Bacterin International Holdings, Inc.
Form 424B5
July 31, 2014

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Registration No. 333-194944

The information in this preliminary prospectus supplement is not complete and may be changed. A registration statement relating to these securities has been declared effective by the Securities and Exchange Commission. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JULY 31, 2014

PROSPECTUS SUPPLEMENT

(To Prospectus dated March 31, 2014)

Shares of Common Stock, $ per share

Warrants to Purchase Shares of Common Stock

_____

We are offering shares of our common stock and warrants to purchase shares of our common stock (and the shares of common stock that are issuable from time to time upon the exercise of the warrants). Each share of common stock is being sold together with a warrant to purchase of a share of our common stock at an exercise price of $ per share.

Our common stock is listed on the NYSE MKT exchange and traded under the symbol "BONE." On July 30, 2014, the last reported sales price of our common stock was $6.92 per share. We do not intend to list the warrants on the NYSE MKT or any other securities exchange. As of July 31, 2014, the aggregate market value of our outstanding voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold on June 12, 2014, was $32,922,029 based on 5,526,898 shares of outstanding common stock as of July 31, 2014, of which 4,220,773 were held by non-affiliates, as adjusted for our recent 1:10 reverse stock split. During the twelve calendar months prior to and including the date hereof, we have not sold any securities pursuant to General Instruction I.B.6. of Form S-3.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page S-11 of this prospectus supplement and page 4 of the accompanying prospectus to read about factors you should consider before investing in the securities.

We expect that delivery of the securities being offered pursuant to this prospectus supplement and the accompanying prospectus will be made to purchasers on or about , 2014.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share and Corresponding Warrant	Total
Public offering price	$	$
Underwriting discount[(1)]	$	$
Proceeds, before expenses, to Bacterin International Holdings, Inc.	$	$

———————

[(1)] We have also agreed to reimburse the underwriters for all reasonable out-of-pocket expenses incurred by them in connection with the offering, including the fees and disbursement of counsel, up to a maximum of $150,000. For additional information about compensation paid to the underwriters, see "Underwriting" beginning on page S-30.

Northland Capital Markets

The date of this prospectus supplement is , 2014.

Table of Contents

Prospectus Supplement

Accompanying Prospectus

ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a "shelf" registration process. Under this shelf registration process, we may sell, either separately or together, common stock, preferred stock, warrants, and units from time to time in one or more offerings up to an aggregate initial offering price of $50,000,000.

The accompanying prospectus provides you with a general description of the securities we may offer. In this prospectus supplement, we provide you with specific information about this offering of shares of our common stock, $0.000001 par value per share, and warrants to purchase shares of our common stock. Both this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, include important information about us, our common stock, the warrants and other information you should know before investing. Any statement contained in this prospectus supplement, the accompanying prospectus or in a document incorporated by reference shall be deemed to be modified or superseded to the extent that a statement contained herein or in any subsequently filed document which is incorporated by reference modifies or supersedes such earlier statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement or the accompanying prospectus. You should read both this prospectus supplement and the accompanying prospectus as well as the documents incorporated herein and therein before investing in our securities.

You should rely only on the information incorporated by reference or presented in this prospectus supplement and the accompanying prospectus. Neither we nor the placement agent have authorized anyone else to provide you with different information. You should not assume that the information in this prospectus supplement, the accompanying prospectus or in any document incorporated herein or therein by reference is accurate as of any date other than the dates on the front of those documents, regardless of the time of delivery of this prospectus supplement or any sale of our securities.

As used in this prospectus, unless the context otherwise requires, references to "we," "us," "our," "Bacterin" and "the Company" refer to Bacterin International Holdings, Inc. and its wholly owned subsidiary, Bacterin International, Inc.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this prospectus that are not purely historical are forward-looking statements within the meaning of applicable securities laws. Our forward-looking statements include, but are not limited to, statements regarding our "expectations," "hopes," "beliefs," "intentions," or "strategies" regarding the future. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any

underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “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 prospectus may include, for example, statements about:

- our ability to obtain financing on reasonable terms;
- our ability to increase revenue;
- our ability to remain listed on the NYSE MKT exchange;
- our ability to comply with the covenants in our credit facility;
- our ability to maintain sufficient liquidity to fund our operations;
- the ability of our sales force to achieve expected results;

- our ability to remain competitive;
- government regulations;
- our ability to 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;
- our ability to successfully integrate future business combinations or acquisitions;
- product liability claims and other litigation to which we may be subjected;
- product recalls and defects;
- timing and results of clinical studies;
- our ability to obtain and protect our intellectual property and proprietary rights;
- infringement and ownership of intellectual property;
- influence by our management; and
- our ability to issue preferred stock.

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

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents incorporated by reference. This summary is not complete and does not contain all of the information that you should consider before investing in our securities. To fully understand this offering and its consequences to you, you should read this entire prospectus supplement and the accompanying prospectus carefully, including the information referred to under the heading "Risk Factors" in this prospectus supplement beginning on page S-11, the financial statements and other information incorporated by reference in this prospectus supplement and the accompanying prospectus when making an investment decision. This is only a summary and may not contain all the information that is important to you.

About Bacterin International Holdings, Inc.

We develop, manufacture and market biologics products to domestic and international markets through our biologics division. Our bone graft products are used in a variety of applications including enhancing fusion in spine surgery, relief of back pain through facet joint stabilization, promotion of bone growth in foot and ankle surgery, promotion of skull healing following neurosurgery and subchondral bone repair in knee and other joint surgeries. Our acellular dermis scaffolds are utilized in wound care and plastic and reconstructive procedures.

Our medical devices division develops coatings for medical devices and custom surgical instruments for use with allografts processed by our biologics division. Our medical devices division also works with our biologics division to produce and distribute OsteoSelect® DBM putty, a Class II device that is an osteoinductive product used by surgeons as a bone void filler in the extremities and pelvis. DBM putty is considered a combination product by regulatory agencies — both a tissue and a medical device.

We are a Delaware corporation. Our executive offices are located at 664 Cruiser Lane, Belgrade, Montana 59714 and our telephone number is (406) 388-0480. Our website is located at www.bacterin.com. The information on our website is not part of this prospectus.

Recent Developments

On July 25, 2014, we filed a Certificate of Amendment of Restated Certificate of Incorporation (the "Amendment") with the Delaware Secretary of State. The Amendment provided for the reclassification and combination of each ten shares of our common stock into one share of common stock effective July 25, 2014 at 5:00 p.m. Eastern Time (the "Reverse

Stock Split"). The Reverse Stock Split was effective for trading purposes beginning Monday, July 28, 2014. All share and per share amounts in this prospectus supplement are stated on a post-reverse split basis.

Securities Being Offered

We are offering shares of our common stock, par value $0.000001 per share, together with warrants to purchase shares of common stock in this offering. Each share of common stock sold in this offering will be sold with a warrant to purchase ___ of a share of common stock at an exercise price of $____ per share. The warrants are exercisable for a period of five years beginning the first day after the closing of this offering.

Subject to compliance with any applicable securities laws, any portion of a warrant may be transferred by the warrant holder upon surrender of the warrant. The warrants will not be listed on the NYSE MKT or any other securities exchange and there is currently no established trading market for the warrants. We do not intend to make a market in the warrants and do not expect that one will develop. Therefore, the warrant holders may have to hold the warrants they purchase in this offering, until such time, if any, as they wish to exercise them. The warrant holders do not have the rights or privileges of holders of common stock and any voting rights until they exercise their warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the warrants, each holder will be entitled to one vote for each share held on record on all matters to be voted on by stockholders.

Pursuant to the terms of the warrants, warrant holders are not permitted to exercise the warrants for an amount of common stock that would result in a holder owning more than 9.99% of our common stock outstanding after the exercise.

We will not be required to issue any fractional shares of our common stock upon the exercise of a warrant. Instead, the Company may elect to either pay cash equal to the product of such fraction multiplied by the closing price of one warrant share on the date of exercise or have the number of shares of common stock exercised will be rounded up to the nearest whole number.

The exercise price and number of shares of common stock issuable on exercise of the warrants may be adjusted in certain circumstances including in the event of our recapitalization, reorganization, merger or consolidation.

We will attempt to maintain the effectiveness of a current prospectus covering the common stock issuable upon exercise of the warrants until the expiration of the warrants. However, we cannot assure you that we will be able to do so and we may not be able to maintain our eligibility to use such current prospectus. If the prospectus relating to the common stock issuable upon the exercise of the warrants is not current or if we are not eligible to use such current prospectus or if the common stock is not qualified or exempt from qualification in the jurisdictions in which the holders of the warrants reside, the warrants may have no value.

NYSE MKT Below Compliance Status

Our common stock is currently listed on the NYSE MKT in below compliance status due to our failure to maintain $6 million in shareholder equity.

