank equal in right of payment with our existing and future unsecured indebtedness that is not junior to the notes, and are senior in right of payment to any of our existing and future indebtedness that is expressly subordinated to the notes. The notes, however, are effectively subordinated to our existing and future secured indebtedness to the extent of the value of the collateral securing such indebtedness. As of December 31, 2015, on a consolidated basis, we had \$112.7 million of debt outstanding, \$44.7 million of which was indebtedness of our operating subsidiaries that was guaranteed by us and secured by a lien on substantially all of our and our subsidiaries' assets. The promissory notes and the indenture governing the initial notes do not prohibit or restrict us or our subsidiaries from incurring additional indebtedness, including a secured indebtedness, in the future. In the event of our bankruptcy, liquidation, dissolution or reorganization, or of a similar proceeding, any assets that we pledge as collateral for any of our other obligations will not be available to pay our obligations under the notes until we have paid such other obligations in full.

None of our subsidiaries guarantees the notes. Accordingly, the notes are also structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent we are not a holder thereof) preferred equity, if any, of our subsidiaries. In the event of a bankruptcy, liquidation, dissolution, reorganization or similar proceeding with respect to any of our subsidiaries, we, as a common equity owner of such subsidiary, and, therefore, the holders of the notes, will rank behind such subsidiary's creditors, including such subsidiary's trade creditors, and such subsidiary's preferred equity holders. In this regard, holders of the notes should be aware that we have little or no assets of our own aside from our ownership interest in our wholly owned subsidiaries. Even if we were a creditor of any of our subsidiaries, our rights as a creditor would be subordinated to any security interest of others in the assets of that subsidiary and any indebtedness of that subsidiary senior to that held by us. As of December 31, 2015, our subsidiaries had indebtedness and other liabilities (including trade payables) of \$134.2 million, excluding intercompany liabilities. The promissory notes and the indenture governing the initial notes do not prohibit our subsidiaries from incurring additional indebtedness or issuing preferred equity.

We may rely on our subsidiaries for funds necessary to meet our financial obligations, including the notes.

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

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, including the notes, 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.

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

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

The promissory notes and indenture governing the initial notes contain limited protections against certain types of important corporate events and may not protect your investment upon the occurrence of those and other events.

The promissory notes and indenture governing the initial notes do not:

- require us to maintain any financial ratios or specific levels of net worth, revenues, income, cash flows or liquidity;

- protect holders of the notes in the event that we experience significant adverse changes in our financial condition or results of operations;

- limit our ability to pledge assets to secure our existing or future debt;

- limit our ability to incur indebtedness that is equal in right of payment to the notes;

- limit our ability to incur indebtedness with a maturity date earlier than the maturity date of the notes;

- restrict the ability of our subsidiaries to issue securities or incur liability that would be structurally senior to our indebtedness;

- restrict our ability to purchase or prepay our securities; or

restrict our ability to make investments or to purchase or pay dividends or make other payments in respect of our common stock or other securities ranking junior to the notes.

In addition, the promissory notes and the indenture governing the initial notes contain no covenants or other provisions to afford protection to holders of the notes in the event of a fundamental change involving us, except to the extent described under “Description of the Initial Notes — Fundamental Change Permits Holders to Require Us to Repurchase Initial Notes,” “Description of the Initial Notes — Increase in the Conversion Rate for Conversions in Connection with a Make-Whole Fundamental Change,” “Description of the Initial Notes — Consolidation, Merger and Sale of Assets,” “Description of the Promissory Notes — Fundamental Change Permits Holders to Require Us to Repurchase Promissory Notes,” “Description of the Promissory Notes — Increase in the Conversion Rate for Conversions in Connection with a Make-Whole Fundamental Change” and “Description of the Promissory Notes — Consolidation, Merger and Sale of Assets.” Accordingly, your rights under the notes may be substantially and adversely affected upon any fundamental change or if we or our subsidiaries take certain actions that could either increase the probability that we default on the notes or reduce the recovery that you may to receive upon any such default.

Past and future regulatory actions and other events may adversely affect the trading price and liquidity of the notes.

