Xtant Medical Holdings, Inc.
Form 10-Q
November 16, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2015

OR

.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001-34951

XTANT MEDICAL HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

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

664 CRUISER LANE

BELGRADE, MONTANA 59714

(Address of principal executive offices) (Zip code)

(406) 388-0480 (Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Number of shares of common stock, $0.000001 par value, of registrant outstanding at November 12, 2015: 11,886,101

XTANT MEDICAL HOLDINGS, INC.

FORM 10-Q

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this Form 10-Q 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," "estimat "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should" and "would," as well as simi may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward looking. Forward-looking statements in this Form 10-Q may include, for example, statements about:

- our ability to integrate our acquisition of X-spine Systems, Inc. and any future business combinations or acquisitions successfully;
- our ability to increase revenue;
- our ability to obtain financing on reasonable terms and maintain sufficient liquidity to fund our operations;
- our ability to comply with the covenants in our credit facility;
- the ability of our sales force to achieve expected results;
- our ability to remain competitive;
- government regulations;
- our ability to expand our production capacity;
- our ability to innovate and develop new products;
- our ability to obtain donor cadavers for our products;
- our ability to engage and retain qualified technical personnel and members of our management team;

- government and third-party coverage and reimbursement for our products;

- our ability to obtain regulatory approvals;

- product liability claims and other litigation to which we may be subject;

- product recalls and defects;

- timing and results of clinical studies;

- our ability to obtain and protect our intellectual property and proprietary rights; and

- infringement and ownership of intellectual property.

The forward-looking statements contained in this Form 10-Q 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 Quarterly Report on Form 10-Q. 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.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

XTANT MEDICAL HOLDINGS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	As of September 30, 2015 (unaudited)	As of December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$7,970,433	$4,468,208
Trade accounts receivable, net of allowance for doubtful accounts of $2,416,984 and $1,392,989, respectively	13,318,450	4,427,081
Inventories, net	22,042,508	9,558,648
Prepaid and other current assets	1,039,562	654,140
Total current assets	44,370,953	19,108,077
Non-current inventories	1,681,138	1,934,258
Goodwill	23,997,218	-
Property and equipment, net	11,433,064	4,654,527
Intangible assets, net	42,223,856	655,490
Other assets	2,520,464	1,598,539
Total Assets	$126,226,693	$27,950,891
LIABILITIES & STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	$7,485,220	$3,876,760
Accounts payable - related party	1,035,449	250,629
Accrued liabilities	6,716,897	1,921,301
Warrant derivative liability	1,399,294	1,320,371
Current portion of capital lease obligations	47,246	61,970
Current portion of royalty liability	-	1,000,750
Current portion of long-term debt	53,172	50,671
Total current liabilities	16,737,278	8,482,452
Long-term Liabilities:		
Capital lease obligation, less current portion	18,962	11,808

Long-term royalty liability, less current portion	-	6,361,216
Long-term convertible debt	68,000,000	-
Long-term debt, less current portion	44,301,474	20,870,330
Total Liabilities	129,057,714	35,725,806
Commitments and Contingencies		
Stockholders' (Deficit) Equity		
Preferred stock, $0.000001 par value; 5,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock, $0.000001 par value; 95,000,000 shares authorized; 11,886,107 shares issued and outstanding as of September 30, 2015 and 6,679,646 shares issued and outstanding as of December 31, 2014	11	7
Additional paid-in capital	81,798,160	63,091,620
Accumulated deficit	(84,629,192)	(70,866,542)
Total Stockholders’ Deficit	(2,831,021)	(7,774,915)
Total Liabilities & Stockholders’ Deficit	$126,226,693	$27,950,891

See notes to unaudited condensed consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue				
Orthopedic product sales	$ 17,421,397	$ 8,246,325	$ 36,431,354	$ 25,712,586
Other revenue	271,623	207,179	657,395	537,821
Total Revenue	17,693,020	8,453,504	37,088,749	26,250,407
Cost of Sales	6,035,673	3,017,734	12,883,439	9,718,952
Gross Profit	11,657,347	5,435,770	24,205,310	16,531,455
Operating Expenses				
General and administrative	3,980,805	2,282,386	8,805,104	6,664,982
Sales and marketing	8,430,303	3,927,028	18,179,552	12,387,459
Research and development	794,464	378,252	1,519,196	955,111
Depreciation and amortization	1,541,220	58,763	1,765,994	216,343
Acquisition and integration related expenses (See Note 2, “Business Combination” below)	3,856,519	-	3,856,519	-
Extinguishment of debt	(2,345,019)	-	(2,345,019)	-
Impairment of assets	233,748	-	233,748	-
Non-cash consulting expense	50,000	39,697	190,869	81,924
Total Operating Expenses	16,542,040	6,686,126	32,205,963	20,305,819
Loss from Operations	(4,884,693)	(1,250,356)	(8,000,653)	(3,774,364)
Other Income (Expense)				
Interest expense	(2,111,721)	(1,498,508)	(4,930,941)	(4,216,109)
Change in warrant derivative liability	397,366	1,653,425	(78,923)	1,038,190
Non-cash consideration associated stock agreement	-	-	(558,185)	-
Other income (expense)	(89,926)	(70,344)	(193,052)	(253,289)
Total Other Income (Expense)	(1,804,281)	84,573	(5,761,101)	(3,431,208)
Net Loss from Operations	$ (6,688,974)	$ (1,165,783)	$ (13,761,754)	$ (7,205,572)
Net loss per share:				

Basic	$ (0.64)	$ (0.19)	$ (1.70)	$ (1.26)
Dilutive	$ (0.64)	$ (0.19)	$ (1.70)	$ (1.26)
Shares used in the computation:				
Basic	10,432,622	6,233,751	8,100,226	5,711,452
Dilutive	10,432,622	6,233,751	8,100,226	5,711,452

See notes to unaudited condensed consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
Operating activities:		
Net loss	$(13,761,754)	$(7,205,572)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,403,934	498,343
Non-cash interest	1,665,172	387,294
Extinguishment of debt	(2,345,019)	-
Non-cash consideration associated with stock purchase agreement	558,185	-
Loss on sale of fixed assets	11,377	33,373
Impairment of Assets	233,748	-
Amortization of debt discount	707,281	1,207,859
Non-cash consulting expense/stock option expense	881,681	938,785
Provision for losses on accounts receivable and inventory	805,684	601,190
Change in derivative warrant liability	78,923	(1,038,190)
Changes in operating assets and liabilities:		
Accounts receivable	(2,801,124)	346,151
Inventories	477,818	(350,198)
Prepaid and other assets	(325,976)	22,109
Accounts payable	694,326	884,436
Accrued liabilities	1,688,664	(1,495,107)
Net cash used in operating activities	(9,027,080)	(5,169,527)
Investing activities:		
Acquisition of X-spine Systems, Inc.	(73,033,049)	-
Purchases of property and equipment and intangible assets	(444,312)	(190,601)
Proceeds from sale of fixed assets	102,587	10,149
Net cash used in investing activities	(73,374,774)	(180,452)
Financing activities:		
Net proceeds from the issuance of convertible debt	66,322,366	-
Payment on royalty obligation	(542,905)	-
Net proceeds from equity private placement	515,395	-
Payments on capital leases	(78,490)	-
Net proceeds from issuance of long term debt	17,479,159	4,000,000
Payments on long-term debt	(38,668)	(492,695)
Proceeds from the issuance of capital leases	70,921	(126,686)
Net proceeds from the issuance of stock	2,118,483	5,876,299
Net cash provided by financing activities	85,846,261	9,256,918

Net change in cash and cash equivalents	3,444,407	3,906,939
Cash and cash equivalents at beginning of period	4,526,026	3,046,340
Cash and cash equivalents at end of period	$7,970,433	$6,953,279

See notes to unaudited condensed consolidated financial statements.

Notes to Unaudited Condensed Consolidated Financial Statements

(1) Business Description and Summary of Significant Accounting Policies

Business Description

The accompanying consolidated financial statements include the accounts of Xtant Medical Holdings, Inc. ("Xtant"), formerly known as Bacterin International Holdings, Inc., a Delaware corporation, and its wholly owned subsidiaries, Bacterin International, Inc., ("Bacterin") a Nevada corporation and X-Spine Systems, Inc. ("X-spine"), an Ohio corporation, (Xtant, Bacterin and X-spine are jointly referred to herein as the "Company"). All intercompany balances and transactions have been eliminated in consolidation. Xtant develops, manufactures and markets regenerative orthopedic products for domestic and international markets. Xtant products serve the combined specialized needs of orthopedic and neurological surgeons, including orthobiologics for the promotion of bone healing, implants and instrumentation for the treatment of spinal disease, tissue grafts for the treatment of orthopedic disorders to promote healing following spine, cranial and foot surgeries.

The Company also previously developed and licensed coatings for various medical device applications. As of December 31, 2014, the Company made a strategic decision to discontinue the medical device coatings business which resulted in an impairment of related assets. (See Note 5, "Impairment of Assets" below).

An operating segment is a component of an enterprise whose operating results are regularly reviewed by the enterprise's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance. The primary performance measure used by management is net income or loss. Up until December 31, 2014, the Company operated two distinct lines of business consisting of the biologics and the device divisions; however, due to immaterial revenue from the device division, the Company has reported as one segment.