On May 13, 2013, we received a deficiency notice from the NYSE MKT exchange notifying us that we are not in compliance with Section 1003(a)(iii) of the Company Guide with stockholders' equity of less than $6,000,000 and net losses in five of our most recent fiscal years and Section 1003(a)(ii) with stockholders' equity of less than $4,000,000 and net losses in three of our four most recent fiscal years. On June 12, 2013 we submitted a plan to regain compliance with the continued listing requirements, and on June 21, 2013 the NYSE MKT informed us of the acceptance of our plan and gave us an extension until November 13, 2014 to regain compliance with the continued listing standards. On November 19, 2013, we received another letter from the NYSE MKT notifying us that we are not in compliance with Section 1003(a)(i) of the Company Guide with stockholders' equity of less than $2,000,000 as of September 30, 2013 and net losses in two of three of our most recent fiscal years, and we submitted an amended plan to regain compliance. In order to regain compliance, we need to increase our shareholders' equity to $6,000,000 by November 13, 2014. There can be no assurance that we will be able to regain compliance with the NYSE MKT continued listing standards.

Government Regulations

Food and Drug Administration

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

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

· product design, development and manufacture;

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

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

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

- notices of correction or removal and recall regulations.

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

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

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

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

FDA's premarket clearance and approval requirements

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

• Class I devices, which are subject to only general controls (e.g., labeling, medical devices reporting, and prohibitions against adulteration and misbranding) and, in some cases, to the 510(k) premarket clearance requirements;

• Class II devices, generally requiring 510(k) premarket clearance before they may be commercially marketed in the United States; and

• Class III devices, consisting of devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device, generally requiring submission of a PMA supported by clinical trial data.

510(k) Clearance Pathway

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

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

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

Premarket Approval (PMA) Pathway

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

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

Clinical Trials

Clinical trials are generally required to support a PMA 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 an nonsignificant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an 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. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the United States.

FDA Regulation of Human Tissue Products

The FDA regulates the manufacture of human tissue products under the authority of the PHSA and, in some cases, under the Federal Food, Drug, and Cosmetic Act (FDCA) as well. Human tissues are subject to the FDA's Human Cells, Tissues, and Cellular and Tissue-Based Products Regulations ("HCT/Ps"), or may also be subject to FDA's drug, biological product, or medical device regulations.

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

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

THE OFFERING

Common stock offered by us	shares of common stock. Each share of common stock is being sold together with a warrant to purchase of a share of common stock.
Warrants offered by us	Warrants to purchase up to shares of common stock. Each warrant will have an exercise price of $ per share, will be exercisable for a period of five years beginning the first day after the closing of the offering. This prospectus also relates to the offering of shares of common stock issuable upon the exercise of the warrants.
Public offering price of combined common stock and warrant to purchase of a share of common stock	$
Common stock to be outstanding immediately after the offering	shares
Use of proceeds	We intend to use the net proceeds from the sale of the securities under this prospectus together with our existing cash resources primarily for working capital and general corporate purposes. See “Use of Proceeds.”
Risk factors	Investing in our securities involves a high degree of risk. You should read the “Risk Factors” beginning on page S-11 of this prospectus supplement, on page 2 of the accompanying prospectus and in the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, including our Annual Report on Form 10-K for the year ended December 31, 2013 filed with the SEC on March 27, 2014, for a discussion of factors to consider before deciding to purchase shares of our common stock.
NYSE MKT symbol	Our common stock is listed on the NYSE MKT under the symbol “BONE.” We do not intend to list the warrants on the NYSE MKT or any other securities exchange.

The number of shares of common stock to be outstanding after this offering as reflected in the table above is based on the actual number of shares outstanding as of July 28, 2014 which was 5,526,898, and does not include, as of that date:

- 423,162 shares of common stock issuable upon the exercise of outstanding options granted under our stock option plans, with a weighted average exercise price of $14.9 per share;
- 1,083,820 shares of common stock issuable upon exercise of warrants, with a weighted average exercise price of $16.2 per share;
- Approximately 153,000 shares of common stock reserved for future issuance under our stock option plans; and

_____ shares of common stock issuable upon exercise of warrants in this offering, with an exercise price of $ _____ per share.

RISK FACTORS

An investment in our securities involves a high degree of risk. Before making an investment decision, you should consider carefully the risks discussed below and under the sections captioned "Risk Factors" set forth in the documents and reports filed by us with the SEC, that are incorporated by reference into this prospectus, including in our most recent Annual Report on Form 10-K, as revised or supplemented by our Quarterly Reports on Form 10-Q, each of which are on file with the SEC and are incorporated herein by reference, before deciding whether to invest in our securities. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our securities could decline due to any of these risks, and you may lose all or part of your investment.

See "Risk Factors" beginning on page 2 of the accompanying prospectus.

Risks Related to this Offering

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, including ours, 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;
- halting or suspension of trading in our common stock by the NYSE MKT;
- 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 to reduce premium expense, 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.

Because we became public through a reverse merger, we may not be able to attract the attention of major brokerage firms or certain investors.

There are coverage risks associated with our becoming public through a reverse merger, including, among other things, security analysts of major brokerage firms may not provide coverage of us since there is no incentive to brokerage firms to recommend the purchase of our common stock. In addition, we may not attract the attention of major brokerage firms and certain investors due to our low stock price. We cannot assure you that brokerage firms would want to conduct any public offerings on our behalf in the future.

If securities or industry analysts publish inaccurate or unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who covers us downgrades our common stock, changes their opinion of our shares or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease and we could lose visibility in the financial markets, which could cause our stock price and trading volume to decline.

Shares of common stock are equity securities and are subordinate to any indebtedness.

Shares of our common stock are common equity interests. This means that our common stock will rank junior to any outstanding shares of our preferred stock that we may issue in the future or to our current credit agreement and any future indebtedness we may incur and to all creditor claims and other non-equity claims against us and our assets

available to satisfy claims on us, including claims in a bankruptcy or similar proceeding.

Additionally, unlike indebtedness, where principal and interest customarily are payable on specified due dates, in the case of our common stock, (i) dividends are payable only when and if declared by our board of directors or a duly authorized committee of our board of directors, and (ii) as a corporation, we are restricted to making dividend payments and redemption payments out of legally available assets. We have never paid a dividend on our common stock and have no current intention to pay dividends in the future. Furthermore, our common stock places no restrictions on our business or operations or on our ability to incur indebtedness or engage in any transactions, subject only to the voting rights available to shareholders generally.

We do not anticipate paying dividends in the foreseeable future; you should not buy our stock if you expect dividends.

Sales of securities in this offering may result in substantial dilution to the interests of holders of our securities. The sale of securities in this offering, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at prices that we might otherwise wish to effect sales. Depending on market liquidity at the time, a sale of securities in this offering at any given time could cause the trading price of our common stock to decline. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

Our management will have broad discretion in the use of the net proceeds we receive in this offering and might not apply the proceeds in ways that increase the value of your investment.

Our management will have broad discretion over the use of our net proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment and we might not be able to yield a significant return, if any, on any investment of these net proceeds. Our failure to apply these funds effectively could have a material adverse effect on our business and cause the price of our common stock to decline.

Investors in this offering will experience immediate and substantial dilution.

If you purchase shares in this offering, you will incur immediate and substantial dilution of approximately $ per share, representing the difference between the price per share you pay and the net tangible book value per share of our common stock immediately after this offering. Any exercise of outstanding stock options, warrants or other equity awards will result in further dilution. For a further description of the dilution that you will experience immediately after this offering, see “Dilution.”

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

Sales of securities in this offering may result in substantial dilution to the interests of holders of our securities. The sale of securities in this offering, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at prices that we might otherwise wish to effect sales. Depending on market liquidity at the time, a sale of securities in this offering at any given time could cause the trading price of our common stock to decline. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

There is no public market for the warrants to purchase shares of our common stock offered by us in this offering.

There is no established public trading market for the warrants offered in this offering, and we do not expect a market to develop. In addition, we have not listed, and do not intend to apply to list, the warrants on any securities exchange or other nationally recognized trading system, including the NYSE MKT. Without an active market, the liquidity of

the warrants will be limited.

We may need to split the proceeds from future offerings with ROS Acquisition Offshore LP

Our credit agreements with ROS Acquisition Offshore LP ("ROS") include an obligation on our part to split the net proceeds from equity offerings evenly with ROS above $15 million in the aggregate. We do not anticipate that this offering, when combined with the $4.8 million we raised in our previous offering in June 2012, will exceed the $15 million threshold in the aggregate. However, future offerings may, when combined with previous offerings, take us above the $15 million threshold in the aggregate, at which point we would be obligated to split the net proceeds of any such future offering evenly with ROS. This would reduce the net proceeds to us, which may affect our ability to raise capital in the future.

Risks Related to our Business

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

Our debt agreements with ROS Acquisition Offshore LP ("ROS") contain representations, warranties, fees, affirmative and negative covenants, including a minimum cash balance 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 ROS facility, we pledged substantially all of our assets, including our intellectual property, to ROS. Our failure to comply with the covenants under the ROS credit facility could result in an event of default, the acceleration of our debt and the loss of our assets.

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 will need to raise additional capital, which would result in dilution to our stockholders, or seek additional loans. The incurrence of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. Financing may not be available in amounts or on terms acceptable to us, if at all. Any failure by us to raise additional funds on terms favorable to us, or at all, could result in our inability to pay our expenses as they come due, limit our ability to expand our business operations, and harm our overall business prospects.

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

We may not continue to satisfy the continued listing requirements of the NYSE MKT exchange.

