

Bacterin International Holdings, Inc.  
Form 10-K  
March 27, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, DC 20549**

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2013

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)

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-K

Delaware 20-5313323  
(State or other jurisdiction of (IRS Employer Identification No.)  
incorporation or organization)

664 Cruiser Lane 59714  
Belgrade, Montana  
(Address of Principal Executive Offices) (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

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

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  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  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

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-K

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

(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

The aggregate market value of the common stock held by non-affiliates as of June 30, 2013 was \$18,037,202 (based on the closing price of the Company's common stock on the last business day of the Company's most recently completed second fiscal quarter, as reported on the NYSE MKT).

The number of shares of the Company's common stock, \$0.000001 par value, outstanding as of March 12, 2014 was 54,858,458.

DOCUMENTS INCORPORATED BY REFERENCE

None

**TABLE OF CONTENTS**

<b>PART I</b>	4
ITEM 1. Business	4
ITEM 1A. Risk Factors	10
ITEM 1B. Unresolved Staff Comments	19
ITEM 2. Properties	19
ITEM 3. Legal Proceedings	19
ITEM 4. Mine Safety Disclosures	19
<b>PART II</b>	19
ITEM 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	19
ITEM 6. Selected Financial Data	21
ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operation	21
ITEM 7A Quantitative and Qualitative Disclosures About Market Risk	24
ITEM 8. Financial Statements and Supplementary Data	24
ITEM 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	48
ITEM 9A. Controls and Procedures	48
ITEM 9B. Other Information	48
<b>PART III</b>	49
ITEM 10. Directors, Executive Officers and Corporate Governance	49
ITEM 11. Executive Compensation	53
ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	55
ITEM 13. Certain Relationships and Related Transactions, and Director Independence	57
ITEM 14. Principal Accounting Fees and Services	57
<b>PART IV</b>	58
ITEM 15. Exhibits, Financial Statements Schedules	58
<b>SIGNATURES</b>	59
<b>Exhibit Index</b>	60

## 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 similar words, may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward looking. Forward-looking statements in this Form 10-K may include, for example, statements about:

- .. our ability to obtain financing on reasonable terms;
- “our ability to increase revenue;
- “our ability to remain listed on the NYSE MKT exchange;
- “our ability to comply with the covenants in our credit facility;
- “our ability to maintain sufficient liquidity to fund our operations;
- “our ability to obtain shareholder approval to increase our authorized shares of common stock;
- “the ability of our sales force to achieve expected results;
- “our ability to remain competitive;
- “government regulations;
- “our ability to expand our production capacity;
- .. our ability to innovate and develop new products;

- .. our ability to obtain donor cadavers for our products;
  
- “our ability to engage and retain qualified technical personnel and members of our management team;
  
- “government and third-party coverage and reimbursement for our products;
  
- “our ability to obtain regulatory approvals;
  
- “our ability to successfully integrate future business combinations or acquisitions;
  
- “product liability claims and other litigation to which we may be subjected;
  
- “product recalls and defects;
  
- “timing and results of clinical studies;
  
- “our ability to obtain and protect our intellectual property and proprietary rights;
  - .. infringement and ownership of intellectual property;
  
- “influence by our management; and

our ability to issue preferred stock.

The forward-looking statements contained in this Form 10-K are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties, or assumptions, many of which are beyond our control, which may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the “Risk Factors” section of our Form 10-K. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required under applicable securities laws.

## **PART I**

### **Item 1. Business**

#### **Overview of Our Business**

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

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

#### **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 spinout of the Center for Biofilm Engineering at Montana State University, or the CBE, and we eventually incorporated as “Bacterin, Inc.” in the state of Montana in January 2000. In March 2004, Bacterin, Inc.’s stockholders 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.

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

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.”

## **Industry and Market Overview**

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

## **Products and Services**

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® HD, OsteoSTX™ 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 fill bony defects in the subchondral region of joints. We have received permission from the FDA to market this product as a subchondral bone void filler and are currently marketing it as such.

