Bacterin International Holdings, Inc.
Form 10-K
March 18, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

or

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

For the transition period from _____ to _____

Commission file number: 001-34951

Bacterin International Holdings, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	20-5313323

(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
664 Cruiser Lane Belgrade, Montana (Address of Principal Executive Offices)	59714 (Zip Code)

(406) 388-0480
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common stock, par value $.000001 per share	NYSE MKT LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ¨ No þ

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

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

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

The aggregate market value of the common stock held by non-affiliates as of June 30, 2014 was $31,947,107 (based on the closing price of the Company’s common stock on the last business day of the Company’s most recently completed second fiscal quarter, as reported on the NYSE MKT).

The number of shares of the Company’s common stock, $0.000001 par value, outstanding as of March 10, 2015 was 6,683,056.

DOCUMENTS INCORPORATED BY REFERENCE

None

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this Form 10-K 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 Form 10-K may include, for example, statements about:

- our ability to remain listed on the NYSE MKT;
- our ability to obtain financing on reasonable terms;
- our ability to increase revenue;
- our ability to comply with the covenants in our credit facility;
- our ability to maintain sufficient liquidity to fund our operations;
- the ability of our sales force to achieve expected results;
- our ability to remain competitive;
- government regulations;
- our ability to 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 Form 10-K 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 our Form 10-K. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required under applicable securities laws.

PART I

Item 1. Business

Overview of Our Business

We develop, manufacture and market biologics products to domestic and international markets. Our bone graft products are used in a variety of applications including enhancing fusion in spine surgery, relief of back pain through facet joint stabilization, promotion of bone growth in foot and ankle surgery, promotion of skull healing following neurosurgery and subchondral bone repair in knee and other joint surgeries. Our acellular dermis scaffolds are utilized in wound care and plastic and reconstructive procedures. We also develop custom surgical instruments for use with our allografts, and we produce and distribute OsteoSelect® DBM putty, an osteoinductive product used by surgeons as a bone void filler in the extremities and pelvis. DBM putty is considered a combination product by regulatory agencies - both a tissue and a medical device.

Our Offices

Our headquarters, laboratory and manufacturing facilities are located at 600 Cruiser Lane, Belgrade, Montana 59714. Our telephone number is (406) 388-0480 and our fax number is (406) 388-0422. We also own a facility located at 664 Cruiser Lane, Belgrade, Montana 59714, and lease space at 732 Cruiser Lane, Belgrade, Montana 59714, 8310 S. Valley Highway, Englewood, Colorado 80112 and 10955 Westmoor Drive, Westminster, CO 80021.

Our History

We began operations in 1998 as a spinout of the Center for Biofilm Engineering at Montana State University, or the CBE, and we eventually incorporated as “Bacterin, Inc.” in the state of Montana in January 2000. In March 2004, Bacterin, Inc.’s stockholders entered into a share exchange agreement with a company called Oil & Gas Seekers, Inc., a Nevada corporation, or OGS, which subsequently changed its name to “Bacterin International, Inc.,” to effectively become a publicly-traded corporation. As a result of this transaction, the stockholders of Bacterin, Inc., the Montana corporation, became stockholders of Bacterin International, Inc., the Nevada corporation, and Bacterin, Inc., the Montana corporation, became a wholly owned subsidiary of Bacterin International, Inc., the Nevada corporation. At the end of 2004, management concluded that this transaction was problematic and did not deliver the expected result. Based on this determination, we entered into an agreement in 2005 to amend the terms of the exchange transaction with the former majority stockholder of OGS. In May 2005, we merged Bacterin, Inc., the Montana corporation, up and into Bacterin International, Inc., the Nevada corporation.

We began as a biomaterials testing laboratory and have systematically expanded our strategic vision towards the development of Bacterin-labeled products. Our revenues were initially derived from testing services and milestone payments from collaborative product development agreements with various medical manufacturers. Today we generate most of our revenue from biologics products we manufacture.

On June 30, 2010, Bacterin International, Inc. merged with and into a wholly-owned Nevada subsidiary of Bacterin International Holdings, Inc. f/k/a K-Kitz Incorporated, a Delaware corporation, and as a result, Bacterin International, Inc. became a wholly owned subsidiary of Bacterin International Holdings, Inc.

Before the reverse merger described above, Bacterin International Holdings, Inc. was known as K-Kitz, Incorporated, with a trading symbol of KKTZ.OB. On June 29, 2010, K-Kitz Incorporated changed its corporate name to "Bacterin International Holdings, Inc." which name change became effective for trading purposes on July 1, 2010, following the reverse merger transaction. Effective July 21, 2010, our trading symbol was changed from KKTZ.OB to BIHI.OB. On March 7, 2011, our common stock began trading on the NYSE Amex under the ticker symbol "BONE."

Industry and Market Overview

The orthopedic biomaterials market consists of materials that are organic, inorganic or synthetic in nature. These materials are implanted or applied in or near the indicated bone to facilitate healing, encourage bone tissue augmentation, compensate in areas where bone tissue is depleted and restore structure to allow for repair. Orthopedic biomaterials are capable of producing specific biological action or regenerative responses that are beyond what is observed in normal healing. These materials are often used as substitutes to autograft materials, which are taken from a harvest site in the patient to patch or repair the wounded or unhealthy site. Bone is a biologically active tissue and may or may not regenerate depending on the condition of the patient. The damage may be significant enough that a scaffold may be necessary to help regenerate the surgical site.

Products and Services

Our products include OsteoSponge®, OsteoSponge®SC, OsteoSelect® DBM putty, OsteoWrap®, OsteoLock®, BacFast® HD, OsteoSTX®, hMatrix® and our new line of 3Demin™ products, as well as other allograft products described below:

¨ OsteoSponge® is a form of demineralized bone matrix made from 100% human bone. Derived from trabecular (cancellous) bone, OsteoSponge® provides a natural scaffold for cellular in-growth and exposes bone-forming proteins to the healing environment. The malleable properties of OsteoSponge® enable it to conform to, and fill, most defects. Upon compressing the allograft, OsteoSponge® springs back to completely fill the void. Its unique mechanical and biological properties make OsteoSponge® an ideal bone graft for use in various orthopedic practices including spine, neurology, cranial/maxillofacial, trauma, plastic/reconstruction and general procedures where new bone growth is needed.

¨ OsteoSponge®SC is a form of OsteoSponge® designed to fill bony defects in the subchondral region of joints. We have received permission from the FDA to market this product as a subchondral bone void filler and are currently marketing it as such.

¨ OsteoSelect® DBM putty is engineered with the surgeon in mind. With outstanding handling characteristics, OsteoSelect® can be easily molded into any shape and compressed into bony voids. Bacterin has validated a low-dose, low-temperature gamma sterilization process to provide maximum osteoinductive potential while still affording device level sterility. Every production batch of OsteoSelect® is tested for osteoinductive bone growth characteristics allowing us to make that unique marketing claim.

.. OsteoWrap® is 100% human cortical bone demineralized through a proprietary process to make the graft flexible while maintaining allograft integrity. This product has various applications in orthopedic, neurological, trauma, oral/maxillofacial and reconstructive procedures. OsteoWrap® can wrap around non-union fractures to assist with fusion, can act as a biologic plate or can be used in conjunction with a hardware plate system. Additionally, this product provides the surgeon with superior handling characteristics as the allograft can be easily sized using surgical scissors or a scalpel, and will withhold sutures or staples for fixation.

.. OsteoLock® and BacFast® HD are facet stabilization dowels made from human bone. The shape of our facet stabilization dowel is engineered to maximize osteoconductivity and surface area contact, as well as provide stability to prevent migration from the surgical site. BacFast® HD, having the same design as OsteoLock®, is optimized through our proprietary demineralization technology. This technology increases the surface area of the outer collagen matrix of the graft while exposing native bone morphogenic proteins (BMPs) and growth factors. Because of the hyper-demineralization technology, BacFast® HD has osteoinductive properties, as well as being osteoconductive. OsteoLock® and BacFast® HD can be used to augment spinal procedures, or as a stand-alone procedure for mild spinal conditions.

.. OsteoSTX® are demineralized cortical sticks processed from human allograft bone. Utilizing our patented demineralization technology, the grafts are flexible and feature osteoinductive properties. The nature of demineralized cortical bone provides all the necessary elements for bone regeneration. OsteoSTX® are designed for posterolateral spine surgery applications ranging from one-level to multi-level fusions, including scoliosis procedures. This is a new addition to Bacterin’s biologic products portfolio launched in March 2014.

..

hMatrix® dermal scaffold is an extension of Bacterin's core biologics technology. hMatrix® is an acellular matrix made from donated human dermal tissue that is used to replace a patient's damaged tissue. hMatrix® provides a natural collagen tissue scaffold that promotes cellular ingrowth, tissue vascularization and regeneration. The hMatrix® scaffold tissue reabsorbs into the patient's dermal tissue for a biocompatible, natural repair.

.. Our new line of 3Demin™ products consists of 3Demin™ Cortical Fibers, 3Demin™ Boats and 3Demin™ Strips. These 3Demin products are made from cortical bone and primarily used in spine procedures.

All of the Company's biologics are terminally sterilized and packaged to enhance the safety of our grafts for our physician customers and their patients.

We also process and sell (i) sports allografts which are processed specifically for anterior and posterior cruciate ligament repairs, anterior cruciate ligament reconstruction and meniscal repair, (ii) milled spinal allografts which are comprised of cortical bone milled to desired shapes and dimensions, and (iii) traditional allografts for multi-disciplinary applications including orthopedics, neurology, podiatry, oral/maxillofacial, genitourinary and plastic/reconstructive. We also develop custom surgical instruments for use with our allografts.

The Company's products are described in multiple physician-initiated studies that continue to prove expanded indications for our products.

At the end of 2014, the Company made the strategic decision to exit the craniomaxillofacial and medical device coatings businesses.

Technology and Intellectual Property

Patents, trademarks and other proprietary rights are very important to our business. We also rely upon trade secrets, manufacturing know-how, continuing technological innovations and licensing opportunities to maintain and improve our competitive position. We review third-party proprietary rights, including patents and patent applications, as available, in an effort to develop an effective intellectual property strategy, avoid infringement of third-party proprietary rights, identify licensing opportunities and monitor the intellectual property owned by others.

Patents

On November 5, 2013, the United States Patent and Trademark Office issued US Patent No. 8,574,825 entitled "Process for Demineralization of Bone Matrix with Preservation of Natural Growth Factors." The issued claims in the patent are for a method to produce a demineralized cancellous bone matrix, such as Bacterin's OsteoSponge® product line. Bacterin has a pending divisional application in the United States to pursue protection of other aspects of its bone demineralization technology and is pursuing related applications in Canada, Europe and Korea. We have other provisional applications pending in the United States and other countries that relate to aspects of the technology used in many of our products. Our policy is to file patent applications in the United States and other countries when we believe it is commercially advantageous to do so. We do not consider our business to be materially dependent upon any individual patent.

Our patent efforts are focused on the development of innovative and novel, engineered tissue implants or constructs which employ acellular tissue and processes, and enhanced demineralized bone matrix products. We also hold patents related to our medical device coatings business. At the end of 2014, the Company made the strategic decision to exit the medical device coatings business.

We believe our patent filings and patent position will facilitate growth and enhance our proprietary core competencies. We expect that additional patent applications will be filed and prosecuted as inventions are discovered, technological improvements and processes are developed and specific applications are identified. There can be no assurance that we will be able to obtain final approval of any patents.

Trademarks

We believe in the superiority of our technology and products. As a result, we have invested in the development of the names of our products in order to drive consumer awareness and loyalty to the brand. To protect this investment, we have registered, and continue to seek registration, of these trademarks and continuously monitor and aggressively pursue users of names and marks that potentially infringe upon our registered trademarks. We currently own the following registered trademarks: OsteoSponge®, OsteoWrap®, OsteoLock®, BacFast®, OsteoSelect®, Elutia®, OsteoSTX®, hMatrix®, BACTERINSE® and Circle of Life®.

Trade Secrets

To safeguard our proprietary knowledge and technology, we rely upon trade secret protection and non-disclosure/confidentiality agreements with employees, consultants and third party collaboration partners with access to our confidential information. There can be no assurance, however, that these measures will adequately protect against the unauthorized disclosure or use of confidential information, or that third parties will not be able to independently develop similar technology. Additionally, there can be no assurance that any agreements concerning confidentiality and non-disclosure will not be breached, or if breached, that we will have an adequate remedy to protect us against losses. Although we believe our proprietary technology has value, because of rapid technological changes in the medical industry, we also believe that proprietary protection is of less significance than factors such as the intrinsic knowledge and experience of our management, advisory board, consultants and personnel and their ability to identify unmet market needs and to create, invent, develop and market innovative and differentiated products.

Donor Procurement

We have agreements with multiple recovery agencies and we continue to expand our network for donor tissue in anticipation of increased production. We expect to be able to continue to build our network for donor tissue as our production capabilities and sales increase.

Sales and Marketing

We sell our product in the United States through a hybrid distribution network including direct employees and independent distributors. As of February 2015, we have one President, one Vice President of Sales and one Vice President of Marketing to lead this effort, and we have two market development managers, ten regional managers, three national account managers, eleven sales representatives, one distribution manager and sixteen associate sales representatives in the field.

Growth Strategy

In an effort to capitalize on our core markets, as well as new market opportunities, we have diversified our supply of donor tissue, expanded our production capabilities, developed our hybrid sales force and refined the message to our market.

We are pursuing a high-level, national effort to present our products as a value proposition to hospital chains and other purchasing organizations. To this end, we have entered into agreements with Banner Hospitals, Dignity Health, Franciscan Health System, the Hospital for Special Surgery, William Beaumont Hospital, Catholic Healthcare West, Franciscan Alliance, McLaren Healthcare, Pinnacle Health Systems, Proliance Surgeons, Baptist Health South Florida, MedAssets, Novation, Premier, ROi, Health Trust Purchasing Group, Scripps and Bon Secour among others.

These agreements are paving the way for our sales representatives to call on additional physicians, as the hospital process has already been approved.

Competition

The orthopedic biomaterials market is comprised of a great number of players, each offering a multitude of products, and it is expected that several new products will emerge over the coming years. Competitors in the orthopedic biomaterials markets include: Medtronic, DePuy/Synthes, Arthrex, Smith & Nephew, Nuvasive, OrthoFix, Biomet, MTF, Stryker, RTI Surgical, AlloSource, Lifenet Health, Integra, ConMed/Linvatec, Wright Medical, Exactech, KCI, Baxter and Alphatec.

Government Regulation

We are registered with the FDA as a manufacturer of human cellular and tissue products (HCT/Ps) as well as medical devices, and we are an accredited member of the American Association of Tissue Banks in good standing. We meet all licensing requirements for the distribution of HCT/Ps in states with licensing requirements, including Florida, California, Louisiana, Maryland and New York. Our industry is highly regulated and we cannot predict the impact of future regulations on either us or our customers.

Human Tissue

Human tissue products have been regulated by the FDA since 1993. In May 2005, three new comprehensive regulations went into effect that address manufacturing activities associated with 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. Together, they are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and communicable disease transmission to recipients. Several of our products including OsteoSponge® and OsteoWrap® are regulated as HCT/Ps as determined by the Tissue Reference Group and regulated under Section 361 of the Public Health Service Act and 21 CFR Part 1271.

Medical Devices

Our medical devices require the clearance of the FDA prior to sale within the United States. The FDA process requires a pre-market notification, or a 510(k) submission, to the FDA to demonstrate that the medical device is safe and effective and is substantially equivalent to a legally marketed device that is not subject to pre-market approval. Applicants must compare the device to one or more similar devices that are commercially available in the U.S.

(known as the "predicate device"), and make and support a claim of substantial equivalency to such predicate device. Support for such claims must include descriptive data and, when necessary, performance data. In some cases, data from clinical trials must also be submitted in support of a 510(k) Submission. The FDA must then issue an order finding substantial equivalency before the devices may be commercially distributed in the U.S. The Center for Devices and Radiological Health regulates medical devices, including our OsteoSelect® DBM putty.

