Bacterin International Holdings, Inc.
Form 10-K
March 27, 2013

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, 2012

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, 2012 was $35,147,703 (based on the closing price of the Company’s common stock on June 29, 2012, 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 5, 2013 was 42,649,964.

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:

- the future performance and market acceptance of our products;
- our ability to maintain our competitive position;
- negative media publicity;
- our ability to obtain donor cadavers for our products;
- our ability to expand our production capacity;
- our efforts to innovate and develop new products;
- our ability to engage and retain qualified technical personnel and members of our management team;
- our reliance on our current facilities;
- our ability to generate funds or raise capital to finance our growth;
- our efforts to expand our sales force;
- the ability of our sales force to achieve expected results;

- government regulations;
- fluctuations in our operating results;
- government and third-party coverage and reimbursement for our products;
- our ability to manage our growth;
- our ability to successfully integrate future business combinations or acquisitions;
- our ability to obtain regulatory approvals;
- product liability claims and other litigation to which we may be subjected;
- product recalls and defects;
- timing and results of clinical trials;
- our ability to obtain and protect our intellectual property and proprietary rights;
- infringement and ownership of intellectual property;
- our ability to attract broker coverage;
- the trading market, market prices, dilution, and dividends of our common stock;
- 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

Unless the context otherwise requires, "we," "our," "us" and similar expressions used in this Business section refer to Bacterin International, Inc. ("Bacterin") prior to the closing of the Reverse Merger on June 30, 2010, and Bacterin International Holdings, Inc., f/k/a K-Kitz, Incorporated (the "Company"), as successor to the business of Bacterin, following the closing of the Reverse Merger transaction.

Overview of Our Business

We develop, manufacture and market biologics products to domestic and international markets through our biologics division. Our 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 subcondral bone defect repair in knee and other joint surgeries.

Our medical devices division develops medical devices intended for use in several diverse clinical areas including orthopedic, plastic, and cardiovascular surgery. Our background and expertise is in the research, testing, and development of coatings for medical devices. In addition to the manufacture and sales of coated medical devices, the medical devices division works with our biologics division to produce and distribute OsteoSelect® DBM putty, an osteoinductive product used by surgeons as a bone void filler in the extremities and pelvis. DBM putty is considered a combination product by regulatory agencies - both a tissue and a medical device.

The medical devices division also develops custom surgical instruments for use with allografts processed by our biologics division. These state-of-the-art instruments are designed based upon the needs and inputs of surgeons. The instruments are intended to provide optimal placement of our proprietary allografts. Objectives of allograft use include pain relief, aid in the regeneration of tissue, and to provide a scaffold for bone fusion in spinal and sports medicine procedures.

The medical devices division actively develops intellectual property associated with our devices and coating platforms, for the purposes of protecting our Bacterin-branded devices and for use in alliance projects. The manufacturing and operations of the biologics and medical devices divisions are organized separately while products from both are marketed through several channels including independent distributors, joint development projects and our direct sales network.

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 and 8310 S. Valley Highway, No. 300, Englewood, Colorado 80112.

Our History

We began operations in 1998 as a sole proprietorship founded by Guy Cook, our Chief Executive Officer, as a spinout of the Center for Biofilm Engineering at Montana State University, or the CBE. Mr. Cook is an expert in microbial testing methods and has been recognized by the U.S. Food and Drug Administration, or the FDA, industry, and academia for his contributions to the development of bioactive coatings. This sole proprietorship was eventually incorporated as "Bacterin, Inc." in the state of Montana in January 2000 to further Mr. Cook's work. In March 2004, Bacterin, Inc.'s stockholders completed the terms of 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.

Leveraging off the "state of the art" research and development activities ongoing at the CBE in biofilm technology, we began as a biomaterials testing laboratory and have systematically expanded our strategic vision towards the development of Bacterin-labeled medical devices. Our revenues were historically derived from testing services and milestone payments from collaborative product development agreements with various "blue chip" medical manufacturers. Today, however, we generate revenue from a number of sources including the following: sales from products developed and manufactured by us, sales of products manufactured by a third party and sold and distributed by us, and contract revenue from analytical testing, development and manufacturing services provided to medical device manufacturer clients, which tailor our coating process to the client's specific product/medical application.

During 2008, we reached an important transition point in our history. Most of our business endeavors prior to that time had been devoted to developing our products with revenue generated from a variety of limited sources, including testing, government grants and unsubstantial product sales. In 2008, however, revenue from product sales either under our name or "private label" became our primary source of revenue.

On June 30, 2010, we completed a reverse merger transaction, or the Reverse Merger, in which we caused Bacterin International, Inc. to be 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. The Reverse Merger was consummated under Nevada corporate law pursuant to an Agreement and Plan of Merger, dated as of June 30, 2010. As a result of the Reverse Merger, Bacterin International, Inc. became our wholly owned subsidiary and we are now engaged, through Bacterin International, Inc., in the business of biomaterials research, development, and commercialization.

Before the Reverse Merger, 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."

Recent Developments

On April 23, 2012, the Company secured an accounts receivable credit facility with Midcap Financial LLC and Silicon Valley Bank. The revolving loan credit facility allowed Bacterin to borrow up to $5 million through January 1, 2015. The facility allowed borrowings based upon a predetermined formula of up to 80% of Bacterin's eligible accounts receivable, as defined in the credit and security agreement. The Company also amended its existing Loan and Security Agreement with MidCap to allow the Company to borrow up to an additional $3 million for the next nine months in connection with a permitted acquisition. The credit facility carried an interest rate of LIBOR plus 4%, subject to a LIBOR floor rate of 2.5%. The Company also agreed to pay a 0.5% collateral management fee on the average outstanding balance of the facility and 1% of the average unused portion of the facility, as well as a 1% origination fee. The Company repaid this accounts receivable credit facility in full with the proceeds from the credit facility with ROS Acquisition Offshore LP on August 24, 2012.

On August 24, 2012, the Company entered into a Credit Agreement with ROS Acquisition Offshore LP ("ROS"), whereby ROS agreed to provide an initial $20 million term loan and Bacterin may also borrow an additional $5 million upon achievement of certain revenue objectives prior to December 31, 2013. 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 each of the next ten years.. Bacterin has the right to repurchase the loan and royalty interest at an amount to be determined based on the date of repurchase

and the amount of prior principal, interest and royalty payments. We received net proceeds of approximately $10 million following repayment of the existing term loan and accounts receivable credit facility with MidCap Financial. The loan is secured by substantially all of our assets.

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 to help regenerate the surgical site may be necessary.

Products and Services

We have developed and currently manufacture and sell several human tissue-based products, primarily allografts, in the medical marketplace through our biologics division. In addition, we also manufacture and sell, directly under our own name and indirectly through distributors, various coating and surgical drain products through our medical devices division.

Biologics Division

Our biologics products include OsteoSponge®, OsteoSponge®SC, OsteoWrap®, OsteoLock®, BacFast® and hMatrix® as well as certain other allograft products which are briefly 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 be used in joint surgery. Bacterin has shown, in goat studies, the ability to re-generate cartilage in joint repair and we believe that this product has the potential to significantly change the standard of care in human joint surgery. We have received permission from the FDA to market this product as a subchondral bone void filler and are currently marketing it as such. In order to market OsteoSponge®SC as a cartilage re-generation scaffold, we would need to obtain FDA approval to begin marketing for that indication.

- 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® 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® can be used to augment spinal procedures, or as a stand-alone procedure for mild spinal conditions.

- hMatrix® dermal scaffold is an extension of Bacterin's core biologics technology and our third human acellular biological scaffold. 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.

In addition, we make 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 allografts which are comprised of cortical bone milled to desired shapes and dimensions, also called milled spinal allografts, and (iii) traditional allografts for multi-disciplinary applications including orthopedics, neurology, podiatry, oral/maxillofacial, genitourinary and plastic/reconstructive.

The Company has multiple physician-initiated studies that continue to prove expanded indications for our products.

Medical Device Products

Our medical devices division researches, tests and develops coatings for medical devices. This division also produces and distributes OsteoSelect® DBM putty, an osteoinductive and osteoconductive product used by surgeons as a bone void filler.

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. Taking the design a step further, 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.

Our medical devices division also develops custom surgical instruments for use with allografts processed by our biologics division. These instruments offer state-of-the-art design based upon the needs and inputs of surgeons who desire to use advanced minimally invasive techniques. These instruments are intended to provide optimal placement of our proprietary allografts. Objectives of allograft use include pain relief, aid in tissue regeneration, and provision of a scaffold for bone fusion in spinal and sports medicine procedures. Additionally, we sell a hubless surgical drain series called ViaTM, which is used to drain exudate from a surgical site. Via™ is available in five sizes, with and without an attached trocar to aid in placement. Building upon the ViaTM platform, Bacterin created a second generation product called Elutia® surgical drains which are performance enhanced via our proprietary coating technology.

As a consequence of a joint development project with RyMed Technologies, Inc., we treat RyMed's InVision-Plus CS™ with a proprietary coating technology. We receive a fixed price for each InVision-Plus CS™ unit sold by RyMed on all devices treated for RyMed.

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

We have numerous provisional applications pending in the United States 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 have been, and will continue to be, primarily focused in two key areas:

- The addition of bioactive agents impregnated into or onto metals, polymers or tissues which are intended to protect the surface of medical devices against microbial contamination; and

- The development of innovative and novel, engineered tissue implants or constructs which employ acellular tissue and processes, and enhanced demineralized bone matrix products.

The following table summarizes our current patent portfolio, including patents covering technology licensed by us for use or inclusion in certain of our products:

Title	First Inventor	Serial or Patent Number	Date Filed or Granted	Status
1. Pending U.S. Applications				
MEDICAL DEVICE INCLUDING A BIOACTIVE IN A NON-IONIC AND AN IONIC FORM AND	Mike Johnson	11/864,360	9/28/2007	Pending

METHODS OF PREPARATION THEREOF				
ANTIMICROBIAL COATING FOR INHIBITION OF BACTERIAL ADHESION AND BIOFILM FORMATION	Guy Cook	10/891,885	7/15/2004	Pending
PROCESS FOR DEMINERALIZATION OF BONE MATRIX WITH PRESERVATION OF NATURAL GROWTH FACTORS	Nancy J. Shelby	12/130,384	5/30/2008	Pending
PROCESS FOR DEMINERALIZATION OF BONE MATRIX WITH PRESERVATION OF NATURAL GROWTH FACTORS	Nancy J. Shelby	13/453818	4/23/2012	Pending
DRIVER-FIXATOR SYSTEM, METHOD, AND APPARATUS	R. Robinson	US20080243135	1/6/2008	Pending
2. Pending Foreign Applications				
MEDICAL DEVICE INCLUDING A BIOACTIVE IN A NON-IONIC AND AN IONIC FORM AND METHODS OF PREPARATION THEREOF	Mike Johnson	PCT/US2007/079924	9/28/2007	Pending
ANTIMICROBIAL COATING FOR INHIBITION OF BACTERIAL ADHESION AND BIOFILM FORMATION	Guy Cook	PCT/US2005/015162	4/28/2005	Issued in Australia, otherwise pending
PROCESS FOR DEMINERALIZATION OF BONE MATRIX WITH PRESERVATION OF NATURAL GROWTH FACTORS	Nancy J. Shelby	PCT/US2008/006942	6/2/2008	Pending
AN ELASTOMERIC ARTICLE INCORPORATED WITH A BROAD	Benjamin P. Luchsinger	PCT/US2009/005103	9/11/2009	Pending

SPECTRUM ANTIMICROBIAL				
SURGICAL KIT AND METHOD FOR BONE REPAIR	Guy S. Cook	PCT/US2012/042858	06/18/2012	Pending

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We believe our patent filings and patent position will facilitate growth and enhance our proprietary core competencies, enabling us to protect and expand revenue growth and stockholder value in the future. 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.