On July 31, 2015, Xtant acquired all of the outstanding capital stock of X-spine Systems, Inc. for approximately $60 million in cash, repayment of approximately $13 million of X-spine debt, and approximately 4.24 million shares of Xtant common stock (See Note 2, "Business Combination" below). X-spine is engaged in the development, manufacturing and sale of medical devices for use in orthopedic spinal surgeries.

The markets in which the Company competes are highly competitive and rapidly changing. Significant technological advances, changes in customer requirements, or the emergence of competitive products with new capabilities or technologies could adversely affect the Company's operating results. The Company's business could be harmed by a

decline in demand for, or in the prices of, its products or as a result of, among other factors, any change in pricing or distribution methods, increased price competition, changes in government regulations or a failure by the Company to keep up with technological change. Further, a decline in available donors could have an adverse impact on our business.

The accompanying interim condensed consolidated financial statements of the Company for the nine months ended September 30, 2015 and 2014 are unaudited and are prepared in accordance with accounting principles generally accepted in the United States of America. They do not include all disclosures required by generally accepted accounting principles for annual financial statements, but in the opinion of management, include all adjustments, consisting only of normal recurring items, necessary for a fair presentation. Interim results are not necessarily indicative of results which may be achieved in the future for the full year ending December 31, 2015.

These financial statements should be read in conjunction with the financial statements and notes thereto which are included in our Annual Report on Form 10-K for the year ended December 31, 2014. The accounting policies set forth in those annual financial statements are the same as the accounting policies utilized in the preparation of these financial statements, except as modified for appropriate interim financial statement presentation.

Name Change

Following the closing of the acquisition, on July 31, 2015, Bacterin International Holdings, Inc. changed its name to Xtant Medical Holdings, Inc.

New Subsidiary

On August 6, 2015 Xtant formed a new wholly owned subsidiary, Xtant Medical, Inc., a Delaware corporation. The creation of the subsidiary will facilitate the integration of Bacterin and X-spine.

Reverse Stock Split

Xtant completed a 1:10 reverse split of its common stock, effective at the close of business on Friday, July 25, 2014 and in effect for trading purposes on Monday, July 28, 2014. The reverse stock split was approved by Xtant shareholders at the 2014 Annual Meeting of Shareholders on June 11, 2014. All references to common stock, stock options, restricted stock units, warrants, and per share amounts have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Public Offering

In August 2014, Xtant offered 1,143,000 shares of its common stock at $5.70 per share and warrants to purchase 571,500 shares of its common stock at an exercise price of $7.12 per share to the public. Gross proceeds of the offering were approximately $6.5 million. Net proceeds from the offering were approximately $5.9 million and were used for working capital and general corporate purposes. The offering closed on August 6, 2014. The warrants have a five year term and expire on August 6, 2019. We utilize a valuation model to determine the fair market value and account for these warrants as a derivative liability (see "Derivative Instruments" below). (Also, See Note 11, "Warrants" below).

Aspire Capital Transaction

We entered into a Common Stock Purchase Agreement on March 16, 2015, as amended and restated on April 17, 2015 (the "Purchase Agreement"), with Aspire Capital Fund, LLC ("Aspire Capital"), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of our shares of common stock over the approximately 24-month term of the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, in the first quarter of 2015 we issued 207,182 shares of our common stock to Aspire Capital for $750,000 in aggregate proceeds, along with 154,189 shares of our common stock which were valued at $3.62 per share and included as $558,185 on the Statement of Operations to Aspire Capital as a commitment fee. In the second quarter of 2015, following the effectiveness of our Registration Statement on Form S-1, we issued 417,000 shares of our common stock to Aspire Capital for $1,387,439 in aggregate proceeds, which were used for working capital and general corporate purposes. (See Note 3, "Equity" below).

Private Placement Offering

During the third quarter of 2015, we issued 140,053 shares of our common stock to certain members of our Board of Directors at the closing price on September 4, 2015, for aggregate proceeds of $515,395 (See Note 3, "Equity" below).

Concentrations and Credit Risk

The Company's accounts receivable are due from a variety of health care organizations and distributors throughout the world. Approximately 95% and 98% of sales were in the United States respectively for the nine months ended 2015 and 2014. No single customer accounted for more than 10% of revenue or accounts receivable for the comparable periods. The Company provides for uncollectible amounts when specific credit issues arise. Management's estimates for uncollectible amounts have been adequate during prior periods, and management believes that all significant credit risks have been identified at September 30, 2015.

For the three months ended September 30, 2015, approximately 13% of total cost of goods sold was with one vendor, Norwood Medical (See note 15, "Related Party Transactions").

Revenue by geographical region is as follows:

	Nine Months Ended September 30,	
	2015	2014
United States	$35,419,434	$25,792,878
Rest of World	1,669,315	457,529
	$37,088,749	$26,250,407

Use of Estimates

The preparation of the financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the period. Significant estimates include the carrying amount of property and equipment, goodwill, and intangible assets; valuation allowances for trade receivables, inventory valuation, and deferred income tax assets; valuation of the warrant derivative liability; inventory reserve; royalty liability; and estimates for the fair value of stock options grants and other equity awards upon which the Company determines stock-based compensation expense. Actual results could differ from those estimates.

Long-Lived Assets

Long-lived assets, including intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. See Note 5, “Impairment of Assets”.

Goodwill

Goodwill represents the excess of costs over fair value of assets of businesses acquired. Goodwill and intangible assets acquired in a purchase business combination and determined to have indefinite useful lives are not amortized, instead are tested for impairment at least annually and whenever events or circumstances indicate the carrying amount of the asset may not be recoverable. In its evaluation of goodwill, the Company performs an assessment of qualitative factors to determine if it is more-likely-than-not that goodwill might be impaired and whether it is necessary to perform the two-step goodwill impairment. The Company conducts its annual impairment test on December 31 of each year.

Revenue Recognition

Revenue is recognized when all of the following criteria are met: a) the Company has entered into a legally binding agreement with the customer; b) the products or services have been delivered; c) the Company's fee for providing the products and services is fixed or determinable; and d) collection of the Company’s fee is probable.

The Company’s policy is to record revenue net of any applicable sales, use, or excise taxes. If an arrangement includes a right of acceptance or a right to cancel, revenue is recognized when acceptance is received or the right to cancel has expired.

The Company ships to certain customers under consignment arrangements whereby the Company’s product is stored by the customer. The customer is required to report the use to the Company and upon such notice, the Company invoices the customer and revenue is recognized when above criteria have been met.

The Company also receives royalty revenue from third parties related to licensing agreements which represented less than 1% of total revenue for the three and nine months ended September 30, 2015 and 2014.

Advertising Costs

The Company expenses advertising costs as incurred. The Company had advertising expense of $93,854 and $29,027 for the nine months ended September 30, 2015 and 2014, respectively.

Research and Development

Research and development costs, which are principally related to internal costs for the development of new regenerative orthopedic products technologies and processes are expensed as incurred.

Net Loss Per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. Diluted net income (loss) per share is computed in a manner consistent with that of basic earnings per share while giving effect to all potentially dilutive common shares outstanding during the period, which include the assumed exercise of stock options and warrants using the treasury stock method. Diluted net loss per share was the same as basic net loss per share for the three and nine months ended September 30, 2015 and 2014, as shares issuable upon the exercise of stock options and warrants were anti-dilutive as a result of the net losses incurred for those periods. Dilutive earnings per share are not reported as their effects of including 1,896,253 and 1,877,948 outstanding stock options and warrants for the nine months ended September 30, 2015 and 2014, respectively, are anti-dilutive.

Fair Value of Financial Instruments

The carrying values of financial instruments, including trade accounts receivable, accounts payable, other accrued expenses and long-term debt, approximate their fair values based on terms and related interest rates.

The Company follows a framework for measuring fair value. The framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy are described below:

Level 1: Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets.

Level 2: Inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.

Level 3: Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. During the three and nine months ended September 30, 2015 and 2014, there was no reclassification in financial assets or liabilities between Level 1, 2 or 3 categories.

The following table sets forth by level, within the fair value hierarchy, our liabilities as of September 30, 2015 and December 31, 2014 that are measured at fair value on a recurring basis:

Warrant derivative liability

	As of September 30, 2015	As of December 31, 2014
Level 1	-	-
Level 2	-	-
Level 3	$ 1,399,294	$ 1,320,371

The valuation technique used to measure fair value of the warrant liability is based on a valuation model and significant assumptions and inputs determined by us (See Note 11, “Warrants” below).

Level 3 Changes

The following is a reconciliation of the beginning and ending balances for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the nine months ended September 30, 2015:

Warrant derivative liability

Balance at January 1, 2015	$1,320,371
Loss recognized in earnings in first half of 2015	476,289
Balance at June 30, 2015	1,796,660
Gain recognized in earnings in third quarter of 2015	(397,366)
Balance at September 30, 2015	$1,399,294

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During the first nine months ended September 30, 2015, the Company did not change any of the valuation techniques used to measure its liabilities at fair value.