ISO Certification

In March 2010, we announced that we received certification from the International Organization for Standardization, or ISO, for fulfilling the requirements of ISO 13485:2003, and in February 2013 we announced that we also received ISO certification for our biologics division. ISO 13485:2003 specifies requirements for a quality management system. To obtain ISO 13485:2003 certification, an organization must demonstrate its ability to provide medical devices that consistently meet applicable customer and regulatory requirements. The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for quality management systems. All requirements of ISO 13485:2003 are specific to organizations providing medical devices, regardless of the type or size of the organization. The certification assures our customers and partners of our commitment to quality, and in the quality of our innovative products and processes. Additionally, we believe that our ISO 13485:2003 certification offers new markets and business opportunities for our products in the global marketplace.

Employees

As of February, 2015, we had 148 full-time employees and 150 total employees, of whom 52 were in operations, 42 were in sales, 5 were in marketing, 8 were in R&D, 14 were in QA/QC, and 29 were in administrative functions. In addition, we make use of a varying number of outsourced services to manage normal business cycles. None of our employees are covered by a collective bargaining agreement and management considers relations with employees and service partners to be good.

Facilities

We lease approximately 17,700 square feet in a building located at 600 Cruiser Lane, Belgrade, Montana 59714. This space includes six Class 100 (ISO 5) clean rooms, a fully equipped diagnostics laboratory, microbiology laboratory and testing laboratory. We lease the building under a ten-year operating lease which runs through August 2023 and has a monthly lease payment of $13,000. The lease also has a ten-year renewal option.

In November 2007, we purchased a 14,000 square foot facility at 664 Cruiser Lane, Belgrade, Montana 59714. This building is an FDA registered facility with a Class 10,000 (ISO 7) environmentally controlled area. The validated manufacturing areas and laboratory facilities located in this facility provide processing and testing space to

manufacture medical devices pursuant to FDA, GMP regulations, and ISO 13485:2003. The facility is registered with the FDA for device design, device manufacture, and contract manufacture, as well as for screening, testing, storing, and distributing biological tissues.

We also lease a 21,000 square foot facility at 732 Cruiser Lane, Belgrade, Montana 59714, where one Class 1,000 (ISO 6) clean room is located, and we lease office space in Englewood, Colorado and Westminster, Colorado, where certain of our administrative functions are housed.

ITEM 1A. RISK FACTORS

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

Our Common Stock may be delisted from the NYSE MKT, and we may move to the OTCQX marketplace.

On May 13, 2013, we received a deficiency notice from the NYSE MKT 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. On November 14, 2014, we received a letter notifying us that the staff of NYSE Regulation, Inc. (the "Staff") determined to commence proceedings to delist our common stock from the NYSE MKT because we did not cure our non-compliance with Sections 1003(a)(i), (ii) and (iii) of the NYSE MKT Company Guide by the end of the maximum 18 month compliance period, which expired on November 13, 2014. We appealed the Staff's delisting determination and attended a hearing on January 21, 2015. On January 26, 2015, following our January 21, 2015 hearing with a Listing Qualifications Panel (the "Panel") of the NYSE MKT LLC's Committee on Securities (the "Committee"), we received a letter notifying us that the Panel affirmed the determination of the Staff to delist our common stock. We have subsequently requested a full Committee review of the Panel's decision.

If we are delisted from the NYSE MKT, we anticipate that our common stock will trade on the OTCQX marketplace. If our common stock is delisted from the NYSE MKT, our stock price and liquidity may be negatively affected, some shareholders may sell their shares, and we may not be able to attract institutional investors in future financing transactions. In addition, under current SEC rules, our common stock must be listed on a national securities exchange in order to utilize a Form S-3 registration statement (i) for a primary offering, if our public float is not at least $75.0 million as of a date within 60 days prior to the date of filing the Form S-3, or a re-evaluation date, whichever is later, and (ii) to register the resale of our securities by persons other than us (i.e., a resale offering). If we were unable to utilize a Form S-3 registration statement for primary and secondary offerings of our common stock, we would be required to file a Form S-1 registration statement, which could delay our ability to raise funds in the future, may limit the type of offerings of common stock we could undertake, and could increase the expenses of any offering, as, among other things, registration statements on Form S-1 are subject to SEC review and comments whereas take downs pursuant to a previously effective Form S-3 are not. There can be no assurance that our common stock will remain

listed on the NYSE MKT.

If our Common Stock were delisted from the NYSE MKT, we would no longer be subject to the NYSE MKT rules, including rules limiting the number of shares we may issue without shareholder approval and certain corporate governance standards.

Our ability to issue common stock is currently limited by the NYSE MKT's shareholder approval requirements. For example, the NYSE MKT requires that we obtain shareholder approval before issuing 20% or more of our common stock in an acquisition. We must also generally seek shareholder approval before issuing 20% or more of our common stock in a financing transaction, unless the transaction satisfies certain pricing requirements or is considered a "public offering" by the NYSE MKT staff. If our common stock is delisted from the NYSE MKT, we would no longer be subject to such shareholder approval requirements, and we could issue shares in excess of 20% of our outstanding shares in acquisitions or financing transactions without shareholder approval. Any such issuance would dilute the ownership of our current stockholders. In addition, following a delisting of our common stock, we would no longer be subject to the NYSE MKT rules requiring us to meet certain corporate governance standards, which could decrease investor interest in our common stock.

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

Our credit agreement with ROS includes an obligation on our part to split the net proceeds from equity offerings evenly with ROS above $15 million in the aggregate. So far we have not exceeded the $15 million threshold; 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.

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.

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 PPACA imposes a 2.3 percent excise tax on medical devices, which applies to United States sales of our medical device products, including our OsteoSelect® DBM putty. 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.

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.

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

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

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

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

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

Even if our 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 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 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, would require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

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

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to 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.

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.

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.

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, suspension of trading or delisting of 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.

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

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.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We lease approximately 17,700 square feet in a building located at 600 Cruiser Lane, Belgrade, Montana 59714. This space includes six Class 100 (ISO 5) clean rooms, a fully equipped diagnostics laboratory, microbiology laboratory and testing laboratory. We lease the building under a ten-year operating lease which runs through August 2023 and has a monthly lease payment of $13,000. The lease also has a ten-year renewal option.

In November 2007, we purchased a 14,000 square foot facility at 664 Cruiser Lane, Belgrade, Montana 59714. This building is an FDA registered facility with a Class 10,000 (ISO 7) environmentally controlled area.

We also lease space approximately 21,000 square feet in a building located at 732 Cruiser Lane, Belgrade, Montana 59714, where one Class 1,000 (ISO 6) clean room is located, and we lease office space in Englewood and Westminster, Colorado, where certain of our administrative functions are housed.

Item 3. Legal Proceedings

On March 17, 2014, a complaint was served on the Company in the following state court action in the District Court for the County of Arapahoe, State of Colorado: Robert Taggart v. Guy Cook, Bacterin International, Inc., a Nevada Corporation and Bacterin International Holdings, Inc., a Delaware corporation, Civil Action No. 14CV30401. The complaint involves claims under an employment agreement between plaintiff and the Company seeking commissions on Company sales, a commission on funds obtained by the Company as a result of a reverse merger and vesting of certain stock options. Plaintiff seeks damages in excess of $5 million. The Company believes this case lacks legal merit and has filed counterclaims for plaintiff's breach of his employment agreement and breach of his duty of loyalty to the Company, asserting the right to recover all compensation paid to Plaintiff during his employment as well as other damages.

On July 9, 2014, a complaint was served on the Company in the following action in the United States District Court, District of New Jersey: Middlebury Securities, LLC v. Bacterin International, Inc., Case Number 2:14-CV-03905-WJM-MF. The complaint alleges that Bacterin owes Middlebury an $80,000 fee, along with $80,000 in warrants, in connection with the March 6, 2014 extension of credit by ROS Acquisition Offshore LP, a Cayman Islands Exempted Limited Partnership. Bacterin believes this case lacks merit because there is no agreement between the parties regarding the transaction in question.

On July 14, 2014, a complaint was served on the Company in the following action in the United States Bankruptcy Court, Southern District of New York, In re: Rodman & Renshaw, LLC, Debtor, Case No. 13-10087 (REG): YANN GERON, Chapter 7 Trustee of the Estate of Rodman & Renshaw, LLC, Plaintiff, against Bacterin International Holdings, Inc. The complaint alleges that Bacterin owes a $150,000 investment banking fee in connection with Bacterin's April 2012 accounts receivable credit facility with MidCap Financial LLC. Bacterin believes this case lack merit because the accounts receivable credit facility was not a debt or equity security covered by the engagement letter.

Item 4. Mine Safety Disclosures

Not Applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock trades on the NYSE MKT under the symbol BONE. The following table sets forth the range of the high and low prices for our common stock for each quarter, as reported by the NYSE MKT from January 1, 2013 through December 31, 2014. Prices have been adjusted to reflect the Company's July 25, 2014 1:10 reverse stock split.

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

Holders of Record

As of February 5, 2015, we had 219 holders of record.

Dividends

We have not paid any cash dividends and do not expect to do so in the foreseeable future. In addition, our Credit Agreement with ROS Acquisition Offshore LP precludes us from paying dividends.

Recent Sales of Unregistered (and Registered) Securities

Not applicable.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 6. Selected Financial Data

Not required.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation

Safe Harbor Declaration

The comments made throughout this Annual Report on Form 10-K should be read in conjunction with our Financial Statements and the Notes thereto, and other financial information appearing elsewhere in this document. In addition to historical information, the following discussion and other parts of this document contain certain forward-looking information. When used in this discussion, the words "believes," "anticipates," "expects," "plan," "possible," "should," "might," "may" and similar expressions are intended to identify forward-looking statements. Such statements are subject to certain risks and uncertainties, which could cause actual results to differ materially from projected results, due to a number of factors beyond our control. We do not undertake to publicly update or revise any of our forward-looking statements, even if experience or future changes show that the indicated results or events will not be realized. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. See "Cautionary Note Regarding Forward Looking Statements." Readers are also urged to carefully review and consider our discussions regarding the various factors that affect our business, which are described in the section entitled "Risk Factors" in Item 1A. of this Form 10-K.

Comparison of Year Ended December 31, 2014 and December 31, 2013

	Year Ended December 31, 2014		2013	
	Amount	% of Revenue	Amount	% of Revenue
Revenue				
Tissue sales	$34,569,160	97.84 %	$32,563,933	98.46 %
Royalties and other	762,652	2.16 %	509,481	1.54 %
Total Revenue	35,331,812	100.00 %	33,073,414	100.00 %
Cost of sales	13,034,314	36.89 %	14,185,719	42.89 %
Gross Profit	22,297,498	63.11 %	18,887,695	57.11 %
Operating Expenses				
General and administrative	8,886,972	25.15 %	10,204,659	30.85 %
Sales and marketing	16,912,865	47.87 %	16,017,229	48.43 %
Research and development	1,443,018	4.08 %	572,361	1.73 %
Depreciation and amortization	271,748	0.77 %	377,524	1.14 %
Non-cash consulting expense	135,075	0.38 %	(5,117)	-0.02 %
Total Operating Expenses	27,649,678	78.26 %	27,166,656	82.14 %
Loss from Operations before Impairment	(5,352,180)	-15.15 %	(8,278,961)	-25.03 %
Impairment of Assets	912,549	2.58 %	728,618	2.21 %
Loss from Operations	(6,264,729)	-17.73 %	(9,007,579)	-27.24 %
Other Income (Expense)				
Interest expense	(5,660,357)	-16.02 %	(4,653,232)	-14.07 %
Change in warrant derivative liability	1,736,053	4.91 %	875,041	2.65 %
Other income (expense)	(318,836)	-0.90 %	92,645	0.28 %
Total Other Income (Expense)	(4,243,140)	-12.01 %	(3,685,546)	-11.14 %
Net Loss from Operations Before (Provision) Benefit for Income Taxes	(10,507,869)	-29.74 %	(12,693,125)	-38.38 %
Benefit (Provision) for Income Taxes				
Current	-	0.00 %	-	0.00 %
Deferred	-	0.00 %	-	0.00 %
Net Loss	$(10,507,869)	-29.74 %	$(12,693,125)	-38.38 %

Revenue

Total revenue for the year ended December 31, 2014 increased approximately 6.8% to $35,331,812 compared to $33,073,414 in the prior year. The increase of $2,258,398 is due to improved sales force productivity realized from increased sales headcount and manufacturer representatives as part of a restructuring of the sales function.

Cost of tissue sales

Costs of tissue sales consist primarily of tissue and device manufacturing costs. Costs of tissue sales decreased by 8.1% or $1,151,405 to $13,034,314 for the year ended December 31, 2014 from $14,185,719 for the year ended December 31, 2013. As a percentage of tissue sales, cost of tissue sales was 36.9% of revenues for 2014 compared to 42.9% in 2013. The fiscal year 2013 amount included a one time adjustments for aged and expiring inventory.

Operating Expenses

Operating expenses include general and administrative expenses, selling and marketing expenses, depreciation, research and development expenses, and compensation costs, including incentive compensation. Operating expenses increased 1.8%, or $483,022 for the year ended December 31, 2014 compared to the year ended December 31, 2013, primarily due to the reasons set forth below.

General and Administrative

General and administrative expenses consist principally of corporate personnel cash based and stock option compensation related costs and corporate expenses for legal, accounting and other professional fees as well as occupancy costs. General and administrative expenses decreased 12.9%, or $1,317,687, to $8,886,972, for the year ended December 31, 2014 compared to 2013 due to cost reduction measures implemented during the year.

Selling and Marketing

Selling and marketing expenses primarily consist of costs for sales and marketing personnel, sales commissions, costs for trade shows, sales conventions and meetings, travel expenses, advertising and other sales and marketing related costs. In addition, stock option compensation expense associated with our sales force is also included in sales and marketing expenses. Selling and marketing expenses increased 5.6%, or $895,636, to $16,912,865 for the twelve months ended December 31, 2014 from $16,017,229 for the prior year as a result of increased revenues between the two periods. As a percentage of revenue, selling and marketing expenses decreased to 47.9% in 2014 from 48.4% in the prior year.

Research and Development

Research and development expenses consist primarily of internal costs for the development of new technologies and processes for tissue and coatings. Research and development expenses increased $870,657 or 152% from $572,361 for the twelve months ended December 31, 2013 to $1,443,018 for the same period of 2014. The increase is due to increased spending on research and development projects and the transfer of research and development personnel expenses from General and Administrative to Research and Development.

Impairment of Assets

In 2013, management engaged an independent third party to review the asset for impairment in accordance with and pursuant to ASC 350 “Intangibles - Goodwill and Other” and ASC 360-10 “Impairment and Disposal of Long-Lived Assets”. The independent third party concluded that the goodwill associated with an acquisition the Company made in 2011 was impaired and should be written down fully to $0 resulting in a charge of $728,618.

During the fourth quarter of 2014, management made a strategic decision to dispose of product lines that were not components of the Company’s core strategy. The component groups are the inventory and fixed assets associated with the Device Coatings and Cranial Maxillofacial Fixation (CMF) lines of business.

Sales for these product lines represented 1.2% of total revenue in 2013 and 1.4% of total revenue in 2014. Gross profit associated with these product lines were less than 1% of total gross profit for both the years 2013 and 2014.

Management has committed to a plan to sell the component assets and the assets are available for immediate sale in their present condition. As of February 2015, management has identified a potential buyer for the device coatings product line and has entered into an agreement with another buyer for the inventory of the CMF product line.

Total assets associated with the two lines includes $80,042 of related fixed assets, net of depreciation, and related inventory of $832,507 for a total value of $912,549. These assets were transferred to Assets held for Sale and are classified on the balance sheet as part of “Prepaid and other current assets”. After the impairment provision, the net balance of the Assets held for Sale is $0.

Depreciation

Depreciation expense consists of depreciation of long-lived property and equipment. Depreciation expense decreased 28% to $271,748 for the year ended December 31, 2014 from $377,524 in 2013.