We anticipate that there may be instances in which we enter into collaborative research and development agreements with other companies under such terms that the other company may or will retain a right to make future patent filings arising from such cooperative development agreements. In such instances, we will attempt to protect our overall patent use rights by agreements which limit the right of the collaborative party to an exclusive right only as it pertains to the field of use, as defined by the applicable project's scope of work. In this manner, we anticipate that we will receive future benefit and use of such intellectual property outside the field of use, as defined by any given scope of work. 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®, QuickScrew® and hMatrix®.

Trade Secrets

To safeguard our proprietary knowledge and technology, we rely heavily 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 tissue banks 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 began implementing a direct sales network in July 2009, and we are committed to building our direct sales channel into the primary method of distributing our products. We have one National Sales Manager and four executive vice-presidents to lead this effort and we have established 13 regions with regional managers in charge of all activities within the region. We have hired and trained 39 sales representatives, two distribution managers, and two associate sales representatives. We have also hired a VP of Business Development.

We also market our products through independent commission based distributors and stocking distributors who receive a discount off of our list price and then sell to their customer base.

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 direct sales force, refined the message to our market and started gathering proof points on how to scale our revenue in these markets.

As discussed in “Sales and Marketing” above, we began implementing a direct sales network in July 2009. We currently have one National Sales Manager, 4 executive vice presidents, 13 regional managers, 39 sales representatives, 2 distribution managers and 2 associate sales representatives.

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, the Hospital for Special Surgery, MedAssets, Novation, Premier, ROi, and Access Mediquip. These agreements are paving the way for our sales representatives to call on additional physicians, as the hospital process has already been approved.

Competition

Because the orthopedic biomaterials market overlaps with a number of medical fields - spine, trauma, joint reconstruction, sports medicine, pharmaceuticals and biotechnology - fragmentation is to be expected. However, there is one clear leader in the market: Medtronic. Medtronic’s lead is based on the strength of their Infuse® growth factor product. However, the growth potential of Infuse® has been affected by some negative media attention regarding off-label usage and adverse events with specific indications.

Beyond Medtronic, the orthopedic biomaterials market is comprised of a great number of players, each offering a multitude of products. It is expected that several new products will emerge over the coming years. These assumptions are based on the advance of technology and the clinical promise of regenerative therapies such as stem cells and bone marrow concentration.

Competitors in the orthopedic biomaterials markets include: Medtronic, DePuy, Arthrex, Smith & Nephew, Nuvasive, OrthoFix, Biomet, Orthovita, MTF, Stryker, RTI, AlloSource, Lifenet Health, Integra, ConMed/Linvatec, Wright, Exactech, ArthroCare, Harvest, and Arteriocyte.

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 the States of 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, which we sell through our biologics division, 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 of communicable disease transmission to recipients. Our HCT/P products such as OsteoSponge® are regulated by the Center for Biologics Evaluation and Research. Our OsteoSponge® and OsteoWrap® products are regulated as a HCT/P as determined by the Tissue Reference Group and regulated solely 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 manufacturers and licensees who use our coating technology in their medical devices have the burden of demonstrating the safety and efficacy of the medical devices, and we assist such manufacturers and licensees in demonstrating safety and efficacy to the extent our coating technologies are at issue. Sales of medical devices using our coating technology in the European Union require CE Mark certification and sales of such medical devices in Canada require approval from the Medical Device Bureau of Canada.

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. This process can take anywhere from three months to two or three years, and can be extremely expensive. The Center for Devices and Radiological Health regulates medical devices, including our OsteoSelect® DBM putty.

ISO Certification

In March 2010, we announced that we had 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. The Geneva based International Organization for Standardization is the world's largest developer and publisher of International Standards. 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 the ISO 13485:2003 certification offers new markets and business opportunities for our products in the global marketplace.

Employees

As of January 28, 2013, we had 177 full-time employees and 189 total employees, of whom 91 were in production, 62 were in sales, 6 were in marketing, and 30 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 services partners to be good.

Facilities

We lease approximately 16,000 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. In addition, eight new clean rooms are under construction. We lease the building under a ten-year operating lease which runs through August 2013 and has a monthly lease payment of $10,000. The lease also has a ten-year renewal option which we recently exercised.

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 and currently houses our medical device coatings operations. 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. We expect this facility to meet all of our regulatory requirements for the manufacture of current and future Bacterin-label medical device products, including our surgical drains (Via™ and Elutia®), as well as

production requirements for coated medical devices from our medical device partners. 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 space at 732 Cruiser Lane, Belgrade, Montana 59714, where one Class 1,000 (ISO 6) clean room is under construction, and we lease office space in Englewood, 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.

The impact of United States healthcare reform legislation remains uncertain.

In 2010 federal legislation to reform the United States healthcare system was enacted into law. The law was upheld by a Supreme Court decision announced on June 28, 2012. The legislation is far-reaching and is intended to expand access to health insurance coverage, improve quality and reduce costs over time. Among other things, the new law imposes a 2.3 percent excise tax on medical devices beginning January 2013, which will apply to United States sales of our medical device products, including our wound drains and OsteoSelect® DBM putty. Due to multi-year pricing agreements and competitive pricing pressure in our industry, there can be no assurance that we will be able to pass the cost of the device tax on to our customers. Other provisions of this legislation, including Medicare provisions aimed at improving quality and decreasing costs, comparative effectiveness research, an independent payment advisory board, and pilot programs to evaluate alternative payment methodologies, could meaningfully change the way healthcare is developed and delivered. We cannot predict the impact of this legislation or other healthcare programs and regulations that may ultimately be implemented at the federal or state level, the effect of any future legislation or regulation in the United States or internationally or whether any changes will have the effect of lowering prices for our products or reducing medical procedure volumes.

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

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

Future regulatory action remains uncertain.

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

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 about to be available or may develop products to compete with ours. Many of these products may 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. Competition for qualified technical personnel is intense, and we may encounter difficulty in engaging and retaining qualified personnel needed to implement our growth plan. 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 Guy Cook, our President and Chief Executive Officer, and other key members of our management team and the loss of his or any of their services could have an adverse effect on our future operations. We do not currently maintain a key-man life insurance policy insuring the life of Mr. Cook or any other member of our management team.

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

Any failure in the physical infrastructure of our facilities or services could lead to significant costs and disruptions that could reduce our revenues and harm our business reputation and financial results. We are highly reliant on our Belgrade, Montana facilities. Any natural or man-made event that impacts our ability to utilize these facilities could have a significant impact on our operating results, reputation and ability to continue operations. The regulatory process for approval of facilities is time-consuming and our ability to rebuild facilities would take a considerable amount of time and expense and cause a significant disruption in service to our customers. Further, the FDA or some other regulatory agency could identify deficiencies in future inspections of our facilities or our supplies that could disrupt our business, reducing profitability. We carry business interruption insurance of up to $1 million per location to help in these instances, but it may not cover all costs or our standing in the market.

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

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

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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, and general economic conditions. There can be no assurance that the level of revenues and profits, if any, achieved by us in any particular fiscal period will not be significantly lower than in other comparable fiscal periods. Our expense levels are based, in part, on our expectations as to future revenues. As a result, if future revenues are below expectations, net income or loss may be disproportionately affected by a reduction in revenues, as any corresponding reduction in expenses may not be proportionate to the reduction in revenues.

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

Our success will depend on our ability, or that of our licensees, to obtain timely regulatory approval for products employing our technology. Moreover, our success will 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. If growth significantly decreases our reserves, we may be required to obtain additional financing, which may increase our indebtedness or result in dilution to our stockholders. Further, there can be no assurance that we would be able to obtain any additional financing.

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

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

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

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

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

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

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

In the United States, the procurement and transplantation of allograft bone tissue is subject to federal law pursuant to the National Organ Transplant Act, or NOTA, a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including bone and related tissue, for "valuable consideration." NOTA permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. We provide services in all of these areas in the United States, with the exception of removal and implantation, and receive payments for all such services. We make payments to certain of our clients and tissue banks for their services related to recovering allograft bone tissue on our behalf. If NOTA is interpreted or enforced in a manner which prevents us from receiving payment for services we render or which prevents us from paying tissue banks or certain of our clients for the services they render for us, our business could be materially and adversely affected.

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

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

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

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

Human tissues intended for transplantation have been regulated by the FDA since 1993. In May 2005, three new comprehensive regulations went into effect that address manufacturing activities associated with human cells, tissues and cellular and tissue-based products, or HCT/Ps. The first requires that companies that produce and distribute HCT/Ps register with the FDA. The second provides criteria that must be met for donors to be eligible to donate tissues and is referred to as the “Donor Eligibility” rule. The third rule governs the processing and distribution of the tissues and is often referred to as the “Current Good Tissue Practices” rule. The “Current Good Tissue Practices” rule covers all stages of allograft processing, from procurement of tissue to distribution of final allografts. Together they are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients. These regulations increased regulatory scrutiny within the industry in which we operate and have lead to increased enforcement action which affects the conduct of our business. In addition, these regulations can increase the cost of tissue recovery activities.

Other regulatory entities include state agencies with statutes covering tissue banking. Regulations issued by Florida, New York, California and Maryland will be particularly relevant to our business. Most states do not currently have tissue banking regulations. However, recent incidents of allograft related infections in the industry may stimulate the development of regulation in other states. It is possible that others may make allegations against us or against donor recovery groups or tissue banks about non-compliance with applicable FDA regulations or other relevant statutes or regulations. Allegations like these could cause regulators or other authorities to take investigative or other action, or could cause negative publicity for our business and the industry in which we operate.

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

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

Clinical trials are required to develop products, gain market acceptance and obtain 510(k) certifications from the FDA. These trials often take several years to execute and are subject to factors within and outside of our control. The outcome of any trial is uncertain and may have a significant impact on the success of our current and future products and future profits.

The commencement or completion of any clinical trial may be delayed or halted for numerous reasons, including, but not limited to, a regulatory body placing clinical trials on hold, patients not enrolling in clinical trials at the rate we expect, patients experiencing adverse side effects, third party contractors failing to perform in accordance with our anticipated schedule or consistent with good clinical practices, inclusive or negative interim trial results or our inability to obtain sufficient quantities of raw materials to produce our products. Our development costs may increase if we have material delays in clinical trials or if we need to perform more or larger clinical trials than planned. If this occurs, our financial results and the commercial prospects for our products may be harmed.

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

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

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

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

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

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

In addition to the risks involved with patent protection, we also face the risk that our competitors will infringe on our trademarks. Any infringement could lead to a likelihood of confusion and could result in lost sales.

There can be no assurance that we will prevail in any claims we make to protect our intellectual property.

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

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

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

The result of 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.

We have found material weaknesses in our system of internal controls over financial reporting that have not been fully remediated as of December 31, 2012, which could adversely affect our ability to record, process, summarize and report certain financial data.

In connection with the evaluation of the effectiveness of our internal controls over financial reporting as of December 31, 2012, management discovered the following deficiencies: (i) insufficient number of personnel with the appropriate level of experience and technical expertise to appropriately resolve account reconciliations, while completing the financial statement close process; and (ii) the documentation surrounding equity transactions for employees and consultants needs to be strengthened to comply with procedures outlined by the Company to ensure that all equity transactions are properly recorded in the appropriate periods. In light of these material weaknesses, management has concluded that we did not maintain effective internal control over our disclosure controls and procedures as of December 31, 2012, which constituted a material weakness in our internal controls over financial reporting because they resulted in a reasonable possibility that a material misstatement could occur in our annual or interim financial statements which could not be prevented or detected. Although we are working to remediate these deficiencies as outlined in Item 9A of this Annual Report on Form 10-K, there can be no assurance that our remediation efforts will resolve all of our internal control deficiencies or that we will not discover additional material weaknesses or significant deficiencies as we evaluate and test such controls in the future. Such material weaknesses or deficiencies could adversely affect our ability to record, process, summarize and report our financial information, which could cause current and potential stockholders to lose confidence in our financial reporting which could have a negative effect on the trading price of our common stock.