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

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

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

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

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

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's products are described in 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. 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. Additionally, we sell a hubless surgical drain series called Via™, 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 Via™ 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 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*

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

Our patent efforts have been, and will continue to be, primarily focused in two key areas:

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

..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.

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

### *Trademarks*

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

### *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 sell our product in the United States through a hybrid distribution network including direct employees and independent distributors. As of February 2014, we have one Vice President of Sales and two executive vice-presidents to lead this effort, and we have 9 regional managers, 15 sales representatives, 3 distribution managers, 1 associate sales representative and 5 clinical specialists in the field.

## **Growth Strategy**

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

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

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

## **Government Regulation**

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

## ***Human Tissue***



Human tissue products, 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. Several of our products including OsteoSponge® and OsteoWrap® are regulated as a HCT/P as determined by the Tissue Reference Group and regulated under Section 361 of the Public Health Service Act and 21 CFR Part 1271.

### *Medical Devices*

Our medical devices require the clearance of the FDA prior to sale within the United States. The 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. The Center for Devices and Radiological Health regulates medical devices, including our OsteoSelect® DBM putty.

## **ISO Certification**

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

## **Employees**

As of February, 2014, we had 128 full-time employees and 131 total employees, of whom 43 were in operations, 38 were in sales, 5 were in marketing, 7 were in R&D, 15 were in QA/QC, and 23 were in administrative functions. In addition, we make use of a varying number of outsourced services to manage normal business cycles. None of our employees are covered by a collective bargaining agreement and management considers relations with employees and service partners to be good.

## **Facilities**

We lease approximately 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 2023 and has a monthly lease payment of \$13,000. The lease also has a ten-year renewal option.

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

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

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

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

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

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

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

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

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

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

***The impact of United States healthcare reform legislation remains uncertain.***

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

***We face risks and uncertainties relating to an OIG subpoena.***

In February 2013, we received a subpoena from the Office of the Inspector General of the U.S. Department of Health and Human Services ("OIG") seeking documents in connection with an investigation into possible false or otherwise improper claims submitted to Medicare. The subpoena requested documents related to physician referral programs operated by the Company, which we believe refers to the Company's prior practice of compensating physicians for performing certain educational and promotional services on behalf of the Company. This program was discontinued in 2010. We provided an initial response to the OIG subpoena and have not received any further correspondence or requests from the OIG. Although it does not appear that the OIG is actively pursuing the investigation at the present time, we cannot assure you that the OIG will not resume the investigation in the future. Any further investigation by the OIG could divert management's attention from business demands and subject us to significant legal expenses.

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

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

***Future regulatory action remains uncertain.***

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

***Competition from former Chief Executive Officer***

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

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

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





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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***Future revenue will depend on our ability to increase sales.***

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

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

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

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

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

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

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental change. The ability of hospitals to pay fees for allograft bone tissue products depends in part on the extent to which reimbursement for the costs of such materials and related treatments will continue to be available from governmental health administration authorities, private health coverage insurers and other organizations. We may have difficulty gaining market acceptance for our products if government and third-party payors do not provide adequate coverage and reimbursement to hospitals. Major third-party payors of hospital services and hospital outpatient services, including Medicare, Medicaid and private healthcare insurers, annually revise their payment methodologies, which can result in stricter standards for reimbursement of hospital charges for certain medical procedures or the elimination of reimbursement. Further, Medicare, Medicaid and private healthcare insurer cutbacks could create downward price pressure on our products.