Non-cash Consulting Expense

Non-cash consulting expense consists of non-cash expense associated with granting restricted stock and stock to consultants and directors. Non-cash consulting expense increased $140,191 to $135,074 for the year ended December 31, 2014 from a negative $5,117 in the prior year.

Interest Expense

Interest expense is from our promissory notes and debt instruments. Interest expense for 2014 increased $1,007,125 to $5,660,357 as compared to $4,653,232 in 2013. The increase was the result of a $431,000 increase in loan interest expense and a $576,000 increase in non-cash debt issuance expense.

Change in Warrant Derivative Liability

For 2014, the Company recorded a gain from a decrease in its non-cash warrant derivative liability of $1,736,053 which was primarily driven by the decrease in the closing price of the Company’s common stock at December 31, 2014 compared to December 31, 2013 which was partially offset by the issuance of additional derivative warrants in 2014. The liability is associated with the issuance of warrants as part of the Company’s prior convertible debt financing, the Company’s 2010 financing and the Company’s 2014 equity financing which contain certain provisions requiring the Company to record a change in the warrant derivative liability from period to period.

Other Expense/Income

Other Expense for 2014 was $318,836 as compared to income of $92,645 in 2013. The increase is related to payments made in connection with a legal settlement. See note 15, “Related Party Transactions” below for further discussion.

Liquidity and Capital Resources

Since our inception, we have historically financed our operations through operating cash flows, as well as the private placement of equity securities and convertible debt, an equity credit facility and other debt transactions. In March 2014, we received an additional $4 million in term loan debt from ROS Acquisition Offshore LP. In June 2014, the Company closed on a $5.9 million equity financing with existing and new investors. At December 31, 2014, we had $8,895,289 of cash and cash equivalents and accounts receivables. See note 16, Subsequent Event, describing an additional $10 million Common Stock Purchase Agreement with Aspire Capital Fund, LLC which will provide additional liquidity over the next 24 months.

Net cash used in operating activities for 2014 was $7,324,059, primarily related to funds required to finance the Company’s operations. For 2013, net cash used in operating activities was $4,892,306. The increase in net cash used in operations between 2014 and 2013 is primarily the result of decreases in the Company’s Accrued Liabilities.

Net cash used by investment activities for 2014 was $298,352 due to the sale/retirement of property and equipment offset by increases in intangible assets.

Net cash provided by financing activities was $9,044,279 for 2014 primarily due to proceeds from the sale of equity securities and the issuance of additional debt (net of financing fees and warrants) which is partially offset by payments and debt and capital lease obligations.

Off Balance Sheet Arrangements

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

Cash Requirements

We believe that our December 31, 2014 cash on hand and accounts receivable balance of $8,895,289 along with anticipated cash receipts from sales expected from operations will be sufficient to meet our anticipated cash requirements through March 31, 2016. We incurred approximately $17 million in sales and marketing expenses in 2014 and expect to incur $19 million in 2015 based upon our current sales estimates. The sales and marketing expenses are largely variable expenses and are anticipated to be funded from operating cash flow. An increase of these expenses may impact our operating results and there can be no assurance of their effectiveness. If we do not meet our revenue objectives over that period, we may need to sell additional equity securities, which could 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 limit our ability to expand our business operations and could harm our overall business prospects.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

Bacterin International Holdings, Inc.

Belgrade, Montana

We have audited the accompanying consolidated balance sheets of Bacterin International Holdings, Inc. and subsidiary (the "Company") as of December 31, 2014 and 2013, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Bacterin International Holdings, Inc. and subsidiary as of December 31, 2014 and 2013, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ EKS&H LLLP

March 18, 2015

Denver, Colorado

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BACTERIN INTERNATIONAL HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS

	As of December 31, 2014	As of December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	$4,468,208	$3,046,340
Trade accounts receivable, net of allowance for doubtful accounts of $1,392,989 and $1,309,859, respectively	4,427,081	4,793,834
Inventories, net	9,558,648	10,753,600
Prepaid and other current assets	654,140	574,910
Total current assets	19,108,077	19,168,684
Non-current inventories	1,934,258	2,119,952
Property and equipment, net	4,654,527	5,180,556
Intangible assets, net	655,490	586,965
Other assets	1,598,539	1,821,471
Total Assets	$27,950,891	$28,877,628
LIABILITIES & STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	$3,876,760	$2,767,639
Accounts payable - related party	250,629	647,844
Accrued liabilities	1,921,301	3,585,037
Warrant derivative liability	1,320,371	1,594,628
Current portion of capital lease obligations	61,970	171,926
Current portion of royalty liability	1,000,750	836,750
Current portion of long-term debt	50,671	47,727
Total current liabilities	8,482,452	9,651,551
Long-term Liabilities:		
Capital lease obligation, less current portion	11,808	73,777
Long-term royalty liability, less current portion	6,361,216	6,609,232
Long-term debt, less current portion	20,870,330	16,385,245
Total Liabilities	35,725,806	32,719,805
Commitments and Contingencies		
Stockholders' (Deficit) Equity		
Preferred stock, $0.000001 par value; 5,000,000 shares authorized; no shares issued and Outstanding	-	-
Common stock, $0.000001 par value; 95,000,000 shares authorized; 6,679,646 shares issued and outstanding as of December 31, 2014 and 5,343,282 shares issued	7	5

and outstanding as of December 31, 2013		
Additional paid-in capital	63,091,620	56,516,491
Accumulated deficit	(70,866,542)	(60,358,673)
Total Stockholders' Deficit	(7,774,915)	(3,842,177)
Total Liabilities & Stockholders' Deficit	$27,950,891	$28,877,628

See notes to audited consolidated financial statements.

BACTERIN INTERNATIONAL HOLDINGS, INC.

Consolidated Statements of Operations

	Year Ended December 31,	
	2014	2013
Revenue		
Tissue sales	$34,569,160	$32,563,933
Royalties and other	762,652	509,481
Total Revenue	35,331,812	33,073,414
Cost of sales	13,034,314	14,185,719
Gross Profit	22,297,498	18,887,695
Operating Expenses		
General and administrative	8,886,972	10,204,659
Sales and marketing	16,912,865	16,017,229
Research and development	1,443,018	572,361
Depreciation and amortization	271,748	377,524
Impairment of assets	912,549	728,618
Non-cash consulting expense	135,075	(5,117)
Total Operating Expenses	28,562,227	27,895,274
Loss from Operations	(6,264,729)	(9,007,579)
Other Income (Expense)		
Interest expense	(5,660,357)	(4,653,232)
Change in warrant derivative liability	1,736,053	875,041
Other (expense)	(318,836)	92,645
Total Other Income (Expense)	(4,243,140)	(3,685,546)
Net Loss from Operations Before (Provision) Benefit for Income Taxes	(10,507,869)	(12,693,125)
(Provision) Benefit for Income Taxes		
Current	-	-
Deferred	-	-
Net Loss	$(10,507,869)	$(12,693,125)
Net loss per share:		
Basic	$(1.76)	$(2.80)
Dilutive	$(1.76)	$(2.80)

Shares used in the computation:		
Basic	5,954,195	4,530,072
Dilutive	5,954,195	4,530,072

See notes to audited consolidated financial statements.

BACTERIN INTERNATIONAL HOLDINGS, INC.

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

	Common Stock Shares	Amount	Additional Paid-In-Capital	Retained Deficit	Total Shareholders' Equity (deficit)
Balance at December 31, 2012	4,287,777	$ 3	$ 51,897,930	$(47,665,548)	$ 4,232,385
Stock-based compensation	31,628	-	996,307	-	996,307
Exercise of options	23,000	-	27,575	-	27,575
Net proceeds from the issuance of stock	850,877	1	4,449,993		4,449,994
Issuance of warrants in conjunction with the issuance of stock	-	-	(1,485,313)	-	(1,485,313)
Issuance of stock to ROS in exchange for debt waiver	150,000	1	629,999	-	630,000
Net loss	-	-	-	(12,693,125)	(12,693,125)
Balance at December 31, 2013	5,348,282	$ 5	$ 56,516,491	$(60,358,673)	$ (3,842,177)
Stock-based compensation	38,364	-	935,316	-	935,316
Net proceeds from the issuance of stock	1,143,000	2	5,869,633	-	5,869,635
Issuance of restricted stock to employees	-	-	136,977	-	136,977
Issuance of warrants in conjunction with the issuance of stock	-	-	(1,461,796)	-	(1,461,796)
Issuance of stock to ROS to amend Credit Agreement to borrow additional $4 million	150,000	-	1,094,999	-	1,094,999
Net loss	-	-	-	(10,507,869)	(10,507,869)
Balance at December 31, 2014	6,679,646	$ 7	$ 63,091,620	$(70,866,542)	$ (7,774,915)

See notes to audited consolidated financial statements.

BACTERIN INTERNATIONAL HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2014	2013
Operating activities:		
Net loss	$(10,507,869)	$(12,693,125)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	952,320	753,522
Non-cash interest	814,374	633,398
Impairment of Assets	912,549	728,618
Loss (Gain) on sale of fixed assets	25,269	(500)
Amortization of debt discount	1,632,245	1,251,125
Non-cash consulting expense/stock option expense	935,316	838,847
Provision for losses on accounts receivable and inventory	647,765	2,320,955
Gain in derivative warrant liability	(1,736,053)	(875,041)
Decrease of contingent liability	-	(91,740)
Changes in operating assets and liabilities:		
Accounts receivable	283,624	797,680
Inventories	(17,392)	747,691
Prepaid and other assets	(455,048)	263,352
Accounts payable	715,706	(1,001,228)
Accrued liabilities	(1,526,865)	1,434,140
Net cash used in operating activities	(7,324,059)	(4,892,306)
Investing activities:		
Purchases of property and equipment and intangible assets	(299,978)	(623,045)
Proceeds from sale of fixed assets	1,626	(70,255)
Net cash used in investing activities	(298,352)	(693,300)
Financing activities:		
Proceeds from issuance of debt	4,000,000	-
Payments on long-term debt	(653,397)	(621,967)
Payments on capital leases	(171,957)	(149,729)
Proceeds from exercise of options	-	27,575
Net proceeds from issuance of stock	5,869,633	4,450,001
Net cash provided by financing activities	9,044,279	3,705,880
Net change in cash and cash equivalents	1,421,868	(1,879,726)
Cash and cash equivalents at beginning of period	3,046,340	4,926,066
Cash and cash equivalents at end of period	$4,468,208	$3,046,340

See notes to condensed consolidated financial statements.

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Notes to Condensed Consolidated Financial Statements

(1) Business Description and Summary of Significant Accounting Policies

Business Description

The accompanying consolidated financial statements include the accounts of Bacterin International Holdings, Inc., a Delaware corporation, and its wholly owned subsidiary, Bacterin International, Inc., a Nevada corporation, (collectively, the “Company” or “Bacterin”). All intercompany balances and transactions have been eliminated in consolidation. Bacterin develops, manufactures and markets biologics products to domestic and international markets. Bacterin’s proprietary methods are used in human allografts to create scaffolds and promote bone and other tissue growth. These products are used in a variety of applications including enhancing fusion in spine surgery, relief of back pain with a facet joint stabilization, promotion of bone growth in foot and ankle surgery, promotion of skull healing following neurosurgery and regeneration in knee and other joint surgeries.

Bacterin also develops and licenses coatings for various medical device applications. As of December 31, 2014, Bacterin made a strategic decision to discontinue the medical device coatings business which resulted in an impairment of related assets. See Note 4, “Impairment of Assets”.

An operating segment is a component of an enterprise whose operating results are regularly reviewed by the enterprise’s chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance. The primary performance measure used by management is net income or loss. Up until December 31, 2014, the Company operated two distinct lines of business consisting of the biologics and the device divisions. With the strategic exit from the devices business as of December 31, 2014, the Company will be operating as a single business segment in 2015.

The Company's revenue is derived principally from the sale of its biologics products. The markets in which the Company competes are highly competitive and rapidly changing. Significant technological advances, changes in customer requirements, or the emergence of competitive products with new capabilities or technologies could adversely affect the Company's operating results. The Company's business could be harmed by a decline in demand for, or in the prices of, its products or as a result of, among other factors, any change in pricing or distribution model, increased price competition, changes in government regulations or a failure by the Company to keep up with technological change. Further, a decline in available tissue donors could have an adverse impact on our business.

Reverse Stock Split

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

Public Offering

In August 2014, the Company offered 1,143,000 shares of its common stock at $5.70 per share and warrants to purchase 571,500 shares of its common stock at an exercise price of $7.12 per share to the public. Gross proceeds of the offering were approximately $6.5 million. Net proceeds from the offering were approximately $5.9 million and will be used for working capital and general corporate purposes, including the continued expansion of the company's sales force and increasing inventory levels to support anticipated future growth. The offering closed on August 6, 2014.

The warrants have a five year term and expire on August 6, 2019. The Company utilizes a lattice model to determine the fair market value and accounts for these warrants as a derivative liability (see "Derivative Instruments" below). Also, see Note 10, "Warrants" below.

Concentrations and Credit Risk

The Company’s accounts receivable are due from a variety of health care organizations and distributors throughout the world. Approximately 98% of sales were in the United States for 2014 and 2013. No single customer accounted for more than 10% of revenue or accounts receivable for 2014 and 2013. The Company provides for uncollectible amounts when specific credit issues arise. Management’s estimates for uncollectible amounts have been adequate during prior periods, and management believes that all significant credit risks have been identified at December 31, 2014.

Revenue by geographical region is as follows:

	Year ended December 31,	
	2014	2013
United States	$34,643,571	$32,458,822
Rest of World	688,241	584,592
	$35,331,812	$33,073,414

Use of Estimates

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

Reclassifications

Certain comparative balances for year ended December 31, 2013 have been reclassified to make them consistent with the current year presentation. The reclassifications had no effect on the net income for 2013.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity date of three months or less to be cash equivalents. Cash equivalents are recorded at cost, which approximates market value. At times the Company maintains deposits in financial institutions in excess of federally insured limits.

Accounts Receivable

Accounts receivable represents amounts due from customers for which revenue has been recognized. Normal terms on trade accounts receivable are net 30 days and some customers are offered discounts for early pay. The Company performs credit evaluations when considered necessary, but generally does not require collateral to extend credit.

The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing receivables. The Company determines the allowance based on factors such as historical collection experience, customer's current creditworthiness, customer concentration, age of accounts receivable balance, general economic conditions that may affect a customer's ability to pay and management judgment. Actual customer collections could differ from estimates. Account balances are charged to the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. Provisions to the allowance for doubtful accounts are charged to expense. The Company does not have any off-balance sheet credit exposure related to its customers.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using the specific identification method and includes materials, labor and overhead. The Company calculates an inventory reserve for estimated obsolescence or excess inventory based on historical usage and sales, as well as assumptions about future demand for its products. These estimates for excess and obsolete inventory are reviewed and updated on a quarterly basis. Increases in the inventory reserves result in a corresponding expense, which is recorded to cost of tissue and medical devices sales. Inventories where the sales cycle is estimated to be beyond twelve months are classified as Non-current inventories.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally three to seven years for computers and equipment, and 30 years for buildings. Leasehold improvements are depreciated over the shorter of their estimated useful life or the remaining term of the lease. Repairs and maintenance are expensed as incurred.

Goodwill

Goodwill represents the excess of costs over fair value of assets of businesses acquired. Goodwill and intangible assets acquired in a purchase business combination and determined to have indefinite useful lives are not amortized, instead are tested for impairment at least annually and whenever events or circumstances indicate the carrying amount of the asset may not be recoverable. The Company conducts its annual impairment test on December 31 of each year. In its evaluation of goodwill in 2013, the Company performed an assessment of qualitative factors to determine if it is more-likely-than-not that goodwill might be impaired and whether it is necessary to perform the two-step goodwill impairment. See Note 4, “Impairment of Assets”.