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

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. We cannot assure you that brokerage firms will want to conduct any public offerings on our behalf in the future.

The market price of our common stock may be volatile and may decline in value.

The market price of our common stock has been and will likely continue to be highly volatile, as is the stock market in general. Some of the factors that may materially affect the market price of our common stock are beyond our control, such as changes in financial estimates by industry and securities analysts, conditions or trends in the industry in which we operate or sales of our common stock. These factors may materially adversely affect the market price of our common stock, regardless of our performance. In addition, the public stock markets have experienced extreme price and trading volume volatility. This volatility has significantly affected the market prices of securities of many companies for reasons frequently unrelated to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock.

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

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

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

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

Our current management can exert significant influence over us and make decisions that are not in the best interests of all stockholders.

Our executive officers and directors beneficially own as a group approximately 35% of our outstanding shares of common stock. As a result, these stockholders will be able to assert significant influence over all matters requiring stockholder approval, including the election and removal of directors and any change in control. In particular, this concentration of ownership of our outstanding shares of common stock could have the effect of delaying or preventing a change in control, or otherwise discouraging or preventing a potential acquirer from attempting to obtain control. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our stockholders from realizing a premium over the market prices for their shares of common stock. Moreover, the interests of the owners of this concentration of ownership may not always coincide with our interests or the interests of other stockholders and, accordingly, could cause us to enter into transactions or agreements that we would not otherwise consider.

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

We currently intend to retain our future earnings to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our 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 16,000 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. In addition, eight new clean rooms are under construction. We lease the building under a ten-year operating lease which runs through August 2013 and has a monthly lease payment of $10,000. The lease also has a ten-year renewal option which we recently exercised.

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 and currently

houses our medical device coatings operations. 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. We expect this facility to meet all of our regulatory requirements for the manufacture of future Bacterin-label medical device products, including our surgical drains (ViaTM and Elutia®), as well as production requirements for coated medical devices from our medical device partners. 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 space at 732 Cruiser Lane, Belgrade, Montana 59714, where one Class 1,000 (ISO 6) clean room is under construction, and we lease office space in Englewood, Colorado, where certain of our administrative functions are housed.

Item 3. Legal Proceedings

On April 4, 2012, Bacterin International, Inc. filed suit against SeaArk Capital, LLC and its principal, Mark Bartosh, seeking recovery of $1,648,993.58 for product delivered to SeaArk in 2011. The case is pending in the United States District Court of the Eastern District of Pennsylvania and the parties are engaged in settlement negotiations. In connection with this litigation, Bacterin also filed a motion for a prejudgment writ of replevin or attachment in the Third Judicial District Court in the State of Utah to recover product previously sold to SeaArk. The Utah case was removed to the United States District Court for the District of Utah and Bacterin's motion for prejudgment writ was granted. SeaArk has returned all Bacterin products previously stored in Utah.

On April 19, 2012, Bacterin International, Inc. filed a lawsuit in federal court in Dallas, Texas, seeking injunctive relief and damages against Shantal Howell, a former regional vice president of the company. The suit arises out of the former employee's breach of contract, breach of fiduciary duties, interference with Bacterin's business relationships, and misappropriation of Bacterin's trade secrets. On June 8, 2012, Howell asserted a counterclaim against Bacterin for breach of contract and defamation, seeking damages for allegedly owed commissions and loss of business. The parties entered into a settlement agreement in January of 2013 whereby Ms. Howell agreed to pay Bacterin $15,000, and Ms. Howell also agreed not to compete with Bacterin or solicit customers of Bacterin for one year.

On January 29, 2013, we received two warning letters from the Food and Drug Administration ("FDA") related to our procedures to ensure compliance with regulatory requirements. The concerns included (i) procedures for implementing corrective and preventative action; (ii) procedures for receiving, reviewing and evaluating complaints; (iii) procedures related to changes to a specification, method, process or procedure; (iv) procedures to ensure that purchased or otherwise received products or services conform to specified requirements; (v) procedures to control documents; (vi) procedures to identify training needs and to ensure all personnel are trained to adequately perform assigned responsibilities; (vii) procedures related to medical device reporting; (viii) procedures to control product that does not conform to specified requirements; (ix) procedures for finished device acceptance; and (x) marketing materials related to our Elutia wound drain. The company has responded to the warning letters and is committed to actively working with the FDA to address their concerns.

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On February 11, 2013, we received a subpoena from the Office of the Inspector General of the U.S. Department of Health and Human Services ("OIG") in connection with an investigation into possible false or otherwise improper claims submitted to Medicare. The subpoena requests 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 and involved payments to only a small number of physicians that we believe were made in accordance with all applicable laws. We intend to cooperate with the OIG's investigation.

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

From July 1, 2010 to March 4, 2011, our common stock was traded on the OTC Bulletin Board under the symbol BIHI.OB. Beginning on March 7, 2011, our common stock began trading 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 OTC Bulletin Board from January 1, 2011 through March 4, 2011 and by the NYSE MKT from March 7, 2011 through December 31, 2012.

	High	Low
First Quarter 2011 (January 1, 2011 – March 31, 2011)	$9.00	$3.00
Second Quarter 2011 (April 1, 2011 – June 30, 2011)	$4.90	$2.60
Third Quarter 2011 (July 1, 2011 – September 30, 2011)	$3.15	$1.61
Fourth Quarter 2011 (October 1, 2011 – December 31, 2011)	$3.93	$1.76
First Quarter 2012 (January 1, 2012 – March 31, 2012)	$3.54	$2.08

Second Quarter 2012 (April 1, 2012 – June 30, 2012)	$2.61	$1.10
Third Quarter 2012 (July 1, 2012 – September 30, 2012)	$2.00	$1.28
Fourth Quarter 2012 (October 1, 2012 – December 31, 2012)	$1.61	$.94

Holders of Record

As of March 5, 2013, we had 234 holders of record.

Dividends

We have not paid any cash dividends and do not expect to do so in the foreseeable future.

Securities authorized for issuance under equity compensation plans

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))	
Equity compensation plans approved by security holders	5,266,535	$ 2.02	1,559,898	(1)
Equity compensation plans not approved by security holders	N/A	$N/A	N/A	
Total		$		

(1) In addition to options outstanding, the Company also has 733,900 shares of restricted stock that have been issued under the Plan to consultants.

Bacterin International Equity Incentive Plan

All of our stock options were granted under the Amended and Restated Bacterin International Equity Incentive Plan. The following is a summary of the material terms of that plan.

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 incentive compensation 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 incentive 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 will be reflected in a written stock option agreement.

There are 9,000,000 shares of our common stock authorized to be issued under the plan. As of December 31, 2012, we had outstanding options to purchase 5,266,535 shares granted and 733,900 shares of restricted stock issued, to directors, executives, employees and consultants, leaving approximately 1,559,898 shares available for issuance thereunder.

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. 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 Twelve Months Ended December 31, 2012 and December 31, 2011

	Twelve Months Ended December 31,					
	2012			2011		
	Amount	% of Revenue		Amount	% of Revenue	
Revenue						
Tissue sales	$32,414,026	98.28	%	$29,657,423	98.37	%
Royalties and other	565,873	1.72	%	492,059	1.63	%
Total Revenue	32,979,899	100.00	%	30,149,482	100.00	%
Cost of tissue sales	10,337,303	31.34	%	9,109,250	30.21	%
Gross Profit	22,642,596	68.66	%	21,040,232	69.79	%
Operating Expenses						
General and administrative	11,135,058	33.76	%	6,935,101	23.00	%
Sales and marketing	15,617,416	47.35	%	18,501,204	61.36	%
Depreciation and amortization	406,888	1.23	%	379,387	1.26	%
Non-cash consulting expense	427,787	1.30	%	1,675,008	5.56	%
Total Operating Expenses	27,587,149	83.65	%	27,490,700	91.18	%
Loss from Operations	(4,944,553)	-14.99	%	(6,450,468)	-21.39	%
Other Income (Expense)						
Interest expense	(1,864,901)	-5.65	%	(1,162,597)	-3.86	%
Change in warrant derivative liability	1,360,160	4.12	%	6,377,671	21.15	%
Other expense	(2,264,528)	-6.87	%	(1,771,075)	-5.87	%
Total Other Income (Expense)	(2,769,269)	-8.40	%	3,443,999	11.42	%
Net Loss Before Benefit (Provision) for Income Taxes	(7,713,822)	-23.39	%	(3,006,469)	-9.97	%
Benefit (Provision) for Income Taxes						
Current	-	0.00	%	-	0.00	%
Deferred	-	0.00	%	-	0.00	%
Net Income (Loss)	(7,713,822)	-23.39	%	(3,006,469)	-9.97	%

Revenue

Total revenue for the year ended December 31, 2012 increased 9% to $32,979,899 compared to $30,149,482 in the prior year. The increase of $2,830,417 was largely the result of increased sales generated from our direct sales force

and independent distributors compared to 2012. Since 2009, we have been transitioning from a 100% distributor based sales model to a hybrid model which includes sales from our direct sales force as well as independent distributors which has increased the market penetration of our products.

Cost of tissue sales

Costs of tissue sales consist primarily of tissue and device manufacturing costs. Costs of tissue sales increased by 13% or $1,228,053 to $10,337,303 for the year ended December 31, 2012 from $9,109,250 for the year ended December 31, 2011. The increase was largely the result of increased costs associated with our higher sales. As a percentage of tissue sales, cost of tissue sales was 31.3% of revenues for 2012 compared to 30.2% in 2011. The slight increase is the result of increasing production capacity resulting in increased product costs in 2012.

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%, or $96,449, for the year ended December 31, 2012 compared to the year ended December 31, 2011, 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 increased 61%, or $4,199,957, to $11,135,058, for the year ended December 31, 2012 compared to 2011. The increase is primarily due to higher general and administrative expenses allocated to cost of tissue sales in 2011 compared to 2012. In addition, we incurred higher administrative costs supporting the higher revenue in addition to added rental and maintenance expense for increased operational space.

Selling and Marketing

Selling and marketing expenses primarily consist of 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 decreased 16%, or $2,883,788, to $15,617,416 for the twelve months ended December 31, 2012 from $18,501,204 for the prior year. As a percentage of revenue, selling and marketing expenses decreased to 47% in 2012 from 61% in the prior year. The decreases were primarily the result of more variable compensation paid to our direct sales force compared to fixed salaries earned in the comparable period of 2011 and a lower corporate sales commission structure

for direct sales representatives and independent distributors.

Depreciation

Depreciation expense consists of depreciation of long-lived property and equipment. Depreciation expense increased 7% to $406,888 for the year ended December 31, 2012 from $379,387 in 2011. The increase reflects increased equipment purchases made in 2012 and a full year of depreciation in 2012 on the assets acquired in the second quarter of 2011 acquisition of Robinson MedSurg.

Non-cash Consulting Expense

Non-cash consulting expense consists of non-cash expense associated with granting restricted stock to consultants. Non-cash consulting expense decreased $1,247,221 to $427,787 for the year ended December 31, 2012 from $1,675,008 in the prior year, a decrease of 75%. The decrease is due to the lower closing price of the Company's common stock at December 31, 2012 which was partially offset by more contracts in place in 2012.