We are currently listed on the NYSE MKT exchange, which imposes both objective and subjective requirements for continued listing. Continued listing criteria include the financial condition of the company, market capitalization, shareholder equity, total assets, annual revenue, and low selling price. We currently have a below compliance status with the NYSE MKT, we are operating at a loss, we have negative shareholder equity, and our market capitalization, total assets and annual revenue are all currently less than $50 million, so our continued listing is at risk. If the NYSE MKT determines that we fail to satisfy the requirements for continued listing, we could be de-listed from the exchange, which could result in reduced liquidity for our shareholders. There can be no assurance that we will satisfy the continued listing requirements of the NYSE MKT or that we will continue to be listed on any exchange.

On May 13, 2013, we received a deficiency notice from the NYSE MKT exchange notifying us that we are not in compliance with Section 1003(a)(iii) of the Company Guide with stockholders' equity of less than $6,000,000 and net losses in five of our most recent fiscal years and Section 1003(a)(ii) with stockholders' equity of less than $4,000,000 and net losses in three of our four most recent fiscal years. On June 12, 2013 we submitted a plan to regain compliance with the continued listing requirements, and on June 21, 2013 the NYSE MKT informed us of the acceptance of our plan and gave us an extension until November 13, 2014 to regain compliance with the continued

listing standards. On November 19, 2013, we received another letter from the NYSE MKT notifying us that we are not in compliance with Section 1003(a)(i) of the Company Guide with stockholders' equity of less than $2,000,000 as of September 30, 2013 and net losses in two of three of our most recent fiscal years, and we submitted an amended plan to regain compliance. We will continue to be subject to periodic review by the NYSE MKT during the extension period and failure to make progress consistent with our Plan or to regain compliance by the end of the extension period could result in our delisting from the Exchange.

In order to regain compliance, we will either need to increase our market capitalization or shareholders' equity. In order to increase our shareholder's equity, we may need to raise substantial equity capital, which would be dilutive to existing shareholders and may require shareholder approval. There can be no assurance that we will obtain any necessary shareholder approval or raise sufficient equity capital to regain compliance with the NYSE MKT continued listing standards.

The impact of United States healthcare reform legislation remains uncertain.

In 2010 federal legislation, the Patient Protection and Affordable Care Act (PPACA), to reform the United States healthcare system was enacted into law. The law was upheld by a Supreme Court decision announced in June 2012. The legislation is far-reaching and is intended to expand access to health insurance coverage, improve quality and reduce costs over time. Among other things, the new law imposes a 2.3 percent excise tax on medical devices beginning January 2013, which applies to United States sales of our medical device products, including our wound drains and OsteoSelect® DBM putty. 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 this legislation, 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 face risks and uncertainties relating to an OIG subpoena.

In February 2013, we received a subpoena from the Office of the Inspector General of the U.S. Department of Health and Human Services ("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. This program was discontinued in 2010. We provided an initial response to the OIG subpoena and have not received any further correspondence or requests from the OIG. Although it does not appear that the OIG is actively pursuing the investigation at the present time, we cannot assure you that the OIG will not resume the investigation in the future. Any further investigation by the OIG could divert management's attention from business demands and subject us to significant legal expenses.

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 payer 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.

Competition from former Chief Executive Officer

Our former Chief Executive Officer, Guy Cook, has acquired an ownership interest in a tissue bank that sells competitive products. Because our former CEO has in depth knowledge about our customers, employees, consultants, products, policies, practices and prospects, and is not bound by a non-compete agreement, we may be adversely affected by increased competition with that business.

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

Our business is in a very competitive and evolving field. Rapid new developments in this field have occurred over the past few years, and are expected to continue to occur. Other companies already have competing products available or may develop products to compete with ours. Many of these products have short regulatory timeframes and our competitors, many with more substantial development resources, may be able to develop competing products that are

equal to or better than ours. This may make our products obsolete or undesirable by comparison and reduce our revenue. Our success will depend, in large part, on our ability to maintain a competitive position concerning our intellectual property, and to develop new technologies and new applications for our technologies. Many of our competitors have substantially greater financial and technical resources, as well as greater production and marketing capabilities, and our ability to compete remains uncertain.

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

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

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

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

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

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

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

The markets for our products and services are characterized by rapid technological change, frequent new introductions, changes in customers' demands and evolving industry standards. Accordingly, we will need to continue

to innovate and develop additional products. These efforts can be costly, subject to long development and regulatory delays and may not result in products approved for sale. These costs may hurt operating results and may require additional capital. If additional capital is not available, we may be forced to curtail development activities. In addition, any failure on our behalf to react to changing market conditions could create an opportunity for other market participants to capture a critical share of the market within a short period of time.

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

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

Loss of key members of our management who 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.

We will be required to invest in facilities and equipment on a continuing basis, which will put pressure on us to finance these investments.

We have invested, and intend to continue to invest, in facilities and state-of-the-art equipment in order to increase, expand or update our capabilities and facilities. Changes in technology or sales growth beyond currently established production capabilities, which we anticipate, will require further investment. We currently anticipate that we will need to spend between $4 and $5 million over the next five years in order to increase, expand or update our existing facilities to meet our expected growth over that period. However, there can be no assurance that we will generate sufficient funds from operations to maintain our existing facilities and equipment or to finance any required capital investments or that other sources of funding will be available. Additionally, there can be no guarantee that any future expansion will not negatively affect earnings.

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.

We are dependent on the ability of our licensees and development partners for obtaining regulatory approvals and market acceptance of their products, for which we may have no control.

Our success may depend on our ability, or that of our licensees, to obtain timely regulatory approval for products employing our technology. Moreover, our success may also depend on whether, and how quickly, our licensees gain market acceptance of products incorporating our technology, compared to competitors using competing technologies.

Our revenues will depend upon prompt and adequate 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. We may have difficulty gaining market acceptance for our products if government and third-party payors do not provide adequate coverage and reimbursement to hospitals. 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 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.

Future business combinations or acquisitions may be difficult to integrate and cause our attention to be diverted.

We may pursue various business combinations with other companies or strategic acquisitions of complementary businesses, product lines or technologies. There can be no assurance that such acquisitions will be available at all, or on terms acceptable to us. These transactions may require additional financing which may increase our indebtedness or outstanding shares, resulting in dilution to stockholders. The inability to obtain such future financing may inhibit our growth and operating results. Integration of acquisitions or additional products can be time consuming, difficult and expensive and may significantly impact operating results. Furthermore, the integration of any acquisition may divert management’s time and resources from our core business. We may sell some or all of our product lines to other companies or may agree to combine with another company. Selling some of our product lines may inhibit our ability to generate positive operating results going forward.

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

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

U.S. governmental regulation could restrict the use of our 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. 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 other 510(k)-cleared products. 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.

Some of our new products will require FDA clearance of a 510(k). Other products will require the approval of a PMA. In addition some of our new 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 an nonsignificant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an 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 products are 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 for which we obtain clearance or approval, 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 FDA's Quality System Regulations, or QSR, 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 for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce the QSR 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 products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances or HDE 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 adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

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

We received a Warning Letter from the FDA on January 28, 2013 concerning the facility located at 600 Cruiser Lane, Belgrade, MT (Site 600). The Warning Letter addressed issues regarding aspects of Bacterin's quality system with a focus on OsteoSelect DBM Putty which is both a tissue and a device. We responded to the Warning Letter on February 2, 2013, and provided periodic response updates on March 20, 2013, April 15, 2013 and May 20, 2013. We developed and implemented a corrective action strategy that we believed addressed all of FDA's concerns. While we believe that we have developed and have implemented a corrective action strategy that we believe addresses all of FDA's concerns, there is a chance that FDA will not agree with our proposed corrective actions. If FDA does not agree with our proposed actions, they could issue another Warning Letter, request that we take additional actions, or take additional enforcement actions. FDA conducted a re-inspection of Site 600 from July 8, 2013 to July 12, 2013, which evaluated the completion of the corrective actions and resulted in the issuance of an unrelated FDA-Form 483 on July 12, 2013. We responded to the FDA-Form 483 on August 1, 2013, and provided periodic response updates on August 13, 2013, September 26, 2013, October 31, 2013 and December 4, 2013. On October 29, 2013, we received an Establishment Inspection Report (EIR) for this re-inspection. At this time, we do not know whether or when FDA will conduct an additional follow up inspection. In addition, from July 22, 2013 to August 2, 2013, FDA conducted a tissue-focused inspection of Site 600 which resulted in an FDA-Form 483. We responded to the FDA-Form 483 on August 22, 2013. At this time, we do not know whether this inspection will lead to an enforcement action or when FDA will close out this inspection.

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

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. Under FDA HCT/P reporting regulations, 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, 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, will 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 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 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.

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 human cells, tissues and cellular and tissue-based products, or 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 include state agencies with statutes 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 European Union 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.

Many companies to which we supply our products also are subject to extensive regulation by the U.S. Food and Drug Administration. Their failure to meet strict regulatory requirements could adversely affect our business.

Medical devices that incorporate coatings technology are subject to extensive regulation by the FDA and equivalent foreign regulatory authorities. Generally, any medical device manufacturer that wishes to incorporate our coatings technology into its products will be responsible for obtaining FDA clearance or approval for the medical devices it intends to market though we will assist in the 510(k) or PMA filing submitted by licensees. Some of these products may require clinical trials to support regulatory approval and we may not successfully complete these clinical trials. The FDA process can take several months to several years in the United States. The time required to obtain approval for international sales may be longer or shorter, depending on the laws of the particular country. There can be no assurance that our licensees will be able to obtain FDA or international approval on a timely basis. The FDA may not approve or clear these customer products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our licensees' requests for 510(k) clearance or premarket approval of their products. Failure to receive clearance or approval for our licensees' products would have an adverse effect on our ability to expand our business.