Derivative Instruments

The Company accounts for its derivative instruments in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 815 “Accounting for Derivative Instruments and Hedging Activities”. The only derivative instruments presented in the accompanying consolidated financial statements relate to warrants issued in connection with certain debt and equity financings. The Company has not designated its warrant derivative liability as a hedging instrument as described in ASC 815 and any change in the fair market value of the warrant derivative liability is recognized in the consolidated statement of operations during the period of change. See Note 10, “Warrants” below.

Intangible Assets

Intangible assets with estimable useful lives must be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment whenever events or circumstances indicate their carrying amount may not be recoverable. Intangible assets include trademarks and patents and include costs to acquire and protect Company patents. Intangible assets are carried at cost less accumulated amortization. The Company amortizes these assets on a straight-line basis over their estimated useful lives of fifteen years.

Other Assets

Other Assets consist of the short-term and the long-term portion of prepaid expenses, security deposits, the capitalized portion of debt related issuance costs and kits that are used in the implantation of certain biologic products. The items are stated at cost and in the case of debt related issuance costs and kits are amortized on a straight line basis over their estimated useful lives.

Accounts Payable - Related Party

Accounts payable to a related party includes amounts due to American Donor Services and West Coast Tissue Services, as suppliers of donors to the Company for 2014 and 2013. See Note 15, “Related Party Transactions” below.

Revenue Recognition

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

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

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

The Company also receives royalty revenue from third parties related to licensing agreements. The Company has royalty agreements with RyMed and Bard Access Systems. Revenue under these agreements represented less than 0.5% of total revenue for the years ended December 31, 2014 and 2013.

Non-Cash Consulting Expense

From time to time, the Company issues restricted stock awards to consultants and advisors to the Company. These awards are measured at fair value at each reporting date, recognized ratably over the vesting period and are recorded in non-cash consulting expense.

Advertising Costs

The Company expenses advertising costs as incurred. The Company had advertising expense of $34,970 and $47,000 for the years ended December 31, 2014 and 2013, respectively.

Research and Development

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

Income Taxes

The Company accounts for income taxes under the asset and liability method of accounting for deferred taxes as prescribed under FASB ASC 740, "Accounting for Income Taxes". Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. When applicable, a valuation allowance is established to reduce any deferred tax asset when it is determined that it is more likely than not that some portion of the deferred tax asset will not be realized. ASC 740 also requires reporting of taxes based on tax positions that meet a more-likely-than-not standard and that are measured at the amount that is more-likely-than-not to be realized. Differences between financial and tax reporting which do not meet this threshold are required to be recorded as unrecognized tax benefits. ASC 740 also provides guidance on the presentation of tax matters and the recognition of potential IRS interest and penalties. The Company classifies penalty and interest expense related to income tax liabilities as an income tax expense. There are no significant interest and penalties recognized in the statement of operations or accrued on the balance sheet. See Note 12, “Income Taxes” below.

Long-Lived Assets

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

the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. See Note 4, “Impairment of Assets”.

Net Loss Per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. Diluted net income (loss) per share is computed in a manner consistent with that of basic earnings per share while giving effect to all potentially dilutive common shares outstanding during the period, which include the assumed exercise of stock options and warrants using the treasury stock method. Diluted net loss per share was the same as basic net loss per share for the years ended December 31, 2014 and 2013, as shares issuable upon the exercise of stock options and warrants were anti-dilutive as a result of the net losses incurred for those periods. Dilutive earnings per share are not reported as their effects of including 2,350,656 and 1,846,148 outstanding stock options and warrants for the years ended December 31, 2014 and 2013, respectively, are anti-dilutive.

Stock-Based Compensation

The Company records stock-compensation expense according to the provisions of FASB ASC 718 “Compensation – Stock Compensation”. Under ASC 718, stock-based compensation costs are recognized based on the estimated fair value at the grant date for all stock-based awards. The Company estimates grant date fair values using the Black-Scholes-Merton option pricing model, which requires assumptions of the life of the award and the stock price volatility over the term of the award. The Company records Compensation cost of stock-based awards using the straight line method, which is recorded into earnings over the vesting period of the award.

Fair Value of Financial Instruments

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

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

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

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

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

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. During the years ended December 31, 2014 and 2013, there was no reclassification in financial assets or liabilities between Level 1, 2 or 3 categories.

The following tables set forth by level, within the fair value hierarchy, our assets and liabilities as of the years ended December 31, 2014 and December 31, 2013, respectively, that are measured at fair value on a recurring basis:

Accrued stock compensation

	As of December 31, 2014	**As of December 31, 2013**
Level 1	$ -	$ 211,212
Level 2	-	-
Level 3	-	-

The valuation technique used to measure fair value of the accrued stock compensation is based on quoted stock market prices.

Warrant derivative liability

	As of December 31, 2014	As of December 31, 2013
Level 1	-	-
Level 2	-	-
Level 3	$ 1,320,371	$ 1,594,628

The valuation technique used to measure fair value of the warrant liability is based on a lattice model and significant assumptions and inputs determined by us.

Level 3 Changes

The following is a reconciliation of the beginning and ending balances for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the year ending December 31, 2014:

Warrant derivative liability

Balance at January 1, 2014	$1,594,628
Warrants issued with stock offering	1,461,796
Gain recognized in earnings	(1,736,053)
Balance at December 31, 2014	$1,320,371

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During the year ended December 31, 2014, the Company did not change any of the valuation techniques used to measure its liabilities at fair value.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. ASU 2014-09 supersedes the revenue recognition guidance in Topic 605, Revenue Recognition. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods and services to customers in an amount that reflects the consideration to which the entity expects to be entitled in the exchange for those goods or services. This standard is effective for annual reporting periods beginning after December 15, 2016. ASU 2014-09 is not expected to have a material impact on our consolidated financial position, results of operations, or cash flows.

In August 2014, FASB issued ASU No. 2014-15, *Preparation of Financial Statements - Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. Under GAAP, continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity's liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. If and when an entity's liquidation becomes imminent, financial statements should be prepared under the liquidation basis of accounting in accordance with Subtopic 205-30, Presentation of Financial Statements-Liquidation Basis of Accounting. Even when an entity's liquidation is not imminent, there may be conditions or events that raise substantial doubt about the entity's ability to continue as a going concern. In those situations, financial statements should continue to be prepared under the going basis of accounting, but the amendments in this Update should be followed to determine whether to disclose information about the relevant conditions and events. The amendments in this Update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company will evaluate the going concern considerations in this ASU, but has not elected early application.

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

(2) Equity

On June 10, 2013, the Company issued approximately 851,000 shares of common stock to new and existing investors at a price per share of $5.70, which represented a 10% discount to the closing price on June 4, 2013. For each common share purchased in the offering, investors received a warrant providing the right to purchase 0.5 shares of Bacterin common stock at an exercise price of $7.20, a 15% premium to the June 4, 2013 closing price. The warrants will be exercisable for seven years beginning 6 months from the date of issuance. The transaction resulted in net proceeds to the Company of approximately $4.45 million, after deducting approximately $400,000 for placement agent’s fees and offering expenses. Proceeds from the transaction were used to fund the Company's operations and working capital requirements.

On November 14, 2013, the Company received a waiver from ROS Acquisition Offshore LP (“ROS”) for failure to achieve $10.5 million of revenue in the third quarter of 2013. In exchange for the waiver and reduction of future quarterly minimum revenue thresholds, the Company issued 150,000 shares of restricted stock to an affiliate of ROS on November 25, 2013.

During the first quarter of 2014, the Company issued 150,000 shares of common stock to an affiliate of ROS pursuant to a Sixth Amendment to our Credit Agreement with ROS whereby we borrowed an additional $4 million under our Credit Agreement. This issuance has been accounted for as a debt discount and will be amortized over the life of the loan. See Note 8, “Long-Term Debt” below.

In August 2014, the Company offered 1,143,000 shares of its common stock at $5.70 per share and warrants to purchase 571,500 shares of its common stock at an exercise price of $7.12 per share to the public. Gross proceeds of the offering were approximately $6.5 million. Net proceeds from the offering were approximately $5.9 million and are expected to be used for working capital and general corporate purposes including the continued expansion of the company's sales force and increasing inventory levels to support anticipated future growth. The offering closed on August 6, 2014.

The warrants have a five year term and expire on August 6, 2019. The Company utilizes a valuation model to determine the fair market value and accounts for these warrants as a derivative liability (See Note 1, Derivative Instruments" above). Also, see Note 10, "Warrants" below.

(3) Inventories

Inventories consist of the following:

	December 31, 2014	December 31, 2013
Current inventories		
Raw materials	$ 3,836,635	$ 2,710,091
Work in process	2,484,635	3,333,672
Finished goods	5,163,458	5,775,813
	11,484,728	11,819,576
Reserve for obsolescence	(1,926,080)	(1,065,976)
Current inventories, total	9,558,648	10,753,600
Non-current inventories		
Finished goods	2,860,248	3,341,411
Reserve for obsolescence	(925,990)	(1,221,459)
Non-current inventories, total	1,934,258	2,119,952
Total inventories	$ 11,492,906	$ 12,873,552

(4) Impairment of Assets

In 2013, after reviewing the full year product line sales associated with the goodwill asset and the fact that the sales were not meeting original projections, management engaged an independent third party to review the asset for impairment in accordance with and pursuant to ASC 350 and ASC 360-10. The implied fair value of the goodwill was determined in the same manner as the amount of goodwill recognized in a business combination, as determined under ASC 805. In 2013, the management concluded that the goodwill asset was in fact impaired and should be written down fully to $0 indicating a goodwill impairment amount of $728,618.

During the fourth quarter of 2014, management decided to dispose of a group of components because of a shift in strategy for the Company. The component groups are the inventory and fixed assets associated with the Device Coatings and Cranial Maxillofacial Fixation (CMF) lines of business.

Sales for these product lines represented 1.2% of total revenue in 2013 and 1.4% of total revenue in 2014. Gross profit associated with these product lines were less than 1% of total gross profit for both the years 2013 and 2014.

Management has committed to a plan to sell the component assets and the assets are available for immediate sale in their present condition. As of February 2015, management has identified a potential buyer for the device coatings product line and has entered into an agreement with another party for the inventory of the CMF product line.

Total assets associated with the two lines includes $80,042 of related fixed assets, net of depreciation, and related inventory of $832,507 for a total value of $912,549. These assets were transferred to Assets held for Sale and are classified on the balance sheet as part of “Prepaid and other current assets”. After the impairment provision, the net balance of the Assets held for Sale is $0.

Because the device coatings agreement is in the early stage of negotiations and the sale of the CMF inventory did not result in any tangible compensation, management has decided to reserve for the entire amount and has recorded a loss from impairment of assets of $912,549 on the 2014 Consolidated Statement of Operations.

(5) Property and Equipment, Net

Property and equipment, net are as follows:

	December 31, 2014	December 31, 2013
Buildings	$ 1,657,579	$ 1,653,263
Equipment	4,724,608	5,768,478
Computer equipment	225,009	312,650
Computer software	345,039	395,146
Furniture and fixtures	153,834	170,118
Leasehold improvements	2,380,617	1,808,461
Vehicles	41,099	41,099
Total cost	9,527,785	10,149,215
Less: accumulated depreciation	(4,873,258)	(4,968,659)
	$ 4,654,527	$ 5,180,556

The Company leases certain equipment under capital leases. For financial reporting purposes, minimum lease payments relating to the assets have been capitalized. As of December 31, 2014, the Company has recorded $443,060 gross assets in Equipment, and $191,174 of accumulated depreciation relating to assets under capital leases. As of December 31, 2013, the Company had recorded $549,604 gross assets in Equipment, and $159,722 of accumulated depreciation relating to assets under capital leases.

Maintenance and repairs expense for the years ended 2014 and 2013 was $293,707 and $244,398, respectively. Depreciation expense related to property and equipment, including property under capital lease for the years ended 2014 and 2013 was $570,726 and $677,856, respectively.

(6) Intangible Assets

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

The following table sets forth information regarding intangible assets:

	December 31, 2014	December 31, 2013
Intellectual Property		
Gross carrying value	$ 1,036,580	$ 891,034
Accumulated amortization	(381,090)	(304,069)
Net carrying value	$ 655,490	$ 586,965
Aggregate amortization expense for the years ended December 31, 2014 and 2013, respectively:	$ 77,022	$ 75,668

The following is a summary of estimated future amortization expense for intangible assets as of December 31, 2014:

2015	$90,055
2016	58,639
2017	58,639
2018	58,639
2019	55,105
Thereafter	334,413
Total	$655,490

(7) Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2014	December 31, 2013
Accrued stock compensation	$ -	$ 211,212
Wages/commissions payable	1,434,743	1,728,576
Other accrued expenses	486,558	1,645,249
	$ 1,921,301	$ 3,585,037

(8) Long-term Debt

On August 24, 2012, the Company entered into a Credit Agreement with ROS, which provided for an initial $20 million term loan. The Credit Agreement also provided for an additional $5 million upon achievement prior to December 31, 2013 of certain revenue objectives, which were not achieved. The Company received net proceeds from ROS of approximately $10 million following repayment of the existing term loan and accounts receivable credit facility with MidCap Financial, including prepayment penalties. The Company used the net proceeds for working capital and general corporate purposes. The loan carries an interest rate of LIBOR plus 12.13%, subject to a LIBOR floor rate of 1.0%. Bacterin also agreed to pay a royalty of 1.75% on the first $45,000,000 of net sales, plus 1.0% of net sales in excess of $45,000,000 for ten years. Upon the occurrence of a defined event of default, ROS has the option to require the Company to purchase from ROS all of its rights to the remaining royalty payments that will become due in accordance with the royalty agreement (the “ROS Put Option”). The ROS Put Option meets the definition of an embedded derivative and we concluded it had an immaterial value at December 31, 2014 and 2013.

As such, the Company has not recorded a derivative liability related to the ROS Put Option and has not recognized any change in the fair value of this derivative liability in the consolidated financial statements because the impact is immaterial. Management will reassess the fair value of the embedded derivative instrument at each reporting period and record if and when it becomes material to the consolidated financial statements.

Bacterin has the right to repurchase the loan and royalty interest at amounts to be determined based on the date of repurchase, less the amount of prior principal, interest and royalty payments. We will also have to pay fees, currently in the amount of 3.5% of the aggregate principal amount of the loan, as a result of waivers and modifications we have received in connection with the financial covenants in the Credit Agreement. The loan is secured by substantially all of our assets. The estimate of the royalty component of the facility over the life of the agreement resulted in a debt discount and a royalty liability of $7,361,966. The debt discount will be amortized to interest expense over the seven year term of the loan using the effective interest method. The royalty liability will be accreted to $12.3 million through interest expense over the ten year term of the royalty agreement using the effective interest method.

The repurchase price, per the table below, following the additional $4 million we borrowed on March 6, 2014 and before deducting the amount of prior principal, interest and royalty payments, is as follows: (a) $40,000,000 if we exercise the repurchase option between August 24, 2014 and August 24, 2015; (b) $45,000,000 if we exercise the purchase option between August 24, 2015 and August 24, 2016; (c) $52,500,000 if we exercise the repurchase option between August 24, 2016 and August 24, 2017; and (d) $56,250,000 if we exercise the repurchase option after August 24, 2017. The following table provides an approximation of the repurchase price based on revenue equal to the minimum revenue required pursuant to the financial covenants in our Credit Agreement and four years of interest only payments with principal and interest amortized over years five through seven. Any modification in the payment schedule or in actual revenue achieved would change the Net Buyout Amount in the table below. The estimated amounts in the table below do not include fees payable on the aggregate principal amount of the loan pursuant to waivers and modifications to the Credit Agreement. The table below is for illustration purposes only and there can be no assurance that we will achieve the minimum revenue required by the financial covenants or that we will make all required payments on a timely basis.