We expect that many investors in, and potential purchasers of, the notes will employ, or seek to employ, a convertible arbitrage strategy with respect to the notes. Investors would typically implement such a strategy by selling short the common stock underlying the notes and dynamically adjusting their short position while continuing to hold the notes. Investors may also implement this type of strategy by entering into swaps on our common stock in lieu of or in addition to short selling the common stock.

The SEC and other regulatory and self-regulatory authorities have implemented various rules and taken certain actions, and may in the future adopt additional rules and take other actions, that may impact those engaging in short selling activity involving equity securities (including our common stock). These rules and actions include Rule 201 of SEC Regulation SHO, the adoption by the Financial Industry Regulatory Authority, Inc. (“FINRA”) and the national securities exchanges of a “limit up-limit down” program, the imposition of market-wide circuit breakers that halt trading of securities for certain periods following specific market declines, and the implementation of certain regulatory reforms required by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. Any governmental or regulatory action that restricts the ability of investors in, or potential purchasers of, the notes to effect short sales of our common stock or enter into swaps on our common stock could adversely affect the trading price and the liquidity of the notes.

In addition, if investors and potential purchasers seeking to employ a convertible arbitrage strategy are unable to borrow or enter into swaps on our common stock, in each case on commercially reasonable terms, the trading price and liquidity of the notes may be adversely affected.

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

In the future, we may sell shares of our common stock or equity-related securities to raise capital. In addition, as of December 31, 2015, 1,942,647 shares of our common stock are reserved for issuance upon the exercise of stock options and warrants and additional amounts are reserved for issuance upon conversion of the notes. At December 31, 2015, we also have reserved 1,221,629 shares of common stock for issuance pursuant to a common stock purchase agreement with Aspire Capital Fund, LLC. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance and sale of substantial amounts of common stock or equity-related securities, or the perception that such issuances and sales may occur, could adversely affect the trading price of the notes and the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

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

The notes bear interest semi-annually at a rate of 6.00% per year. In addition, in certain circumstances, we are obligated to pay additional interest or special interest on the notes. In addition, if a fundamental change occurs, holders of the notes may require us to repurchase all or a portion of their notes in cash. Any of the cash payments described above could be significant, and we may not have enough available cash or be able to obtain financing so that we can make such payments when due. In addition, our ability to repurchase the notes, to pay additional interest or special interest on the notes, or to pay cash upon conversions of the notes may be limited by law or by agreements governing our existing or future indebtedness. For example, under the amended and restated credit facility that we entered into in connection with the initial issuance of the notes, we are restricted from making any payment or distribution with respect to, or purchasing, redeeming, defeasing, retiring or acquiring, the notes, other than payments of scheduled interest on the notes, issuance of conversion shares, and payment of cash in lieu of fractional shares. Regardless of these restrictions, if we fail to pay interest on the notes or repurchase the notes when required, we will be in default under the promissory notes and the indenture governing the initial notes. See “Description of the Initial Notes — Interest,” “Description of the Initial Notes — Fundamental Change Permits Holders to Require Us to Repurchase Initial Notes,” “Description of the Initial Notes — Events of Default,” “Description of the Promissory Notes — Interest,” “Description of the Promissory Notes — Fundamental Change Permits Holders to Require Us to Repurchase Promissory Notes” and “Description of the Promissory Notes — Events of Default.” A default under the promissory notes and the indenture governing the initial notes would be a default under our credit agreement and could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated, we may not have sufficient funds to repurchase the notes or make cash payments upon conversions of the notes.

The adjustment to the conversion rate for notes converted in connection with a make-whole fundamental change may not adequately compensate you for any value that your notes lose as a result of such transaction.