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

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

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

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

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

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

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

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

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

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

We are engaged through our marketing employees, independent sales agents and sales representatives in ongoing efforts designed to educate the medical community as to the benefits of our products, and we intend to continue our educational activities. Although we believe that NOTA permits payments in connection with these educational efforts as reasonable payments associated with the processing, transportation and implantation of our products, payments in

connection with such education efforts are not exempt from NOTA's restrictions and our inability to make such payments in connection with our education efforts may prevent us from paying our sales representatives for their education efforts and could adversely affect our business and prospects. No federal agency or court has determined whether NOTA is, or will be, applicable to every allograft bone tissue-based material which our processing technologies may generate. Assuming that NOTA applies to our processing of allograft bone tissue, we believe that we comply with NOTA, but there can be no assurance that more restrictive interpretations of, or amendments to, NOTA will not be adopted in the future which would call into question one or more aspects of our method of operations.

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

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

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

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

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

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

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

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

The commencement or completion of any clinical trial may be delayed or halted for numerous reasons, including, but not limited to, a regulatory body placing clinical trials on hold, patients not enrolling in clinical trials at the rate we

expect, patients experiencing adverse side effects, third party contractors failing to perform in accordance with our anticipated schedule or consistent with good clinical practices, inclusive or negative interim trial results or our inability to obtain sufficient quantities of raw materials to produce our products. Our development costs may increase if we have material delays in clinical trials or if we need to perform more or larger clinical trials than planned. If this occurs, our financial results and the commercial prospects for our products may be harmed.

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

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

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

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



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

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

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

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

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

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

“we were the first to make the inventions covered by each of our patent applications;

“we were the first to file patent applications for these inventions;

“others will not independently develop similar or alternative technologies or duplicate any of our technologies;

“any of our pending patent applications will result in issued patents;

“any of our issued patents or those of our licensors will be valid and enforceable;

..any patents issued to us or our collaborators will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties;

..we will develop additional proprietary technologies that are patentable;

..the patents of others will not have a material adverse effect on our business rights; or

..the measures we rely on to protect the intellectual property underlying our products will be adequate to prevent third parties from using our technology, all of which could harm our ability to compete in the market.

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

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

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

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

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

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

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

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

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

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

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

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

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

..our quarterly operating results;

..developments or disputes concerning patent or other proprietary rights;

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

..acquisitions or divestitures;

..litigation and government proceedings;

“adverse legislation, including changes in governmental regulation;

“third-party reimbursement policies;

“changes in securities analysts’ recommendations;

“short selling;

“changes in health care policies and practices;

.. halting or suspension of trading in our common stock by NYSE  
MKT;

“economic and other external factors; and

“general market conditions.

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

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

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

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

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

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

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

We currently intend to retain our future earnings to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our 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 2023 and has a monthly lease payment of \$13,000. The lease also has a ten-year renewal option.

In November 2007, we purchased a 14,000 square foot facility at 664 Cruiser Lane, Belgrade, Montana 59714. This building is an FDA registered facility with a Class 10,000 (ISO 7) environmentally controlled area 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 (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 located, and we lease office space in Englewood, Colorado, where certain of our administrative functions are housed.

### Item 3. Legal Proceedings

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

### 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 NYSE MKT from January 1, 2012 through December 31, 2013.

	High	Low
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



Edgar Filing: Bacterin International Holdings, Inc. - Form 10-K

Fourth Quarter 2012 (October 1, 2012 – December 31, 2012)	\$1.61	\$0.94
First Quarter 2013 (January 1, 2013 – March 31, 2013)	\$1.48	\$0.81
Second Quarter 2013 (April 1, 2013 – June 30, 2013)	\$0.98	\$0.45
Third Quarter 2013 (July 1, 2013 – September 30, 2013)	\$0.80	\$0.47
Fourth Quarter 2013 (October 1, 2013 – December 31, 2013)	\$0.82	\$0.37

## Holder of Record

As of February 12, 2014, we had 254 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	5,583,285	\$ 1.81	1,006,648	(1)
Equity compensation plans not approved by security holders	2,000,000	\$ 0.60	N/A	
Total	7,583,285	\$ 1.49	1,006,648	

(1) In addition to options outstanding, the Company also has 643,500 shares of restricted stock that have been issued under the Plan to employees and consultants.