Calculation of ROS Buyout	Repurchase Price	Interest/ Principal Payments	Estimated Royalty on Minimum revenue	Estimated Total Cumulative Payments	Net Buyout Amount
Between August 24, 2014 and August 24, 2015	$40,000,000	$3,151,200	$638,750	$10,508,117	$29,491,883
Between August 24, 2015 and August 24, 2016	$45,000,000	$3,151,200	$665,000	$14,324,317	$30,675,683
Between August 24, 2016 and August 24, 2017	$52,500,000	$9,721,896	$665,000	$24,711,213	$27,788,787
After August 24, 2017	$56,250,000	$9,721,896	$665,000	$35,098,109	$21,151,891

In 2013, we entered into a number of waivers and amendments to our credit facility with ROS, including amendments that increased the amount payable to ROS. These waivers and amendments are summarized below.

On May 16, 2013, we entered into an amendment to our Credit Agreement with ROS, whereby ROS agreed to reduce our minimum liquidity requirement from $1,500,000 to $750,000 until September 30, 2013. In exchange, we agreed to pay a fee in the amount of 1.5% of the aggregate amount of any principal payment, prepayment or repayment.

On August 12, 2013, we entered into a Waiver and Second Amendment to our Credit Agreement with ROS whereby we granted ROS Board observer rights in exchange for a waiver of our failure to replace our former Chief Executive Officer within 90 days of his resignation.

On August 12, 2013, we also entered into a Waiver and Third Amendment to our Credit Agreement with ROS whereby we agreed to pay an additional fee in the amount of 2% (in addition to our prior fee of 1.5%, for a total of 3.5%) of the aggregate amount of any principal payment, prepayment or repayment in exchange for a waiver of our failure to achieve the minimum revenue required in the second quarter of 2013.

On August 30, 2013, we entered into a Fourth Amendment to our Credit Agreement with ROS to revise the Board observer rights we granted to ROS.

On November 14, 2013, we entered into a Waiver and Fifth Amendment to our Credit Agreement with ROS whereby we agreed to issue 150,000 shares of common stock to an affiliate of ROS in exchange for a waiver of our failure to achieve the minimum required revenue for the third quarter of 2013 and a reduction of future quarterly minimum revenue thresholds.

On March 6, 2014, we entered into a Sixth Amendment to our Credit Agreement with ROS whereby we borrowed an additional $4 million under our Credit Agreement with ROS and agreed to issue 150,000 shares to an affiliate of ROS. We plan to use the proceeds for working capital and general corporate purposes.

Long-term debt consists of the following:

	December 31, 2014	December 31, 2013
Loan payable to ROS Acquisition Offshore, LIBOR plus 12.13% maturing August 2019	$ 24,000,000	$ 20,000,000
Adjustment fee payable to ROS Acquisition Offshore, due in August 2019	700,000	700,000
6.00% loan payable to Valley Bank of Belgrade, $10,746 monthly payments including interest, maturing December 24, 2030; secured by building	1,325,814	1,375,030
	26,025,814	22,075,030
Less: current portion	(50,671)	(47,727)
Debt discount	(5,104,813)	(5,642,058)
Long-term debt	$ 20,870,330	$ 16,385,245

The following is a summary of maturities due on the debt as of December 31, 2014:

2015	$50,609
2016	2,112,064
2017	8,290,378
2018	8,293,897
2019	6,239,295
2020 and thereafter	1,039,571
Total	$26,025,814

The following is a summary of estimated future royalty payments as of December 31, 2014:

2015	$1,000,750
2016	1,229,250
2017	1,360,250
2018	1,462,750
2019	1,575,250
Thereafter	5,626,325
Total	$12,254,575

(9) Stock-Based Compensation

Our Equity Incentive Plan ("The Plan") provides for stock awards, including options and performance stock awards, to be granted to employees, consultants, independent contractors, officers and directors. The purpose of the Plan is to enable us to attract, retain and motivate key employees, directors and, on occasion, independent consultants, by providing them with stock options and restricted stock grants. Stock options granted under the Plan may be either incentive stock options to employees, as defined in Section 422A of the Internal Revenue Code of 1986, or non-qualified stock options. The Plan is administered by the compensation committee of our Board of Directors. The administrator of the Plan has the power to determine the terms of any stock options granted under the Plan, including the exercise price, the number of shares subject to the stock option and conditions of exercise. Stock options granted under the Plan are generally not transferable, vest in installments over the requisite service period and are exercisable during the stated contractual term of the option only by such optionee. The exercise price of all incentive stock options granted under the Plan must be at least equal to the fair market value of the shares of common stock on the date of the grant. 900,000 shares are authorized under the Plan and at December 31, 2014, we had approximately 107,700 shares available for issuance. Shares issued under the Plan may be authorized, but unissued or reacquired shares.

Stock compensation expense recognized in the statement of operations for the year ended December 31, 2014 and 2013 is based on awards ultimately expected to vest and reflects an estimate of awards that will be forfeited. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The estimated fair value of stock options granted is done using the Black-Sholes-Merton method applied to individual grants. The Company utilizes historical employee termination behavior to determine the estimated forfeiture rates. If the actual forfeitures differ from those estimated by management, adjustments to compensation expense will be made in future periods. An assumed forfeiture rate of 20% was used for the year ended 2014.

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

¨ Risk-Free Rate: The risk-free rate is determined by reference to U.S. Treasury yields at or near the time of grant for time periods similar to the expected term of the award. We used a weighted-average rate of 1.92% and 1.16% for years ended December 31, 2014 and December 31, 2013, respectively.

.. Expected Term: We do not have adequate history to estimate an expected term of stock-based awards, and accordingly, we use the simplified method as prescribed by Staff Accounting Bulletin 107 to determine an expected term. We used a weighted-average expected term of 5.4 and 6.2 years for the years ended December 31, 2014 and December 31, 2013, respectively.

¨ Volatility: We estimate expected volatility based on peer-companies as prescribed by ASC 718. We used a weighted-average volatility rate of 57% and 66% for the years ended December 31, 2014 and December 31, 2013, respectively.

¨ Dividend Yield: The dividend yield assumption is based on our history and expectation of dividend payouts and was 0% as of December 31, 2014 and 2013.

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

Stock option activity under the Plan, plus the Non-Plan Grants, was as follows:

	2014			2013		
	Shares	Weighted Average Exercise Price	Weighted Average Fair Value at Grant Date	Shares	Weighted Average Exercise Price	Weighted Average Fair Value at Grant Date
Outstanding at January 1	758,328	$ 14.90	$ 8.60	526,653	$ 20.20	$ 10.30
Granted	169,300	5.78	2.65	333,125	6.30	5.30
Exercised	(6,666)	10.00	0.04	(23,000)	1.00	0.60
Cancelled or expired	(225,626)	11.38	6.07	(78,450)	17.60	8.90
Outstanding at December 31	695,336	$ 11.09	$ 5.35	758,328	$ 14.90	$ 8.60
Exercisable at December 31	311,080	$ 15.25	$ 7.35	264,272	$ 20.10	$ 10.30

The aggregate intrinsic value of options outstanding as of December 31, 2014 is approximately $23,345. The aggregate intrinsic value of exercisable options as of December 31, 2014 is approximately $23,345. As of December 31, 2014, there were 384,256 unvested options with a weighted average fair value at the grant date of $12.54 per option. As of December 31, 2014, there is approximately $795,221 of compensation expense related to unvested awards not yet recognized.

On May 24, 2013, the Company issued 33,500 restricted stock awards to certain employees. These restricted shares vested after one year and were issued when the stock price was $6.80 per share. The total expense of $227,800 was recognized ratably over the vesting period in General and Administrative and Sales and Marketing Expenses.

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

The Company recognized non-cash consulting expense for the years ended 2014 and 2013 as $135,075 and a negative $5,117, respectively.

Total share based compensation recognized for employees and consultants were $935,316 and $975,905 for the years ended December 31, 2014 and 2013, respectively.

The following table summarizes restricted stock award activity during the year ended December 31, 2014:

	Shares
Outstanding at January 1, 2013	73,390
Cancelled	(27,868)
Vested	(14,672)
Outstanding at January 1, 2014	30,850
Awarded	39,312
Cancelled	(30,850)
Vested	-
Outstanding at December 31, 2014	39,312

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

(10) Warrants

The following table summarizes our warrant activities for the period ended December 31, 2014:

	Weighted Average

	Shares	Exercise Price
Outstanding as of January 1, 2013	732,167	$ 22.00
Issued	435,222	7.20
Expired	(79,569)	20.00
Outstanding at January 1, 2014	1,087,820	$ 16.20
Issued	571,500	7.12
Expired	(4,000)	20.00
Outstanding at December 31, 2014	1,655,320	13.06

We utilize a lattice model to determine the fair market value of the warrants accounted for as liabilities. The valuation model accommodates the probability of exercise price adjustment features as outlined in the warrant agreements. We recorded an unrealized gain of $1,736,053 resulting from the change in the fair value of the warrant derivative liability for 2014. Under the terms of the warrant agreement, at any time while the warrant is outstanding, the exercise price per share can be reduced to the price per share of future subsequent equity sales of our common stock or a common stock equivalent that is lower than the exercise price per share as stated in the warrant agreement.

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

	Year ended December 31,	
	2014	2013
Value of underlying common stock (per share)	$3.03	$5.00
Risk free interest rate	0.80 %	0.89 %
Expected term	5.00 years	5.56 years
Dividend yield	0	0
Volatility	75 %	65 %

The following table summarizes our activities related to warrants accounted for as a derivative liability for the year ended December 31, 2014 and 2013:

	2014	2013
Balance at January 1, 2014	600,192	164,971
Derivative warrants issued	571,500	435,221
Derivative warrants exercised	-	-
Balance at December 31, 2014	1,171,692	600,192

(11) Commitments and Contingencies

Operating Leases

We lease two office facilities under non-cancelable operating lease agreements with expiration dates in 2019 and 2023. We have the option to extend both the leases for another ten year term and for one facility, we have the right of first refusal on any sale. We lease an additional office facility under a month-to-month arrangement. Future minimum payments for the next five years and thereafter as of December 31, 2014, under these leases, are as follows:

2015	$334,317
2016	269,400
2017	269,400
2018	269,400
2019	269,400
Thereafter	559,000
Total	$1,970,917

Rent expense was $365,000 and $283,000 for the years ended December 31, 2014 and 2013, respectively. Rent expense is determined using the straight-line method of the minimum expected rent paid over the term of the agreement. We have no contingent rent agreements.

Indemnifications

Our arrangements generally include limited warranties and certain provisions for indemnifying customers against liabilities if our products or services infringe a third-party's intellectual property rights. To date, we have not incurred

any material costs as a result of such warranties or indemnifications and have not accrued any liabilities related to such obligations in the accompanying financial statements.

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

Pending and Threatened Litigation

On March 17, 2014, a complaint was served on the Company in the following state court action in the District Court for the County of Arapahoe, State of Colorado: Robert Taggart v. Guy Cook, Bacterin International, Inc., a Nevada Corporation and Bacterin International Holdings, Inc., a Delaware corporation, Civil Action No. 14CV30401. The complaint involves claims under an employment agreement between plaintiff and the Company seeking commissions on Company sales, a commission on funds obtained by the Company as a result of a reverse merger and vesting of certain stock options. Plaintiff seeks damages in excess of $5 million. The Company believes this case lacks legal merit and has filed counterclaims for plaintiff's breach of his employment agreement and breach of his duty of loyalty to the Company, asserting the right to recover all compensation paid to Plaintiff during his employment as well as other damages.

On July 9, 2014, a complaint was served on the Company in the following action in the United States District Court, District of New Jersey: Middlebury Securities, LLC v. Bacterin International, Inc., Case Number 2:14-CV-03905-WJM-MF. The complaint alleges that Bacterin owes Middlebury an $80,000 fee, along with $80,000 in warrants, in connection with the March 6, 2014 extension of credit by ROS. Bacterin believes this case lacks merit because there is no agreement between the parties regarding the transaction in question.

On July 14, 2014, a complaint was served on the Company in the following action in the United States Bankruptcy Court, Southern District of New York, In re: Rodman & Renshaw, LLC, Debtor, Case No. 13-10087 (REG): YANN GERON, Chapter 7 Trustee of the Estate of Rodman & Renshaw, LLC, Plaintiff, against Bacterin International Holdings, Inc. The complaint alleges that Bacterin owes a $150,000 investment banking fee in connection with Bacterin's April 2012 accounts receivable credit facility with MidCap Financial LLC. Bacterin believes this case lack merit because the accounts receivable credit facility was not a debt or equity security covered by the engagement letter.

NYSE MKT Deficiency Notice

On May 13, 2013, we received a deficiency notice from the NYSE MKT 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. On November 14, 2014, we received a letter notifying us that the staff of NYSE Regulation, Inc. (the "Staff")

determined to commence proceedings to delist our common stock from the NYSE MKT because we did not cure our non-compliance with Sections 1003(a)(i), (ii) and (iii) of the NYSE MKT Company Guide by the end of the maximum 18 month compliance period, which expired on November 13, 2014. We appealed the Staff's delisting determination and attended a hearing on January 21, 2015. On January 26, 2015, following our January 21, 2015 hearing with a Listing Qualifications Panel (the "Panel") of the NYSE MKT LLC's Committee on Securities (the "Committee"), we received a letter notifying us that the Panel affirmed the determination of the Staff to delist our common stock. We have requested a full Committee review of the Panel's decision. If our common stock is delisted from the NYSE MKT, our stock price might be negatively affected, some shareholders may sell their shares, and we may not be able to attract institutional investors in future financing transactions. There can be no assurance that our common stock will remain listed on the NYSE MKT,

(12) Income Taxes

The Company's provision for income taxes differs from applying the statutory U.S. federal income tax rate to income before taxes. The primary difference results from providing for state income taxes and from deducting certain expenses for financial statement purposes but not for federal income tax purposes.

The components of income (loss) before provision for income taxes consist of the following:

	Year Ended December 31,	
	2014	2013
United States	$(10,507,869)	$(12,693,125)
	$(10,507,869)	$(12,693,125)

The components of the income tax provision are as follows:

	Year Ended December 31,	
	2014	2013
Current:		
Federal	$ -	$ -
State	-	-
Total current	-	-
Deferred:		
Federal	-	-

State	-	-
Total deferred	-	-
	$ -	$ -

The reconciliation of income tax attributable to operations computed at the U.S. Federal statutory income tax rate of 35% to income tax expense is as follows:

	Year Ended December 31,	
	2014	2013
Statutory Federal tax rate	$(3,677,754)	$(4,442,594)
Valuation allowance	4,909,776	4,112,338
State income taxes, net of Federal benefit	(368,826)	(528,034)
Change in state income tax rate	277,076	574,964
Provision to return adjustment	(505,423)	-
Change in Warrant Derivative Liability	(668,554)	(342,666)
Stock issued in exchange for debt waiver	-	581,649
Nondeductible meals, entertainment and other expense	33,705	44,343
	$-	$-

Deferred tax assets and liabilities are as follows:

	At December 31,	
	2014	2013
Deferred tax assets:		
Current deferred tax assets		
Accrued liability for vacation	$102,643	$85,599
Bad debt reserve	536,440	512,941
Charitable contributions carryforward	33,124	19,746
Inventory reserve	1,098,333	895,760
Reserve – assets held for sale	351,423	-
Restricted stock compensation	-	82,640
Total current deferred tax assets	2,121,963	1,596,686
Valuation Allowance	(2,121,963)	(1,596,686)
Net current deferred tax assets	-	-
Noncurrent deferred tax assets		
Net operating loss carryovers	18,200,823	14,863,919
Stock warrants	131,891	134,117
Stock option compensation	1,594,460	1,307,998
Goodwill amortization	82,212	90,868
Debt discount and waiver amortization	1,076,926	455,916
Depreciation	244,004	97,492

Amortization	30,290	25,797
Total noncurrent deferred tax assets	21,360,606	16,976,107
Valuation allowance	(21,360,606)	(16,976,107)
Net noncurrent deferred tax assets	-	-
Net deferred tax assets	$-	$-

The ultimate realization of deferred tax assets is dependent upon the existence, or generation, of taxable income in the periods when those temporary differences and net operating loss carryovers are deductible. Management considers the scheduled reversal of deferred tax liabilities, taxes paid in carryover years, projected future taxable income, available tax planning strategies, and other factors in making this assessment. Based on available evidence, management does not believe it is more likely than not that all of the deferred tax assets will be realized. Accordingly, the Company has established a valuation allowance equal to the net realizable deferred tax assets. The valuation allowance increased by $4,909,776 and $4,112,338 in 2014 and 2013, respectively.