Recent Accounting Pronouncements

In November 2014, FASB issued ASU No. 2014-08, Presentation of Financial Statements (Topic 201) and Property, Plant and Equipment (Topic 360) - Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity. The amendments in this Update are effective for the annual period ending after December 15, 2014, and interim periods within those years. Early adoption is permitted only for disposals (or classifications as held for sale) that have not been reported in financial statements previously issued or available for issuance. ASU 2014-08 is not expected to have a material impact on our consolidated financial position, results of operations, or cash flows.

In April 2015, the FASB issued ASU 2015-3, to simplify the presentation of debt issuance costs. This update requires that debt issuance costs be presented in the balance sheet as a direct deduction from the carrying amount of the associated debt liability, consistent with the required presentation for debt discounts. This update is effective for interim and annual periods beginning after December 15, 2015. ASU 2015-3 is not expected to have a

material impact.

(2) Business Combination

On July 31, 2015 (the “Acquisition Date”), the Company completed its acquisition of 100% of the outstanding common stock of X-spine, pursuant to a Stock Purchase Agreement (the “Purchase Agreement”). X-spine was engaged in the development, manufacturing and sale of medical devices for use in orthopedic spinal surgeries. The primary reasons for the X-spine acquisition are to combine the Company’s product lines into regenerative orthopedic product lines, leverage customer call points, expand sales and marketing coverage, increase revenue, and drive operating efficiencies.

Under the terms of the Purchase Agreement, the Company paid the former X-spine stockholders consideration of approximately $60 million in cash and approximately 4.24 million shares of Xtant common stock. The Company also repaid approximately $13 million of X-spine debt.

The cash consideration was financed in part using the net proceeds from the Company’s offering of $68 million aggregate principal amount of 6% Convertible Senior Notes due 2021 (See Note 9, “Long-Term Debt” below).

The Company accounted for the acquisition as a business combination and recorded the assets acquired, liabilities assumed, and the estimated future consideration obligations at their respective fair values as of the Acquisition Date. The assets acquired and liabilities assumed were recorded as of the Acquisition Date at their respective fair values and consolidated with those of the Company. The reported condensed consolidated balance sheet of the Company after completion of the acquisition reflects these fair values; however, the Company may have to reflect any change from an impact after combined operations are experienced. The results of X-spine operations from the Acquisition Date contributed $91,000 of net profit to the Company’s condensed consolidated financial statements for the fiscal quarter ended September 30, 2015.

The components of the aggregate preliminary purchase price for the acquisition were as follows (in thousands):

Cash	$73,033,018
Fair value of Xtant shares	14,934,146
Total purchase price	$87,967,164

Net Assets Acquired

The transaction has been accounted for using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recognized at their fair values as of the Acquisition Date. The following table summarizes the allocation of assets acquired and liabilities assumed as of the Acquisition Date:

	Allocation of purchase price	Amortization period (in years)
Accounts receivable	$ 5,989,904	
Inventories	13,132,697	
Prepaids and other current assets	208,116	
Property and equipment, net	7,409,667	
Cash	57,818	
Total tangible assets acquired	26,798,202	
Less: liabilities assumed	6,021,756	
Net tangible assets less liabilities	$ 20,776,446	
Intangible assets:		
Technology	28,698,700	10
Customer relationships	9,911,000	14
Tradename	4,543,300	10
Non-compete agreements	40,500	3
Goodwill	23,997,218	
Total purchase price	$ 87,967,164	

The assets acquired and liabilities assumed were recorded at their estimated fair values as of the Acquisition Date. We determined the fair value of the inventory based on its estimated selling price less cost to sell and normal profit margin.

The fair value of the technology and tradename intangible assets were determined based upon a “relief from royalty” approach. The “relief from royalty” method is based on the premise that a third party would be willing to pay a royalty to use these assets owned by the subject company. The projected royalties are converted into their present value equivalents through the application of a risk adjusted discount rate. The customer relationships were valued based on an “excess earnings method.” The “excess earnings method” measures the historical customer churn analysis and discussions with management extended until excess earning cash flow approximates zero. The non-compete agreements were valued based on a “with and without” approach. The “with and without” method measures an asset value by estimating the difference in cash flows generated by the business with the asset in-use versus without the asset. The difference in cash flows is attributable to incremental earnings or cost savings associated with the asset. These fair value measurements are based on significant unobservable inputs, based on management’s estimates and assumptions.

The fair value of the identifiable assets, including the intangible assets noted above, may be impacted by the Company's evaluation of deferred taxes as further discussed below and possibly by future factors that may or may not impact the fair value of the identifiable assets, including the intangible assets noted above.

The Company recorded the excess of the aggregate purchase price over the estimated fair values of the identifiable assets acquired as goodwill, which is not deductible for tax purposes. Goodwill is primarily attributable to the benefits the Company expects to realize by expanding its product offerings and addressable markets, thereby contributing to an expanded revenue base. The Company will also increase the size of its sales organization, while realizing cost synergies associated with eliminating redundant positions, primarily in selling, general and administrative functions.

The assets and liabilities assumed in the acquisition have been included in the Company’s condensed consolidated balance sheet as of September 30, 2015. The results of X-spine operations were included in the Company’s condensed consolidated financial statements from the Acquisition Date.

The Company is currently evaluating the impact of the X-spine acquisition on reportable operating segments requirements.

Acquisition Costs

Acquisition-related expenses were $3.9 million for the three and nine months ended September 30, 2015, and primarily included investment banking, accounting, consulting, legal fees and integration expenses. Integration expenses include samples, travel and meetings, severance due to reduction in force, retention bonuses and software. We anticipate additional integration expenses to occur during the fourth quarter of 2015 and the first quarter of 2016.

Taxes

The Company did not acquire X-spine's net operating loss carryforwards for federal tax purposes because X-spine was an S-corporation tax filer prior to the acquisition and any carryforwards were taken by the former shareholders of X-spine in their federal tax filings. The Company is currently evaluating the realizability of the net deferred tax assets acquired net of the deferred tax liabilities that may arise from the recording of intangible assets as part of the purchase price allocation.

Given its significant prior accumulated tax losses, the Company does not expect to incur U.S. federal tax expense in the year ending December 31, 2015 or the foreseeable future. The Company does, however, expect to incur state tax expense during 2015.

Unaudited Supplemental Pro Forma Financial Information

The unaudited pro forma results presented below include the combined results of both entities as if the acquisition had been consummated as of January 1, 2014. Certain pro forma adjustments have been made to reflect the impact of the purchase transaction, primarily consisting of amortization of intangible assets with determinable lives and interest expense on long-term debt. In addition, certain historical expenses, such as warrant expense and interest expense associated with debt that was immediately repaid, were eliminated from these pro-forma results. The pro forma information does not necessarily reflect the actual results of operations had the acquisition been consummated at the beginning of the fiscal reporting period indicated nor is it indicative of future operating results. The pro forma information does not include any adjustment for potential revenue enhancements, cost synergies or other operating efficiencies that could result from the acquisition.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	$20,901,292	$19,619,310	$64,401,225	$58,135,543
Net loss	$(5,357,091)	$(2,769,827)	$(16,061,103)	$(11,250,171)

(3) Equity

During the first quarter of 2014, the Company issued 150,000 shares of common stock to an affiliate of ROS Acquisition Offshore LP (“ROS”) pursuant to a Sixth Amendment to our Credit Agreement with ROS whereby we borrowed an additional $4 million under our Credit Agreement. This issuance accounted for as a debt discount and will be amortized over the life of the loan. (See Note 9, “Long-Term Debt” below).

In August 2014, the Company offered 1,143,000 shares of its common stock at $5.70 per share and warrants to purchase 571,500 shares of its common stock at an exercise price of $7.12 per share to the public. Gross proceeds of the offering were approximately $6.5 million. Net proceeds from the offering were approximately $5.9 million and were used for working capital and general corporate purposes. The offering closed on August 6, 2014. The warrants have a five year term and expire on August 6, 2019. The Company utilizes a valuation model to determine the fair market value and accounts for these warrants as a derivative liability (See Note 1, “Fair Value of Financial Instruments" above). (Also, see Note 11, "Warrants" below).

We entered into a Common Stock Purchase Agreement on March 16, 2015, as amended and restated April 17, 2015, with Aspire Capital which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million in shares of our common stock over the 24-month term. The stock purchase transactions are at the Company’s option. Pursuant to the terms and conditions in the Common Stock Purchase Agreement, in the first quarter of 2015, we issued 207,182 shares of our common stock for $750,000 in aggregate proceeds, along with 154,189 shares of our common stock as a commitment fee. In the second quarter of 2015, following the effectiveness of our Registration Statement on Form S-1, we issued 417,000 shares of our common stock to Aspire Capital for $1,387,439 in aggregate proceeds, which were used for working capital and general corporate purposes. The Company did not issue any shares to Aspire Capital in the quarter ending September 30, 2015.

Under the Common Stock Purchase Agreement, we have the right, at our sole discretion, to present Aspire Capital with purchase notices, directing Aspire Capital (as principal) to purchase up to 50,000 shares of our common stock, per trading day, provided that the aggregate price of each such purchase shall not exceed $500,000 per trading day, at a per share price equal to the lesser of:

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

In addition, we also have the right to present Aspire Capital with volume-weighted average price purchase notices directing Aspire Capital to purchase an amount of our common stock equal to up to 30% of the aggregate shares of our common stock on the next trading day, subject to the terms, conditions and limitations in the Purchase Agreement.