## **Bacterin International Equity Incentive Plan and Inducement Grant to our Chief Executive Officer**

We have granted stock options, shares of common stock and restricted stock units under our Amended and Restated Bacterin International Equity Incentive Plan (the “Plan”), as well as one inducement grant of an option to purchase 2,000,000 shares of our common stock to our Chief Executive Officer granted outside of our Plan. The following is a summary of the material terms of our Plan and the inducement grant to our Chief Executive Officer.

The purpose of the Bacterin International Equity Incentive Plan is to enable us to attract, retain and motivate key employees, directors and independent consultants, by providing them with stock options and restricted stock grants. Stock options granted under the Plan may be either incentive stock options to employees, as defined in Section 422A of the Internal Revenue Code of 1986, or non-qualified stock options. The plan is administered by the compensation committee of our board of directors. The administrator of the plan has the power to determine the terms of any stock options granted under the incentive plan, including the exercise price, the number of shares subject to the stock option and conditions of exercise. Stock options granted under the 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 are 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, 2013, we had outstanding options to purchase 5,583,285 shares and 643,500 shares of restricted stock issued, to directors, executives, employees and consultants, leaving approximately 1,006,648 shares available for issuance thereunder.

The inducement grant to our Chief Executive Officer was approved by the Compensation Committee of our Board of Directors and granted outside of the Plan as an inducement material to entering into employment with the Company pursuant to Section 711(a) of the NYSE MKT Company Guide. The inducement grant consists of a stock option to purchase up to 2,000,000 shares of the Company's common stock, with a per share exercise price of \$0.60, which was the closing price of the Company's common stock on the August 14, 2013 grant date. The option vests over five years, with 20% of the underlying shares vesting after one year and the remaining eighty percent (80%) vesting in forty-seven (47) equal monthly installments as to 33,334 underlying shares, beginning September 15, 2014, and one final installment as to 33,302 underlying shares.

## **Recent Sales of Unregistered (and Registered) Securities**

On November 25, 2013, we issued 1,500,000 shares of our common stock to Royalty Opportunities S.A. R.L. as consideration for a Waiver and Fifth Amendment to our credit facility with ROS Acquisition Offshore LP (“ROS”)

whereby ROS (i) waived our failure to achieve the revenue required by Section 8.4.1 of the Credit Agreement for the quarter ended September 30, 2013, and (ii) agreed to reduce our future revenue requirements.

The issuance was exempt from the registration requirements of the Securities Act under Section 4(2) of the Securities Act as a transaction by an issuer not involving any public offering. We did not receive any proceeds in this transaction.

#### **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, 2013 and December 31, 2012*

	Twelve Months Ended December 31,		2012	
	2013	% of	2012	% of
	Amount	Revenue	Amount	Revenue
Revenue				
Tissue sales	\$32,563,933	98.46 %	\$32,414,026	98.28 %
Royalties and other	509,481	1.54 %	565,873	1.72 %
Total Revenue	33,073,414	100.00 %	32,979,899	100.00 %
Cost of sales	14,185,719	42.89 %	10,337,303	31.34 %
Gross Profit	18,887,695	57.11 %	22,642,596	68.66 %
Operating Expenses				
General and administrative	10,777,020	32.34 %	11,135,058	33.76 %
Sales and marketing	16,017,229	48.47 %	15,617,416	47.35 %
Depreciation and amortization	377,524	1.14 %	406,888	1.23 %
Impairment of Goodwill	728,618	2.20 %	-	0.00 %
Non-cash consulting expense	(5,117 )	-0.02 %	427,787	1.30 %
Total Operating Expenses	27,895,274	84.15 %	27,587,149	83.65 %
Loss from Operations	(9,007,579 )	-27.04 %	(4,944,553 )	-14.99 %
Other Income (Expense)				
Interest expense	(4,653,232 )	-14.07 %	(1,864,901 )	-5.65 %
Change in warrant derivative liability	875,041	3.06 %	1,360,160	4.12 %
Other income (expense)	92,645	0.28 %	(2,264,528 )	-6.87 %
Total Other Income (Expense)	(3,685,546 )	-10.73 %	(2,769,269 )	-8.40 %
Net Loss Before Benefit (Provision) for Income Taxes	(12,693,125)	-37.77 %	(7,713,822 )	-23.39 %
Benefit (Provision) for Income Taxes				
Current	-	0.00 %	-	0.00 %
Deferred	-	0.00 %	-	0.00 %
Net Income (Loss)	\$(12,693,125)	-37.77 %	\$(7,713,822 )	-23.39 %