Approval or clearance may place substantial restrictions on the indications for which the licensees' products may be marketed or to whom it may be marketed, warnings that may be required to accompany the product or additional restrictions placed on the sale and/or use of the product. Changes in regulations or adoption of new regulations could also cause delays in obtaining product approval. In addition, regulatory approval is subject to continuing compliance with regulatory standards, and product approval is subject to withdrawal if a licensee fails to comply with standards, or if an unforeseen event should occur concerning a product. Significant delays in obtaining product approval could have a significantly detrimental impact on our business.

In addition, modifications to our licensees' products may require new regulatory approvals or clearances, including 510(k) clearances or premarket approvals, or require them to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA may not approve or clear these product modifications for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our licensees' requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products. Failure of our licensees to receive clearance or approval for new or modified products would have an adverse effect on our ability to supply our product.

Finally, FDA and equivalent foreign regulatory authorities may conduct periodic audits or inspections of our licensees' facilities to monitor their compliance with applicable regulatory standards. If the FDA finds that a facility has failed to comply with applicable regulations, the agency can institute a wide variety of enforcement actions, ranging from warning letters or untitled letters; fines and civil penalties; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, products; withdrawal or suspension of approval of products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; orders for physician notification or device repair, replacement or refund; interruption of production; operating restrictions; injunctions; and criminal prosecution. Any adverse action by an applicable regulatory agency could impair our licensees' ability to produce products and thus could significantly increase our costs and impact our ability to provide our products to them.

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, or the FDASIA, 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-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 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.

S-25

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 future intellectual property litigation that may arise but there can be no assurance that we will prevail in these matters. An unfavorable judgment may result in a financial burden on us. An unfavorable judgment may also result in restrictions on our ability to sell certain products and therefore may impact future operating results.

USE OF PROCEEDS

We estimate that the net proceeds to us of the sale of the common stock and warrants that we are offering will be approximately $ after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and excluding the proceeds, if any, from the exercise of the warrants issued pursuant to this offering.

We intend to use the net proceeds from this offering primarily for working capital and general corporate purposes. General corporate purposes may include providing working capital, funding capital expenditures, or paying for acquisitions. As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses of the proceeds from this offering.

Our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of these proceeds.

Pending application of the net proceeds from this offering, we may invest such proceeds in short-term, interest-bearing, investment-grade securities.

DILUTION

Our net negative tangible book value on March 31, 2014 was approximately $7.2 million, or approximately $1.20 per share of common stock. After giving effect to the sale of shares of common stock offered by us in this offering at a price of $ per share, less the underwriting discounts and other expenses of this offering payable by us, our pro forma as adjusted net tangible book value on March 31, 2014 would have been approximately $ million, or $ per share of common stock. The following table illustrates this dilution on a per share basis:

Public offering price per share		$
Net tangible book value per share as of March 31, 2014	$1.20	
Increase in net tangible book value per share attributable to offering	$	
Pro forma net tangible book value per share after giving effect to this offering		$
Dilution per share to investors in the offering		$

The above discussion and table are based on 5,498,212 common shares outstanding at March 31, 2014, and do not include, as of that date:

- shares issuable pursuant to our equity incentive plan, including 758,028 shares issuable upon the exercise of outstanding stock options with a weighted-average exercise price of $14.90 per share and approximately 51,600 shares available for future issuance under our equity incentive plan; and

- 1,087,820 shares of common stock issuable upon exercise of warrants, with a weighted average exercise price of $16.2 per share.

If any shares of our common stock are issued upon exercise of outstanding options or warrants, or warrants issued in this offering, you will experience further dilution.

CAPITALIZATION

Our authorized capital stock consists of 95,000,000 shares of common stock, $0.000001 par value per share, and 5,000,000 shares of preferred stock, $0.000001 par value per share. As of July 28, 2014, we had 5,526,898 outstanding shares of common stock and no outstanding shares of preferred stock.

As of July 28, 2014, we had 423,162 shares of common stock issuable upon the exercise of outstanding options granted under our equity incentive plan at a weighted average exercise price of $14.9 per share, 1,083,820 shares of common stock issuable upon exercise of warrants at a weighted average exercise price of $16.2 per share, and approximately 153,000 shares of common stock available for future issuance under our stock option plans.

Holders of common stock are entitled to one vote for each share held on all matters submitted to a vote of shareholders including in all elections for directors; stockholders are not entitled to cumulative voting in the election of directors.

Holders of outstanding shares of our common stock are entitled to those dividends declared by the Board of Directors out of legally available funds, and, in the event of our liquidation, dissolution or winding up of our affairs, holders are entitled to receive ratably our net assets available to the shareholders. Holders of our outstanding common stock have no preemptive, conversion or redemption rights. All of the issued and outstanding shares of our common stock are, and all unissued shares of our common stock, when offered and sold will be, duly authorized, validly issued, fully paid and nonassessable. To the extent that additional shares of our common stock may be issued in the future, the relative interests of the then existing shareholders may be diluted.

Our authorized but unissued shares of common stock are available for future issuances without shareholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Additional information about our common stock is provided in the accompanying prospectus under “Description of Common Stock.”

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

Listing. The shares of our common stock are currently listed on the NYSE MKT under the symbol “BONE.”

UNDERWRITING

Under the terms and subject to the conditions contained in an underwriting agreement between us and Northland Securities, Inc., as representative of the underwriters, with respect to the shares of common stock and warrants subject to this offering, we have agreed to sell to the underwriters, and the underwriters have severally agreed to purchase, the number shares and warrants provided below opposite their names.

Underwriters	Number of Shares	Number of Warrants
Northland Capital Markets	[ ]	[ ]
Total		

The underwriters are offering the shares of common stock and warrants subject to their acceptance of the securities from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the securities offered by this prospectus supplement are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the securities if any such securities are taken. The underwriters may, but are not obligated to, retain other selected dealers that are qualified to offer and sell the securities and that are members of the Financial Industry Regulatory Authority (FINRA).

Discounts, Commissions and Expenses

The underwriters have advised us that they propose to offer the shares of common stock and warrants to the public at the public offering price set forth on the cover page of this prospectus supplement and to certain dealers at that price less a concession not in excess of $ per share. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of $ per share to certain brokers and dealers. After this offering, the public offering price, concession and reallowance to dealers may be changed by the underwriters. No such change shall change the amount of proceeds to be received by us as set forth on the cover page of this prospectus supplement. The securities are offered by the underwriters as stated herein, subject to receipt and acceptance by them and subject to their right to reject any order in whole or in part.

The underwriters initially propose to offer the shares of common stock and warrants to investors at the public offering price set forth on the cover of this prospectus supplement. The underwriting discount is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. There is no arrangement for funds to be received in escrow, trust or similar arrangement.

We have also agreed to pay the underwriters' reasonable out-of-pocket expenses (including fees and expense of the underwriters' counsel) incurred by the underwriters in connection with this offering up to $150,000. In addition, we estimate that our share of the total expenses of this offering, excluding underwriting discounts and commissions and payment of the underwriters' expenses referred to above, will be approximately $ [ ].

Except as disclosed in this prospectus supplement, the underwriter has not received and will not receive from us any other item of compensation or expense in connection with this offering considered by FINRA to be underwriting compensation under its rule of fair price.

The following table summarizes the compensation and estimated expenses we will pay.

	Per Share of Common Stock and Corresponding Warrant	Total
Public offering price	$	$
Underwriting discount paid by us	$	$

Indemnification of Underwriters

We will indemnify the underwriters against some civil liabilities, including liabilities under the Securities Act of 1933, as amended, and liabilities arising from breaches of our representations and warranties contained in the underwriting agreement. If we are unable to provide this indemnification, we will contribute to payments the underwriters may be required to make in respect of those liabilities.

No Sales of Common Stock

The underwriters have required each of our directors and officers to agree not to offer, sell, agree to sell, directly or indirectly, or otherwise dispose of any shares of common stock without the prior written consent of Northland Securities, Inc. for a period of 90 days after the date of the final prospectus supplement.

The restrictions described in the immediately preceding paragraph do not apply to certain items, including transfers as a bona fide gift or gifts, transfers by will or intestate succession, or to any trust for the direct or indirect benefit of the director or officer or his or her immediate family, provided that in each case any such recipient agrees to be bound by the terms of the restrictions described above, and transfers in connection with the exercise of any stock options that expire during the period described above, to the extent necessary to fund the exercise price of the stock options and any withholding taxes resulting from such exercise.

We have agreed that for a period of 90 days after the date of the final prospectus supplement, we will not, without the prior written consent of Northland Securities, Inc., offer, sell or otherwise dispose of any shares of common stock, except for the shares of common stock offered in this offering, pursuant to our stock option, stock bonus and other stock plans as in effect on such date, pursuant to warrants to purchase capital stack outstanding as of such date or pursuant to certain unregistered private offerings.