The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us. The Purchase Agreement also provides for customary events of default, upon the occurrence of which Aspire Capital may terminate the Purchase Agreement. Aspire Capital has agreed that neither it nor any of its agents, representatives or affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement. Any proceeds we receive under the Purchase Agreement are expected to

be used for working capital and general corporate purposes.

On July 31, 2015, the Company acquired all of the outstanding capital stock of X-spine for approximately $60 million in cash, repayment of approximately $13 million in debt and 4,242,655 shares of our common stock.

Related to the acquisition, on October 8, 2015 the Company granted 78,510 restricted stock units to five X-spine employees at $3.19 a share for a total cost of $250,447 to be expensed ratably over twelve months in Acquisition and integration related expenses from the Acquisition Date.

On September 4, 2015, the Company sold an aggregate of 140,053 shares of our common stock to certain members of our Board of Directors in a private placement transaction for aggregate cash proceeds of $515,395.

(4) Inventories

Inventories consist of the following:

	September 30, 2015	December 31, 2014
Current inventories		
Raw materials	$ 4,685,993	$ 3,836,635
Work in process	3,089,413	2,484,635
Finished goods	17,639,292	5,163,458
	25,414,698	11,484,728
Reserve for obsolescence	(3,372,190)	(1,926,080)
Current inventories, total	22,042,508	9,558,648
Non-current inventories		
Finished goods	2,177,090	2,860,248
Reserve for obsolescence	(495,952)	(925,990)
Non-current inventories, total	1,681,138	1,934,258
Total inventories	$ 23,723,646	$ 11,492,906

(5) Impairment of Assets

During the fourth quarter of 2014, management decided to dispose of a group of components because of a shift in strategy for the Company. The component groups consisted of the inventory and fixed assets associated with the Device Coatings and Cranial Maxillofacial Fixation (CMF) lines of business. Sales for these product lines represented less than 1% of total revenue in both the first nine months of 2015 and 2014. Gross profit associated with these product lines was less than 1% of total gross profit for both periods. Total assets associated with the two lines at December 31, 2014 included $80,042 of related fixed assets, net of depreciation, and related inventory of $832,507 for a total value of $912,549. These assets were transferred to Assets held for Sale and are classified on the balance sheet at December 31, 2014 as part of “Prepaid and other current assets”. After the impairment provision, the net balance of the Assets Held for Sale was $0 at December 31, 2014.

The sale of the CMF inventory occurred during the first quarter of 2015 and did not result in any tangible payment to the Company. The sale of the Device Coatings line of business occurred in the third quarter of 2015. The terms of the sale call for cash consideration to the Company of approximately $250,000, and additional contingent cash consideration of $100,000, both of which are secured by promissory notes. The gain on sale will only be recognized when payment on the promissory notes is received. The final terms of the sale of the Device Coatings line of business resulted in an impairment gain of $51,476.

During the third quarter of 2015, Intangible Assets were reviewed and found to be impaired. The impact, net of amortization, was $285,224.

(6) Property and Equipment, Net

Property and equipment, net are as follows:

	September 30, 2015	December 31, 2014
Buildings	$ 1,657,579	$ 1,657,579
Equipment	5,279,695	4,724,608
Computer equipment	364,966	225,009
Computer software	469,301	345,039
Furniture and fixtures	256,721	153,834
Leasehold improvements	2,477,281	2,380,617
Vehicles	10,000	41,099
Surgical instruments	6,610,189	-
Total cost	17,125,732	9,527,785
Less: accumulated depreciation	(5,692,668)	(4,873,258)
	$ 11,433,064	$ 4,654,527

The Company leases certain equipment under capital leases. For financial reporting purposes, minimum lease payments relating to the assets have been capitalized. As of September 30, 2015, the Company has recorded $461,036 gross assets in Equipment, and $199,020 of accumulated depreciation relating to assets under capital leases.

Maintenance and repairs expense for the nine months of 2015 and 2014 was $272,811 and $233,547, respectively. Depreciation expense related to property and equipment, including property under capital lease for the first nine months of 2015 and 2014 was $563,790 and $440,397, respectively.

(7) Intangible Assets

The Company has applied for various patents with regards to processes for its products.

The following table sets forth information regarding intangible assets:

	September 30, 2015	December 31, 2014
Intellectual Property		
Gross carrying value	$ 43,691,182	$ 1,036,580
Accumulated amortization	(1,467,326)	(381,090)
Net carrying value	$ 42,223,856	$ 655,490
Aggregate amortization expense:	$ 1,423,983	$ 77,022

The following is a summary of estimated future amortization expense for intangible assets as of September 30, 2015:

Remainder of 2015	$2,050,466
2016	4,465,216
2017	4,625,114
2018	4,640,027
2019	4,531,176
Thereafter	21,911,857
Total	$42,223,856

(8) Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2015	December 31, 2014
Accrued stock compensation	$ 91,741	$ -
Wages/commissions payable	2,547,860	1,434,743
Accrued integration expense	241,132	-
Other accrued expenses	3,836,164	486,558
	$ 6,716,897	$ 1,921,301

(9) Long-Term Debt

On March 6, 2014, we entered into a Sixth Amendment to our Credit Agreement with ROS whereby we borrowed an additional $4.0 million under our Credit Agreement with ROS and issued 150,000 shares to an affiliate of ROS. We used the proceeds for working capital and general corporate purposes.

On July 31, 2015, concurrent with the acquisition of X-spine, we completed an offering of $65.0 million aggregate principal amount of 6.00% convertible senior unsecured notes due 2021 (the “Notes”) in a private offering to qualified institutional buyers, as defined in Rule 144A under the Securities Act of 1933, as amended. Certain private investment funds for which OrbiMed Advisors LLC, serves as the investment manager, purchased $52.0 million aggregate principal amount of the Notes directly from the Company in the offering. On August 10, 2015, the initial purchaser exercised its option with respect to an additional $3 million aggregate principal amount of Notes.

The Notes bear interest at a rate equal to 6.00% per year. Following the first interest payment date, which will be on April 15, 2016, interest on the Notes will be payable semiannually in arrears on January 15 and July 15 of each year. Interest will accrue 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. 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, holders may convert their Notes into shares of Xtant 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). 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 Xtant common stock. The conversion rate will be subject to adjustment as described in the Indenture. In addition, Xtant 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 the Indenture). No sinking fund is provided for the Notes. Xtant may not redeem the Notes at its option prior to their maturity. If a “fundamental change” (as defined in the Indenture) occurs, holders will have the right, at their option, 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 Xtant's senior, unsecured obligations, rank equal in right of payment with its existing and future unsecured indebtedness that is not junior to the Notes, are senior in right of payment to any of its existing and future indebtedness that is expressly subordinated to the Notes, and are effectively subordinated to its 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 Xtant is not a holder thereof) preferred equity, if any, of its subsidiaries.

Amended and Restated Credit Agreement

On July 31, 2015, we refinanced approximately $24 million in existing term loans and borrowed an additional $18 million pursuant to an Amended and Restated Credit Agreement with ROS (the "New Facility"). The maturity date of the New Facility is July 31, 2020 (the "Maturity Date"). Interest under the New Facility is bifurcated into a "cash pay" portion and a "payment-in-kind" ("PIK") portion. Until June 30, 2018 (the "First Period"), interest on loans outstanding under the New Facility will accrue at a rate equal to the sum of (a) 9% per annum, which portion of interest will be payable in cash, plus (b) additional interest ("PIK Interest") in an amount equal to (i) the sum of 14% per annum, plus the higher of (x) LIBOR and (y) 1% per annum, minus (ii) 9% per annum, which portion of interest will be payable "in kind." During the portion of the First Period before December 31, 2015 (the "Optional PIK Period"), we may elect at our option to have all or any portion of interest on loans outstanding under the New Facility to accrue during the Optional PIK Period at a rate equal to the sum of 14% per annum, plus the higher of (x) LIBOR and (y) 1% per annum, which portion of interest will be payable "in kind." On or after June 30, 2018 until the New Facility is repaid in full (the "Second Period"), interest on loans outstanding under the New Facility will accrue at a rate equal to the sum of (a) 12% per annum, which portion of interest will be payable in cash, plus (b) PIK Interest in an amount equal to the difference of (i) the sum of 14% per annum, plus the higher of (x) LIBOR and (y) 1% per annum, minus (ii) 12% per annum, which portion of interest will be payable "in kind." In both the First Period and the Second Period, the portion of accrued interest constituting PIK Interest will not be payable in cash but will instead be added to the principal amount outstanding under the New Facility. However, at our option, we may choose to make any "payment-in-kind" interest payment in cash. Until the third anniversary of the closing date of the New Facility, we will not be allowed to voluntarily prepay the New Facility. Whenever loans outstanding under the New Facility are prepaid or paid, whether voluntarily, involuntarily or on the Maturity Date, a fee of 7.5% on the amount paid will be due and payable. The New Facility contains financial and other covenant requirements, including, but not limited to, financial covenants that require the Company to maintain revenue and liquidity at levels set forth in the New Facility and ensure that the Company's senior consolidated leverage ratio does not exceed levels set forth in the New Facility. The New Facility also restricts us 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 shares of our common stock upon conversion of the Notes, and payment of cash in lieu of fractional shares. The loans under the New Facility are guaranteed by Xtant and its current and future subsidiaries and are secured by substantially all of the current and future assets of Xtant and its subsidiaries. The additional amount borrowed under the New Facility was used to pay a portion of the X-spine acquisition, with the balance being available for general corporate purposes.