*Revenue*

Total revenue for the year ended December 31, 2013 increased slightly to \$33,073,414 compared to \$32,979,899 in the prior year. The increase of \$93,515 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 37.2% or \$3,848,416 to \$14,185,719 for the year ended December 31, 2013 from \$10,337,303 for the year ended December 31, 2012. As a percentage of tissue sales, cost of tissue sales was 42.9% of revenues for 2013 compared to 31.3% in 2012. The increase is the result of changes in product mix, one time adjustments for aged and expiring inventory, and scrap resulting from process improvements for the hMatrix product line. Excluding the adjustments for aged and expiring inventory and the scrap related to process improvements, cost of tissue sales was 36.2% of revenues in 2013.

### *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 \$308,125, for the year ended December 31, 2013 compared to the year ended December 31, 2012, primarily due to the reasons set forth below.

### *General and Administrative*

General and administrative expenses consist principally of corporate personnel cash based and stock option compensation related costs and corporate expenses for legal, accounting and other professional fees as well as occupancy costs. General and administrative expenses decreased 3%, or \$358,038, to \$10,777,020, for the year ended December 31, 2013 compared to 2012.

### *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 increased 3%, or \$399,813, to \$16,017,229 for the twelve months ended December 31, 2013 from \$15,617,416 for the prior year. As a percentage of revenue, selling and marketing expenses increased slightly to 48.5% in 2013 from 47.4% in the prior year. The Company is in the process of dramatically reorganizing the sales function with the goal of increasing the efficiency and productivity of the sales force.

### *Depreciation*

Depreciation expense consists of depreciation of long-lived property and equipment. Depreciation expense decreased 7% to \$377,524 for the year ended December 31, 2013 from \$406,888 in 2012.

### *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 \$432,904 to negative \$5,117 for the year ended December 31, 2013 from \$427,787 in the prior year, a decrease of 101%. The decrease is due to the lower closing price of the Company's common stock during 2013 which also resulted in previously accrued non-cash consulting expense to be revised downward.

#### *Interest Expense*

Interest expense is from our promissory notes and debt instruments. Interest expense for 2013 increased \$2,788,331 to \$4,653,232 as compared to \$1,864,901 in 2012. The increase was the result a higher average debt balance in 2013 and the higher interest rate related to the 2012 debt financing with ROS Acquisition Offshore LP.

#### *Change in Warrant Derivative Liability*

For 2013, the Company recorded a gain from a decrease in its non cash warrant derivative liability of \$875,041 which was primarily driven by the decrease in the closing price of the Company's common stock at December 31, 2013 compared to December 31, 2012 which was partially offset by the issuance of additional derivative warrants in 2013. The liability is associated with the issuance of warrants as part of the Company's prior convertible debt financing, the Company's 2010 financing and the Company's 2013 equity financing which contain anti dilution adjustment provisions and are accounted for as derivative instruments with any changes in fair value is recognized in the consolidated statement of operations during the period of change.

#### *Write-off of Debt Related Expenses and Other Expense*

Other Income for 2013 was \$92,565 as compared to an expense of \$2,264,528 in 2012. 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.