At December 31, 2014 and 2013, the Company had total domestic Federal and state net operating loss carryovers of approximately $47,262,588 and $37,976,891, respectively. Federal net operating loss carryovers expire at various dates between 2025 and 2034, while state net operating loss carryovers expire between 2025 and 2034.

Under the Tax Reform Act of 1986, as amended, the amounts of and benefits from net operating loss carryovers and research and development credits may be impaired or limited in certain circumstances. Events which cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, over a three year period. The Company does not believe that such an ownership change has occurred in 2014 or 2013.

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

The Company did not recognize any interest or penalties related to income taxes for the years ended December 31, 2014 and 2013.

(13) Employee Benefit Plans

The Company has a 401(k) retirement plan. Qualified employees may defer their salary and the deferrals are matched up to 2%. The plan covers substantially all full-time employees. Under the terms of the plan, participants may contribute up to the lower of $17,500 of their salary or the statutorily prescribed limit to the plan. Employees are eligible after six months of employment and may enroll twice a year in January and July.

(14) Supplemental Disclosure of Cash Flow Information

Supplemental cash flow information is as follows:

	Twelve Months Ended December 31,	
	2014	**2013**
Supplemental disclosure of cash flow information		
Cash paid during the period for:		
Interest	$3,192,854	$2,681,459
Non-cash activities:		
Settlement of SeaArk accounts receivable	$-	$1,829,647
Inventory received in SeaArk settlement	$-	$409,838
Write-off of SeaArk allowance for doubtful accounts	$-	$1,419,809
Issuance of Warrants related to stock issuance	$1,461,796	$1,485,313
Increase in long-term debt, ROS adjustment fee	$-	$700,000
Issuance of shares, ROS adjustment fee	$-	$630,000
Issuance of shares related to debt issuance	$1,094,999	$-
Issuance of restricted stock to employees	$136,977	$-

(15) Related Party Transactions

Guy Cook was our President, Chief Executive Officer and Chairman of our Board of Directors until April 5, 2013, when he resigned. Mr. Cook has advised us that he is currently an owner and executive officer of Lattice Biologics, Inc., a competitor of ours that was formerly known as International Biologics, LLC. International Biologics, LLC was a former customer of Bacterin and was indebted to us in the amount of approximately $33,468, which was paid.

Mr. Cook assisted unrelated parties in the initial capitalization of Holgan, LLC, a former stocking distributor that purchased a bulk shipment of products from Bacterin at a discount in 2012 (“Holgan”). Holgan subsequently obtained financing from Lacuna Hedge Fund LLLP (“Lacuna”), formerly a significant Bacterin shareholder. Holgan failed to fully pay for the products it acquired from Bacterin and defaulted under its credit agreement with Lacuna. We reached a settlement with Lacuna whereby we paid Lacuna $350,000 in exchange for a release of all claims Lacuna may have against Bacterin and its current and former directors and officers, and we understand that Mr. Cook’s new company, Lattice, purchased substantially all of the Bacterin products held by Holgan, with the proceeds to be paid to Lacuna.

Mr. Cook’s spouse was employed by Bacterin as the Director of Human Resources until April 9, 2013. Mr. Cook, together with his adult children, owned and operated Silver Forest Fund, LP (“Silver Forest”), a former distributor of Bacterin products. We terminated the contractual relationship with Silver Forest on October 24, 2013. In 2012, Silver Forest purchased Bacterin products from an unaffiliated former distributor and subsequently exchanged some of those products for different Bacterin products of equivalent value. Other than product exchanges and payment of amounts owed by the non-affiliated distributor, we are not aware of any other direct transactions between Bacterin and Silver Forest.

Mr. Cook also formerly served as a board member of West Coast Tissue Services (“WCTS”) and American Donor Services (“ADS”). Mr. Cook did not receive any compensation for his board service from either entity. Darrel Holmes, our Chief Operating Officer, and Mitchell Godfrey, a former director, also serve on the board of ADS, and Mr. Godfrey also serves as secretary and treasurer for ADS. Mssrs. Godfrey and Holmes receive $5,000 per year for their service to ADS. ADS and WCTS recover tissue from donors. We reimburse them for their recovery fees, which are comprised primarily of labor costs. The approximate aggregate amount of all transactions with WCTS for the years ended December 31, 2014 and 2013 was $98,600 and $840,100, respectively, and the approximate aggregate amount of all transactions with ADS for the years ended December 31, 2014 and 2013 was $2,406,926 and $2,055,523, respectively. These relationships have benefited us, as these entities provide us with donors, thus insuring that we have a pipeline of current and future donors, which is necessary to our success.

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

(16) Subsequent Event

On March 16, 2015, we entered into a Common Stock Purchase Agreement (the “Purchase Agreement”) with Aspire Capital Fund, LLC, an Illinois limited liability company (“Aspire Capital”) which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of shares of our common stock over the 24-month term after a registration statement is declared effective by the U.S. Securities and Exchange Commission (“SEC”) relating to the transaction. The stock purchase transactions are at the Company’s option. Concurrently with entering into the Purchase Agreement, we also entered into a Registration Rights agreement with Aspire Capital (the “Registration Rights Agreement”), in which we agreed to file one or more registration statements to register under the Securities Act of 1933, as amended (the “Securities Act”), the sale of the shares of our common stock that may be issued to Aspire Capital under the Purchase Agreement. Under the Purchase agreement, within five business days after approval of the transaction by the NYSE MKT, we also agreed to sell, and Aspire Capital agreed to buy, 207,182 shares of our common stock (the "Initial Purchase Shares") for $750,000 in aggregate proceeds. We also agreed at such time to issue to Aspire Capital 154,189 shares of our common stock as a commitment fee (the "Commitment Shares").

After a registration statement is declared effective by the SEC relating to the transaction, we have the right to sell up to an additional $9,250,000 of our common stock in the aggregate to Aspire Capital over a 24-month period. More specifically, we have the right, in our sole discretion, to present Aspire Capital with purchase notices (each, a “Purchase Notice”), directing Aspire Capital (as principal) to purchase up to 50,000 shares of our common stock, per trading day, provided that the aggregate price of each such purchase shall not exceed $500,000 per trading day at a per share price (the “Purchase Price”) equal to the lesser of:

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

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

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

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

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management with the participation of our chief executive officer and chief financial officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a–15(e) under the Exchange Act) as of December 31, 2014. Based upon that evaluation, our chief executive officer and chief financial officer concluded that as of December 31, 2014, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in rule 13a-15 (f) under the Securities and Exchange Act of 1934 as amended. Under the supervision and with the participation of senior and executive management, we conducted an evaluation of our internal controls over financial reporting based upon the framework Internal Control – Integrated Framework (2013) as outlined by COSO, the Committee of Sponsoring Organizations of the Treadway Commission. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of an evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Based on our evaluation under the framework Internal Control – Integrated Framework (2013), management concluded that our internal control over financial reporting was effective as of December 31, 2014.

This report does not include an attestation report of the Company's independent public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors and Executive Officers of the Registrant

Executive Officers and Directors

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

Name	Age	Position
Daniel Goldberger	56	Director, Chief Executive Officer
Kent Swanson	70	Chairman of the Board
Michael Lopach	66	Director
Jon Wickwire	71	Director
John Deedrick	52	Director
David Goodman, MD	59	Director
John Gandolfo	54	Chief Financial Officer
Robert Di Silvio	61	President
Darrel Holmes	61	Chief Operating Officer
Gregory Juda	39	Chief Scientific Officer

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

Daniel Goldberger, Director, Chief Executive Officer, has more than 25 years of experience as a leader of both publicly traded and privately held medical technology companies, with a proven track record of building revenue and profits through the introduction of market changing product innovations. He was most recently CEO and a director of Sound Surgical Technologies from April 2007 through its merger with Solta Medical (Nasdaq SLTM) in February 2013. Previously, he was President/CEO and a director of Xcorporeal (Amex XCR) an innovator in portable dialysis

and Glucon (private) a developer of glucose measurement technology and several other successful enterprises. Mr. Goldberger is a named inventor on more than 60 US patents. He holds a BS in Mechanical Engineering from the Massachusetts Institute of Technology and an MS in Mechanical Engineering from Stanford University. Mr. Goldberger contributes medical industry and management experience to the Board of Directors.

Kent Swanson, Chairman of the Board, was with Accenture for over 32 years, retiring from the firm in 2001 as a Senior Partner. He held global leadership and management positions in a wide range of industries and geographies. From 2001 to 2008, he was the Board Chair of ALN Medical Management; providing outsourced services for clinic-based physician practices. Also from 2001 to 2008, he was Board Chair for Boys Hope Girls Hope of Colorado, a charitable organization providing a home and scholarship education for disadvantaged children with significant capabilities and promise. From 2002 to 2009, he was a Board member, Audit Committee member and Compensation Committee Chair for MPC Computers. Mr. Swanson graduated with distinction from the University of Minnesota earning an M.S. in Business and received an M.B.A. from the University of Chicago in 1969. Mr. Swanson contributes significant management experience to the Board of Directors.

Michael Lopach, Director, is a certified public accountant with over 40 years of accounting experience. Mr. Lopach spent 27 years of his career with Galusha, Higgins, Galusha & Co., the largest privately held accounting firm in Montana and northern Idaho, where he served as president and CEO. In 1999, Mr. Lopach founded Lopach & Carparelli PC, an accounting firm that focuses on medical practitioners. Mr. Lopach received his MBA from the University of Notre Dame. Mr. Lopach serves as chairman of the Audit Committee. Mr. Lopach contributes significant accounting experience to the Board of Directors.

Jon Wickwire, Director, is an attorney and founding shareholder of Wickwire Gavin, P.C., a national construction law firm which merged with Akerman Senterfitt, one of the top 100 law firms in the United States. Mr. Wickwire served as lead counsel on major infrastructure litigation and alternative dispute resolutions, both domestically and internationally, throughout his 35 year career, and was the founding fellow of the American College of Construction Lawyers. Mr. Wickwire also served as the founding chairman of the College of Scheduling, an organization dedicated to advancing the techniques, practice and profession of project scheduling, and has authored several books and articles on construction and public contract law, including *Construction Management: Law and Practice* and *The Construction Subcontracting Manual: Practice Guide with Forms* . Mr. Wickwire currently serves on the advisory board for Crunchies Food Company. Mr. Wickwire is a graduate of the University of Maryland and Georgetown University Law Center. Mr. Wickwire serves as chairman of the Nominations and Corporate Governance Committee. Mr. Wickwire contributes legal experience to the Board of Directors.

John Deedrick, Director, is an experienced senior executive with 30 years experience in healthcare, defense, and business consulting. He was a co-founder and managing director for Accuitive Medical Ventures and a corporate venture capitalist for Mayo Clinic. Mr. Deedrick currently serves as President and CEO of CHIP Solutions and is Founder and Chairman of GreatDeeds, a Minnesota non-profit organization. Mr. Deedrick has served on the board of numerous early, mid and growth stage healthcare companies over the last 17 years, including GreatDeeds and Ironwood Springs Ranch. Mr. Deedrick received his undergraduate degree from the University of Northwestern St. Paul (Roseville, MN) and his MBA from St. Thomas University (St. Paul, MN). Mr. Deedrick contributes significant financial, management and industry experience to the Board of Directors.

David Goodman, MD, Director, has devoted his career to improving health through the development and integration of innovative technologies into clinical practice. Dr. Goodman currently serves as Co-Founder and Chief Medical Officer of FirstVitals Health & Wellness, a technology-enabled service company focused on preventing complications such as foot ulcers and lower extremity amputations in people with diabetes. Dr. Goodman also serves on the board of directors of NEUROMetrix (Nasdaq: NURO), a neurotechnology company focused on the early detection of diabetic peripheral neuropathy (DPN) and treatment of painful diabetic neuropathy (PDN). In addition, Dr. Goodman served as a director of Sound Surgical Technologies LLC, a private manufacturer of aesthetic surgical tools until its successful acquisition by Solta Medical (Nasdaq:SLTM) in 2013. Dr. Goodman has a long track record of accomplishment in executive management as well as through his own entrepreneurial efforts. As an executive, Dr. Goodman served as CEO of SEDLine, an EEG-based brain monitoring company as well as the EVP of Business Development for Masimo (Nasdaq:MASI), a leading company in non-invasive patient monitoring. As an entrepreneur, Dr. Goodman was the founding CEO of LifeMasters Supported SelfCare, a pioneering disease management company, and Aradigm, a developer of electronic aerosol drug delivery systems. Dr. Goodman began his career as the first engineer at Nellcor, the company that developed modern pulse oximetry. He holds a B.A.S. in applied science and bioengineering and a M.S.E. in bioengineering from the University of Pennsylvania. Dr. Goodman also received an M.D. cum laude from Harvard Medical School and the Harvard-M.I.T. Division of Health Sciences and Technology. Dr. Goodman completed his internship at the University of California, San Francisco (UCSF) in the Department of Medicine. He holds 18 issued and 4 pending US patents and maintains clinical practices in California and Hawaii. Dr. Goodman contributes medical and industry experience to the Board of Directors.

John Gandolfo, Chief Financial Officer, joined Bacterin as its interim Chief Financial Officer on a part-time basis, effective June 4, 2010, and filled this position full time commencing on July 6, 2010. Mr. Gandolfo also served as Interim Co-Chief Executive Officer from April 5, 2013 to August 14, 2013, and as a Director from July 9, 2013 to August 14, 2013. Mr. Gandolfo has 25 years of experience as chief financial officer of rapidly growing private and publicly held companies with a primary focus in the life sciences, healthcare and medical device areas. Mr. Gandolfo has had direct responsibility over capital raising, including four public offerings, financial management, mergers and acquisition transactions and SEC reporting throughout his professional career. Prior to joining Bacterin, Mr. Gandolfo served as the Chief Financial Officer for Progenitor Cell Therapy LLC, a leading manufacturer of stem cell therapies. Prior to joining Progenitor, Mr. Gandolfo served as the Chief Financial Officer for Power Medical Interventions, Inc., a publicly held developer and manufacturer of computerized surgical stapling and cutter systems, from January 2007 to January 2009. Prior to joining PMI, Mr. Gandolfo was the Chief Financial Officer of Bioject Medical Technologies, Inc., a publicly held supplier of needle-free drug delivery systems to the pharmaceutical and biotechnology industries, from September 2001 to May 2006, and served on the Bioject's Board of Directors from September 2006 through May 2007. Prior to joining Bioject, Mr. Gandolfo was the Chief Financial Officer of Capital Access Network, Inc., a privately held specialty finance company, from 2000 through September 2001, and Xceed,

Inc., a publicly held Internet consulting firm, from 1999 to 2000. From 1994 to 1999, Mr. Gandolfo was Chief Financial Officer and Chief Operating Officer of Impath, Inc., a publicly held, cancer-focused healthcare information company. From 1987 through 1994, he was Chief Financial Officer of Medical Resources, Inc., a publicly held manager of diagnostic imaging centers throughout the United States. A graduate of Rutgers University, Mr. Gandolfo is a certified public accountant (inactive status) who began his professional career at Price Waterhouse.