We accounted for the Notes and for the New Facility with ROS in accordance with ASC Subtopic 470-50, Debt Modifications and Extinguishments, and ASC Subtopic 470-60, Troubled Debt Restructurings by Debtors. Based on the facts and circumstances surrounding the changes to the loan and applying the calculation methodology per the

above mentioned ASC subtopics, the Company recognized a gain from the extinguishment of debt of $2,345,019. The expense consists of the write-off of the royalty liability offset by the debt discount and capitalized expenses associated with the original debt agreement, including amendments, with ROS.

In addition, the Company calculated a fair value of the New Facility on a non-recurring basis by taking the five year cash flow and discounting it at a market interest rate. There was no significant difference between the calculated value and the stated value of the New Facility.

Approximately $4.8 million of expenses were incurred in conjunction with the acquisition, the issuance of convertible debt and the amendment and restatement of our credit facility with ROS. Of that amount, approximately $2.2 million of debt issuance costs will be capitalized and amortized over the life of the debt and we expensed approximately $2.6 million in the third quarter of 2015 related to the acquisition itself.

Long-term debt consists of the following:

	September 30, 2015	December 31, 2014
Loan payable to ROS Acquisition Offshore (See details above)	$42,000,000	$24,000,000
Adjustment fee was payable to ROS Acquisition Offshore, due in August 2019	-	700,000
6% convertible senior unsecured notes due 2021 (See details above)	68,000,000	
PIK Interest payable to ROS	1,067,500	
6.00% loan payable to Valley Bank of Belgrade, $10,746 monthly payments including interest, maturing December 24, 2030; secured by building	1,287,146	1,325,814
	112,354,646	26,025,814
Less: current portion	(53,172)	(50,671)
Debt discount	-	(5,104,813)
Long-term debt	$112,301,474	$20,870,330

The following is a summary of maturities due on the debt as of September 30, 2015:

Remainder of 2015	$12,953
2016	53,796
2017	57,114
2018	60,637
2019	64,377
Thereafter	112,105,769
Total	$112,354,646

(10) Stock-Based Compensation

The Amended and Restated Xtant Medical Equity Incentive Plan ("The Plan") provides for stock awards, including options and performance stock awards, to be granted to employees, consultants, independent contractors, officers and directors. The purpose of the Plan is to enable us to attract, retain and motivate key employees, directors and, on occasion, independent consultants, by providing them with stock options and restricted stock grants. Stock options granted under the Plan may be either incentive stock options to employees, as defined in Section 422A of the Internal Revenue Code of 1986, or non-qualified stock options. The Plan is administered by the compensation committee of our Board of Directors. Stock options granted under the Plan are generally not transferable, vest in installments over the requisite service period and are exercisable during the stated contractual term of the option only by such optionee. The exercise price of all incentive stock options granted under the Plan must be at least equal to the fair market value of the shares of common stock on the date of the grant. 1,400,000 shares are authorized under the Plan and at September 30, 2015, we had approximately 480,000 shares available for issuance which are authorized, but unissued or reacquired shares.

Stock compensation expense recognized in the statement of operations for the nine months ended September 30, 2015 and 2014 is based on awards ultimately expected to vest and reflects an estimate of awards that will be forfeited. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The estimated fair value of stock options granted is done using the Black-Scholes-Merton method applied to individual grants. Key assumptions used to estimate the fair value of stock awards are as follows:

	Nine Months Ended September 30, 2015		**Nine Months Ended September 30, 2014**	
Risk-free interest rate	1.30	%	1.81	%
Expected volatility	75	%	58	%
Expected term	6.0	Years	5.25	Years
Expected forfeiture rate	20	%	20	%
Dividend yield	0	%	0	%

In July 2014, the Company granted the President of Bacterin an option to purchase 55,000 shares of our common stock outside of the Plan, and in August 2013, the Company granted our Chief Executive Officer an option to purchase 200,000 shares of our common stock outside of the Plan (collectively the “Non-Plan Grants”).

Stock option activity, including options granted under the Plan and the Non-Plan Grants, was as follows:

	2015			2014		
	Shares	Weighted Average Exercise Price	Weighted Average Fair Value at Grant Date	Shares	Weighted Average Exercise Price	Weighted Average Fair Value at Grant Date
Outstanding at January 1	695,336	$ 11.09	$ 5.35	758,328	$ 14.90	$ 8.60
Granted	45,000	4.00	2.81	169,200	5.78	5.00
Exercised	-	-	-	(6,666)	10.00	.04
Cancelled or expired	(31,604)	12.71	6.02	(147,396)	19.95	9.20
Outstanding at September 30	708,732	$ 10.54	$ 5.29	773,466	$ 11.99	$ 7.10
Exercisable at September 30	388,498	$ 13.53	$ 6.43	297,962	$ 17.03	$ 6.50

The aggregate intrinsic value of options outstanding and the aggregate intrinsic value of exercisable options as of September 30, 2015 were approximately $26,000 and are equal because no options were exercisable at September 30, 2015. As of September 30, 2015, there were 320,234 unvested options with a weighted average fair value at the grant date of $3.90 per option. As of September 30, 2015, we had approximately $799,901 in compensation expense related to unvested awards not yet recognized.

From time to time we may grant stock options and stock grants to consultants. We account for consultant stock options in accordance with ASC 505-50. Consulting expense for the grant of stock options to consultants is determined based on the estimated fair value of the stock options at the measurement date as defined in ASC 505-50 and is recognized over the vesting period.

The Company recognized non-cash consulting expense for the nine months ended September 30, 2015 and 2014 as $190,869 and $81,924, respectively.

Total share based compensation recognized for employees, directors and consultants was $479,289 and $938,785 for the nine months ended September 30, 2015 and 2014, respectively.

On November 10, 2014, the company granted 39,312 shares of restricted stock units to the independent Directors of the Company. These restricted shares vested on July 1, 2015 and were issued when the stock price was $4.07 per share. The total expense of $160,000 was recognized ratably over the period as General and administrative expense.

On July 1, 2015, the company granted 58,820 restricted stock units to the independent Directors of the Company. These restricted shares vest on July 1, 2016 and were granted when the stock price was $3.40 per share. The total expense of $200,000 is being recognized ratably over the period as General and administrative expense. In the period ending September 30, 2015, $50,000 was expensed.

On October 8, 2015 the Company granted 78,510 restricted stock units to five X-spine employees at $3.19 a share for a total cost of $250,447 to be expensed ratably from the Acquisition Date over twelve months as Acquisition and integration related expense. In the period ending September 30, 2015, $41,741 was expensed.

(11) Warrants

The following table summarizes our warrant activities for the period ended September 30, 2015:

	Common Stock Warrants	Weighted Average Exercise Price
Outstanding as of January 1, 2014	1,087,820	$ 16.20
Issued	571,500	7.12
Expired	(4,000)	20.00
Outstanding at January 1, 2015	1,655,320	$ 13.06
Issued	-	-
Expired	(467,799)	22.55
Outstanding at September 30, 2015	1,187,521	$ 9.32

We utilize a valuation model to determine the fair market value of the warrants accounted for as liabilities. The valuation model accommodates the probability of exercise price adjustment features as outlined in the warrant agreements. We recorded an unrealized loss of $78,923 resulting from the change in the fair value of the warrant derivative liability for the first nine months of 2015. Under the terms of some of our warrant agreements, at any time while the warrant is outstanding, the exercise price per share can be reduced to the price per share of future subsequent equity sales of our common stock or a common stock equivalent that is lower than the exercise price per share as stated in the warrant agreement.

The estimated fair value was derived using the valuation model with the following weighted-average assumptions:

	Nine Months ended September 30,	
	2015	2014
Value of underlying common stock (per share)	$3.26	$4.48
Risk free interest rate	1.37 %	1.81 %
Expected term	4.25 years	5.25 years
Volatility	75 %	58 %
Dividend yield	0 %	0 %

The following table summarizes our activities related to warrants accounted for as a derivative liability for the nine months ended September 30, 2015 and 2014:

	2015	**2014**
Balance at January 1,	1,171,692	600,192
Derivative warrants issued	-	571,500
Derivative warrants exercised	-	-
Balance at September 30,	1,171,692	1,171,692

(12) Commitments and Contingencies

Operating Leases

We lease three office facilities under non-cancelable operating lease agreements with expiration dates in 2016, 2019 and 2023. We have the option to extend the three leases for up to another ten year term and for one facility, we have the right of first refusal on any sale. We lease additional office space under a month-to-month arrangement. Future minimum payments for the next five years and thereafter as of September 30, 2015, under these leases, are as follows:

Remainder of 2015	$175,055
2016	609,317
2017	280,527
2018	286,754
2019	166,940

Thereafter	559,000
Total	$2,077,593

Rent expense was $484,064 and $245,884 for the nine months ended September 30, 2015 and 2014, respectively. Rent expense is determined using the straight-line method of the minimum expected rent paid over the term of the agreement. We have no contingent rent agreements.

In October of 2015, we entered into a sale leaseback transaction (See Note 16, “Subsequent Events” below).