Interest Expense

Interest expense is from our promissory notes and convertible debt instruments. Interest expense for 2012 increased $702,304 to $1,864,901 as compared to $1,162,597 in 2011. The increase was the result a higher average debt balance in 2012 and the higher interest rate related to the 2012 debt financing with ROS Acquisition Offshore LP.

Change in Warrant Derivative Liability

For 2012, the Company recorded a decrease in its non cash warrant derivative liability of $1,360,160 based upon the decrease in the closing price of the Company's common stock at December 31, 2012 compared to December 31, 2011. The liability is associated with the issuance of warrants as part of the Company's prior convertible debt financing, and the Company's 2010 WTI financing which contain anti dilution adjustment provisions requiring the Company to record a change in the warrant derivative liability from period to period.

Write-off of Debt Related Expenses and Other Expense

For 2012, the Company recorded a non-cash charge of approximately $706,000 of debt discounts and loan origination fees written off in addition to approximately $944,000 of prepayment penalties related to the term financing with MidCap and Silicon Valley Bank that was prepaid in connection with the new 2012 term loan financing with ROS Acquisition Offshore LP. In addition, 2012 also included the amortization of the higher prepaid and loan origination fees from the 2012 ROS Acquisition Offshore LP financing as well as approximately $342,000 for warrants issued for services. Other non-operating expense in 2011 consisted of a non cash charge of approximately $1,300,000 of debt discounts written off in connection with the 2011 term loan financing with MidCap Financial and Silicon Valley Bank.

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 line and other debt transactions. In August 2012, we closed on a $20 million term loan transaction with ROS Acquisition Offshore LP. The proceeds were used to pay off the previous loans with MidCap Financial LLC and Silicon Valley Bank of approximately $9.3 million with the remainder adding to our working capital. At December 31, 2012, we had $12,080,131 of cash and cash equivalents and accounts receivables.

Net cash used in operating activities for 2012 was $10,792,332. This was primarily related to cash used to fund our operations as well as an increase in our inventory balance of $4,979,394. For 2011, net cash used in operating activities was $7,362,138.

Net cash used in investing activities for 2012 was $1,836,777 due to the purchase of property and equipment.

Net cash provided by financing activities was $16,804,064 for 2012 which was primarily due to the net proceeds of the new term loan with ROS Acquisition Offshore LP in addition to cash raised through the issuance of 1,475,037 shares of our common stock to Lincoln Park Capital for aggregate proceeds of approximately $3,899,996.

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, 2012 cash on hand and accounts receivable balance of $12,080,131 and anticipated cash receipts from sales expected from operations will be sufficient to meet our anticipated cash requirements through December 31, 2013. We incurred approximately $16 million in sales and marketing expenses in 2012 and expect to incur $18 million in 2013 based upon our 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.

In addition, we currently anticipate that we will need to spend between $4 and $5 million over the next 5 years in order to increase, expand or update our existing facilities to meet our expected growth over that period.

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 sheet of Bacterin International Holdings, Inc. and subsidiary (the "Company") as of December 31, 2012 and 2011and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years then ended. These 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 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 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 audit 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 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, 2012 and 2011, 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 27, 2013

Denver, Colorado

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BACTERIN INTERNATIONAL HOLDINGS, INC.

Consolidated Balance Sheets as of December 31, 2012 and 2011

	As of December 31, 2012	2011
ASSETS		
Current Assets:		
Cash and cash equivalents	$4,926,066	$751,111
Trade accounts receivable, net of allowance for doubtful accounts of $1,576,955 and $1,232,806, respectively	7,154,065	7,083,354
Inventories, net	13,141,421	8,479,710
Prepaid and other current assets	353,271	289,326
Total current assets	25,574,823	16,603,501
Non-current Assets:		
Non-current inventories	1,238,225	920,542
Property and equipment, net	5,234,867	3,774,140
Intangible assets, net	592,378	656,133
Goodwill	728,618	728,618
Other assets	1,126,643	486,914
Total Assets	$34,495,554	$23,169,848
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$3,997,789	$2,654,263
Accounts payable - related party	418,922	513,193
Accrued liabilities	2,400,090	3,762,211
Warrant derivative liability	984,356	2,344,516
Current portion of capital lease obligations	149,729	33,791
Current portion of royalty liability	698,408	-
Current portion of long-term debt	45,135	1,632,978
Total current liabilities	8,694,429	10,940,952
Long-term Liabilities:		
Capital lease obligation, less current portion	245,703	89,580
Long term royalty liability, less current portion	6,839,935	-
Long-term debt, less current portion	14,483,102	6,638,270
Total Liabilities	30,263,169	17,668,802
Commitments and Contingencies		
Stockholders' Equity:		
	-	-

Preferred stock, $.000001 par value; 5,000,000 shares authorized; no shares issued and outstanding		
Common stock, $.000001 par value; 95,000,000 shares authorized; 42,877,770 shares issued and outstanding as of December 31, 2012 and 40,841,218 shares issued and outstanding as of December 31, 2011	43	40
Additional paid-in capital	51,897,890	45,452,732
Accumulated deficit	(47,665,548)	(39,951,726)
Total Stockholders' Equity	4,232,385	5,501,046
Total Liabilities & Stockholders' Equity	$34,495,554	$23,169,848

See notes to audited consolidated financial statements.

BACTERIN INTERNATIONAL HOLDINGS, INC.

Consolidated Statements of Operations

For the Years Ended December 31, 2012 and 2011

	Twelve Months Ended December 31,	
	2012	2011
Revenue		
Tissue sales	$ 32,414,026	$ 29,657,423
Royalties and other	565,873	492,059
Total Revenue	32,979,899	30,149,482
Cost of tissue and medical devices sales	10,337,303	9,109,250
Gross Profit	22,642,596	21,040,232
Operating Expenses		
General and administrative	11,135,058	6,935,101
Sales and marketing	15,617,416	18,501,204
Depreciation and amortization	406,888	379,387
Non-cash consulting expense	427,787	1,675,008
Total Operating Expenses	27,587,149	27,490,700
Loss from Operations	(4,944,553)	(6,450,468)
Other Income (Expense)		
Interest expense	(1,864,901)	(1,162,597)
Change in warrant derivative liability	1,360,160	6,377,671
Write-off of debt related costs	(705,885)	(1,300,000)
Other income (expense)	(1,558,643)	(471,075)
Total Other Income (Expense)	(2,769,269)	3,443,999
Net Loss Before (Provision) Benefit for Income Taxes	(7,713,822)	(3,006,469)
(Provision) Benefit for Income Taxes		
Current	-	-
Deferred	-	-
Net Loss	$ (7,713,822)	$ (3,006,469)
Net loss per share:		
Basic	$ (0.18)	$ (0.08)
Dilutive	$ (0.18)	$ (0.08)

Shares used in the computation:		
Basic	42,445,386	38,944,256
Dilutive	42,445,386	38,944,256

See notes to audited consolidated financial statements.

BACTERIN INTERNATIONAL HOLDINGS, INC.

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

For the Years Ended December 31, 2012, and 2011

	Common Stock		Additional	Retained	Total Shareholders'
	Shares	Amount	Paid-In-Capital	Deficit	Equity (deficit)
Balance at December 31, 2010	36,994,715	37	36,325,976	(36,945,257)	(619,244)
Issuance of common stock, options and warrants:					
Private placement	939,377	1	2,974,618	-	2,974,619
Exercise of warrants	977,679	1	1,358,459	-	1,358,460
Stock grants	230,499	-	548,261	-	548,261
Stock-based compensation	538,500	-	2,007,467	-	2,007,467
Exercise of options	775,833	1	1,010,563	-	1,010,564
Debt discount - WTI	-	-	227,388	-	227,388
Acquisition of RMS	384,615	-	1,000,000	-	1,000,000
Net loss	-	-	-	(3,006,469)	(3,006,469)
Balance at December 31, 2011	40,841,218	$ 40	$ 45,452,732	$(39,951,726)	$ 5,501,046
Stock-based compensation	394,668	1	1,956,054	-	1,956,055
Exercise of options	39,375	-	46,003	-	46,003
Exercise of warrants	129,972	-	-	-	-
Issuance of warrants	-	-	563,357	-	563,357
Private placement	1,472,537	$ 2	$ 3,879,744	-	3,879,746
Net loss	-	-	-	(7,713,822)	(7,713,822)
Balance at December 31, 2012	42,877,770	$ 43	$ 51,897,890	$(47,665,548)	$ 4,232,385

See notes to audited consolidated financial statements.

BACTERIN INTERNATIONAL HOLDINGS, INC.

Consolidated Statements of Cash Flows

For the Years Ended December 31, 2012 and 2011

	Twelve Months Ended December 31,	
	2012	2011
Operating activities:		
Net loss	$ (7,713,822)	$ (3,006,469)
Noncash adjustments:		
Depreciation and amortization	782,889	755,387
Amortization of debt discount	502,044	302,465
Write-off of debt discount	705,885	1,307,977
Write-off of accounts receivable-related party	-	795,000
Non-cash consulting expense/stock option expense	1,554,657	2,555,727
Warrants issued for services	342,485	-
Non-cash interest	196,823	-
Provision for losses on accounts receivable and inventory	636,704	1,425,537
Loss on disposal of assets	7,902	-
Change in derivative warrant liability	(1,360,160)	(6,377,671)
Reduction of contingent liability	(358,426)	-
Changes in operating assets and liabilities:		
Accounts receivable	(414,860)	(4,636,860)
Accounts receivable - related party	-	(181,966)
Inventories	(5,271,950)	(2,365,403)
Prepaid and other current assets	(1,049,458)	(190,550)
Accounts payable	1,249,255	334,183
Accrued liabilities	(602,300)	1,920,505
Net cash used in operating activities	(10,792,332)	(7,362,138)
Investing activities:		
Purchases of property and equipment	(1,825,614)	(962,306)
Notes receivable from stockholder	-	82,398
Intangible asset additions	(11,163)	(137,411)
Net cash used in investing activities	(1,836,777)	(1,017,319)
Financing activities:		
Proceeds from the issuance of long-term debt	22,741,719	9,579,687
Payments on long-term debt	(9,784,482)	(5,115,504)
Payments on capital leases	(78,925)	(36,182)
Proceeds from issuance of stock	3,879,749	2,974,618
Proceeds from exercise of options	46,003	1,010,563
Proceeds from exercise of warrants	-	389,905
Net cash provided by financing activities	16,804,064	8,803,087

Net change in cash and cash equivalents	4,174,955	423,630
Cash and cash equivalents at beginning of period	751,111	327,481
Cash and cash equivalents at end of period	$ 4,926,066	$ 751,111

See notes to audited consolidated financial statements.

Notes to 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’s biologics division develops, manufactures and markets biologics products to domestic and international markets. Bacterin’s proprietary methods are used in human allografts to create stem cell 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’s device division develops bioactive coatings based upon proprietary knowledge of the phenotypical changes made by microbes as they sense and adapt to changes in their environment. Bacterin develops, employs, and licenses bioactive coatings for various medical device applications.

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. The Company operates in two distinct lines of business consisting of the biologics and devices divisions. However, due to the immaterial revenue from devices to date, the Company reports as one segment.

The Company's revenue is derived principally from the sale or license of its medical products, coatings and device implants. 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 the business.

Presentation

Certain amounts in the 2011 consolidated financial statements have been reclassified to conform to the 2012 presentation.

Concentrations and Credit Risk

The Company's accounts receivable are due from a variety of health care organizations and distributors throughout the world. Approximately 97% and 98% of sales were in the United States for 2012 and 2011, respectively. One customer accounted for approximately 5% and 6% of the Company's revenue for 2012 and 2011, respectively. One customer represented 22% and 21% of accounts receivable at December 31, 2012 and 2011, respectively. 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, 2012.