If a make-whole fundamental change occurs prior to the maturity date, we will, under certain circumstances, increase the conversion rate by a number of additional shares of our common stock for notes converted in connection with such make-whole fundamental change. The increase in the conversion rate will be determined based on the date on which the make-whole fundamental change becomes effective and either the average of the last reported sale prices per share of our common stock over the five trading day period immediately preceding the effective date of the make-whole fundamental change or the cash price paid per share of our common stock in the transaction, in each case, as described below under “Description of the Initial Notes — Increase in the Conversion Rate for Conversions in Connection with a Make-Whole Fundamental Change” and “Description of the Promissory Notes — Increase in the Conversion Rate for Conversions in Connection with a Make-Whole Fundamental Change.” The adjustment to the conversion rate for notes converted in connection with a make-whole fundamental change may not adequately compensate you for any lost value of your notes as a result of such transaction.

In addition, if the average of the last reported sale price per share of our common stock over the five trading day period immediately preceding the effective date of the make-whole fundamental change or the cash price paid per share of our common stock in the make-whole fundamental change, as the case may be, is greater than \$30.00 per share or less than \$3.17 per share (in each case, subject to adjustment) with respect to the initial notes or greater than \$24.00 per share or less than \$2.37 per share (in each case, subject to adjustment) with respect to the promissory notes, no additional shares will be added to the conversion rate.

Moreover, in no event will the conversion rate be increased pursuant to the make-whole fundamental change provisions to exceed 315.4564 shares of common stock per \$1,000 principal amount of initial notes and 422.3297 shares of common stock per \$1,000 principal amount of promissory notes, subject to adjustment in the same manner, at the same time and for the same events for which we must adjust the conversion rate as set forth under “Description of the Initial Notes — Conversion Rights — Conversion Rate Adjustments” and “Description of the Promissory Notes — Conversion Rights — Conversion Rate Adjustments.”

Our obligation to increase the conversion rate upon the occurrence of a make-whole fundamental change could be considered a penalty, in which case the enforceability thereof would be subject to general principles of reasonableness of economic remedies.

The conversion rate of the notes may not be adjusted for all dilutive events.

As described under “Description of the Initial Notes — Conversion Rights — Conversion Rate Adjustments” and “Description of the Promissory Notes — Conversion Rights — Conversion Rate Adjustments, we will adjust the conversion rate of the notes for certain events, including, among others:

· the issuance of certain share and cash dividends on our common stock;

· the issuance of certain rights or warrants;

· certain subdivisions and combinations of our capital stock;

· certain distributions of capital stock, indebtedness or assets; and

· certain tender or exchange offers.

We will not adjust the conversion rate for other events, such as for an issuance of our common stock for cash or in connection with an acquisition, that may dilute our common stock, thereby adversely affecting its market price.

Because the trading price of the notes depends on the market price our common stock, any event that dilutes our common stock and adversely affects the market price of our common stock will likely also adversely affect the trading price of the notes.

We are not obligated to purchase the notes upon the occurrence of all significant transactions that are likely to affect the market price of our common stock and/or the trading price of the notes.

Because the term fundamental change is limited to certain specified transactions, it does not include all events that could adversely affect our financial condition or the market price of our common stock and the trading price of the notes. For example, we are not required to purchase any notes upon the occurrence of certain transactions that would otherwise constitute a fundamental change, if at least 90% of the consideration received by holders of our common stock in the transaction consists of shares of common stock traded on the NASDAQ Stock Market or the New York Stock Exchange. Furthermore, certain other transactions, such as leveraged recapitalizations, refinancings, restructurings or certain acquisitions of other entities by us or our subsidiaries, would not constitute a fundamental change requiring us to purchase the notes or to increase the conversion rate, even though each of these transactions could increase the amount of our indebtedness or otherwise adversely affect our capital structure, which could adversely affect holders of the notes.

An active trading market may never develop for the notes.

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

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

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

As a holder of notes, you will not be entitled to any rights with respect to our common stock, but you will be subject to all changes made with respect to our common stock.

If you hold notes, you will not be entitled to any rights with respect to our common stock (including, without limitation, voting rights and rights to receive any dividends or other distributions on our common stock) until the conversion date for those notes, but you will be subject to all changes affecting our common stock. For example, in the event that an amendment is proposed to our Restated Certificate of Incorporation or to our Amended and Restated Bylaws requiring stockholder approval and the record date for determining the stockholders of record entitled to vote on the amendment occurs before the date you are deemed the record owner of the shares of our common stock due upon conversion, you will not be entitled to vote on the amendment, although you will nevertheless be subject to any changes in the powers, preferences or special rights of our common stock.