Indemnifications

Our arrangements generally include limited warranties and certain provisions for indemnifying customers against liabilities if our products or services infringe a third-party's intellectual property rights. To date, we have not incurred any material costs as a result of such warranties or indemnification provisions and have not accrued any liabilities related to such obligations in the accompanying financial statements.

We have also agreed to indemnify our directors and executive officers for costs associated with any fees, expenses, judgments, fines and settlement amounts incurred by any of these persons in any action or proceeding to which any of those persons is, or is threatened to be, made a party by reason of the person's service as a director or officer, including any action by us, arising out of that person's services as our director or officer or that person's services provided to any other company or enterprise at our request.

Litigation

Other than as previously disclosed in our Form 10-Q for the quarterly period ended June 30, 2015, there is no material litigation pending to which we are a party or to which our property is subject, other than ordinary routine litigation incidental to our business, including product liability disputes.

(13) Income Taxes

In evaluating the realizability of the net deferred tax assets, we take into account a number of factors, primarily relating to the ability to generate taxable income. Where it is determined that it is likely that we will be unable to realize deferred tax assets, a valuation allowance is established against the portion of the deferred tax asset. Because it cannot be accurately determined when or if we will become profitable, a valuation allowance was provided against the entire deferred income tax asset balance.

The 2011 through 2014 tax years remain open to examination by the Internal Revenue Service and the 2009 to 2014 tax years remain open to the Montana Department of Revenue and Ohio Department of Revenue. These taxing authorities have the authority to examine those tax years until the applicable statute of limitations expire.

The Company did not recognize any interest or penalties related to income taxes for the nine months ended September 30, 2015 and 2014.

(14) Supplemental Disclosure of Cash Flow Information

Supplemental cash flow information is as follows:

	Nine months Ended September 30,	
	2015	2014
Supplemental disclosure of cash flow information		
Cash paid during the period for:		
Interest	$2,372,453	$2,379,439
Non-cash activities:		
Issuance of shares related to debt issuance	$-	$1,094,999
Issuance of capital leases	$70,020	$-
Issuance of share for non-cash consulting expense	$190,869	$81,924
Issuance of restricted stock to employees	$41,741	$142,601
Issuance of shares in conjunction with the acquisition of X-spine	$14,934,146	$-

(15) Related Party Transactions

Darrel Holmes, our Chief Operating Officer, and Mitchell Godfrey, a former director, serve on the board of American Donor Services Inc. (“ADS”), and Mr. Godfrey also serves as secretary and treasurer for ADS. Mssrs. Godfrey and Holmes each receive $5,000 per year for their service to ADS. ADS recovers tissue from donors and we reimburse ADS for its recovery fees, which are comprised primarily of labor costs. The approximate aggregate amount of all transactions with ADS for the nine months ended September 30, 2015 and 2014 was $1,367,487 and $1,900,952 respectively. Our relationship with ADS has benefited us, as ADS provides us with current donors and a pipeline for future donors, which is necessary to our success.

Certain of X-spine’s former shareholders, now own over 10% of our common stock as of the Acquisition Date, and have owned a controlling interest of X-spine’s largest supplier, Norwood Tool Company d/b/a Norwood Medical. For the three months ended September 30, 2015, Norwood Medical sold approximately $337,000 of supplies to the Company (See Item 1A. Risk Factors - Risks Related to X-spine’s Business, “*X-spine’s business depends, in part, on a relationship with a key supplier, which is a related party” below).*

Unless delegated to the Compensation Committee by the Board of Directors, the Audit Committee or the disinterested members of the full Board of Directors reviews and approves all related party transactions.

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(16) Subsequent Events

On October 23, 2015, the Company entered into a sale-leaseback transaction for the property located at 664 Cruiser Lane, Belgrade, Montana, 59714 which formerly secured the 6% loan payable to Valley Bank of Belgrade (See Note 9, “Long-Term Debt” above) Our new lease agreement has a ten year term with an option to extend for two additional five year terms for a total of ten years.

On October 19, 2015, our common stock began trading on the NYSE MKT under the new symbol “XTNT”.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operation

This Management’s Discussion and Analysis of Financial Condition and Results of Operations contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include statements relating to the intended usage and markets for our products and services, the market for our common stock, the ability of our sales force to achieve expected results; and our liquidity, results of operations, and ability to meet our anticipated cash requirements. Actual results could differ materially from those currently anticipated as a result of a number of factors, including those set forth under “Risk Factors” in this Quarterly Report on Form 10-Q.

You should read the following discussion of our financial condition and results of operations in conjunction with our financial statements and related notes set forth in this report.

Results of Operations

Comparison of Three Months Ended September 30, 2015 and September 30, 2014

Revenue

As with all line items stated in this comparison, the results only include X-spine results as of the Acquisition Date, July 31, 2015 (See Note 2, " Business Combination" above).

Total revenue for the three months ended September 30, 2015 increased approximately 109.3% to $17,693,020 compared to $8,453,504 in the prior year. The increase of $9,239,516 is due to the X-spine acquisition and improved sales force productivity realized from increased sales headcount and manufacturer representatives.

Cost of sales

Costs of sales consist primarily of manufacturing costs and the depreciation of surgical trays. Costs of sales increased by 100% or $3,017,939 to $6,035,673 for the three months ended September 30, 2015 from $3,017,734 for the three months ended September 30, 2014. As a percentage of sales, cost of sales was 34.1% of revenues for the three months ended September 30, 2015 compared to 35.7% in the same period in 2014. The decrease is the result of improved manufacturing efficiencies including the impact of new products and a change in product and customer mix between the two periods and the impact of the X-spine acquisition.

Operating Expenses

Operating expenses include general and administrative expenses, selling and marketing expenses, depreciation, research and development expenses, and compensation costs, including incentive compensation. Operating expenses increased 147.4%, or $9,855,914 for the three months ended September 30, 2015 compared to the three months ended September 30, 2014, primarily due to the reasons set forth below and the expenses due to X-spine acquisition which includes "Acquisition and Integration related expenses" and the "Extinguishment of Debt".

General and Administrative

General and administrative expenses consist principally of corporate personnel, cash based and stock option compensation related costs and corporate expenses for legal, accounting and other professional fees as well as occupancy costs. General and administrative expenses increased 74.4%, or $1,698,419, to $3,980,804 for the three months ended September 30, 2015 compared to $2,282,386 for the same period of 2014. Most of the increase is due to the acquisition of X-spine, additional head count in operations as a result of increased sales activity and a one time entry of bad debt expense.

Sales and Marketing

Sales and marketing expenses primarily consist of costs for sales and marketing personnel, sales commissions, costs for trade shows, sales conventions and meetings, travel expenses, advertising and other sales and marketing related costs. Sales and marketing expenses increased 114.7%, or $4,503,275, to $8,430,303 for the three months ended September 30, 2015 compared to $3,927,028 for the same period of 2014. The increase is due to the acquisition of X-spine and to increased commissions tied to increased revenues. As a percentage of revenue, sales and marketing expenses increased to 47.6% in the three months ended September 30, 2015 from 46.5% compared to the same period of 2014.

Research and Development

Research and development expenses consist primarily of internal costs for the development of new technologies and processes for regenerative orthopedic products. Research and development expenses increased $416,212 or 110.0% from $378,252 for the three months ended September 30, 2014 to $794,464 for the same period of 2015. The increase is due to the acquisition of X-spine.

Depreciation and Amortization

Depreciation and amortization expense consists of depreciation of long-lived property and equipment, patents and intangible assets that resulted from the acquisition of X-spine. Depreciation and amortization expense increased $1,482,457 to $1,541,220 for the three months ended September 30, 2015 from $58,763 in the same period in 2014. Almost all of the increase is due to the amortization of the intangible assets that resulted from the acquisition of X-spine.

Acquisition and Integration Related Expenses

Acquisition and Integration related expenses are $3,856,519 for the three months ended September 30, 2015. Acquisition related expenses consisted of investment banking, accounting, consulting, legal fees and miscellaneous expenses associated with the due diligence and execution of the acquisition. Integration related expenses consist of samples, travel and meeting, severance due to reduction in force, retention bonuses and software. We anticipate additional expenses to occur during the fourth quarter of 2015 and the first quarter of 2016.

Extinguishment of Debt

Extinguishment of Debt expenses are $2,345,019 for the three months ended September 30, 2015 and are related to the Amended and Restated Credit Agreement with ROS Acquisition Offshore LP (“ROS”) and is recorded in accordance with ASC Subtopic 470-50, Debt Modifications and Extinguishments and ASC Subtopic 470-60, Troubled Debt Restructuring by Debtors. The expense consists of the write-off of the royalty liability offset by the debt discount and capitalized expenses associated with the issuance of the original debt agreement, including amendments, with ROS.

Non-cash Consulting Expense

In this quarter, non-cash consulting expense consists of non-cash expense associated with stock to directors and consultants. Non-cash consulting expense increased $10,303 to $50,000 for the three months ended September 30, 2015 from $39,697 in the same period in the prior year.

Interest Expense

Interest expense is from our debt instruments. Interest expense for the three months ended September 30, 2015 increased $613,213 to $2,111,721 as compared to $1,498,508 in the same period in 2014 due to increased long term and convertible debt issued in part to finance the acquisition of X-spine.