Revenue by geographical region is as follows:

	Year ended December 31,	
	2012	2011
United States	$31,947,757	$29,571,446
Rest of World	1,032,142	578,036
	$32,979,899	$30,149,482

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; 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; contingent consideration from acquisitions; 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.

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.

Accounts Payable - Related Party

Accounts payable to a related party included amounts due to American Donor Services, a supplier of donors to the Company. See Note 15, “Related Party Transactions” below.

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 generally 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. In its evaluation of goodwill, the Company performs an assessment of qualitative factors to determine if it is more-likely-than-not that goodwill might be impaired and whether it is necessary to perform the two-step goodwill impairment. The Company conducts its annual impairment test on December 31 of each year. See Note 3, “Goodwill” below.

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 relates to warrants issued in connection with certain debt financings. The Company has not designated its warrant derivative liability as a hedging instrument as described in ASC 815 and any changes 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, customer lists 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 five years for customer lists and 15 years for all other intangible assets.

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 has been met.

The Company also receives royalty revenue from third parties related to licensing agreements. The Company has royalty agreements with Nufix, RyMed and Bard Access Systems. Revenue under these agreements represented less than 1% of total revenue for 2012 and 2011.

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. Advertising costs of approximately $51,000 and $81,000 were expensed for the years ended December 31, 2012 and 2011, 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. No impairment was recorded during the years ended December 31, 2012 or 2011.

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, 2012 and 2011 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 5,266,535 and 5,008,670 outstanding stock options and warrants for the twelve months ended December 31, 2012 and 2011, respectively are anti-dilutive.

Stock-Based Compensation

The Company records stock-compensation expense according to the provisions of ASC 718. 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. Pursuant to the income tax provisions included in ASC 718-740, the Company has elected the “short cut method” of computing its hypothetical pool of additional paid-in capital that is available to absorb future tax benefit shortfalls.

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.

We follow 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 twelve months ended December 31, 2012 and 2011, 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 December 31, 2012 and December 31, 2011 that are measured at fair value on a recurring basis:

Accrued stock compensation

	As of December 31, 2012	As of December 31, 2011
Level 1	218,850	608,933
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, 2012	As of December 31, 2011
Level 1	-	-
Level 2	-	-
Level 3	$ 984,356	$ 2,344,516

Acquisition contingent consideration liability

	As of December 31, 2012	As of December 31, 2011
Level 1	-	-
Level 2	-	-

Level 3	$ 91,740	450,166

The valuation technique used to measure fair value of the warrant liability and contingent consideration 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 period ending December 31, 2012:

Warrant derivative liability

Balance at January 1, 2012	$2,344,516
Gain recognized in earnings	(1,360,160)
Balance at December 31, 2012	$984,356

Acquisition contingent consideration liability

Balance at January 1, 2012	$450,166
Gain recognized in earnings	(358,426)
Balance at December 31, 2012	$91,740

During the year ended December 31, 2012, the Company did not change any of the valuation techniques used to measure its liabilities at fair value.

Items measured at fair value on a non-recurring basis:

The Company's royalty liability is carried at its estimated fair value based upon the discounted present value of the payments using an estimated discount rate. The Company did not have access to a readily traded market for similar credit risks and the estimated interest rate was based upon the Company's estimate of a market interest rate to obtain similar financing. The Company originally discounted the $16.8 million of estimated payments at an interest rate of 16.7%. This was adjusted to an estimated royalty total of $13.8 million as of December 31, 2012. Accordingly, these inputs are classified as Level 3 inputs.

Recent Accounting Pronouncements

There are no recently issued accounting standards for which the Company expects a material impact to its consolidated financial statements.

(2) Equity

On May 27, 2011, we entered into a Purchase Agreement and Registration Rights Agreement with Lincoln Park Capital Fund, LLC (“LPC”) whereby LPC agreed to purchase up to $31 million of our common stock from time to time pursuant to the terms of the Purchase Agreement and we agreed to register the shares purchased by LPC. Upon signing the Purchase Agreement, LPC purchased 326,798 shares of our common stock for $1,000,002 and also received warrants to purchase 130,719 shares at an exercise price of $3.06 per share, the closing price on May 26, 2011. This was part of a private placement transaction pursuant to Rule 506 of Regulation D in the second quarter of 2011 in which we raised a total of $3,027,504 and issued 939,377 shares of our common stock and warrants to purchase 375,747 shares of our common stock.

During the first quarter of 2012, we issued 1,475,037 shares of our common stock to LPC for aggregate proceeds of $3,899,996. We used the proceeds for working capital and general corporate purposes.

The Purchase Agreement allowed us to require LPC to purchase up to $30 million of our common stock from time to time, and also allowed us to terminate the Purchase Agreement for any reason or for no reason with one business day's notice to LPC. On May 3, 2012, we terminated the LPC Purchase Agreement.

(3) Acquisition

On July 11, 2011, we signed an Asset Purchase Agreement (“Agreement”) with Robinson MedSurg, LLC (“Seller”), a company engaged in the manufacture, distribution and sale of implantable medical devices for maxillofacial, craniofacial and orthopedic uses. Under the terms of the Agreement, we purchased certain assets from Seller, as described in the Agreement, for $1 million in common stock. In addition, we agreed to pay Seller an additional $500,000 in common stock if gross revenue from the sale of products resulting from the purchased assets (“Products”) equals or exceeds $1 million, and an additional $500,000 in common stock when gross revenue from the sale of Products equals or exceeds $2 million, provided that such gross revenue thresholds are achieved within 2 years. As of December 31, 2012, these revenue thresholds have not been achieved. We also engaged the sole member of Seller as a consultant. We accounted for this business combination under the acquisition method in accordance with ASC 805 - Business Combinations, which requires the acquiring entity in a business combination to recognize all (and only) the assets acquired and liabilities assumed in the transaction; establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed; and requires the acquirer to disclose to investors and other users all of the information they need to evaluate and understand the nature and financial effect of the business combination.

The purchase price was allocated as follows:

Finished inventory	$504,827
Customer list	157,077
Trademark	59,644
Goodwill	728,618
Total purchase price	$1,450,166

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Goodwill is primarily made up of business synergies expected from the additional product offerings through our established distribution network.

The consideration for the purchase price was made up of the following components:

Stock issued	$1,000,000
Contingent consideration	450,166
Total consideration	$1,450,166

The initial valuation of the contingent consideration was based upon management's estimates of the probability of reaching the milestones that would trigger the requirement to pay the contingent amounts. During 2012, management reviewed and adjusted the assumptions associated with the contingent liability which resulted in a reduction of the contingent liability to $91,740 as of December 31, 2012.

The useful lives of the Customer List and the Trademark are 5 years and 15 years, respectively resulting in the following amortization schedule:

2013	35,392
2014	35,392
2015	35,392
2016	26,229
2017	3,976
Thereafter	27,252
Total	$163,633

(4) Inventories

Inventories consist of the following:

	December 31,	
	2012	2011
Current inventories		
Raw materials	$1,919,250	$1,612,901
Work in process	4,991,032	2,586,047

Finished goods	7,350,332	5,107,400
	14,260,614	9,306,348
Reserve for obsolescence	(1,119,193)	(826,638)
Current inventories, total	$13,141,421	$8,479,710
Non-current inventories		
Finished goods	$1,238,225	$920,542
Non-current inventories, total	$1,238,225	$920,542
Total inventories	$14,379,646	$9,400,252

(5) Property and Equipment, Net

Property and equipment, net are as follows:

	December 31,	
	2012	2011
Buildings	$1,653,263	$1,653,263
Equipment	5,172,523	3,597,471
Computer equipment	312,650	392,375
Computer software	392,206	228,054
Furniture and fixtures	170,118	171,418
Leasehold improvements	1,793,756	1,357,218
Vehicles	78,306	68,306
Total cost	9,572,822	7,468,105
Less: accumulated depreciation	(4,337,955)	(3,693,965)
	$5,234,867	$3,774,140

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, 2012, the Company has recorded $549,604 gross assets in Equipment, and $66,886 of accumulated depreciation relating to assets under capital leases.

Maintenance and repairs expense for 2012 and 2011 was $287,811 and $109,171, respectively. Depreciation expense related to property and equipment, including property under capital lease for 2012 and 2011 was $707,971 and $701,748, 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, 2012	December 31, 2011
Intellectual Property		
Gross carrying value	$ 820,778	$ 809,615
Accumulated amortization	$ (228,400)	$ (153,482)
Net carrying value	$ 592,378	$ 656,133
Aggregate amortization expense:	$ 74,918	$ 53,638
Estimated amortization expense:		
2013		$ 74,918
2014		$ 74,918
2015		$ 74,918
2016		$ 74,918
2017		$ 74,918
Thereafter		$ 217,788
Total		$ 592,378

(7) Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2012	2011
Acquisition contingent liability	$91,740	$450,166
Accrued stock compensation	218,850	608,933
Wages/commissions payable	1,013,909	1,289,827
Other accrued expenses	1,075,591	1,413,285
	$2,400,090	$3,762,211

(8) Long-term Debt

On July 29, 2011, we entered into Loan and Security Agreement with MidCap Funding III, LLC (“MidCap”), whereby MidCap and Silicon Valley Bank (“SVB”) agreed to provide a $15 million credit facility which allowed us to borrow $7 million and up to an additional $8 million in connection with a permitted acquisition through December 31, 2011. The $8 million portion expired unused as of December 31, 2011. The credit facility was secured by substantially all of our assets and carried an interest rate of LIBOR plus 7.5%, subject to a LIBOR floor rate of 3% and contained covenants based upon revenue thresholds. Repayment was interest only for the first nine months, with principal and interest for the subsequent 33 months. In the second quarter of 2012, the interest only period was extended through December 31, 2012. We repaid this loan in full with the proceeds from our credit facility with ROS Acquisition Offshore LP (“ROS”) on August 24, 2012.

On April 23, 2012, the Company secured an accounts receivable credit facility with Midcap Financial LLC and Silicon Valley Bank. The revolving loan credit facility allowed Bacterin to borrow up to $5 million through January 1, 2015. The facility allowed borrowings based upon a predetermined formula of up to 80% of Bacterin's eligible accounts receivable, as defined in the credit and security agreement. The Company also amended its existing Loan and Security Agreement with MidCap to allow the Company to borrow up to an additional $3 million for the next nine months in connection with a permitted acquisition. The credit facility carried an interest rate of LIBOR plus 4%, subject to a LIBOR floor rate of 2.5%. The Company also agreed to pay a 0.5% collateral management fee on the average outstanding balance of the facility and 1% of the average unused portion of the facility, as well as a 1% origination fee. The Company repaid this accounts receivable credit facility in full with the proceeds from the credit facility with ROS on August 24, 2012.

On August 24, 2012, the Company entered into a Credit Agreement with ROS, whereby ROS agreed to provide an initial $20 million term loan and Bacterin may also borrow an additional $5 million upon achievement of certain revenue objectives prior to December 31, 2013. 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 each of the next ten years. Bacterin has the right to repurchase the loan and royalty interest at amount to be determined based on the date of repurchase and the amount of prior principal, interest and royalty payments. 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 $7,341,520. 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 $13.8 million through interest expense over the ten year term of the royalty agreement using the effective interest method. Payments made under the royalty agreement, per the table below, will directly reduce the royalty liability.

Other non-operating expense in 2012 consisted of a non cash charge of approximately $706,000 of debt discounts and loan origination fees written off in addition to approximately $944,000 of prepayment penalties related to the term financing with MidCap and Silicon Valley Bank that was prepaid in connection with the new 2012 term loan financing with OrbiMed. Other non-operating expense in 2011 consisted of a non cash charge of approximately $1,300,000 of debt discounts written off in connection with the new 2011 term loan financing with MidCap Financial and Silicon Valley Bank.