The notes will not be convertible by a holder to the extent that the convertibility or conversion would result in that holder or any of its affiliates beneficially owning more than 9.99% of the then-outstanding shares of our common stock.

Notwithstanding anything to the contrary in the promissory notes or the indenture governing the initial notes, no note will be convertible by the holder thereof, and we will not effect any conversion of any note, in each case to the extent (and only to the extent) that such convertibility or conversion would result in such holder or any of its affiliates beneficially owning in excess of 9.99% of the then-outstanding shares of our common stock. For these purposes, beneficial ownership and all determinations and calculations (including, without limitation, with respect to calculations of percentage ownership) will be determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and the rules and regulations promulgated thereunder.

We do not expect the notes to be rated, but if the notes are rated, they may receive a lower rating than anticipated, which would likely adversely affect the trading price of the notes.

We do not intend to seek a rating for the notes and believe it is unlikely that the notes will be rated. However, if one or more rating agencies rates the notes and assigns the notes a rating lower than the rating expected by investors, reduces its rating of the notes or announces its intention to put us on credit watch, the market price of our common stock and the trading price of the notes would likely decline.

Certain provisions in the promissory notes and the indenture governing the initial notes could delay or prevent an otherwise beneficial takeover or takeover attempt of us.

Certain provisions in the promissory notes and the indenture governing the initial notes could make it more difficult or more expensive for a third party to acquire us. For example, if a takeover would constitute a fundamental change, holders of the notes have the right to require us to repurchase their notes in cash. In addition, if a takeover constitutes a make-whole fundamental change, we may be required to increase the conversion rate for holders who convert their notes in connection with such takeover. In either case, and in other cases, our obligations under the promissory notes and the indenture governing the initial notes could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management.

The OrbiMed purchasers own a significant portion of the initial notes and will be able to exert control over certain amendments or waivers relating to the initial notes or the indenture governing the initial notes.

The OrbiMed purchasers purchased \$52,000,000 aggregate principal amount of the initial notes. Accordingly, the OrbiMed purchasers currently own approximately 76.5% of the outstanding initial notes. Subject to certain exceptions, the indenture governing the initial notes may be modified or amended, and past defaults under such indenture may be waived, with the consent of the holders of at least a majority of the aggregate principal amount of the initial notes then outstanding. Because the OrbiMed purchasers currently own a majority of the outstanding initial notes, they will be able to exert control over the outcome of any consents that we may solicit in connection with any amendments or waivers to the indenture governing the initial notes. The OrbiMed purchasers may have interests that differ, or, in some cases, conflict with, your interests as holders of the initial notes. Accordingly, the OrbiMed purchasers may exercise this control in a manner with which you may disagree or that may be detrimental to you. Furthermore, even though the indenture governing the initial notes provides that certain provisions of such indenture may not be amended, and certain defaults may not be waived, without the consent of each affected holder, the influence that the OrbiMed purchasers may exercise over other amendments or waivers may significantly and adversely affect your rights as a holder of initial notes. See “Description of the Initial Notes — Modification and Amendment.”

The initial notes are held in book-entry form and, therefore, holders of the initial notes must rely on the procedures and the relevant clearing systems to exercise their rights and remedies.

The initial notes are held in book-entry form through DTC. Unless and until certificated notes are issued in exchange for book-entry interests in those initial notes, owners of the book-entry interests are not considered owners or holders of initial notes. Instead, DTC, or its nominee, is the sole holder of the initial notes. Payments of principal, interest and other amounts owing on or in respect of the initial notes in global form will be made to the paying agent, which will make payments to DTC. Thereafter, such payments will be credited to DTC participants’ accounts that hold book-entry interests in the initial notes in global form and credited by such participants to indirect participants. Unlike record holders of the initial notes, owners of book-entry interests do not have the direct right to act upon our solicitations for consents or requests for waivers or other actions from holders of the initial notes. Instead, if a holder owns a book-entry interest, such holder is permitted to act only to the extent such holder has received appropriate proxies to do so from DTC or, if applicable, a DTC participant. We cannot assure holders that the procedures implemented for the granting of such proxies will be sufficient to enable holders to vote on any requested actions on a timely basis.