The 90-day restricted period in all of the agreements described above is subject to extension if (i) during the last 17 days of the restricted period we issue an earnings release or material news or a material event relating to us occurs or (ii) prior to the expiration of the restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the lock-up period, in which case the restrictions imposed in these lock-up agreements shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event, unless Northland Securities, Inc. waives the extension in writing.

Short Sales, Stabilizing Transactions and Penalty Bids

In order to facilitate this offering, persons participating in this offering may engage in transactions that stabilize, maintain, or otherwise affect the price of our common stock during and after this offering. Specifically, the underwriters may engage in the following activities in accordance with the rules of the SEC.

Short sales. Short sales involve the sales by the underwriters of a greater number of shares than they are required to purchase in the offering. Covered short sales are short sales made in an amount not greater than the underwriters' over-allotment option to purchase additional shares from us in this offering. The underwriters may close out any covered short position by either exercising their over-allotment option to purchase shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are any short sales in excess of such over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

Stabilizing transactions. The underwriters may make bids for or purchases of the shares for the purpose of pegging, fixing, or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.

Penalty bids. If the underwriters purchase shares in the open market in a stabilizing transaction or syndicate covering transaction, they may reclaim a selling concession from the underwriters and selling group members who sold those shares as part of this offering. Stabilization and syndicate covering transactions may cause the price of the shares to be higher than it would be in the absence of these transactions. The imposition of a penalty bid might also have an effect on the price of the shares if it discourages presales of the shares.

The transactions above may occur on the NYSE MKT or otherwise. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares. If these transactions are commenced, they may be discontinued without notice at any time.

Additional Information

In the ordinary course of its business, the underwriters and their affiliates may actively trade or hold our securities for their own accounts or for the accounts of customers and, accordingly, may at any time hold long or short positions in our securities. The underwriters and their affiliates may in the future perform various financial advisory and investment banking services for us, for which they will receive customary fees and expense.

Northland Capital Markets is the trade name for certain capital markets and investment banking services of Northland Securities, Inc., member FINRA/SIPC.

This prospectus supplement may be made available on web sites maintained by the underwriters and the underwriters may distribute prospectuses electronically.

Foreign Regulatory Restrictions on Purchase of the Common Stock

No action may be taken in any jurisdiction other than the United States that would permit a public offering of the common stock or the possession, circulation or distribution of this prospectus supplement in any jurisdiction where action for that purpose is required. Accordingly, the common stock may not be offered or sold, directly or indirectly, and neither the prospectus supplement nor any other offering material or advertisements in connection with the common stock may be distributed or published in or from any country or jurisdiction except under circumstances that will result in compliance with any applicable rules and regulations of any such country or jurisdiction.

If you purchase shares of common stock offered by this prospectus supplement, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus supplement.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference the information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of the prospectus supplement. These documents may include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as Proxy Statements. Any documents that we subsequently file with the SEC will automatically update and replace the information previously filed with the SEC. Thus, for example, in the case of a conflict or inconsistency between information set forth in this prospectus supplement and the accompanying prospectus and information incorporated by reference into this prospectus supplement, you should rely on the information contained in the document filed later.

This prospectus supplement incorporates by reference the documents listed below that we previously have filed with the SEC and any additional documents that we may file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus and the termination of the offering of the securities. These documents contain important information about us.

- Our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 27, 2014;

- Our Quarterly Report on Form 10-Q for the period ended March 31, 2014, filed with the SEC on May 12, 2014;

- Our Current Reports on Form 8-K (other than portions thereof furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits accompanying such reports that are related to such items) filed with the SEC on March 10, 2014 (Items 2.01 and 2.03), May 5, 2015 (Item 5.02), June 13, 2014 (Item 5.07), July 1, 2014 (Item 5.02), July 23, 2014 (Item 8.01), July 25, 2014 (Items 3.03, 5.03 and 8.01), and July 29, 2014 (Item 5.02);

- The description of our common stock contained in our registration statement on Form 8-A, filed on November 5, 2010, as amended March 4, 2011, including any amendment or reports filed for the purpose of updating such description; and

- All documents filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and before the termination of the offering.

We are not, however, incorporating by reference any documents, or portions of documents, whether specifically listed above or arising in the future, which are not deemed “filed” with the SEC.

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

Bacterin International Holdings, Inc.

664 Cruiser Lane

Belgrade, MT 59714

Attn: Corporate Secretary

(406) 388-0480

S-33

WHERE YOU CAN FIND MORE INFORMATION

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

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

LEGAL MATTERS

Certain legal matters with respect to the securities offered hereby have been passed upon our General Counsel, Jill Gilpin, and by Ballard Spahr LLP, Phoenix, Arizona. Faegre Baker Daniels LLP, Minneapolis, Minnesota, is acting as counsel for the underwriter in connection with certain legal matters relating to the securities offered by this prospectus supplement.

EXPERTS

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

PROSPECTUS

UP TO $50,000,000 OF OUR
COMMON STOCK
PREFERRED STOCK
WARRANTS

From time to time, we may offer up to $50,000,000 in total of:

- shares of common stock;
- shares of preferred stock;
- warrants to purchase shares of common stock or preferred stock; or
- any combination of our common stock, preferred stock or warrants.

We may offer the common stock, preferred stock, and warrants, separately or together, in amounts, at prices and on terms to be set forth in one or more supplements to this prospectus. The preferred stock and warrants we may offer may be convertible into or exercisable or exchangeable for common or preferred stock or other securities. When we decide to issue securities, we will provide you with the specific terms and the public offering price of the securities in prospectus supplements. In the case of shares of preferred stock, these terms will include, as applicable, the specific title and stated value, and any dividend, liquidation, redemption, conversion, voting and other rights. You should read this prospectus and any applicable prospectus supplement carefully before you invest. This prospectus may not be used to offer or sell securities unless accompanied by a prospectus supplement.

Our common stock is listed on the NYSE MKT exchange and traded under the symbol “BONE.” None of our other securities are currently publicly traded. We may sell these securities to or through underwriters and also to other purchasers or through agents. We will set forth the names of any underwriters or agents in an accompanying

prospectus supplement, if applicable.

The last reported sale price of our common stock on the NYSE MKT on March 28, 2014 was $0.87 per share. As of March 28, 2014, the aggregate market value of the voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold on that date, was approximately $32,802,202, based on 54,858,458 shares of outstanding common stock, of which approximately 37,703,681 were held by non-affiliates. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below $75.0 million. We have not offered any securities pursuant to General Instruction I.B.6 of Form S-3 during the 12 calendar months prior to and including the date of this prospectus.

Investing in our securities involves risks. Please see "Risk Factors" beginning on page 2 for more information. You should read carefully this prospectus, the documents incorporated by reference in this prospectus and any prospectus supplement before you invest.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2014

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement filed with the Securities and Exchange Commission ("SEC") using a "shelf" registration process. Under this shelf process, we may from time to time offer up to $50,000,000 in total of shares of common stock, $0.000001 par value per share, shares of preferred stock, $0.000001 par value per share, or warrants to purchase shares of common stock or preferred stock, each at prices and on terms to be determined at the time of sale. The common stock, preferred stock and warrants are collectively referred to in this prospectus as "securities." The securities offered pursuant to this prospectus may be one or more series of issuances. The total offering price of the securities will not exceed $50,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement with specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. If there is any inconsistency between the information in this prospectus and the prospectus supplement, you should rely on the information in the prospectus supplement. You should read both this prospectus and any prospectus supplement together with the additional information described below under the heading "Where You Can Find More Information" and "Incorporation of Certain Information by Reference."

The registration statement that contains this prospectus, including the exhibits to the registration statement and the information incorporated by reference, contains additional information about the securities offered under this prospectus. The registration statement can be read at the SEC website or at the SEC offices mentioned below under the heading "Where You Can Find More Information."

We have not authorized anyone to provide any information or to make any representations other than those contained or incorporated by reference in this prospectus or in any accompanying prospectus supplement. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you.

Neither this prospectus nor any accompanying prospectus supplement constitutes an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus or any prospectus supplement constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

You should not assume that the information in this prospectus or any supplement to this prospectus is accurate at any date other than the date indicated on the cover page of these documents or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference.

ii

SUMMARY

This summary contains a general summary of the information contained in this prospectus. It may not include all the information that is important to you. You should read the entire prospectus, the prospectus supplement delivered with the prospectus, if any, and the documents incorporated by reference before making an investment decision.

About Bacterin International Holdings, Inc.

We develop, manufacture and market biologics products to domestic and international markets through our biologics division. Our bone graft products are used in a variety of applications including enhancing fusion in spine surgery, relief of back pain through facet joint stabilization, promotion of bone growth in foot and ankle surgery, promotion of skull healing following neurosurgery and subchondral bone repair in knee and other joint surgeries. Our acellular dermis scaffolds are utilized in wound care and plastic and reconstructive procedures.

Our medical devices division develops coatings for medical devices and custom surgical instruments for use with allografts processed by our biologics division. Our medical devices division also works with our biologics division to produce and distribute OsteoSelect® DBM putty, an osteoinductive product used by surgeons as a bone void filler in the extremities and pelvis. DBM putty is considered a combination product by regulatory agencies — both a tissue and a medical device.

We are a Delaware corporation. Our executive offices are located at 664 Cruiser Lane, Belgrade, Montana 59714 and our telephone number is (406) 388-0480. Our website is located at *www.bacterin.com*. The information on our website is not part of this prospectus.