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

Darrel Holmes, Chief Operating Officer, Mr. Holmes has over 25 years of experience in the medical device, biologics, and diagnostic industries. He previously served as Operations Executive for American Qualex, HYCOR Biomedical and Stratagene, and as Executive Vice President and COO of Big Spring Water Company. Since joining Bacterin International, Inc. in 2003, Mr. Holmes has assumed responsibilities for all aspects of medical device and biologic product design and development, process scale-up, and production, and Mr. Holmes also served as Interim Co-Chief Executive Officer from April 5, 2013 to August 14, 2013. Mr. Holmes has worked with numerous regulatory agencies at the federal, state, and local level and coordinates Bacterin's ISO 13485 compliance and environmental health and safety programs. He oversees Bacterin's operations and production, facility management, engineering and information technology (IT) to produce Bacterin's medical devices and biologic products, and to accommodate business growth. He directs the design, purchase, validation and implementation of capital assets and facility expansions for the company, and is responsible for strategic planning as well as the development and administration of division-level budgets. Currently, Mr. Holmes serves as the Tissue Bank Director and on Bacterin's Medical Advisory Committee, as a member of Montana State University's Employer Advisory Board, as a Scientific Advisory Board Member for Montana Molecular in Bozeman, Montana, and as member of the Board of Directors of American Donor Services. Mr. Holmes graduated from California State University at Long Beach with a degree in Biological Science.

Gregory Juda, Chief Scientific Officer, joined Bacterin in 2005 and has played an integral role in the growth of Bacterin's orthobiologics business. During his time with the company, Dr. Juda has been responsible for guiding the development, commercialization, and marketing of four revolutionary, life-enhancing allograft products; Bacterin's OsteoSponge® allograft family, OsteoSelect® Demineralized Bone Matrix Putty, hMatrix® Acellular Dermal Matrix and Bacterin's new line of 3Demin products. Dr. Juda is an expert in the design, manufacturing, regulation, and marketing of biologics and biologic based medical devices. He was responsible for directing equipment, facility, and process validation efforts for Bacterin's state-of-the-art allograft tissue processing facility. These efforts included the design and validation of programs for tissue processing and decontamination, facility cleaning and monitoring, and sterilization of finished product. Currently, Dr. Juda directs research and development efforts for Bacterin's orthobiologic product lines and serves as the primary source of technical expertise for Bacterin's direct and indirect sales initiatives. Dr. Juda received a Bachelor of Science in Biochemistry from Virginia Polytechnic Institute and State University and a Doctorate of Philosophy in Biochemistry from Montana State University-Bozeman.

Board Composition and Terms of Office

The composition of our board of directors, audit committee, compensation committee, and nominations and governance committee, is subject to the corporate governance provisions of the NYSE MKT, including rules relating to the independence of directors. A majority of our board members and all of our board committee members are independent directors. All directors hold office for staggered three year terms and until the election and qualification of their successors. Officers are elected by, and serve at the discretion of, the board of directors.

Board Committees

We have established an audit committee, compensation committee and nominations and corporate governance committee, in compliance with applicable corporate governance requirements, and the Board also formed a Business Development Committee in 2014. The charters of our audit committee, compensation committee and nominations and corporate governance committee have been posted on our website at www.bacterin.com. The contents of our website are not incorporated by reference into this annual report on Form 10-K.

Audit Committee

The purpose of the Audit Committee is to assist the oversight of our Board of Directors with the integrity of our financial statements, our compliance with legal and regulatory matters, our internal audit function, and our independent auditor's qualifications, independence, and performance. The primary responsibilities of the Audit Committee are set forth in its charter and include various matters with respect to the oversight of our accounting and financial reporting process and audits of our financial statements. The Audit Committee also selects the independent

auditor, reviews the proposed scope of the audit, reviews our accounting and financial controls with the independent auditor and financial accounting staff, and reviews and approves transactions between us and our directors, officers, and their affiliates.

The Audit Committee currently consists of Messrs. Lopach, Swanson and Wickwire, each an independent director under NYSE MKT listing standards as well as under rules adopted by the SEC pursuant to the Sarbanes-Oxley Act of 2002. Mr. Lopach serves as the Chairman of the Audit Committee. The Board of Directors has determined that Messrs. Lopach and Swanson (whose backgrounds are detailed above) each qualify as an "audit committee financial expert" in accordance with applicable rules and regulations of the SEC.

Compensation Committee

The primary purposes of the Compensation Committee are to determine or recommend the compensation of our CEO and other executive officers, and to oversee our Equity Incentive Plan. Our Compensation Committee currently consists of John Deedrick, Michael Lopach and David Goodman, each of whom is an independent director. Mr. Deedrick serves as the Chairman of the Compensation Committee.

Nominations and Corporate Governance Committee

The purposes of the Nominations and Corporate Governance Committee include the selection or recommendation to our Board of Directors of nominees to stand for election as directors, the oversight of the selection and composition of the committees of our Board of Directors, the oversight of the evaluations of our Board of Directors and management, and the development and recommendation to our Board of Directors of a set of corporate governance principles applicable to our company. The Nominations and Corporate Governance Committee currently consists of Messrs. Wickwire, Deedrick and Goodman, each of whom is an independent director of our company under NYSE MKT listing standards as well as under rules adopted by the SEC pursuant to Sarbanes-Oxley. Mr. Wickwire serves as the Chairman of the Nominations and Corporate Governance Committee.

Business Development Committee

In September 2014, the Board formed a Business Development Committee to advise the Board on strategic direction and growth strategies. The Business Development Committee currently consists of Messrs. Deedrick (Chair) and Swanson.

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Nominations to the Board of Directors

Our directors take a critical role in guiding our strategic direction and overseeing the management of our company. Board candidates are considered based upon various criteria, such as their broad-based business and professional skills and experiences, a global business and social perspective, concern for the long-term interests of the stockholders, diversity, personal integrity and judgment.

In addition, directors must have time available to devote to board activities and to enhance their knowledge in the growing business. Accordingly, we seek to attract and retain highly qualified directors who have sufficient time to attend to their substantial duties and responsibilities.

Family Relationships

There are no family relationships among our directors and executive officers.

Compliance with Section 16(a) of the Exchange Act

Section 16(a) requires directors, executive officers and holders of more than 10% of an equity security registered pursuant to Section 12 of the Exchange Act of 1934 to file various reports with the SEC.

To the Company's knowledge, based solely on our review of the Section 16 reports furnished to us with respect to 2014, we believe all reports required pursuant to Section 16(a) were filed on a timely basis except for the following: Darrel Holmes filed one Form 4 late due to a delay in receipt of transaction information from his broker.

Code of Ethics

We have adopted a Code of Conduct and a Code of Ethics for our CEO and Senior Financial Officers, both of which are posted on our website at www.bacterin.com. We intend to disclose any changes in, or waivers from, these codes by posting such information on the same website or by filing a Form 8-K. The contents of our website are not incorporated by reference into this annual report on Form 10-K.

Procedures for Shareholder Recommendation of Nominees to the Board of Directors

The procedures by which shareholders may recommend nominees to the Board of Directors are contained in our Bylaws.

Item 11. Executive Compensation

The table below summarizes the compensation earned for services rendered to the Company for the fiscal years indicated, by our Chief Executive Officer and two most highly-compensated named executive officers other than our Chief Executive Officer.

Name and Principal Position	Year	Salary	Bonus	Stock Awards (1)	Option Awards (1)	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Daniel Goldberger	2014	400,000	100,154	-		-	-	143,422(2)	643,576
Chief Executive Officer	2013	143,077	-	-	1,098,055	-	-	-	1,241,132
From August 14, 2013 to present									
John Gandolfo	2014	330,000	20,000	-	90,841	-	-	-	440,841
Chief Financial Officer	2013	321,462	100,800	68,340	34,745	-	-	-	525,347
Interim Co-Chief Executive Officer from April 5 2013 to August 14, 2013									
Robert Di Silvio	2014	153,750	-	-	150,090	-	-	129,300(3)	433,140
President									
From July 1, 2014 to present									

(1) Key assumptions used to estimate the grant date fair value of restricted stock and option awards are contained in Note 9 to the financial statements in Item 8. of this Annual Report on Form 10-K.

(2) Relocation reimbursement.

(3) Consulting fees paid to Mr. Di Silvio for services provided prior to his employment.

Employment Agreements

Employment agreements for our current executive officers are set forth as exhibits to this Form 10-K. The employment agreements require each of the executives to perform such duties as are customarily performed by one holding their positions and provide for a fixed annual base salary. In addition, each executive is entitled to receive certain cash bonuses and grants under our equity incentive plan as may be determined by the compensation committee of our board of directors.

The employment agreements contain covenants (a) restricting the executives from engaging in any activity competitive with our business, (b) prohibiting the executive from disclosing confidential information regarding our company, and (c) requiring that all intellectual property developed by the executive and relating to our business constitutes our sole and exclusive property. The employment agreements also contain severance provisions in the event of termination without cause, resignation for good reason, or termination in connection with a change of control.

Bacterin International Equity Incentive Plan and Inducement Grants

The following is a summary of the material terms of the Bacterin International Equity Incentive Plan (the “Plan”):

The purpose of the Plan is to enable us to attract, retain and motivate key employees, directors and independent consultants, by providing them with stock options and restricted stock grants. Stock options granted under the Plan may be either incentive stock options to employees, as defined in Section 422A of the Internal Revenue Code of 1986, or non-qualified stock options. The Plan is administered by the Compensation Committee of the Board of Directors. The administrator of the Plan has the power to determine the terms of any stock options granted under the Plan, including the exercise price, the number of shares subject to the stock option and conditions of exercise. Stock options granted under the Plan are generally not transferable, vest in installments and are exercisable during the lifetime of the optionee only by such optionee. The exercise price of all incentive stock options granted under the Plan must be at least equal to the fair market value of the shares of common stock on the date of the grant.

There are 900,000 shares of our common stock authorized to be issued under the Plan. As of December 31, 2014, we had outstanding options to purchase 440,336 shares and 39,312 shares of restricted stock issued, to directors, executives, employees and consultants, leaving approximately 107,700 shares available for issuance thereunder.

We also granted stock options to our Chief Executive Officer and President outside of our Plan as inducements material to entering into employment with the company pursuant to Section 711(a) of the NYSE MKT Company Guide. The inducement grants to our Chief Executive Officer and President were approved by the Compensation Committee of our Board of Directors. The inducement grant to our Chief Executive Officer consists of a stock option to purchase up to 200,000 shares of our common stock, with a per share exercise price of $6.00, which was the adjusted closing price of the Company's common stock on the August 14, 2013 grant date. Our Chief Executive Officer's inducement grant stock option vests over five years, with 20% of the underlying shares vesting after one year and the remaining 80% vesting in forty-seven (47) equal monthly installments as to 3,333 underlying shares, beginning September 15, 2014, and one final installment as to 3,330 underlying shares. The inducement grant to our President consists of a stock option to purchase up to 55,000 shares of our common stock, with a per share exercise price of $6.80, which was the adjusted closing price of our common stock on the July 1, 2014 grant date. Our President's inducement grant stock option vests over five years, with 20% of the underlying shares vesting after one year and the remaining 80% vesting in forty-seven (47) equal monthly installments as to 917 underlying shares, beginning on August 1, 2015, and one final installment as to 901 underlying shares.

Except for the Equity Incentive Plan and the inducement grants to our Chief Executive Officer and President discussed above, we do not have any other stock option plans or other similar incentive compensation plans for officers, directors and employees.

Outstanding Equity Awards at Fiscal Year-End (December 31, 2014)

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options Exercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date	Number of shares or units of stock that have not vested	Market value of shares or units of stock that have not vested
Daniel Goldberger	59,998	140,002	$ 6.00	8/14/23	-	-
John Gandolfo	-	30,000	5.01	9/4/24	-	-
	7,000	-	6.80	5/24/23	-	-
Robert Di Silvio	-	55,000	6.80	7/1/24	-	-

Potential Payments Upon Termination or Change-in-Control

All of our named executive officers have employment agreements that provide for severance payments for termination in connection with a change in control.

Mr. Goldberger's employment agreement provides for an annual base salary of $400,000, along with other incentive compensation as determined by the Board of Directors, with a bonus target of 50%-70% of Mr. Goldberger's annual base salary. Mr. Goldberger's employment agreement contains customary intellectual property provisions and restrictive covenants and provides for six (6) months severance for termination without cause or resignation with good reason and twelve (12) months of severance for termination in connection with a change in control.

Mr. Gandolfo's employment agreement provides for an annual base salary of $330,000, along with other incentive compensation as determined by the Compensation Committee of the Board of Directors, with a bonus target of 30% of Mr. Gandolfo's annual base salary. Mr. Gandolfo's employment agreement contains customary intellectual property provisions and restrictive covenants and provides for twelve (12) months severance for termination without cause, resignation with good reason, or termination in connection with a change in control.

Mr. Di Silvio's employment agreement provides for an annual base salary of $325,000, along with other incentive compensation as determined by the Compensation Committee of the Board of Directors, with a bonus target of 50% of Mr. Di Silvio's annual base salary. Mr. Di Silvio's employment agreement contains customary intellectual property provisions and restrictive covenants and provides for six (6) months severance for termination without cause or resignation with good reason and twelve (12) months of severance for termination in connection with a change in control.

Retirement Plans

The Company has a 401(k) plan available to all full-time employees following a six month probationary period. The Company matches up to 2% of employee contributions at the end of the year.

Director Compensation

Name	Fees Earned or Paid in Cash [1]	Stock Awards[2]	Option Awards [2]	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Kent Swanson	$ 81,250	$ 40,000	$-	$ -	$ -	$ -	$121,250
Michael Lopach	$ 51,625	$ 40,000	$-	$ -	$ -	$ -	$91,625
Jon Wickwire	$ 51,250	$ 40,000	$-	$ -	$ -	$ -	$91,250
John Deedrick	$ 111,000	$ 40,000	$-	$ -	$ -	$ -	$151,000
David Goodman	$ 22,000	$	$13,779	$ -	$ -	$ -	$35,779

(1) Effective September 4, 2014, compensation for our independent Board members was revised as follows: independent directors receive an annual retainer of $40,000 per year, the independent Chairman of our Board receives an additional $20,000 per year, the Audit Committee Chair receives $12,500 per year, other Committee Chairs receive $10,000 per year, Audit Committee members receive $5,000 per year, other Committee members receive $4,000 per year and all independent directors receive an annual equity grant valued at $40,000. In addition, the Chair of our newly formed Business Development Committee earned $60,000 in 2014 and the other member of the Business Development Committee earned $20,000 in 2014.

Prior to September 4, 2014, our independent Board members received an annual retainer of $40,000 per year, our Committee Chairs received an additional $10,000 per year, new independent directors received an option to purchase 5,000 shares of our common stock and continuing directors received an annual grant of options to purchase 3,000 shares of our common stock. Beginning in 2014, our independent Board Chair also received an additional $20,000 per year.

(2) Key assumptions used to estimate the grant date fair value of stock and option awards are contained in Note 9 to the financial statements in this Annual Report on Form 10-K.

Compensation Committee Interlocks and Insider Participation

No interlocking relationship exists between our board of directors and the board of directors or compensation committee of any other company, nor has any interlocking relationship existed in the past.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth information regarding the beneficial ownership of our common stock as of December 31, 2014, by (a) each of our directors and named executive officers, (b) all of our current directors and named executive officers as a group, and (c) each person who is known by us to beneficially own 5% or more of our common stock.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned [2]		Percentage of Shares Beneficially Owned [3]	
Directors and Named Executive Officers [1] **:**				
Daniel Goldberger	72,508	(4)	1.1	%
Kent Swanson	71,000	(5)	1.1	%
Michael Lopach	23,115	(6)	*	
Jon Wickwire	55,373	(7)	*	
John Deedrick	10,000	(8)	*	
David Goodman, MD	-		*	
John P. Gandolfo	14,787	(9)	*	
Robert Di Silvio	1,198	(10)	*	
All executive officers and directors as a group (10 persons)	270,496		4.0	%
Five Percent Shareholders:				
OrbiMed Advisors LLC 601 Lexington Ave., 54th Floor New York, NY 10022	563,158	(11)	8.4	%
Perkins Capital Management, Inc. 730 East Lake Street Wayzata, MN 55391	539,734	(12)	8.1	%
Guy S. Cook	411,482	(13)	6.2	%

246 Painted Hills Rd.
Bozeman, MT 59714

*Less than 1% of outstanding shares of common stock.

(1) The address for directors and named executive officers is c/o Bacterin International, Inc., 664 Cruiser Lane, Belgrade Montana 59714.