You may be subject to tax if we make or fail to make certain adjustments to the conversion rate of the notes, even though you do not receive a corresponding cash distribution.

The conversion rate of the notes is subject to adjustment in certain circumstances, including share splits and combinations, the issuance of shares of common stock as dividends, the payment of cash dividends and certain other actions by us. See “Description of the Initial Notes — Conversion Rights — Conversion Rate Adjustments” and “Description of the Promissory Notes — Conversion Rights — Conversion Rate Adjustments.” If the conversion rate is adjusted as a result of a distribution that is taxable to our common stockholders, such as certain cash dividends, you may be deemed to have received a dividend subject to U.S. federal income tax without the receipt of any cash. In addition, a failure to adjust (or to adjust adequately) the conversion rate after an event that increases your proportionate interest in us could be treated as a deemed taxable dividend to you. If a make-whole fundamental change occurs prior to the maturity date of the notes, under some circumstances, we will increase the conversion rate for notes converted in connection with the make-whole fundamental change. Such increase may also be treated as a distribution subject to U.S. federal income tax as a dividend. See “Certain U.S. Federal Income Tax Considerations.” If you are a non-U.S. holder (as defined in “Certain U.S. Federal Income Tax Considerations”), any deemed dividend would be subject to U.S. federal withholding tax at a 30% rate, or such lower rate as may be specified by an applicable treaty. In certain circumstances, if you are a U.S. holder (as defined in “Certain U.S. Federal Income Tax Considerations”) or a non-U.S. holder, deemed dividends may be subject to back-up withholding tax at a 28% rate or withholding tax at a 30% rate under the Foreign Account Tax Compliance Act. Any of the foregoing withholding taxes may be withheld from interest and payments upon conversion or maturity of the notes or, if the withholding tax is paid on behalf of you by us or another withholding agent, may be set off against payments of cash on the notes or shares of common stock payable on the notes, if any, or sales proceeds subsequently paid or credited to you. See “Certain U.S. Federal Income Tax Considerations.”

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 Our Acquisition of X-spine

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

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

- the possibility that the expected benefits of the transactions may not materialize in the timeframe expected, or at all, or may be more costly to achieve than anticipated;
- the acquired assets may not produce as expected;
- we may be unable to successfully develop the assets;
- there may be adverse stockholder reaction to the acquisitions; and
- the integration of these transactions may divert the attention of our management and other key employees from ongoing business activities, including the pursuit of other opportunities that could be beneficial to us.

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

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

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

projections of X-spine's future results;

our expected capital structure following the acquisition;

the amount of goodwill and intangibles that will result from the acquisition;

certain other purchase accounting adjustments that we expect will be recorded in our financial statements in connection with the acquisition;

cost, cross-selling and balance sheet synergies;

- acquisition costs, including restructuring charges and transaction costs;

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

other financial and strategic risks of the acquisition.

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

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

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

Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”), imposes restrictions on the use of a corporation’s net operating losses, as well as certain recognized built-in losses and other carryforwards, after an “ownership change” occurs. A Section 382 “ownership change” occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock (including certain “public groups” deemed created for Section 382 purposes) increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. It is possible that the issuance of common stock upon conversion of 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.

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 years ended December 31, 2015 and 2014, net sales to this one large distributor exceeded 10% of X-spine's net sales. X-spine's results of operations are directly dependents 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 2015, products purchased from Norwood Medical accounted for approximately 12% of its operating products. X-spine's dependence on Norwood Medical exposes us to risks, including limited control over pricing, availability and delivery schedules. If Norwood Medical ceases to provide X-spine with sufficient quantities of products in a timely manner or on terms acceptable to X-spine, or ceases to manufacture products of acceptable quality, X-spine would have to seek alternate sources of supply. Because of the nature of X-spine's regulatory and quality control requirements, and the proprietary nature of its products, it may not be able to quickly engage additional or replacement suppliers. Any such disruption could harm X-spine's business, results of operations or financial condition.