Securities We are Offering

We may offer any of the following securities from time to time:

·shares of our common stock;

·shares of our preferred stock;

· warrants to purchase shares of our preferred stock or common stock; or

· any combination of our common stock, preferred stock, or warrants.

When we use the term "securities" in this prospectus, we mean any of the securities we may offer with this prospectus, unless we say otherwise. The total dollar amount of all securities that we may issue will not exceed $50,000,000. This prospectus, including the following summary, describes the general terms that may apply to the securities. We will describe the specific terms of any particular securities that we may offer in a separate supplement to this prospectus.

Common Stock. We may offer shares of our common stock. Our common stock currently is listed on the NYSE MKT under the symbol "BONE."

Preferred Stock. We may offer preferred stock in one or more series. For any particular series we offer, the applicable prospectus supplement will describe the specific designation, the aggregate number of shares offered, the rate and periods, or manner of calculating the rate and periods, for dividends, if any, the stated value and liquidation preference amount, if any, the voting rights, if any, the terms on which the series will be convertible into or exchangeable for other securities or property, if any, the redemption terms, if any, and any other specific terms.

Warrants. We may offer warrants to purchase our common stock and preferred stock. For any particular warrants we offer, the applicable prospectus supplement will describe the underlying security; expiration date; the exercise price or the manner of determining the exercise price; the amount and kind, or the manner of determining the amount and kind, of any security to be delivered by us upon exercise; and any other specific terms.

Listing. If any securities will be listed or quoted on a securities exchange or quotation system, the applicable prospectus supplement will say so.

RISK FACTORS

An investment in our securities involves a high degree of risk. Before making an investment decision, you should consider carefully the risks discussed below and under the sections captioned "Risk Factors" set forth in the documents and reports filed by us with the SEC, that are incorporated by reference into this prospectus, including in our most recent Annual Report on Form 10-K, as revised or supplemented by our Quarterly Reports on Form 10-Q, each of which are on file with the SEC and are incorporated herein by reference, as well as any risks described in any applicable prospectus supplement, before deciding whether to invest in our securities. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our securities could decline due to any of these risks, and you may lose all or part of your investment.

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

Our debt agreements with ROS Acquisition Offshore LP ("ROS") contain representations, warranties, fees, affirmative and negative covenants, including a minimum cash balance 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 ROS facility, we pledged substantially all of our assets, including our intellectual property, to ROS. Our failure to comply with the covenants under the ROS facility could result in an event of default, the acceleration of our debt and the loss of our assets.

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 will 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, dispositions of assets, debt financings or restructurings, bank borrowings or other sources. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, products and/or potential markets. If adequate funds are not otherwise available, we would be forced to curtail operations significantly, including reducing our sales and marketing expenses which could negatively impact product sales and we could even be forced to cease operations, liquidate our assets and possibly even seek bankruptcy protection.

We may not continue to satisfy the continued listing requirements of the NYSE MKT exchange.

We are currently listed on the NYSE MKT exchange, which imposes both objective and subjective requirements for continued listing. Continued listing criteria include the financial condition of the company, market capitalization, shareholder equity, total assets, annual revenue, and low selling price. Our common stock is currently trading at less than $1.00 per share, we are operating at a loss, we have negative shareholder equity, and our market capitalization, total assets and annual revenue are all currently less than $50 million, so our continued listing is at risk. If the NYSE MKT determines that we fail to satisfy the requirements for continued listing, we could be de-listed from the exchange, which could result in reduced liquidity for our shareholders. There can be no assurance that we will satisfy the continued listing requirements of the NYSE MKT or that we will continue to be listed on any exchange.

On May 13, 2013, we received a deficiency notice from the NYSE MKT exchange notifying us that we are not in compliance with Section 1003(a)(iii) of the Company Guide with stockholders' equity of less than $6,000,000 and net losses in five of our most recent fiscal years and Section 1003(a)(ii) with stockholders' equity of less than $4,000,000 and net losses in three of our four most recent fiscal years. On June 12, 2013 we submitted a plan to regain compliance with the continued listing requirements, and on June 21, 2013 the NYSE MKT informed us of the acceptance of our plan and gave us an extension until November 13, 2014 to regain compliance with the continued listing standards. On November 19, 2013, we received another letter from the NYSE MKT notifying us that we are not in compliance with Section 1003(a)(i) of the Company Guide with stockholders' equity of less than $2,000,000 as of September 30, 2013 and net losses in two of three of our most recent fiscal years, and we submitted an amended plan to regain compliance. We will continue to be subject to periodic review by the NYSE MKT during the extension period and failure to make progress consistent with our Plan or to regain compliance by the end of the extension period could result in our delisting from the Exchange.

In order to regain compliance, we will either need to increase our market capitalization or shareholders' equity. In order to increase our shareholder's equity, we may need to raise substantial equity capital, which would be dilutive to existing shareholders and may require shareholder approval. We currently have less than 20,000,000 shares available for issuance on a fully diluted basis. To raise sufficient equity capital to achieve $6 million in shareholder equity, we may need to increase the number of authorized shares available for issuance, which requires shareholder approval. There can be no assurance that we will obtain any necessary shareholder approval or raise sufficient equity capital to regain compliance with the NYSE MKT continued listing standards.

The impact of United States healthcare reform legislation remains uncertain.

In 2010 federal legislation to reform the United States healthcare system was enacted into law. The law was upheld by a Supreme Court decision announced in June 2012. The legislation is far-reaching and is intended to expand access to health insurance coverage, improve quality and reduce costs over time. Among other things, the new law imposes a 2.3 percent excise tax on medical devices beginning January 2013, which applies to United States sales of our medical device products, including our wound drains and OsteoSelect® DBM putty. 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 this legislation, 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 face risks and uncertainties relating to an OIG subpoena.

In February 2013, we received a subpoena from the Office of the Inspector General of the U.S. Department of Health and Human Services ("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. This program was discontinued in 2010. We provided an initial response to the OIG subpoena and have not received any further correspondence or requests from the OIG. Although it does not appear that the OIG is actively pursuing the investigation at the present time, we cannot assure you that the OIG will not resume the investigation in the future. Any further investigation by the OIG could divert management's attention from business demands and subject us to significant legal expenses.

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 payer 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.

Future regulatory action remains uncertain.

We operate in a highly regulated environment, and any legal or regulatory action could be time-consuming and costly. If we fail to comply with all applicable laws, standards and regulations, action by the FDA or other regulatory agencies could result in significant restrictions, including restrictions on the marketing or use of our products or the withdrawal of products from the market. Any such restrictions or withdrawals could materially affect our business and operations. In addition, governmental authorities could impose fines, seize our inventory of products, or force us to recall any product already in the market if we fail to comply with governmental regulations.

Competition from former Chief Executive Officer

We believe our former Chief Executive Officer, Guy Cook, has acquired an ownership interest in a tissue bank that sells competitive products. Because our former CEO has in depth knowledge about our customers, employees, consultants, products, policies, practices and prospects, and is not bound by a non-compete agreement, we may be adversely affected by increased competition with that business.

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

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

competitors have substantially greater financial and technical resources, as well as greater production and marketing capabilities, and our ability to compete remains uncertain.

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

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

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

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

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

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

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

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

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

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

Loss of key members of our management who 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.

We will be required to invest in facilities and equipment on a continuing basis, which will put pressure on us to finance these investments.

We have invested, and intend to continue to invest, in facilities and state-of-the-art equipment in order to increase, expand or update our capabilities and facilities. Changes in technology or sales growth beyond currently established production capabilities, which we anticipate, will require further investment. We currently anticipate that we will need to spend between $4 and $5 million over the next five years in order to increase, expand or update our existing facilities to meet our expected growth over that period. However, there can be no assurance that we will generate sufficient funds from operations to maintain our existing facilities and equipment or to finance any required capital investments or that other sources of funding will be available. Additionally, there can be no guarantee that any future expansion will not negatively affect earnings.

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 the price of our securities.

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.

We are dependent on the ability of our licensees and development partners for obtaining regulatory approvals and market acceptance of their products, for which we may have no control.

Our success may depend on our ability, or that of our licensees, to obtain timely regulatory approval for products employing our technology. Moreover, our success may also depend on whether, and how quickly, our licensees gain market acceptance of products incorporating our technology, compared to competitors using competing technologies.

Our revenues will depend upon prompt and adequate 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. We may have difficulty gaining market acceptance for our products if government and third-party payors do not provide adequate coverage and reimbursement to hospitals. 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 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.

Future business combinations or acquisitions may be difficult to integrate and cause our attention to be diverted.

We may pursue various business combinations with other companies or strategic acquisitions of complementary businesses, product lines or technologies. There can be no assurance that such acquisitions will be available at all, or on terms acceptable to us. These transactions may require additional financing which may increase our indebtedness or outstanding shares, resulting in dilution to stockholders. The inability to obtain such future financing may inhibit our growth and operating results. Integration of acquisitions or additional products can be time consuming, difficult and expensive and may significantly impact operating results. Furthermore, the integration of any acquisition may divert management's time and resources from our core business. We may sell some or all of our product lines to other companies or may agree to combine with another company. Selling some of our product lines may inhibit our ability to generate positive operating results going forward.