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



*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 March 2014, we received an additional \$4 million in term loan debt from ROS Acquisition Offshore LP. In June 2013, the Company closed on a \$4.5 million equity financing with existing and new investors. In August 2012, we closed on a \$20 million term loan transaction with ROS Acquisition Offshore LP. The proceeds of the term loan transaction 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, 2013, we had \$7,840,174 of cash and cash equivalents and accounts receivables.

Net cash used in operating activities for 2013 was \$5,620,924, primarily related to funds required to finance the Company's operations. For 2012, net cash used in operating activities was \$10,792,332. The decrease in net cash used in operations between 2013 and 2012 is primarily the result of decreases, net of reserve adjustments in the Company's inventory and accounts receivable balances between the two periods.

Net cash provided by investment activities for 2013 was \$35,318 due to the purchase of property and equipment and increases in intangible assets offset by an impairment of goodwill charge of \$728,618 recorded in the fourth quarter of 2013.

Net cash provided by financing activities was \$3,705,880 for 2013 primarily due to proceeds from the sale of equity securities which is net of financing fees and warrants issued in conjunction with the equity securities and partially offset by payments and debt and capital lease obligations.

#### *Off Balance Sheet Arrangements*

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

#### *Cash Requirements*

We believe that our December 31, 2013 cash on hand and accounts receivable balance of \$7,840,174, net proceeds from the additional \$4,000,000 of term loan debt received from ROS Acquisition Offshore LP in March 2014 and anticipated cash receipts from sales expected from operations will be sufficient to meet our anticipated cash requirements through March 31, 2015. We incurred approximately \$16 million in sales and marketing expenses in 2013 and expect to incur \$17 million in 2014 based upon our current sales estimates. The sales and marketing expenses are largely variable expenses and are anticipated to be funded from operating cash flow. An increase of these expenses may impact our operating results and there can be no assurance of their effectiveness. If we do not meet our revenue objectives over that period, we may need to sell additional equity securities, which could result in dilution to our stockholders, or seek additional loans. The incurrence of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. Financing may not be available in amounts or on terms acceptable to us, if at all. Any failure by us to raise additional funds on terms favorable to us, or at all, could limit our ability to expand our business operations and could harm our overall business prospects.

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**

24

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders

Bacterin International Holdings, Inc.

Belgrade, Montana

We have audited the accompanying consolidated balance sheets of Bacterin International Holdings, Inc. and subsidiary (the "Company") as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our 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 such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Bacterin International Holdings, Inc. and subsidiary as of December 31, 2013 and 2012, 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, 2014

Denver, Colorado

25

**BACTERIN INTERNATIONAL HOLDINGS, INC.****Consolidated Balance Sheets as of December 31, 2013 and 2012**

	As of December 31,	
	2013	2012
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$3,046,340	\$4,926,066
Trade accounts receivable, net of allowance for doubtful accounts of \$1,309,859 and \$1,576,955, respectively	4,793,834	7,154,065
Inventories, net	10,753,600	13,141,421
Prepaid and other current assets	574,910	353,271
Total current assets	19,168,684	25,574,823
Non-current Assets:		
Non-current inventories	2,119,952	1,238,225
Property and equipment, net	5,180,556	5,234,867
Intangible assets, net	586,965	592,378
Goodwill	-	728,618
Other assets	1,821,471	1,126,643
Total Assets	\$28,877,628	\$34,495,554
<b>LIABILITIES &amp; STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$2,767,639	\$3,997,789
Accounts payable - related party	647,844	418,922
Accrued liabilities	3,585,037	2,400,090
Warrant derivative liability	1,594,628	984,356
Current portion of capital lease obligations	171,926	149,729
Current portion of royalty liability	836,750	698,408
Current portion of long-term debt	47,727	45,135
Total current liabilities	9,651,551	8,694,429
Long-term Liabilities:		
Capital lease obligation, less current portion	73,777	245,703
Long term royalty liability, less current portion	6,609,232	6,839,935
Long-term debt, less current portion	16,385,245	14,483,102
Total Liabilities	32,719,805	30,263,169