Risks Related to Our Indebtedness

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

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

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

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

Risks Related to Our Business

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Any failure in the physical infrastructure of our facilities or services could lead to significant costs and disruptions that could reduce our revenues and harm our business reputation and financial results. We are highly reliant on our Belgrade, Montana facilities. Any natural or man-made event that impacts our ability to utilize these facilities could have a significant impact on our operating results, reputation and ability to continue operations. The regulatory process for approval of facilities is time-consuming and our ability to rebuild facilities would take a considerable amount of time and expense and cause a significant disruption in service to our customers. Further, the FDA or some other regulatory agency could identify deficiencies in future inspections of our facilities or our supplies that could disrupt our business, reducing profitability.

Future revenue will depend on our ability to increase sales.

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

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

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

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

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental change. The ability of hospitals to pay fees for allograft bone tissue products depends in part on the

extent to which reimbursement for the costs of such materials and related treatments will continue to be available from governmental health administration authorities, private health coverage insurers and other organizations. In the United States, healthcare providers who purchase our products generally rely on these third-party payors to pay for all or a portion of the cost of our products in the procedures in which they are employed. Because there is often no separate reimbursement for our products, the additional cost associated with the use of our products can impact the profit margin of the hospital or other health care facility where the surgery is performed. Some of our target customers may be unwilling to purchase our products if they are able to procure less expensive alternatives. In addition, major third-party payors of hospital services and hospital outpatient services, including Medicare, Medicaid and private healthcare insurers, annually revise their payment methodologies, which can result in stricter standards for reimbursement of hospital charges for certain medical procedures or the elimination of or reduction in reimbursement. Further, Medicare, Medicaid and private healthcare insurer cutbacks could create downward price pressure on our products.

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

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

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

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

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

We intend to vigorously defend any existing or future litigation that we may be involved in but there can be no assurance that we will prevail in these matters. An unfavorable judgment or settlement may result in a financial burden on us. Moreover, costs, fees, expenses, settlement amounts, judgments or other liabilities associated with such matters may not be covered by our insurance and we may have to pay out-of-pocket. Company stockholders who collectively own approximately 588,000 shares of our common stock and warrants to purchase additional shares have made claims that our board of directors breached its fiduciary duties in connection with the X-spine acquisition and the financing thereof, which they allege was on commercially unreasonable terms and did not serve the Company's

best interests. No lawsuit has been filed. The Company believes the claims are without merit. If we are required to pay a significant amount to resolve a demand from these stockholders, it could have a material adverse effect on our liquidity, business and financial condition, and efforts required to resolve the demand could distract management from operating our business.

Failure of our information technology systems could disrupt our business.

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

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

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

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

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

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

Future protection for our proprietary rights is uncertain which may impact our ability to successfully compete in our industry.

The degree of future protection for our proprietary rights is uncertain. We cannot ensure that:

- we were the first to make the inventions covered by each of our patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;
- any of our issued patents or those of our licensors will be valid and enforceable;
- any patents issued to us or our collaborators will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies that are patentable;
- the patents of others will not have a material adverse effect on our business rights; or
- the measures we rely on to protect the intellectual property underlying our products will be adequate to prevent third parties from using our technology, all of which could harm our ability to compete in the market.

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

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

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

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

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

Certain private investment funds for which OrbiMed Advisors LLC serves as the investment manager purchased \$52 million of the Notes in our recent offering. Affiliates of OrbiMed also 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. In addition, we owe affiliates of OrbiMed approximately \$2.2 million in aggregate

principal amount of the Promissory Notes issued on April 14, 2016. 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.

Risks Related to Federal Regulations

The impact of United States healthcare reform legislation remains uncertain.