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

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

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 manufacturing and marketing of our biologic products, medical devices and coating technologies involves an inherent risk that our products may prove to be defective. In that event, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority. A recall or withdrawal of one of our products, or a similar product manufactured by another manufacturer, could impair sales of the products we market as a result of confusion concerning the scope of the recall or withdrawal, or as a result of the damage to our reputation for quality and safety.

U.S. governmental regulation could restrict the use of our 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.

Our business is subject to continuing regulatory compliance by the FDA and other authorities which is costly and could result in delays in the commercialization of our products.

As a manufacturer and marketer of medical devices, we are subject to extensive regulation by the FDA and the Center for Medicare Services of the U.S. Department of Health and Human Services and other federal governmental agencies and, in some jurisdictions, by state and foreign governmental authorities. These regulations govern the introduction of new medical devices, the observance of certain standards with respect to the design, manufacture, testing, labeling, promotion and sales of the devices, the maintenance of certain records, the ability to track devices, the reporting of potential product defects, the import and export of devices and other matters. We are facing an increasing amount of scrutiny and compliance costs as more states are implementing regulations governing medical devices, pharmaceuticals and/or biologics which affect many of our products.

Medical devices that incorporate coatings technology are subject to FDA regulation and compliance. Generally, any medical device manufacturer that wishes to incorporate our coatings technology into its products will be responsible for obtaining FDA approval for the medical devices it intends to market though we will assist in the 510(k) filing submitted by licensees. The FDA process can take several months to several years in the United States. The time required to obtain approval for international sales may be longer or shorter, depending on the laws of the particular country. There can be no assurance that our licensees will be able to obtain FDA or international approval on a timely basis. The FDA may also require the more extensive Premarket Approval Application, or PMA, process for certain products, which requires an additional level of FDA scientific review to ensure the safety and effectiveness of such devices. Approval or clearance may place substantial restrictions on the indications for which the product may be marketed or to whom it may be marketed, warnings that may be required to accompany the product or additional restrictions placed on the sale and/or use of the product. Changes in regulations or adoption of new regulations could also cause delays in obtaining product approval. In addition, regulatory approval is subject to continuing compliance with regulatory standards, and product approval is subject to withdrawal if a licensee fails to comply with standards, or if an unforeseen event should occur concerning a product. Significant delays in obtaining product approval could have a significantly detrimental impact on our business.

Human tissues intended for transplantation have been regulated by the FDA since 1993. In May 2005, three new comprehensive regulations went into effect that address manufacturing activities associated with human cells, tissues and cellular and tissue-based products, or HCT/Ps. The first requires that companies that produce and distribute HCT/Ps register with the FDA. The second 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 they 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 lead to increased enforcement action which affects the conduct of our business. In addition, these regulations can increase the cost of tissue recovery activities.

Other regulatory entities include state agencies with statutes 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 European Union 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.

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 required to develop products, gain market acceptance and obtain 510(k) certifications from the FDA. These trials often take several years to execute and are subject to factors within and outside of our control. 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.

The commencement or completion of any clinical trial may be delayed or halted for numerous reasons, including, but not limited to, a regulatory body placing clinical trials on hold, 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. 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.

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 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 future intellectual property litigation that may arise but there can be no assurance that we will prevail in these matters. An unfavorable judgment may result in a financial burden on us. An unfavorable judgment may also result in restrictions on our ability to sell certain products and therefore may impact future operating results.

Because we became public through a reverse merger, and our stock is currently trading below $1.00 per share, we may not be able to attract the attention of major brokerage firms or certain investors.

There are coverage risks associated with our becoming public through a reverse merger, including, among other things, security analysts of major brokerage firms may not provide coverage of us since there is no incentive to brokerage firms to recommend the purchase of our common stock. In addition, we may not attract the attention of major brokerage firms and certain investors due to our low stock price. We cannot assure you that brokerage firms would want to conduct any public offerings on our behalf in the future.

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, including ours, 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;
- halting or suspension of trading in our common stock by the NYSE MKT;
- 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 to reduce premium expense, 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.

Shares of common stock are equity securities and are subordinate to any indebtedness.

Shares of our common stock are common equity interests. This means that our common stock will rank junior to any outstanding shares of our preferred stock that we may issue in the future or to our current credit agreement and any future indebtedness we may incur and to all creditor claims and other non-equity claims against us and our assets available to satisfy claims on us, including claims in a bankruptcy or similar proceeding.

Additionally, unlike indebtedness, where principal and interest customarily are payable on specified due dates, in the case of our common stock, (i) dividends are payable only when and if declared by our board of directors or a duly authorized committee of our board of directors, and (ii) as a corporation, we are restricted to making dividend payments and redemption payments out of legally available assets. We have never paid a dividend on our common stock and have no current intention to pay dividends in the future. Furthermore, our common stock places no restrictions on our business or operations or on our ability to incur indebtedness or engage in any transactions, subject only to the voting rights available to shareholders generally.

Our stockholders may experience significant dilution if future equity offerings are used to fund operations or acquire complementary businesses.

If our future operations or acquisitions are financed through the issuance of equity securities, our stockholders could experience significant dilution. In addition, securities issued in connection with future financing activities or potential acquisitions may have rights and preferences senior to the rights and preferences of our common stock. We also have established an equity incentive plan for our management, consultants and employees. We expect to grant restricted stock and options to purchase shares of our common stock to our directors, employees and consultants and we will grant additional options in the future. The issuance of shares of our common stock upon the exercise of these options may result in dilution to our stockholders.

We do not anticipate paying dividends in the foreseeable future; you should not buy our stock if you expect dividends.

We currently intend to retain our future earnings to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our securities in the foreseeable future.

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

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

The sale of securities in this offering may cause dilution and could cause the price of our securities to decline.

Sales of securities in this offering may result in substantial dilution to the interests of holders of our securities. The sale of securities in this offering, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at prices that we might otherwise wish to effect sales. Depending on market liquidity at the time, a sale of securities in this offering at any given time could cause the trading price of our common stock to decline. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this prospectus that are not purely historical are forward-looking statements within the meaning of applicable securities laws. Our forward-looking statements include, but are not limited to, statements regarding our "expectations," "hopes," "beliefs," "intentions," or "strategies" regarding the future. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "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 prospectus may include, for example, statements about:

- our ability to obtain financing on reasonable terms;

- our ability to increase revenue;
- our ability to remain listed on the NYSE MKT exchange;
- our ability to comply with the covenants in our credit facility;
- our ability to maintain sufficient liquidity to fund our operations;
- our ability to obtain shareholder approval to increase our authorized shares of common stock;
- 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;

- our ability to successfully integrate future business combinations or acquisitions;
- product liability claims and other litigation to which we may be subjected;
- product recalls and defects;
- timing and results of clinical studies;
- our ability to obtain and protect our intellectual property and proprietary rights;
- infringement and ownership of intellectual property;
- influence by our management; and
- our ability to issue preferred stock.

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

USE OF PROCEEDS

Except as described in any applicable prospectus supplement in connection with a specific offering, we intend to use the net proceeds from the sale of the securities offered under this prospectus for operating costs, working capital, and general corporate purposes.

PLAN OF DISTRIBUTION

We may sell the securities being offered by this prospectus separately or together:

- directly to purchasers;
- through agents;
- to or through underwriters;
- through dealers;
- through a block trade in which the broker or dealer engaged to handle the block trade will attempt to sell the securities as agent, but may position and resell a portion of the block as principal to facilitate the transaction; or
- through a combination of any of these methods of sale.

In addition, we may issue the securities being offered by this prospectus as a dividend or distribution.

We may effect the distribution of the securities from time to time in one or more transactions:

- at a fixed price or prices, which may be changed from time to time;
- at market prices prevailing at the times of sale;
- at prices related to prevailing market prices; or
- at negotiated prices.

We may engage in at-the-market offerings into an existing trading market in accordance with Rule 415(a)(4) under the Securities Act, and we may also sell securities through a rights offering, forward contracts or similar arrangements. In any distribution of subscription rights to stockholders, if all of the underlying securities are not subscribed for, we may then sell the unsubscribed securities directly to third parties or may engage the services of one or more underwriters, dealers or agents, including standby underwriters, to sell the unsubscribed securities to third parties.

Other than our common stock, which is listed on the NYSE MKT, the securities issued and sold under this prospectus will have no established trading market. Any shares of our common stock sold pursuant to this prospectus will be eligible for listing and trading on the NYSE MKT, subject to additional listing approval. Any underwriters to whom securities are sold by us for public offering and sale may make a market in the securities, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. The securities, other than our common stock, may or may not be listed on a national securities exchange or other trading market.

We will describe the method of distribution of the securities in a prospectus supplement. We may directly solicit offers to purchase the securities offered by this prospectus. Agents designated by us from time to time may solicit offers to purchase the securities. We will name any agent involved in the offer of sale of the securities and set forth any commissions payable by us to an agent in a prospectus supplement. Unless otherwise indicated in a prospectus supplement, any agent will be acting on a best efforts basis for the period of its appointment. Any agent may be deemed to be an “underwriter” of the securities as that term is defined in the Securities Act of 1933, as amended (the “Securities Act”).

We may directly solicit offers to purchase the securities, and we may sell directly to institutional investors or others. These persons may be deemed to be underwriters within the meaning of the Securities Act with respect to any resale of the securities. A prospectus supplement will describe the terms of any direct sales, including the terms of any bidding or auction process.