Change in Warrant Derivative Liability

For the three months ended September 30, 2015, the Company recorded a gain from a decrease in its non-cash warrant derivative liability of $397,366 which was primarily driven by the decrease in the closing price of the Company's common stock from June 30, 2015 to September 30, 2015. The liability is associated with the issuance of warrants as part of the Company's prior convertible debt financing, the Company's 2010 financing and the Company's 2014 equity financing which contain certain provisions requiring the Company to record a change in the warrant derivative liability from period to period.

Other Income/Expense

Other expense for the three months ended September 30, 2015 was $89,925 as compared to expense of $70,344 in the same period in 2014.

Comparison of Nine Months Ended September 30, 2015 and September 30, 2014

Revenue

As with all line items stated in this comparison, the results only include X-spine results as of the Acquisition Date, Julu 31, 2015 (See Note 2, " Business Combination" above).

Total revenue for the nine months ended September 30, 2015 increased approximately 41.3% to $37,088,749 compared to $26,250,407 in the prior year. The increase of $10,838,342 is due to the X-spine acquisition and improved sales force productivity realized from increased sales headcount and manufacturer representatives.

Cost of sales

Costs of sales consist primarily of manufacturing costs and depreciation of surgical trays. Costs of sales increased by 32.6% or $3,164,487 to $12,883,439 for the nine months ended September 30, 2015 from $9,718,952 for the first nine months of 2014. As a percentage of tissue sales, cost of sales was 34.7% of revenues for the nine months ended September 30, 2015 compared to 37.0% in the first nine months of 2014. The decrease is the result of improved manufacturing efficiencies including the impact of new products, a change in product and customer mix between the two periods.

Operating Expenses

Operating expenses include general and administrative expenses, selling and marketing expenses, depreciation, research and development expenses, and compensation costs, including incentive compensation. Operating expenses increased 58.6%, or $11,900,144 for the three months ended September 30, 2015 compared to the three months ended September 30, 2014, primarily due to the reasons set forth below and the expenses due to X-spine acquisition which includes "Acquisition and Integration related expenses" and the "Extinguishment of Debt".

General and Administrative

General and administrative expenses consist principally of corporate personnel, cash based and stock option compensation related costs and corporate expenses for legal, accounting and other professional fees as well as occupancy costs. General and administrative expenses increased 32.1%, or $2,140,122, to $8,805,104 for the nine months ended September 30, 2015 compared to the same period of 2014 due. Most of the increase is due to the acquisition of X-spine, additional head count in operations as a result of increased sales activity and a one time entry of bad debt expense.

Sales and Marketing

Sales and marketing expenses primarily consist of costs for sales and marketing personnel, sales commissions, costs for trade shows, sales conventions and meetings, travel expenses, advertising and other sales and marketing related costs. In addition, stock option compensation expense associated with our sales force is also included in sales and marketing expenses. Sales and marketing expenses increased 46.8%, or $5,792,093, to $18,179,552 for the nine months ended September 30, 2015 compared to $12,387,459 for the same period of 2014. The increase is due to the acquisition of X-spine and to increased commissions tied to increased revenues and the addition of the increased number of sales assets. As a percentage of revenue, sales and marketing expenses increased to 49.0% in the first nine months of 2015 from 47.2% in the prior year’s first nine months.

Research and Development

Research and development expenses consist primarily of internal costs for the development of new technologies and processes for our regenerative orthopedic product lines. Research and development expenses increased $564,085 or 59.1% from $955,111 for the first nine months ended September 30, 2014 to $1,519,196 for the same period of 2015. Most of the increase is due to the acquisition of X-spine.

Depreciation and Amortization

Depreciation and amortization expense consists of depreciation of long-lived property and equipment, patents and intangible assets that resulted from the acquisition of X-spine. Depreciation and amortization expense increased $1,549,651 to $1,765,994 for the nine months ended September 30, 2015 from $216,343 in the same period in 2014. Almost all of the increase is due to the amortization of the intangible assets that resulted from the acquisition of X-spine.

Acquisition and Integration Related Expenses

Acquisition and Integration related expenses are $3,856,519 for the nine months ended September 30, 2015. Acquisition related expenses consisted of investment banking, accounting, consulting, legal fees and miscellaneous expenses associated with the due diligence and execution of the acquisition. Integration related expenses consist of samples, travel and meeting, severance due to reduction in force, retention bonuses and software. We anticipate additional expenses to occur during the fourth quarter of 2015 and the first quarter of 2016.

Extinguishment of Debt

Extinguishment of Debt expenses are $2,345,019 for the nine months ended September 30, 2015 and are related to the Amended and Restated Credit Agreement with ROS Acquisition Offshore LP (“ROS”) and is recorded in accordance with ASC Subtopic 470-50, Debt Modifications and Extinguishments and ASC Subtopic 470-60, Troubled Debt Restructuring by Debtors. The expense consists of the write-off of the royalty liability offset by the debt discount and capitalized expenses associated with the issuance of the original debt agreement, including amendments, with ROS.

Non-cash Consulting Expense

Non-cash consulting expense consists of non-cash expense associated with granting restricted stock and stock to directors and consultants. Non-cash consulting expense increased $108,945 to $190,869 for the first nine months ended September 30, 2015 from $81,924 in the same period in the prior year.

Interest Expense

Interest expense is from our debt instruments. Interest expense for the first nine months of 2015 increased $714,832 to $4,930,941 as compared to $4,216,109 in the first nine months of 2014 due to increased long term and convertible debt issued in part to finance the acquisition of X-spine..

Change in Warrant Derivative Liability

For the nine months ended September 30, 2015, the Company recorded an expense in its non-cash warrant derivative liability of $78,923 which was primarily driven by an increase in the closing price of the Company’s common stock from December 31, 2014 to September 30, 2015. The liability is associated with the issuance of warrants as part of the Company’s prior convertible debt financing, the Company’s 2010 financing and the Company’s 2014 equity financing which contain certain provisions requiring the Company to record a change in the warrant derivative liability from period to period.

Non-Cash Consideration Associated with Stock Agreement

In the first quarter of 2015 we issued 154,189 shares of our common stock which were valued at $3.62 per share or $558,185 to Aspire Capital as a commitment fee.

Other Income/Expense

Other expense for the nine months ended September 30, 2015 was $193,052 as compared to an expense of $253,289 in the same period in 2014.

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Liquidity and Capital Resources

Since our inception, we have historically financed our operations through operating cash flows, as well as the private placement of equity securities and convertible debt, an equity credit facility and other debt transactions.

For the nine months ended September 30, 2015, we received $68 million from the issuance of the Notes, and we borrowed an additional $18 million under an amended and restated credit facility with ROS (See Note 9, “Long-Term Debt” above). After payment of the consideration and expenses related to the acquisition and related financing transactions, our cash on hand increased by approximately $8.6 million.

We also received $2,137,439 from the sale of our common stock to Aspire Capital pursuant to a Purchase Agreement. See Note 3, “Equity” above, describing the Purchase Agreement with Aspire Capital. At September 30, 2015, we had $21,770,771 of cash and cash equivalents and accounts receivable.

Net cash used in operating activities for the first nine months of 2015 was $9,027,080, primarily related to funds required to finance the Company’s operations. For comparable period of 2014, net cash used in operating activities was $5,169,527.

Net cash used in investment activities for the first nine months of 2015 was $73,374,774 due mostly to the acquisition of X-spine and also to the sale/retirement/purchase of property and equipment.

Net cash provided by financing activities was $85,846,261 for the first nine months of 2015, primarily due to proceeds from the sale of equity securities and the issuance of common stock, senior convertible notes and amended and restated credit facility associated with the acquisition of X-spine (See Note 3, “Equity” and Note 9, “Long-Term Debt” above).

Off Balance Sheet Arrangements

We do not have any off balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity or capital expenditures or capital resources that are material to an investor in our shares.

Cash Requirements

We believe that our September 30, 2015 cash on hand and accounts receivable balance of $21,770,771 along with anticipated cash receipts from sales expected from operations and proceeds from the Aspire Capital financing will be sufficient to meet our anticipated cash requirements through December 31, 2016. If we do not meet our revenue objectives, we may need to sell additional equity securities, which could result in dilution to our stockholders, or seek additional loans or alternative sources of financing. 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 limit our ability to expand our business operations and could harm our overall business prospects.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(d) or 15d-15(d) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our management with the participation of our chief executive officer and chief financial officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a–15(e) under the Exchange Act) as of September 30, 2015. Based upon that evaluation, and subject to the completion of the evaluation of X-spine's controls, our chief executive officer and chief financial officer concluded that as of September 30, 2015, our disclosure controls and procedures for Xtant were effective.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting during the quarter ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Other than as previously disclosed in our Form 10-Q for the quarterly period ended June 30, 2015, there is no material litigation pending to which we are a party or to which our property is subject, other than ordinary routine litigation incidental to our business, including product liability disputes.

Item 1A. Risk Factors

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

Risks related to 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.