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

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

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

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

- design, development and manufacturing;
- testing, labeling, packaging, content and language of instructions for use, and storage;
- clinical trials;
- product safety;
- premarket clearance and approval;
- marketing, sales and distribution (including making product claims);
- advertising and promotion;
- product modifications;
- recordkeeping procedures;
- reports of corrections, removals, enhancements, recalls and field corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;

complying with the new federal law and regulations requiring Unique Device Identifiers (“UDI”) on devices and also requiring the submission of certain information about each device to FDA’s Global Unique Device Identification Database (“GUDID”); and

product import and export.

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

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

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

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

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

- issuing untitled (notice of violation) letters or public warning letters to us;
- imposing fines and penalties on us;
- obtaining an injunction or administrative detention preventing us from manufacturing or selling our products;

- seizing products to prevent sale or transport or export;
- bringing civil or criminal charges against us;
- recalling our products or engaging in a product correction;
- detaining our products at U.S. Customs;
- delaying the introduction of our products into the market;
- delaying pending requests for clearance or approval of new uses or modifications to our existing products; and/or
- withdrawing or denying approvals or clearances for our products.

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

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

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

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

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

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

the Federal Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services ("CMS"), information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group

purchasing organizations to report annually to CMS ownership and investment interests held by the physicians described above and their immediate family members and payments or other “transfers of value” to such physician owners;

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

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

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

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

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

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

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

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

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

In the United States, the procurement and transplantation of allograft bone tissue is subject to federal law pursuant to the National Organ Transplant Act, 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.

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

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

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

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

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

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

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

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

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

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

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

Our ongoing research and development, pre-clinical testing and clinical study activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. We are currently conducting post-market clinical studies of some of our products to gather information about these products’ performance or optimal use. Additionally, in the future we may conduct clinical studies to support clearance or approval of new products. Clinical studies must be conducted in compliance with FDA regulations and local regulations, and according to principles and standards collectively referred to as “Good Clinical Practices.” Non-compliance could result in regulatory and legal enforcement action and also could invalidate the data. Even if our clinical studies are completed as planned, we cannot be certain that their results will support our product candidates and/or proposed claims or that the FDA or foreign authorities and notified bodies will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical studies does not ensure that later clinical studies will be successful, and we cannot be sure that the results of the later studies will replicate those of earlier or prior studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical studies will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patient subjects enrolled in our clinical studies of our marketed products will experience adverse side effects that are not currently part of the product candidate’s profile and, if so, these findings may result in lower market acceptance, which could have a material and adverse effect on our business, results of operations and financial condition.

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

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

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

Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance. Such trials generally require an investigational device exemption application, or IDE, approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a nonsignificant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board, 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.

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

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

observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees, disgorgement of profits, criminal and civil penalties;

- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;

- operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying our requests for clearance (510(k)) or approval (de novo or PMA) of new products or modified products;

- withdrawing 510(k) clearances or PMAs that have already been granted;

- refusal to grant export approval for our products; or

- criminal prosecution.

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

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

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

• untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

• unanticipated expenditures to address or defend such actions;

• customer notifications for repair, replacement, refunds;

• recall, detention or seizure of our products;

• operating restrictions or partial suspension or total shutdown of production;

• refusing or delaying our requests for 510(k) clearance or premarket approval of new medical device products or modified medical device products;

operating restrictions;

withdrawing 510(k) clearances or PMA 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.

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

Our products currently marketed in the United States have been cleared by the FDA's 510(k) clearance process for use under specific circumstances. Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition on the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside of its cleared or approved indication is known as "off-label" use. We cannot prevent a surgeon from using our products or procedure for off-label use, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials, reimbursement advice or training of sales representatives or physicians constitute promotion of an off-label use, the FDA could request that we modify our training or promotional or reimbursement materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, disgorgement of profits, a civil fine and criminal penalties. Other federal, state or foreign governmental authorities also might take action if they consider our promotion or training materials to constitute promotion of an uncleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. For example, the government may take the position that off-label promotion resulted in inappropriate reimbursement for an off-label use in violation of the Federal False Claims Act for which it might impose a civil fine and even pursue criminal action. In those possible events, our reputation could be damaged and adoption of the products would be impaired. Although we train our sales force not to promote our products for off-label uses, and our instructions for use in all markets specify that our products are not intended for use outside of those indications cleared for use, the FDA or another regulatory agency could conclude that we have engaged in off-label promotion.