The Company received net proceeds of approximately $10 million following repayment of the existing term loan and accounts receivable credit facility with MidCap Financial, including prepayment penalties. The Company plans to use the net proceeds for working capital and general corporate purposes.

Long-term debt consists of the following:

	December 31, 2012	December 31, 2011
Loan payable to ROS Acquisition Offshore, LIBOR plus 12.13% maturing August 2019	$ 20,000,000	$ -
Loan payable to MidCap, LIBOR plus 7.5% maturing January 2015	-	4,666,667
Loan payable to SVB, LIBOR plus 7.5% maturing January 2015	-	2,333,333
6.00% loan payable to Valley Bank of Belgrade, $10,746 monthly payments including interest, maturing December 24, 2030; secured by building	1,421,420	1,464,183
	21,421,420	8,464,183
Less: Current portion	(45,135)	(1,632,978)
Debt discount	(6,893,183)	(192,935)
Long-term debt	$ 14,483,102	$ 6,638,270

The following is a summary of maturities due on the debt as of December 31, 2012:

2013	45,135
2014	47,919
2015	50,875
2016	1,720,679
2017	6,724,041
Thereafter	12,832,771
Total	$21,421,420

The following is a summary of estimated future royalty payments as of December 31, 2012:

2013	788,000
2014	853,000
2015	1,050,000
2016	1,289,000
2017	1,384,000
Thereafter	8,477,000
Total	$13,841,000

(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 incentive compensation 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 incentive compensation 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 currently 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 incentive 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 incentive plan must be at least equal to the fair market value of the shares of common stock on the date of the grant. 9 million shares are authorized under the Plan and at December 31, 2012, we had approximately 1,559,898 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 years ended December 31, 2012 and 2011 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. 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 1.20% for year ended December 31, 2012.

- Expected Term: We do not have adequate history to estimate an expected term of stock-based awards, and accordingly, we use the short-cut method as prescribed by Staff Accounting Bulletin 107 to determine an expected term. We used a weighted-average expected term of 6.7 years for the year ended December 31, 2012.

- Volatility: We estimate expected volatility based on peer-companies as prescribed by ASC 718. We used a weighted-average volatility rate of 66% for the year ended December 31, 2012.

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Dividend Yield: The dividend yield assumption is based on our history and expectation of dividend payouts and was 0% as of December 31, 2012 and 2011.

Activity under our stock option plans was as follows:

	2012			2011		
	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	4,828,910	$ 2.14	$ 1.01	3,850,743	$ 1.38	$ 0.84
Granted	1,716,250	1.79	1.03	2,261,750	2.90	1.39
Exercised	(39,375)	0.87	0.37	(775,833)	1.31	0.66
Cancelled or expired	(1,239,250)	2.17	0.39	(507,750)	2.42	1.23
Outstanding at December 31	5,266,535	$ 2.02	$ 1.03	4,828,910	$ 2.14	$ 1.01
Exercisable at December 31	2,565,301	$ 1.83	$ 0.80	2,194,593	$ 1.63	$ 0.67

The total intrinsic value of options exercised in 2012 was $39,375. The aggregate intrinsic value of options outstanding as of December 31, 2012 is $473,416. The aggregate intrinsic value of exercisable options as of December 31, 2012 is $473,416. As of December 31, 2012, there were 2,701,234 unvested options with a weighted average fair value at the grant date of $1.18 per option. As of December 31, 2012, there is no compensation related to nonvested awards not yet recognized.

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 following table summarizes restricted stock award activity during the year ended December 31, 2012:

	Shares
Outstanding at Jan. 1, 2012	1,632,900
Awarded	151,000
Cancelled	(677,500)
Vested	(372,500)
Outstanding at December 31, 2012	733,900

The restricted stock awards generally vest over three to five year periods. The Company recognized non cash consulting expense of $427,787 and $1,675,008 for the years ended December 31, 2012 and 2011, respectively. As of December 31, 2012, the total expense related to nonvested restricted stock awards not yet recognized is $562,622 and is expected to be recognized over four years.

(10) Warrants

Associated with the second quarter of 2011 private placement of common stock, 375,747 warrants with exercise prices ranging from $2.95 to $3.52 were issued to the participants. Warrants issued with common stock under this private placement were recorded as additional paid in capital at their estimated fair market value of $312,285 during the second quarter of 2011.

In connection with the July 29, 2011MidCap financing described above, MidCap and SVB received 192,157 warrants to purchase shares of our common stock equal to 7% of the amount drawn on the credit facility divided by the exercise price of $2.55 per share. The warrants have a seven year term. MidCap and SVB also had the right to receive additional warrants if additional amounts were drawn under the facility. The fair value of these warrants, $227,388, was recorded as a discount to the underlying debt and additional paid in capital.

In the third quarter of 2012, the Company issued 297,991 warrants with an exercise price of $2.30 to a broker in conjunction with the August 24, 2012 financing arrangement with ROS. These were recorded in “Other Assets” and will be amortized over the life of the financing term. These warrants were issued in the fourth quarter of 2012. In addition, on July 23, 2012 the Company issued 300,895 warrants with an exercise price of $1.03 to a private party resulting in $342,485 recorded in “Other Expense”.

The following table summarizes our warrant activities for the period ended December 31, 2012:

	Shares	Weighted Average Exercise Price
Outstanding at January 1, 2012	6,967,529	$ 2.22
Issued	598,886	1.66
Exercised	(244,748)	1.58
Outstanding at December 31, 2012	7,321,667	$ 2.20

The exercise of 244,748 warrants in 2012 resulted in the issuance of 129,972 shares of common stock as the warrants were exercised using the cashless feature of the warrants.

We utilize a lattice model to determine the fair market value of the warrants accounted for as liabilities. The 1,570,565 warrants issued in connection with a 2010 bridge financing and 375,000 warrants issued in connection with a 2010 debt financing were accounted for as derivative liabilities in connection with the price protection provisions of the warrants in compliance with ASC 815. There were 133,474 additional warrants issued in the first quarter of 2011 and an additional 143,700 warrants in the first quarter of 2012 as a result of the LPC share issuance triggering the anti-dilution clause in the original warrant agreement. The lattice model accommodates the probability of exercise price adjustment features as outlined in the warrant agreements. We recorded an unrealized gain of $1,360,160 resulting from the change in the fair value of the warrant derivative liability for 2012. 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 common stock equivalents 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,	
	2012	2011
Value of underlying common stock (per share)	$1.25	$1.56
Risk free interest rate	0.24 %	0.32 %
Expected term	3.83 years	4.67 years
Dividend yield	0	0
Volatility	72 %	69 %

The following table summarizes our activities related to number of warrants used in the derivative liability for the period ended December 31, 2012 and 2011:

	2012	2011
Balance at January 1	1,506,007	1,595,473
Derivative warrants issued	143,700	133,474
Derivative warrants exercised	-	(222,940)
Balance at December 31	1,649,707	1,506,007

(11) Commitments and Contingencies

Operating Leases

We lease two office facilities under non-cancelable operating lease agreements with expiration dates in 2013 and 2019. 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 have exercised the option to extend the lease that expires in 2013. 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, 2012, under these leases, are as follows:

2013	$244,828
2014	$263,136
2015	$263,136
2016	$263,136
2017	$263,136
Thereafter	$997,264

Total	$2,294,636

Rent expense was approximately $298,000 and $215,000 for the years ended December 31, 2012 and 2011, 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.

Litigation

On April 4, 2012, Bacterin International, Inc. filed suit against SeaArk Capital, LLC and its principal, Mark Bartosh, seeking recovery of $1,648,993.58 for product delivered to SeaArk in 2011. The case is pending in the United States District Court of the Eastern District of Pennsylvania and the parties are engaged in settlement negotiations. In connection with this litigation, Bacterin also filed a motion for a prejudgment writ of replevin or attachment in the Third Judicial District Court in the State of Utah to recover product previously sold to SeaArk. The Utah case was removed to the United States District Court for the District of Utah and Bacterin’s motion for prejudgment writ was granted. SeaArk has returned all Bacterin products previously stored in Utah.

On April 19, 2012, Bacterin International, Inc. filed a lawsuit in federal court in Dallas, Texas, seeking injunctive relief and damages against Shantal Howell, a former regional vice president of the company. The suit arises out of the former employee's breach of contract, breach of fiduciary duties, interference with Bacterin's business relationships, and misappropriation of Bacterin's trade secrets. On June 8, 2012, Howell asserted a counterclaim against Bacterin for breach of contract and defamation, seeking damages for allegedly owed commissions and loss of business. The parties entered into a settlement agreement in January of 2013 whereby Ms. Howell agreed to pay Bacterin $15,000, and Ms. Howell also agreed not to compete with Bacterin or solicit customers of Bacterin for one year.

(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,	
	2012	2011
United States	$(7,713,822)	$(3,006,469)
	$(7,713,822)	$(3,006,469)

The components of the income tax provision are as follows:

	Year Ended December 31,	
	2012	2011
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,	
	2012	2011
Statutory Federal tax rate	$(2,699,838)	$(1,052,264)
Valuation allowance	2,789,646	3,729,905
State income taxes, net of Federal benefit	(443,236)	(172,752)
Change in state income tax rate	823,665	-
Change in Warrant Derivative Liability	(554,211)	(2,598,646)
Nondeductible meals & entertainment expense	83,974	93,757
	$-	$-

Deferred tax components are as follows:

	At December 31,	
	2012	2011
Deferred tax assets:		
Current deferred tax assets		
Accrued liability for vacation	$75,442	$78,972
Bad debt reserve	642,546	540,462
Charitable contributions carrforward	19,686	14,835
Inventory reserve	456,026	362,399
Restricted stock compensation	94,212	266,957
Total current deferred tax assets	1,287,912	1,263,625
Valuation Allowance	(1,287,912)	(1,263,625)
Net current deferred tax assets	-	-
Noncurrent deferred tax assets		
Net operating loss carryovers	11,963,305	9,673,993
Stock warrants	139,549	-
Stock option compensation	1,023,192	749,755
Total noncurrent deferred tax assets	13,126,046	10,423,748
Valuation allowance	(13,172,543)	(10,407,184)
Net noncurrent deferred tax assets	(46,497)	16,564
Deferred tax liabilities:		
Goodwill Amortization	(11,346)	(3,782)
Depreciation	31,055	(31,037)
Amortization	26,788	18,255
Total deferred tax liabilities	46,497	(16,564)
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 $2,789,646 in 2012 and decreased by $2,041,543 in 2011.

At December 31, 2012 and 2011, the Company had total domestic Federal and state net operating loss carryovers of approximately $29,360,685 and $22,069,461, respectively. Federal net operating loss carryovers expire at various dates between 2024 and 2032, while state net operating loss carryovers expire between 2024 and 2032.

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 2012 or 2011.

The 2009 through 2011 tax years remain open to examination by the Internal Revenue Service and the 2007 to 2011 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, 2012 and 2011.

(13) Employee Benefit Plans

As of January 1, 2011, we switched from a SIMPLE IRA to 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 $16,500 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:

	Year ended December 31,	
	2012	2011
Supplemental disclosure of cash flow information		
Cash paid during the period for:		
Interest	$1,873,155	$1,039,703
Income taxes	-	-
Non-cash activities:		
Non-cash consulting expense	$401,395	$1,675,008
Acquisition contingent consideration	$-	$450,166
Warrants issued with debt	$220,872	$227,388
Issuance of stock for business acquisition	$-	$1,000,000
Conversion of accounts payable into common stock	$-	$600,000
Decrease in warrant derivative liability due to warrant exercises	$-	$968,554
Capital lease acquisition	$350,986	$116,263
Issuance of warrants	$220,872	$-
Debt discount related to financing	$7,341,520	$-
Royalty liability related to financing	$7,341,520	$-

(15) Related Party Transactions

Guy Cook, our President and Chief Executive Officer, serves as a board member of West Coast Tissue Services ("WCTS") and formerly served as a director for American Donor Services ("ADS"). Mr. Cook has not received any compensation for his board service for either entity. Mitchell Godfrey, a director, is on the board of ADS and also serves as secretary and treasurer for ADS. Mr. Godfrey received $5,000 for his service to ADS in 2012 and no compensation from ADS in 2011. Mr. Cook's spouse performed bookkeeping and accounting services for ADS in 2011, but she received no compensation for her services. Mr. Cook's spouse is also employed by Bacterin as the Director of Human Resources.