(2) Unless otherwise indicated, includes shares owned by a spouse, minor children and relatives sharing the same home, as well as entities owned or controlled by the named person. Also includes shares if the named person has the right to acquire those shares within 60 days after December 31, 2014, by the exercise or conversion of any warrant, stock option or convertible preferred stock. Unless otherwise noted, shares are owned of record and beneficially by the named person.

(3) The calculation in this column is based upon 6,679,646 shares of common stock outstanding on December 31, 2014. The shares of common stock underlying warrants and stock options are deemed outstanding for purposes of computing the percentage of the person holding them, but are not deemed outstanding for the purpose of computing the percentage of any other person.

(4) Includes (a) 12,510 shares of our common stock, and (b) vested options to purchase 59,998 shares of our common stock.

(5) Includes (a) 35,000 shares of our common stock held directly, (b) 20,000 shares held by a family limited partnership, (c) warrants to purchase 5,000 shares of our common stock, and (d) options to purchase 11,000 shares of our common stock.

(6) Includes (a) 1,694 shares of our common stock held directly, (b) 3,389 shares held by a 401(k) plan, (c) warrants to purchase 2,032 shares, and (d) options to purchase 16,000 shares.

(7) Includes (a) 10,550 shares of our common stock, (b) 25,762 shares of common stock held by trusts, (c) warrants to purchase 3,061 shares of common stock, and (d) options to purchase 16,000 shares of our common stock.

(8) Includes vested options to purchase 10,000 shares of our common stock.

(9) Includes (a) 6,396 shares of our common stock, (b) 994 shares of our common stock held by an IRA, (b) warrants to purchase 397 shares of our common stock, and (c) vested options to purchase 7,000 shares of our common stock.

(10) Includes 1,198 shares of our common stock.

(11) Based on Schedule 13G filed with the SEC on February 17, 2015. Includes 475,439 shares of our common stock and warrants to purchase 87,719 shares of our common stock held by an entity managed by OrbiMed Advisors LLC.

(12) Based on Schedule 13G/A filed with the SEC on January 28, 2015. Includes 459,646 shares of our common stock and warrants to purchase 80,088 shares of our common stock.

(13) Based on Amendment No. 6 to Schedule 13D filed with the SEC on February 25, 2015. Includes (a) 31,482 shares of our common stock held directly, and (b) 380,000 shares of our common stock held by trusts for the benefit of Mr. Cook's children.

Economic Ownership; Stock Ownership Guidelines

Because the table above is limited to shares that are owned or which the person has the right to acquire within 60 days, it does not present a complete view of the economic exposure our directors and executive officers have to our common stock. Excluded from the table above are unvested stock options and unvested warrants which will become vested more than 60 days from December 31, 2014.

Securities authorized for issuance under equity compensation plans

Plan category	**Number of securities to be issued upon exercise of outstanding options,**	**Weighted-average exercise price of outstanding options, warrants and**	**Number of securities remaining available for future issuance under equity**

	warrants and rights	rights	compensation plans (excluding securities reflected in column (a))	
Equity compensation plans approved by security holders	440,336	$ 14.19	107,700	(1)
Equity compensation plans not approved by security holders(2)	255,000	$ 6.17	N/A	
Total	695,336	$ 11.25	107,700	

(1) In addition to options outstanding, the Company also has 39,312 shares of restricted stock outstanding that have been issued under the Plan.

(2) For a description of certain inducement grants not approved by security holders, see “Bacterin International Equity Incentive Plan and Inducement Grants” under Item II above.

Bacterin International Equity Incentive Plan and Two Inducement Grants

We have granted stock options, shares of common stock and restricted stock units under our Amended and Restated Bacterin International Equity Incentive Plan (the “Plan”), as well as two inducement grants consisting of (i) an option to purchase 200,000 shares of our common stock to our Chief Executive Officer, and (ii) an option to purchase 55,000 shares of our common stock to our President, both granted outside of our Plan. The following is a summary of the material terms of our Plan and the two inducement grants.

The purpose of the Bacterin International Equity Incentive Plan is to enable us to attract, retain and motivate key employees, directors and independent consultants, by providing them with stock options and restricted stock grants. Stock options granted under the Plan may be either incentive stock options to employees, as defined in Section 422A of the Internal Revenue Code of 1986, or non-qualified stock options. The Plan is administered by the compensation committee of our board of directors. The administrator of the Plan has the power to determine the terms of any stock options granted under the incentive plan, including the exercise price, the number of shares subject to the stock option and conditions of exercise. Stock options granted under the Plan are generally not transferable, vest in installments and are exercisable during the lifetime of the optionee only by such optionee. The exercise price of all incentive stock options granted under the incentive plan must be at least equal to the fair market value of the shares of common stock on the date of the grant. The specific terms of each stock option grant are reflected in a written stock option agreement.

There are 900,000 shares of our common stock authorized to be issued under the Plan. As of December 31, 2014, we had outstanding options to purchase 440,336 shares and 39,312 shares of restricted stock issued, to directors, executives, employees and consultants, leaving approximately 107,700 shares available for issuance thereunder.

The inducement grants to our Chief Executive Officer and President were approved by the Compensation Committee of our Board of Directors and granted outside of the Plan as an inducement material to entering into employment with the Company pursuant to Section 711(a) of the NYSE MKT Company Guide. The inducement grant to our Chief Executive Officer consists of a stock option to purchase up to 200,000 shares of our common stock, with a per share exercise price of $6.00, which was the adjusted closing price of our common stock on the August 14, 2013 grant date. Our Chief Executive Officer's inducement grant stock option vests over five years, with 20% of the underlying shares vesting after one year and the remaining 80% vesting in forty-seven (47) equal monthly installments as to 3,333 underlying shares, beginning September 15, 2014, and one final installment as to 3,330 underlying shares. The inducement grant to our President consists of a stock option to purchase up to 55,000 shares of our common stock, with a per share exercise price of $6.80, which was the adjusted closing price of our common stock on the July 1, 2014 grant date. Our President's inducement grant stock option vests over five years, with 20% of the underlying shares vesting after one year and the remaining 80% vesting in forty-seven (47) equal monthly installments as to 917 underlying shares, beginning on August 1, 2015, and one final installment as to 901 underlying shares.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Transactions with Related Persons, Promoters and Certain Control Persons

Guy Cook was our President, Chief Executive Officer and Chairman of our Board of Directors until April 5, 2013, when he resigned. Mr. Cook has advised us that he is currently an owner and executive officer of Lattice Biologics, Inc. ("Lattice"), a competitor of ours formerly known as International Biologics, LLC, a former Bacterin customer.

Mr. Cook assisted unrelated parties in the initial capitalization of Holgan, LLC, a former stocking distributor that purchased a bulk shipment of products from Bacterin at a discount in 2012 ("Holgan"). Holgan subsequently obtained financing from Lacuna Hedge Fund LLLP ("Lacuna"), a former Bacterin shareholder. Holgan failed to fully pay for the products it acquired from Bacterin and defaulted under its credit agreement with Lacuna. We reached a settlement with Lacuna in April 2014 whereby we paid Lacuna $350,000 in exchange for a release of all claims Lacuna may have against Bacterin and its current and former directors and officers, and we understand that Mr. Cook's new company Lattice purchased substantially all of the Bacterin products held by Holgan, with the proceeds paid to Lacuna.

Mr. Cook's spouse was employed by Bacterin as the Director of Human Resources until April 9, 2013. Mr. Cook, together with his adult children, owned and operated Silver Forest Fund, LP ("Silver Forest"), a former distributor of Bacterin products. We terminated the contractual relationship with Silver Forest on October 24, 2013. In 2012, Silver Forest purchased Bacterin products from an unaffiliated former distributor and subsequently exchanged some of those products for different Bacterin products of equivalent value. Other than product exchanges and payment of amounts owed by the non-affiliated distributor, we are not aware of any other direct transactions between Bacterin and Silver Forest.

Mr. Cook also formerly served as a board member of West Coast Tissue Services ("WCTS") and American Donor Services ("ADS"). Mr. Cook did not receive any compensation for his board service from either entity. Darrel Holmes, our Chief Operating Officer, and Mitchell Godfrey, a former director, also serve on the board of ADS, and Mr. Godfrey also serves as secretary and treasurer for ADS. Messrs. Holmes and Godfrey receive $5,000 per year for their service to ADS. ADS and WCTS recover tissue from donors. We reimburse them for their recovery fees, which are comprised primarily of labor costs. The approximate aggregate amount of all transactions with WCTS was $98,600 for 2014 and $840,100 for 2013, and the approximate aggregate amount of all transactions with ADS was $2,406,926 for 2014 and $2,055,523 for 2013. These relationships have benefited us, as these entities provide us with donors, thus insuring that we have a pipeline of current and future donors, which is necessary to our success. We no longer obtain donors from WCTS.

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

Director Independence

The following board members are independent directors, as defined under the independence standards of the NYSE MKT LLC: Kent Swanson, Michael Lopach, Jon Wickwire, John Deedrick and David Goodman. All of our board committees are comprised solely of independent directors, and the composition of our board committees is described in Item 10 of this Form 10-K.

Item 14. Principal Accountant Fees and Services

EKS&H LLLP ("EKS&H") served as the independent registered public accounting firm to audit our books and accounts for the fiscal years ending December 31, 2014 and December 31, 2013. The following table presents the aggregate fees billed for professional services rendered by EKS&H for the years ended December 31, 2014 and December 31, 2013.

	2014	2013
Audit fees	$157,500	$138,500
Audit-related fees	$49,546	$11,073
Tax fees	$-	$-
All other fees	$-	$-

In the above table, "audit fees" are fees billed for services provided related to the audit of our annual financial statements, quarterly reviews of our interim financial statements and services normally provided by the independent accountant in connection with statutory and regulatory filings or engagements for those fiscal periods. "Audit-related fees" are fees not included in audit fees that are billed by the independent accountant for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements. "Tax fees" are fees billed by the independent accountant for professional services rendered for tax compliance, tax advice and tax planning. "All other fees" are fees billed by the independent accountant for products and services not included in the foregoing categories.

Audit Committee's Pre-Approval Policy

It is the Audit Committee's policy to approve in advance the types and amounts of audit, audit-related, tax and any other services to be provided by our independent accountants. In situations where it is not possible to obtain full Audit Committee approval, the Audit Committee has delegated authority to the Chairman of the Audit Committee to grant pre-approval of auditing, audit-related, tax and all other services. Any pre-approved decisions by the Chairman are required to be reviewed with the Audit Committee at its next scheduled meeting.

The Audit Committee approved 100% of the services provided by EKS&H.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of or are included in this Annual Report on Form 10-K:

1. Financial statements included in Item 8 of this Annual Report; and

2. Exhibits listed in the Exhibit Index filed as part of this Annual Report.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BACTERIN INTERNATIONAL HOLDINGS, INC .

By: /s/ John Gandolfo
Name: John Gandolfo
Title: Chief Financial Officer
Date: March 18, 2015

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 18, 2015.

Signature	**Title**
/s/ Daniel Goldberger Daniel Goldberger	Chief Executive Officer and Director (Principal Executive Officer)
/s/ John Gandolfo John Gandolfo	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
/s/ Kent Swanson Kent Swanson	Director
/s/ Michael Lopach Michael Lopach	Director
/s/ Jon Wickwire Jon Wickwire	Director
/s/ John Deedrick John Deedrick	Director
/s/ David Goodman David Goodman	Director

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Exhibit Index

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of June 30, 2010, by and among K-Kitz, Inc., KB Merger Sub, Inc. and Bacterin International, Inc. (1)
3.1	Certificate of Amendment of Restated Certificate of Incorporation(4); Restated Certificate of Incorporation (5)
3.2	Amended and Restated Bylaws (3)
4.1	Form of Warrant to Purchase Common Stock (1)(13)(6)
4.2*	Form of Common Stock Certificate
4.3	Registration Rights Agreement dated March 16, 2015 between Bacterin and Aspine Capital Fund, LLC(19)
10.1*	Form of Indemnification Agreement for officers and directors
10.2	Amended and Restated Bacterin International Equity Incentive Plan (7)
10.3	Form of Stock Option Agreement (14) •
10.4*	Form of Restricted Stock Agreement
10.5	Daniel Goldberger Employment Agreement (8) •
10.6	Daniel Goldberger Stock Option Agreement (9) •
10.7	Daniel Goldberger Indemnification Agreement (10)
10.8	John Gandolfo Employment Agreement (11) •
10.9*	Robert Di Silvio Employment Agreement •
10.10*	Robert Di Silvio Stock Option Agreement •
10.11	Darrel Holmes Employment Agreement (11) •
10.12	Greg Juda Employment Agreement (11) •
10.13	Credit Agreement dated August 24, 2012 by and between Bacterin and ROS Acquisition Offshore LP (12)
10.14	First Amendment to Credit Agreement dated May 16, 2013 by and between Bacterin and ROS Acquisition Offshore LP (15)
10.15	Waiver and Second Amendment to Credit Agreement dated August 12, 2013 by and between Bacterin and ROS Acquisition Offshore LP (16)
10.16	Waiver and Third Amendment to Credit Agreement dated August 12, 2013 by and between Bacterin and ROS Acquisition Offshore LP (16)
10.17	Fourth Amendment to Credit Agreement dated August 30, 2013 by and between Bacterin and ROS Acquisition Offshore LP (17)
10.18	Waiver and Fifth Amendment to Credit Agreement dated November 14, 2013 by and between Bacterin and ROS Acquisition Offshore LP (10)
10.19	Sixth Amendment to Credit Agreement dated March 6, 2014 by and between Bacterin and ROS Acquisition Offshore LP (18)
10.20	Royalty Agreement dated August 24, 2012 by and between Bacterin and ROS Acquisition Offshore LP (12)
10.21	First Amendment to Royalty Agreement dated August 12, 2013 by and between Bacterin and ROS Acquisition Offshore LP (16)
10.22	Common Stock Purchase Agreement dated March 16, 2015 between Bacterin and Aspine Capital Fund, LLC(19)
21.1	Subsidiaries of the Registrant (2)
23.1*	Consent of Independent Accounting Firm, EKS&H LLLP
31.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer

32.1**	Section 1350 Certification of Chief Executive Officer
32.2**	Section 1350 Certification of Chief Financial Officer
101.INS*	XBRL INSTANCE DOCUMENT
101.SCH*	XBRL TAXONOMY EXTENSION SCHEMA
101.CAL*	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE
101.DEF*	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE
101.LAB*	XBRL TAXONOMY EXTENSION LABEL LINKBASE
101.PRE*	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE

- Compensation Agreement

* Filed herewith

** Furnished herewith

(1) Incorporated herein by reference to the Registrant's Form 8-K filed with the SEC on June 30, 2010.

(2) Incorporated herein by reference to the Registrant's Form 8-K filed with the SEC on July 7, 2010.

(3) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on July 11, 2013.

(4) Incorporated by reference to Exhibit 3.1 to Registrant's Form 8-K filed with the SEC on July 25, 2014.

(5) Incorporated by reference to the Registrant's Form 10-Q filed with the SEC on November 14, 2011.

(6) Incorporated by reference to Exhibit 4.1 to Registrant's Form 8-K filed with the SEC on July 31, 2014.

(7) Incorporated by reference to Appendix B of the Registrant's Proxy Statement filed with the SEC on June 8, 2011.

(8) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on August 15, 2013.

(9) Incorporated by reference to the Registrant's Registration Statement on Form S-8 filed with the SEC on September 19, 2013.

(10) Incorporated by reference to the Registrant's Form 10-Q filed with the SEC on November 14, 2013.

(11) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on July 29, 2014.

(12) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on August 28, 2012.

(13) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on June 5, 2013.

(14) Incorporated by reference to the Registrant's Form 10-Q filed with the SEC on May 4, 2012.

(15) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on May 22, 2013.

(16) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on August 13, 2013.

(17) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on September 4, 2013.

(18) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on March 10, 2014.

(19) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on March 17, 2015