If a dealer is used in the sale of the securities, we or an underwriter will sell securities to the dealer, as principal. The dealer may resell the securities to the public at varying prices to be determined by the dealer at the time of resale. A prospectus supplement will set forth the name of the dealer and the terms of the transactions.

If we use an underwriter or underwriters in the sale of securities, we will execute an underwriting agreement with the underwriter or underwriters at the time we reach an agreement for sale. We will set forth in a prospectus supplement the names of the specific managing underwriter or underwriters, as well as any other underwriters, and the terms of the transactions, including compensation of the underwriters and dealers. This compensation may be in the form of discounts, concessions or commissions. Underwriters and others participating in any offering of the securities may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. We will describe any of these activities in a prospectus supplement.

Agreements we enter into with agents, underwriters and dealers may entitle them to indemnification by us against specified liabilities, including liabilities under the Securities Act, or to contribution by us to payments they may be required to make in respect of these liabilities. A prospectus supplement will describe the terms and conditions of indemnification or contribution.

We may authorize underwriters, dealers and agents to solicit offers by certain institutional investors to purchase offered securities under contracts providing for payment and delivery on a future date specified in a prospectus supplement. The prospectus supplement will describe the public offering price for the securities and the commission payable for solicitation under any delayed delivery contract. Delayed delivery contracts will contain definite fixed price and quantity terms.

To the extent permitted by and in accordance with Regulation M under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), in connection with an offering an underwriter may engage in over-allotments, stabilizing transactions, short covering transactions and penalty bids. Over-allotments involve sales in excess of the offering size, which creates a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would be otherwise. If commenced, the underwriters may discontinue any of the activities at any time.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

In compliance with the guidelines of the Financial Industry Regulatory Authority, Inc., or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker-dealer may not exceed 8% of the aggregate proceeds of the offering.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business for which they receive compensation.

No securities may be sold under this prospectus without delivery, in paper format, in electronic format on the internet, or both, of the applicable prospectus supplement describing the method and terms of the offering.

DESCRIPTION OF COMMON STOCK

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

Authorized and Outstanding Common Stock

Our Amended and Restated Certificate of Incorporation provides that we have authority to issue (i) 95,000,000 shares of common stock, par value $0.000001 per share, 54,858,458 of which are issued and outstanding as of March 28, 2014, and (ii) 5,000,000 shares of preferred stock, par value $0.000001 per share, none of which are issued and outstanding as of the date of this prospectus. We also have outstanding warrants to purchase approximately 11,660,603 shares of our common stock and there are 9,000,000 shares authorized for issuance under our Amended and Restated Bacterin International Equity Incentive Plan.

Listing

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

Dividends

Our Board of Directors may authorize, and we may make, distributions to our common stockholders, subject to any restriction in our Amended and Restated Certificate of Incorporation and to those limitations prescribed by law. However, we have never paid cash dividends on our common stock or any other securities. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying cash dividends in the foreseeable future.

Fully Paid and Non-Assessable

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

Voting Rights

Each share of our common stock is entitled to one vote in each matter submitted to a vote at a meeting of stockholders including in all elections for directors; stockholders are not entitled to cumulative voting in the election for directors. Our stockholders may vote either in person or by proxy.

Preemptive and Other Rights

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

Staggered Board of Directors

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

Transfer Agent

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

Limitations of Director Liability

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

Indemnification

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

DESCRIPTION OF PREFERRED STOCK

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

Preferred Stock That We May Offer and Sell

Our Amended and Restated Certificate of Incorporation authorizes our Board of Directors, without further stockholder action, to provide for the issuance of up to 5,000,000 shares of preferred stock, in one or more classes or series and to fix the rights, preferences, privileges, and restrictions thereof, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences and the number of shares constituting any series of the designation of such series, without further vote or action by the stockholders. As of the date of this prospectus, no shares of preferred stock are outstanding.

The particular terms of any series of preferred stock being offered by us under this shelf registration statement will be described in the prospectus supplement and certificate of designations relating to the applicable series of preferred stock. Those terms may include:

- the title and liquidation preference per share of the preferred stock and the number of shares offered;
- the purchase price of the preferred stock;
- the dividend rate (or method of calculation), the dates on which dividends will be paid and the date from which dividends will begin to accumulate;
- any redemption or sinking fund provisions of the preferred stock;
- any conversion provisions of the preferred stock;
- the voting rights, if any, of the preferred stock; and
- any additional dividend, liquidation, redemption, sinking fund and other rights, preferences, privileges, limitations and restrictions of the preferred stock.

The preferred stock will be, when issued, fully paid and non-assessable.

Voting Rights

The General Corporation Law of Delaware provides that the holders of preferred stock will have the right to vote separately as a class on any proposal involving fundamental changes in the rights of holders of that preferred stock. This right is in addition to any voting rights that may be provided for in the applicable certificate of designations.

Other

Our issuance of preferred stock may have the effect of delaying or preventing a change in control. Our issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of common stock or other preferred stock or could adversely affect the rights and powers, including voting rights, of the holders of common stock or other preferred stock. The issuance of preferred stock could have the effect of decreasing the market price of our common stock.

Transfer Agent and Registrar

The transfer agent and registrar for the preferred stock will be set forth in the applicable prospectus supplement.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement.

We may issue warrants for the purchase of shares of our common stock or preferred stock. Warrants may be issued independently or together with the shares of common stock or preferred stock offered by any prospectus supplement to this prospectus and may be attached to or separate from such shares. Further terms of the warrants will be set forth in the applicable prospectus supplement.

The applicable prospectus supplement will describe the terms of the warrants in respect of which this prospectus is being delivered, including, where applicable, the following:

· the title of such warrants;

- the aggregate number of such warrants;
- the price or prices at which such warrants will be issued;
- the designation, terms and number of shares of common stock or preferred stock purchasable upon exercise of such warrants;
- the designation and terms of the shares of common stock or preferred stock with which such warrants are issued and the number of such warrants issued with such shares;
- the date on and after which such warrants and the related common stock or preferred stock will be separately transferable, including any limitations on ownership and transfer of such warrants;
- the price at which each share of common stock or preferred stock purchasable upon exercise of such warrants may be purchased;
- the date on which the right to exercise such warrants shall commence and the date on which such right shall expire;
- the minimum or maximum amount of such warrants that may be exercised at any one time;
- information with respect to book-entry procedures, if any;
- a discussion of certain federal income tax consequences; and
- any other terms of such warrants, including terms, procedures and limitations relating to the exchange and exercise of such warrants.

This summary of the warrants is not complete. We urge you to read the warrants filed as exhibits to the registration statement that includes this prospectus and the description of the additional terms of the warrants included in the prospectus supplement. The terms of the warrants we issue may differ materially from warrants we have issued in the past.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including the right to receive dividends, if any, or payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Exercise of Warrants

Each warrant will entitle the holder thereof to purchase the number of shares of preferred stock and the number of shares of common stock at the exercise price as shall in each case be set forth in, or be determinable as set forth in, the applicable prospectus supplement. Warrants may be exercised at any time up to the close of business on the expiration date set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Warrants may be exercised as set forth in the applicable prospectus supplement relating to the warrants offered thereby. Upon receipt of payment of the exercise price, surrender of the original warrant, and submission of a properly completed and duly executed notice of exercise, we will, as soon as practicable, forward the purchased securities. If less than all of the warrants represented by the warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants. Holders of warrants will be required to pay any tax or governmental charge that may be imposed in connection with transferring the underlying securities in connection with the exercise of the warrants.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference the information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of the prospectus. These documents may include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as Proxy Statements. Any documents that we subsequently file with the SEC will automatically update and replace the information previously filed with the SEC. Thus, for example, in the case of a conflict or inconsistency between information set forth in this prospectus and information incorporated by reference into this prospectus, you should rely on the information contained in the document filed later.

This prospectus incorporates by reference the documents listed below that we previously have filed with the SEC and any additional documents that we may file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus and the termination of the offering of the securities. These documents contain important information about us.

- Our Annual Report on Form 10-K for the year ended December 31, 2013;

- Our Current Report on Form 8-K (other than portions thereof furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits accompanying such reports that are related to such items) filed with the SEC on March 10, 2014;

- The description of our common stock contained in our registration statement on Form 8-A, filed on November 5, 2010, as amended March 4, 2011, including any amendment or reports filed for the purpose of updating such description; and

- All documents filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and before the termination of the offering.

We are not, however, incorporating by reference any documents, or portions of documents, whether specifically listed above or arising in the future, which are not deemed “filed” with the SEC.

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

Bacterin International Holdings, Inc.

664 Cruiser Lane

Belgrade, MT 59714

Attn: Corporate Secretary

(406) 388-0480

WHERE YOU CAN FIND MORE INFORMATION

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

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

LEGAL MATTERS

Our General Counsel, Jill Gilpin, has passed upon certain legal matters in connection with the securities offered hereby.

EXPERTS

The financial statements incorporated by reference into this prospectus and registration statement on Form S−3 have been audited by EKS&H LLLP, independent certified public accountants, as set forth in their report thereon appearing in our Annual Report on Form 10-K and incorporated by reference into this prospectus and registration statement on Form S−3, and such report is included in reliance upon the authority of such firm as experts in accounting and auditing.