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 $510,500 for 2011 and $525,900 for 2012, and the approximate aggregate amount of all transactions with ADS was $1,765,908 for 2011 and $1,472,949 for 2012. These relationships benefit us, and thus Msrs. Cook and Godfrey, 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. As of December 31, 2012, we had an accounts payable balance of $418,922 to American Donor Services.

On June 27, 2012, the Board of Directors granted a waiver of certain provisions of the Company's Code of Conduct to allow an entity controlled by two of the CEO's adult children to become a distributor of the Company's products. This entity acquired inventory from Allograft Tissue Management, a non-affiliated distributor that had previously acquired inventory from the Company. The affiliated distributor, Silver Forest Fund, LP, exchanged products initially purchased from the non-affiliated distributor for different Bacterin products of equivalent value. Other than product exchanges and payment of amounts owed by the non-affiliated distributor, there have been no other direct transactions between Bacterin and the affiliated distributor. Mr. Cook pledged 1,850,000 of his shares of Bacterin stock as collateral for loans made to the affiliated distributor by independent third parties.

(16) Subsequent Events

On January 29, 2013, we received two warning letters from the Food and Drug Administration ("FDA") related to our procedures to ensure compliance with regulatory requirements. The concerns included (i) procedures for implementing corrective and preventative action; (ii) procedures for receiving, reviewing and evaluating complaints; (iii) procedures related to changes to a specification, method, process or procedure; (iv) procedures to ensure that purchased or otherwise received products or services conform to specified requirements; (v) procedures to control documents; (vi) procedures to identify training needs and to ensure all personnel are trained to adequately perform assigned responsibilities; (vii) procedures related to medical device reporting; (viii) procedures to control product that does not conform to specified requirements; (ix) procedures for finished device acceptance; and (x) marketing materials related to our Elutia wound drain. The company has responded to the warning letters and is committed to actively working with the FDA to address their concerns.

On February 11, 2013, we received a subpoena from the Office of the Inspector General of the U.S. Department of Health and Human Services ("OIG") in connection with an investigation into possible false or otherwise improper claims submitted to Medicare. The subpoena requests 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 and involved payments to only a small number of physicians that we believe were made in accordance with all applicable laws. We intend to cooperate with the OIG's investigation.

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 senior 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 Rules 13a – 15(e) under the Exchange Act) as of December 31, 2012. Based upon that evaluation, we concluded that as of December 31, 2012, our disclosure controls and procedures were ineffective due to the material weakness in our internal controls over financial reporting detailed below that have not been fully remediated as of December 31, 2012.

Management's Report on Internal Control over Financial Reporting

Management is responsible for 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 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, management concluded that our internal control over financial reporting was ineffective as of December 31, 2012 due to material weaknesses in our internal control over financial reporting that have not been fully remediated as of December 31, 2012 as detailed below:

1) Insufficient number of personnel with the appropriate level of experience and technical expertise to appropriately resolve account reconciliations, while completing the financial statement close process. Until this design deficiency in our internal control over financial reporting is remediated, there is a reasonable possibility that a material misstatement in our annual or interim financial statements could occur and not be corrected or prevented by our internal control system in a timely manner.

Our efforts to remediate this weakness include the following:

- We plan to expand the training of qualified accounting and finance personnel throughout 2013 and include an additional level of management review to the financial close process.

2) The documentation surrounding equity transactions for employees and consultants needs to be strengthened to comply with procedures outlined by the Company to ensure that all equity related transactions are properly recorded in the appropriate periods.

Our efforts to remediate the weakness include the following:

- Continued development of a standard operating procedure for the grant of all equity securities including the approval process by the Compensation Committee and the Board of Directors.

-Additional review by our Human Resources department on all stock option vestings and cancellations and additional review by in house legal counsel on all stock option grants.

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
Guy Cook	48	Chairman of the Board, Chief Executive Officer and President
Mitchell T. Godfrey	67	Director
Kent Swanson	68	Director
Michael Lopach	64	Director
Jon Wickwire	69	Director
John Deedrick	50	Director
John P. Gandolfo	52	Chief Financial Officer
Darrel Holmes	59	Chief Operating Officer
Nicholas Navarro	33	National Sales Manager
Greg Juda	37	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.

Guy Cook, Chairman of the Board, Chief Executive Officer and President, is considered an international expert in biofilm science and its application. He is widely published and has been invited to speak at many prominent biofilm conferences, including the “Anti-Infective Materials” Seminar in Tokyo and the FDA-CDRH Antimicrobial Device Efficacy Testing Seminar. Mr. Cook started his career as a product specialist in the Image Analysis Department for

Laboratory Equipment Company in Chicago. He later became President of Delta Resources in Crystal Lake, Illinois, which specialized in developing customized image analysis solutions for the academic community. In 1996, he moved to Montana and worked as a Confocal Microscopist for the Center for Biofilm Engineering at the Montana State University where he developed several proprietary testing models for the medical device industry. In 1998, Mr. Cook founded Bacterin, and as CEO and President, Mr. Cook has been the driving force behind the Company's growth and development. Mr. Cook attended the University of Indiana and received Bachelor of Science degrees in Finance and Economics.

Mitchell T. Godfrey, Director, has been involved over the past 25 years in a number of private enterprises, including consulting for and participation in firms in the manufacturing, medical devices, nuclear, service and animal health industries. Mr. Godfrey graduated from the University of Utah in 1968 with Bachelor of Science degrees in psychology and mathematics. He served as a Lieutenant in the U.S. Navy for a period of four years in the 1960s. Upon his return from overseas duty, he served as a director of the Utah Vietnam Agent Orange Program. He currently is the Chairman of the Montana based Crow Creek Falls Conservation Group and has been actively involved in many other organizations. Mr. Godfrey joined us in October 2003 as our Chief Financial Officer until December 2007, when his primary responsibility was changed to investor relations. Mr. Godfrey currently serves as a consultant.

Kent Swanson, Director, 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 serves as chairman of the Board's Compensation Committee.

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 Board's Audit Committee.

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.

John Deedrick, Director, is an experienced senior executive with 15 years experience in healthcare venture capital and business consulting. Mr. Deedrick also has 12 years of experience in the high tech defense industry. He has served as a corporate venture capitalist for Mayo Clinic and a Founder and General Partner for Accuitive Medical Ventures. Mr. Deedrick also 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 stage healthcare companies over the last 15 years. Mr. Deedrick received his undergraduate degree from Northwestern College (Roseville, MN) and his MBA from St. Thomas University (St. Paul, MN).

John P. 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 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.

Darrel L. 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. He is also responsible for the establishment and maintenance of an FDA CFR Title 21 Part 820 and 1271-compliant quality system. 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 is the primary regulatory interface for Bacterin's operations and he oversees 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, and as a Scientific Advisory Board Member for Montana Molecular in Bozeman, Montana. Mr. Holmes graduated from California State University at Long Beach with a degree in Biological Science.

Nicholas Navarro, National Sales Manager, has nine years of sales and management experience in the orthopedic industry. As the National Sales Manager, Mr. Navarro is responsible for managing Bacterin's hybrid distribution force by supporting product sales for all Bacterin divisions. Prior to being promoted to this position in February 2012, Mr. Navarro served in various roles at Bacterin, starting as a Direct Representative, advancing to a Regional Sales Manager, and relocating to headquarters to serve as Vice President of Devices. Mr. Navarro's previous experience includes sales roles with Johnson and Johnson, specializing in wound and infection management, and at Wright Medical as a Foot and Ankle Hardware Specialist. Mr. Navarro has a Psychology degree from the University of Iowa and a minor in Business. Mr. Navarro also contributes time and efforts to support Miracle Feet, which helps to correct club feet in developing countries.

Greg 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 three revolutionary, life-enhancing allograft products; Bacterin's OsteoSponge® allograft family, OsteoSelect® Demineralized Bone Matrix Putty, and hMatrix® Acellular Dermal Matrix. 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.

Scientific Advisory Board

Our Scientific Advisory Board assists us with issues relating to our coating and biologic technologies. As our needs evolve, members with required areas of interest and expertise are added. Members of our Scientific Advisory Board are compensated in cash or shares of common stock under our equity incentive plan.

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. All of our board committee members are independent directors. All directors hold office until the next annual meeting of stockholders and 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.

Audit Committee

The purpose of the Audit Committee is to assist the oversight of our Board of Directors of the integrity of the financial statements of our company, our company's compliance with legal and regulatory matters, the independent auditor's qualifications and independence, and the performance of our company's independent auditor and internal audit function. The primary responsibilities of the Audit Committee are set forth in its charter and include various matters with respect to the oversight of our company's accounting and financial reporting process and audits of the financial statements of our company. The Audit Committee also selects the independent auditor to conduct the annual audit of the financial statements of our company; reviews the proposed scope of such audit; reviews accounting and financial controls of our company with the independent auditor and our 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 of our company 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 Kent Swanson and Michael Lopach, each of whom is an independent director. Mr. Swanson 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 at each election of directors, the oversight of the selection and composition of 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 and Swanson, 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.

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 new directors and executive officers and any former or proposed directors or executive officers.

Legal Proceedings

During the past ten years, none of our directors or executive officers has been:

- the subject of any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
- convicted in a criminal proceeding or is subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- subject to any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities;
-

found by a court of competent jurisdiction (in a civil action), the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, that has not been reversed, suspended, or vacated;

- subject of, or a party to, any order, judgment, decree or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of a federal or state securities or commodities law or regulation, law or regulation respecting financial institutions or insurance companies, law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

- subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization, any registered entity or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

None of our directors, officers or affiliates, or any beneficial owner of 5% or more of our common stock, or any associate of such persons, is an adverse party in any material proceeding to, or has a material interest adverse to, us or any of our subsidiaries.

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 in 2012, we believe all reports required pursuant to Section 16(a) were filed on a timely basis except for the following: Guy Cook, John Gandolfo, Darrel Holmes and Nick Navarro filed one Form 4 four days late due to administrative oversight.

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. 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 its Chief Executive Officer and two most highly-compensated officers other than the Chief Executive Officer.

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards[1]	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Guy S. Cook	2012	$500,000	$100,000	$ -	$138,180	$ -	$ -	$ -	$738,180
Chief Executive Officer	2011	500,000	50,000	-	-	-	-	-	550,000
John Gandolfo	2012	299,947	50,000		96,726	-	-	-	446,673
Chief Financial Officer	2011	290,000	35,000	-	-	-	-	-	325,000
Nick Navarro	2012	233,077			261,005			13,344 [2]	507,426
National Sales Manager	2011	177,739	50,000					59,745 [2]	287,484

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

(2) Commission

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 also 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.

Bacterin International Equity Incentive Plan

The following is a summary of the material terms of the Bacterin International Equity Incentive Plan:

The purpose of the incentive compensation 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 incentive compensation 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 our compensation committee. 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 incentive 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 9,000,000 shares of our common stock authorized to be issued under the plan. As of December 31, 2012, we had outstanding options to purchase 5,266,535 shares granted and 733,900 shares of restricted stock issued, to directors, executives, employees and consultants, leaving approximately 1,559,898 shares available for issuance thereunder.