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

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

Risks Related to X-spine's Business

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

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

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

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

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

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

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

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

Certain of X-spine's former shareholders, who now own over 10% of our common stock, own a controlling share of X-spine's largest supplier, Norwood Tool Company d/b/a Norwood Medical. In 2013 and 2014, products purchased from Norwood Medical accounted for approximately 35% and 22% of product purchases, respectively. X-spine's dependence on Norwood Medical exposes us to risks, including limited control over pricing, availability and delivery schedules. If Norwood Medical ceases to provide X-spine with sufficient quantities of products in a timely manner or on terms acceptable to X-spine, or ceases to manufacture products of acceptable quality, X-spine would have to seek alternate sources of supply. Because of the nature of X-spine's regulatory and quality control requirements, and the proprietary nature of its products, it may not be able to quickly engage additional or replacement suppliers. Any such disruption could harm X-spine's business, results of operations or financial condition.

Risks Related to our Business

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

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

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

Our credit agreement with 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.

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. In addition, affiliates of OrbiMed are significant shareholders and we owe affiliates of OrbiMed approximately $42 million in principal, plus interest and exit fees, pursuant to our Amended and Restated Credit Agreement. Accordingly, OrbiMed may be able to exert significant influence over the Company. Although OrbiMed has been a strong supporter of the Company, OrbiMed may have interests that differ, or, in some cases, conflict with, interests of other shareholders.

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

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

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

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

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

liquidate our assets and possibly even seek bankruptcy protection.

The impact of United States healthcare reform legislation remains uncertain.

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

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

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

We are subject to federal and state healthcare laws and regulations pertaining to fraud and abuse, and physician payment transparency. These laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent;

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

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

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable

compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our relationships with customers, physicians and other healthcare providers, some of whom have ownership interests in the company and recommend and/or use our products, could be subject to challenge under one or more of such laws. We are also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, and distributors may engage in fraudulent or other illegal activity. Misconduct by these parties could include, among other infractions or violations, intentional, reckless and/or negligent conduct or unauthorized activity that violates FDA regulations, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, laws that require the true, complete and accurate reporting of financial information or data or other commercial or regulatory laws or requirements. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

Because of the nature of our business, we are involved from time to time in lawsuits, claims, audits and investigations, including whistleblower actions by private parties and subpoenas from governmental agencies such as the Office of Inspector General of the Department of Health and Human Services ("OIG"). In February 2013, we received a subpoena from the OIG seeking documents in connection with an investigation into possible false or otherwise improper claims submitted to Medicare. The subpoena requested documents related to physician referral programs operated by the Company, which we believe refers to the Company's prior practice of compensating physicians for performing certain educational and promotional services on behalf of the Company during 2009 and 2010. We later learned that this subpoena resulted from a qui tam action that was dismissed without prejudice in 2013 after the Department of Justice declined to intervene.

If our operations are found to violate any of the laws described above or any other laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to market our products and materially adversely affect our business, results of operations and financial condition. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

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

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

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

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

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

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

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

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

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

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

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

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.

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

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

We may be subject to 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.

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

In the United States, the procurement and transplantation of allograft bone tissue is subject to federal law pursuant to the National Organ Transplant Act, or NOTA, a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including bone and related tissue, for "valuable consideration." NOTA permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. We provide services in all of these areas in the United States, with the exception of removal and implantation, and receive payments for all such services. We make payments to certain of

our clients and tissue banks for their services related to recovering allograft bone tissue on our behalf. If NOTA is interpreted or enforced in a manner which prevents us from receiving payment for services we render or which prevents us from paying tissue banks or certain of our clients for the services they render for us, our business could be materially and adversely affected.

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

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

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

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

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

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

Modifications to our products may require new regulatory approvals or clearances, including 510(k) clearances, premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer’s decision and may

disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Certain of our products are regulated as HCT/Ps and are not marketed pursuant to the FDA's medical device regulatory authority, and therefore are not subject to FDA clearance or approval. Although we have not obtained premarket approval for these products, they are nonetheless subject to regulatory oversight. Human tissues intended for transplantation have been regulated by the FDA since 1993. Over the course of several years, the FDA issued comprehensive regulations that address manufacturer activities associated with HCT/Ps. The first requires that companies that produce and distribute HCT/Ps register with the FDA. This set of regulations also includes the criteria that must be met in order for the HCT/P to be eligible for marketing solely under Section 361 of the PHS Act and the regulations in 21 CFR Part 1271, rather than under the drug or device provisions of the FD&C Act or the biological product licensing provisions of the PHS Act. The second set of regulations provides criteria that must be met for donors to be eligible to donate tissues and is referred to as the "Donor Eligibility" rule. The third rule governs the processing and distribution of the tissues and is often referred to as the "Current Good Tissue Practices" rule. The "Current Good Tissue Practices" rule covers all stages of allograft processing, from procurement of tissue to distribution of final allografts. Together these regulations are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients.

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

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

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

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

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

human tissues and cells and cellular or tissue-based products. Some EU member states have their own tissue banking regulations.

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

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

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

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

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

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

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

Failure of our information technology systems could disrupt our business.

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

technology systems could result in breach of contract claims and other damages.

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

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

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

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

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

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

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

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

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

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

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

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

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

We intend to vigorously defend any existing or future litigation that we may be involved in but there can be no assurance that we will prevail in these matters. An unfavorable judgment or settlement may result in a financial burden on us. An unfavorable judgment or settlement may also result in restrictions on our ability to sell certain products and therefore may impact future operating results. Moreover, costs, fees, expenses, settlement amounts,

judgments or other liabilities associated with such matters may not be covered by our insurance and we may be have to pay out-of-pocket.

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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

We issued 140,053 restricted shares of our common stock to certain board members at $3.68 per share, the closing price on September 4, 2015, for aggregate proceeds of approximately $515,395, which we used for working capital and general corporate purposes. The shares were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, as transactions not involving a public offering.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

3.1	Restated Certificate of Incorporation of the Company (filed as Exhibit 3.1 to Quarterly Report on Form 10-Q filed November 14, 2011, incorporated by reference herein).
3.2	Amendment to Restated Certificate of Incorporation of the Company (filed as Exhibit 3.1 to Current Report on Form 8-K filed July 25, 2014, incorporated by reference herein).
3.3	Certificate of Amendment to the Certificate of Incorporation of the Company (filed as Exhibit 3.1 to Current Report on Form 8-K filed August 3, 2015, incorporated by reference herein).
3.4	Amended and Restated Bylaws of the Company (filed as Exhibit 3.2 to Current Report on Form 8-K filed October 1, 2015, incorporated by reference herein).
4.1	Indenture, dated as of July 31, 2015, between the Company and Wilmington Trust, National Association, a national banking association, as Trustee (filed as Exhibit 10.2 to Current Report on Form 8-K filed August 3, 2015, incorporated by reference herein).
4.2	Registration Rights Agreement, dated as of July 31, 2015, among the Company, Leerink Partners LLC, OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP (filed as Exhibit 10.3 to Current Report on Form 8-K filed August 3, 2015, incorporated by reference herein).

10.1	Stock Purchase Agreement, dated as of July 27, 2015, by and among the Company, X-spine Systems, Inc., and the Sellers named therein (filed as Exhibit 10.1 to Current Report on Form 8-K filed July 28, 2015, incorporated by reference herein).
10.2	Amended and Restated Credit Agreement, dated as of July 27, 2015, by and among Bacterin International, Inc., as the Borrower, the Lenders party thereto, and ROS Acquisition Offshore LP, as the Administrative Agent (filed as Exhibit 10.2 to Current Report on Form 8-K filed July 28, 2015, incorporated by reference herein).
10.3	Termination of Royalty Agreement, dated as of July 27, 2015, by and between Bacterin International, Inc. and ROS Acquisition Offshore LP (filed as Exhibit 10.3 to Current Report on Form 8-K filed July 28, 2015, incorporated by reference herein).
10.4	Securities Purchase Agreement, dated as of July 27, 2015, by and among the Company, ROS Acquisition Offshore LP and OrbiMed Royal Opportunities II (filed as Exhibit 10.4 to Current Report on Form 8-K filed July 28, 2015, incorporated by reference herein).
10.5	Purchase Agreement, dated as of July 27, 2015, by and between the Company and Leerink Partners LLC (filed as Exhibit 10.5 to Current Report on Form 8-K filed July 28, 2015, incorporated by reference herein).
10.6	Distribution Agreement, dated as of January 23, 2014, between X-spine Systems, Inc. and Zimmer Spine, Inc., as amended (filed as Exhibit 10.1 to Current Report on Form 8-K filed August 3, 2015, incorporated by reference herein).
10.7	Employment Agreement, dated as of July 31, 2015, between X-spine Systems, Inc. and/or the successor thereof, and David Kirschman (filed as Exhibit 10.4 to Current Report on Form 8-K filed August 3, 2015, incorporated by reference herein).
10.8	Amended and Restated Xtant Medical Equity Incentive Plan
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	* Section 1350 Certification of Chief Executive Officer
32.2	* Section 1350 Certification of Chief Financial Officer
101.INS	XBRL INSTANCE DOCUMENT
101.SCH	XBRL TAXONOMY EXTENSION SCHEMA
101.CAL	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE

101.DEF XBRL TAXONOMY EXTENSION DEFINITION LINKBASE

101.LAB XBRL TAXONOMY EXTENSION LABEL LINKBASE

101.PRE XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE

*Furnished herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

XTANT MEDICAL
HOLDINGS, INC.

Date: November 16, 2015 By: /s/ John P. Gandolfo
Name: John P. Gandolfo
Title: Chief Financial Officer