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

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

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

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

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

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

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

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

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

Our promotional materials and training methods for physicians must comply with the FDA and other applicable laws and regulations. We believe that the specific surgical procedures for which our products are marketed fall within the 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.

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

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

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

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

Over the course of several years, the FDA issued comprehensive regulations that address manufacturer activities associated with HCT/Ps. The first requires that companies that produce and distribute HCT/Ps register with the FDA. This set of regulations also includes the criteria that must be met in order for the HCT/P to be eligible for marketing solely under Section 361 of the PHSA and the regulations in 21 CFR Part 1271, rather than under the drug or device provisions of the FD&C Act or the biological product licensing provisions of the PHSA. The second set of regulations provides criteria that must be met for donors to be eligible to donate tissues and is referred to as the "Donor Eligibility" rule. The third rule governs the processing and distribution of the tissues and is often referred to as the "Current Good

Tissue Practices” rule. The “Current Good Tissue Practices” rule covers all stages of allograft processing, from procurement of tissue to distribution of final allografts. Together these regulations are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients.

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

In addition, the FDA could disagree with our conclusion that some of our HCT/Ps meet the criteria for marketing solely under Section 361 of the 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.

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

Other regulatory entities with authority over our products and operations include state agencies enforcing statutes and regulations covering tissue banking. Regulations issued by Florida, New York, California and Maryland will be particularly relevant to our business. Most states do not currently have tissue banking regulations. It is possible that

others may make allegations against us or against donor recovery groups or tissue banks about non-compliance with applicable FDA regulations or other relevant statutes or regulations.

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

Our products may be subject to regulation in the EU as well, should we enter that market. In the European Union, or EU, regulations, if applicable, differ from one EU member state to the next. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the EU, as well as for other countries, the approval process for human derived cell or tissue based medical products may be extensive, lengthy, expensive and unpredictable. Some of our products may be subject to EU member states' regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage, and distribution of human tissues and cells and cellular or tissue-based products. Some EU member states have their own tissue banking regulations.

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

We are accredited with the American Association of Tissue Banks (“AATB”), a private non-profit organization that accredits tissue banks and sets industry standards. Although AATB accreditation is voluntary and not required by law, as a practical matter, many of our customers would not purchase our products if we failed to maintain our AATB accreditation. Although we make every effort to maintain our AATB accreditation, the accreditation process is somewhat subjective and lacks regulatory oversight. There can be no assurance that we will continue to remain accredited with the AATB.

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

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

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

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

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

Risks Related to Our Common Stock

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

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

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

• announcements of technological innovations or new commercial products by us, our collaborative partners or our present or potential competitors;

• our issuance of debt, equity or other securities, which we need to pursue to generate additional funds to cover our operating expenses;

• our quarterly operating results;

• developments or disputes concerning patent or other proprietary rights;

• developments in our relationships with employees, suppliers or collaborative partners;

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

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

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

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

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

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

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

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

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,” “plans” or “strategies” regarding the future. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “show” well as similar expressions, may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward looking. Forward-looking statements set forth and incorporated by reference in this prospectus may include, for example, statements about:

- our ability to integrate the acquisition of X-spine Systems, Inc. and any other business combinations or acquisitions successfully;

- our ability to remain listed on the NYSE MKT;

- our ability to obtain financing on reasonable terms;

- our ability to increase revenue;

- our ability to comply with the covenants in our credit facility;

- our ability to maintain sufficient liquidity to fund our operations;

- the ability of our sales force to achieve expected results;

- our ability to remain competitive;

- government regulations;

- our ability to innovate and develop new products;

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

our ability to issue preferred stock.

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

Use of Proceeds

This prospectus relates to the notes and conversion shares that may be offered and sold from time to time by the selling securityholders. The selling securityholders will receive all of the proceeds from the sale of the notes or the conversion shares offered by this prospectus. We will not receive any proceeds from the sale by any selling securityholder of the notes or the conversion shares offered by this prospectus.

Capitalization

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 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.