Except for the Equity Incentive Plan discussed above, we have not had a stock option plan or other similar incentive compensation plan for officers, directors and employees.

Outstanding Equity Awards at Fiscal Year-End (December 31, 2012)

	Number of Securities Underlying Unexercised Options		Option Awards Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned	Option Exercise	Option Expiration
Name	Exercisable	Unexercisable	Options	Price	Date
Guy Cook	-	-	100,000	$ 2.36	3/27/22
John Gandolfo	100,000	-	150,000	$ 1.60	6/3/20
			70,000	$ 2.36	3/27/22
Nick Navarro	24,000	-	36,000	$ 1.60	4/1/20
	12,000	-	48,000	$ 2.36	3/27/22
	50,000	-	150,000	$ 1.48	5/8/22

Potential Payments Upon Termination or Change-in-Control

SEC regulations state that we must disclose information regarding agreements, plans or arrangements that provide for payments or benefits to our named executive officers in connection with any termination of employment or change in control of the company. Except for Mr. Gandolfo's employment agreement described below, we currently have no employment agreements with any of our named executive officers which have payments upon termination or change in control, nor any compensatory plans or arrangements that provide for any payments or benefits upon the resignation, retirement or any other termination of any of our named executive officers, as the result of a change in control, or from a change in any named executive officer's responsibilities following a change in control.

Pursuant to the terms of Mr. Gandolfo's employment agreement, if Mr. Gandolfo's employment with our company is terminated by us in connection with a "Change of "Control" (as defined therein), Mr. Gandolfo shall be eligible to receive 12 months' salary as severance, if he has delivered to us a complete release of any claims against us in form and substance reasonably satisfactory to us and if Mr. Gandolfo has not breached any section of his employment agreement. Mr. Gandolfo's current salary is $300,000 per year. The severance payments payable to Mr. Gandolfo will be paid biweekly through automatic deposits; provided that the initial payment of any severance hereunder shall begin on the eighth day after Mr. Gandolfo has signed the aforementioned release. A "Change of Control" is defined in Mr. Gandolfo's employment agreement to consist of either Guy Cook no longer serving as the Chief Executive Officer or a sale of all or substantially all of the assets of the Company.

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	Option Awards (2)	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Mitch Godfrey (3)	$ -	$ -	$ -	-	-	$ 95,000	$-
Kent Swanson	$ 50,000	$ -	36,564	-	-	-	$86,564
Michael Lopach	$ 50,000	$ -	25,917	-	-	-	$75,917
Jon Wickwire	$ 50,000	$ -	25,917	-	-	-	$75,917
John Deedrick(4)	$ 10,000	$	54,775				$64,775

(1) Our independent Board members receive an annual retainer of $40,000 per year, and our Committee Chairs receive an additional $10,000 per year.

(2) New independent Board members receive options to purchase 50,000 shares of our common stock, vesting after one year, with an exercise price equal to the closing price of our common stock on the date of grant. Following the first year of service, independent Board members receive an annual continued service grant of options to purchase 30,000 shares with an exercise price equal to the closing price of our common stock on the date of grant. Key assumptions used to estimate the grant date fair value of option awards are contained in Note 9 to the financial statements in Item 8 of this Annual Report on Form 10-K.

(3) Mitchell Godfrey serves as a consultant to the Company and all compensation paid to Mr. Godfrey was in payment for his services as a consultant. Mr. Godfrey does not receive any director fees or options for his service as a director.

(4) Mr. Deedrick joined the Board in September 2012.

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, 2012, by (a) each of our directors and executive officers, (b) all of our directors and 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 (1)	**Number of Shares Beneficially Owned** (2)		**Percentage of Shares Beneficially Owned** (3)	
Name of Beneficial Owner:				
Guy S. Cook	12,097,000	(4)	28.36	%
Mitchell Godfrey	1,062,133	(5)	2.49	%
Kent Swanson	599,842	(6)	1.41	%
Michael Lopach	181,185	(7)		*
Jon Wickwire	503,764	(8)	1.18	%
John Deedrick	-			*
John P. Gandolfo	113,920	(9)		*
Darrel Holmes	119,999	(10)		*
Nick Navarro	116,000	(11)		*
Greg Juda	37,915	(12)		*
All executive officers and directors as a group (10 persons)	14,831,758		34.78	%

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

(1) The address of each person 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, 2012, 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 42,649,964 shares of common stock outstanding on December 31, 2012. 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) 5,937,588 shares of our common stock held directly, (b) 6,000,000 shares of our common stock held by trusts for the benefit of Mr. Cook's children, (c) warrants to purchase 134,412 shares of our common stock, and (d) vested options to purchase 25,000 shares of our common stock held by Mr. Cook's spouse. Mr. Cook pledged 850,000 shares of his common stock to First Security Bank as collateral for a loan to a distributor of Bacterin products owned and operated by two of Mr. Cook's adult children, and Mr. Cook has the right to the return of 1,000,000 shares of previously transferred common stock upon repayment of a loan to Equities First Holdings, LLC.

(5) Includes (a) 711,467 shares of our common stock, (b) 50,666 shares of common stock owned by Mr. Godfrey's spouse, and (c) vested options to purchase 300,000 shares of our common stock.

(6) Includes (a) 250,000 shares of our common stock held directly, (b) 200,000 shares held by a family limited partnership, (c) warrants to purchase 89,842 shares of our common stock, and (d) options to purchase 60,000 shares of our common stock.

(7) Includes (a) 16,949 shares of our common stock held directly, (b) 33,898 shares held by a 401(k) plan, (c) warrants to purchase 20,338 shares, and (d) options to purchase 110,000 shares.

(8) Includes (a) 105,509 shares of our common stock, (b) 257,630 shares of common stock held by trusts, (c) warrants to purchase 30,625 shares of common stock, and (d) options to purchase 110,000 shares of our common stock.

(9) Includes (a) 9,943 shares of our common stock held by an IRA, (b) warrants to purchase 3,977 shares of our common stock, and (c) vested options to purchase 100,000 shares of our common stock.

(10) Includes vested options to purchase 119,999 shares of our common stock.

(11) Includes vested options to purchase 116,000 shares of our common stock.

(12) Includes vested options to purchase 37,915 shares of our common stock

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

Transactions with Related Persons, Promoters and Certain Control Persons

Guy Cook, our President and Chief Executive Officer, serves as a board member of West Coast Tissue Services ("WCTS") and formerly served as a director for American Donor Services ("ADS"). Mr. Cook has not received any compensation for his board service for either entity. Mitchell Godfrey, a director, is on the board of ADS and also serves as secretary and treasurer for ADS. Mr. Godfrey received $5,000 for his service to ADS in 2012 and no compensation from ADS in 2011. Mr. Cook's spouse performed bookkeeping and accounting services for ADS in 2011, but she received no compensation for her services. 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 $510,500 for 2011 and $525,900 for 2012, and the approximate aggregate amount of all transactions with ADS was $1,765,908 for 2011 and $1,472,949 for 2012. These relationships benefit us, and thus Mssrs. Cook and Godfrey, 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.

Mr. Cook's spouse is employed by Bacterin as the Director of Human Resources, and Mr. Cook's adult children own and operate a distributor of Bacterin products, which were purchased from a non-affiliated distributor, with payment made to Bacterin for amounts owed by the non-affiliated distributor. The affiliated distributor, Silver Forest Fund, LP, exchanged products initially purchased from the non-affiliated distributor for different Bacterin products of equivalent value. Other than product exchanges and payment of amounts owed by the non-affiliated distributor, there have been no other direct transactions between Bacterin and the affiliated distributor. Mr. Cook pledged 1,850,000 shares of Bacterin stock as collateral for loans made for the benefit of the affiliated distributor.

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 and John Deedrick. 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, 2012 and December 31, 2011. The following table presents the aggregate fees billed for professional services rendered by EKS&H for the years ended December 31, 2012 and December 31, 2011.

	2012	2011
Audit fees	$122,500	$144,000
Audit-related fees	7,287	43,000
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/ Guy S. Cook
Name: Guy S. Cook
Title: Chief Executive Officer
Date: March 27, 2013

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 27, 2013.

Signature	**Title**
/s/ Guy S. Cook Guy S. Cook	Chief Executive Officer, President and Chairman of the Board of Directors (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/ Mitchell Godfrey Mitchell Godfrey	Director
/s/ Michael Lopach Michael Lopach	Director
/s/ Jon Wickwire Jon Wickwire	Director
/s/ John Deedrick John Deedrick	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	Restated Certificate of Incorporation (5)
3.2	Amended and Restated Bylaws (3)
4.1	Form of Warrant to Purchase Common Stock (1)
4.2	Form of Common Stock Certificate (6)
10.1	Form of Indemnification Agreement for the officers and directors of Bacterin International Holdings, Inc. and Bacterin International, Inc. (2)
10.2	Amended and Restated Bacterin International Equity Incentive Plan (7)
10.3	Form of Stock Option Agreement(14) •
10.4	Guy Cook Employment Agreement (2) •
10.5	First Amendment to Employment Agreement with Guy Cook(15) •
10.6	Mitchell Godfrey Consulting Agreement(11) •
10.7	John Gandolfo Employment Agreement (2) •
10.8	Nicholas Navarro Employment Agreement(11) •
10.9	Darrel Holmes Employment Agreement (2) •
10.10	Greg Juda Employment Agreement(14) •
10.11	Loan and Security Agreement dated as of January 14, 2011 between Bacterin International, Inc. and Bacterin International Holdings, Inc. and Bridge Bank, National Association (4)
10.12	Purchase Agreement, dated as of May 27, 2011, by and between the Company and Lincoln Park Capital Fund, LLC (8)
10.13	Notice of Termination of Purchase Agreement with Lincoln Park Capital Fund, LLC(13)
10.14	Registration Rights Agreement, dated as of May 27, 2011, by and between the Company and Lincoln Park Capital Fund, LLC (8)
10.15	Asset Purchase Agreement between the Company and Robinson MedSurg, LLC (9)
10.16	Loan and Security Agreement dated July 29, 2011 by and between the Company and MidCap Funding III, LLC (10)
10.17	First Loan Modification Agreement dated April 23, 2012 by and among the Company and MidCap Funding III, LLC, as administrative agent and a lender, and Silicon Valley Bank, as a lender(12)
10.18	Credit and Security Agreement dated April 23, 2012 by and among the Company and MidCap Financial, LLC, as administrative agent and a lender, and Silicon Valley Bank, as a lender(12)
10.19	Credit Agreement dated August 24, 2012 by and between Bacterin and ROS Acquisition Offshore LP(16)
10.20	Royalty Agreement dated August 24, 2012 by and between Bacterin and ROS Acquisition Offshore LP(16)
14.1	Code of Conduct (4)
14.2	Code of Ethics for the CEO and Senior Financial Officials (4)
21.1	Subsidiaries of the Registrant (2)
23.1*	Consent of Independent Accounting Firm, EKS&H LLLP
24.1	Power of Attorney (included in the signature page of this Annual Report on Form 10-K)
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

XBRL (eXtensible Business Reporting Language) information is furnished and not filed as part of any registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these Sections.

(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 January 12, 2011.

(4) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on January 21, 2011.

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

(6) Incorporated by reference to the Registrant's Form S-3 Registration Statement filed with the SEC on July 11, 2011.

(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 May 31, 2011.

(9) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on July 14, 2011.

(10) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on August 1, 2011.

(11) Incorporated by reference to the Registrant's Form 10-K filed with the SEC on March 29, 2012.

(12) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on April 24, 2012

(13) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on May 3, 2012

(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 10-Q filed with the Sec on August 10, 2012

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