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-K

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; 53,432,820 shares issued and outstanding as of December 31, 2013 and 42,877,770 shares issued and outstanding as of December 31, 2012	53	43
Additional paid-in capital	56,516,443	51,897,890
Accumulated deficit	(60,358,673)	(47,665,548)
Total Stockholders' Equity	(3,842,177 )	4,232,385
Total Liabilities & Stockholders' Equity	\$28,877,628	\$34,495,554

See notes to audited consolidated financial statements.

**BACTERIN INTERNATIONAL HOLDINGS, INC.****Consolidated Statements of Operations****For the Years Ended December 31, 2013 and 2012**

	Twelve Months Ended December 31,	
	2013	2012
Revenue		
Tissue sales	\$ 32,563,933	\$ 32,414,026
Royalties and other	509,481	565,873
Total Revenue	33,073,414	32,979,899
Cost of sales	14,185,719	10,337,303
Gross Profit	18,887,695	22,642,596
Operating Expenses		
General and administrative	10,777,020	11,135,058
Sales and marketing	16,017,229	15,617,416
Depreciation and amortization	377,524	406,888
Impairment of goodwill	728,618	-
Non-cash consulting expense	(5,117	) 427,787
Total Operating Expenses	27,895,274	27,587,149
Loss from Operations	(9,007,579	) (4,944,553
Other Income (Expense)		
Interest expense	(4,653,232	) (1,864,901
Change in warrant derivative liability	875,041	1,360,160
Write-off of debt related costs	-	(705,885
Other income (expense)	92,645	(1,558,643
Total Other Income (Expense)	(3,685,546	) (2,769,269
Net Loss Before (Provision) Benefit for Income Taxes	(12,693,125	) (7,713,822
(Provision) Benefit for Income Taxes		
Current	-	-
Deferred	-	-
Net Loss	\$ (12,693,125	) \$ (7,713,822



Net loss per share:

Basic	\$ (0.27	)	\$ (0.18	)
Dilutive	\$ (0.27	)	\$ (0.18	)

Shares used in the computation:

Basic	47,530,072	42,445,386
Dilutive	47,530,072	42,445,386

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, 2013, and 2012**

	Common Stock Shares	Common Stock Amount	Additional Paid-In-Capital	Retained Deficit	Total Shareholders' Equity (deficit)
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
Stock-based compensation	316,276	-	996,300	-	996,300
Exercise of options	230,000	-	27,575	-	27,575
Net proceeds from the issuance of stock	8,508,774	9	4,449,992	-	4,450,001
Issuance of warrants in conjunction with the issuance of stock	-	-	(1,485,313 )	-	(1,485,313 )
Issuance of stock to ROS in exchange for debt waiver	1,500,000	1	629,999	-	630,000
Net loss	-	-	-	(12,693,125)	(12,693,125 )
Balance at December 31, 2013	53,432,820	\$ 53	\$ 56,516,443	\$(60,358,673)	\$(3,842,177 )

See notes to audited consolidated financial statements.

**BACTERIN INTERNATIONAL HOLDINGS, INC.****Consolidated Statements of Cash Flows****For the Years Ended December 31, 2013 and 2012**

	Twelve Months Ended December 31,	
	2013	2012
Operating activities:		
Net loss	\$ (12,693,125	) \$ (7,713,822
Noncash adjustments:		
Depreciation and amortization	753,522	782,889
Amortization of debt discount	1,251,125	502,044
Write-off of debt discount	-	705,885
Non-cash consulting expense/stock option expense	838,847	1,554,657
Warrants issued for services	-	342,485
Non-cash interest	633,398	196,823
Provision for losses on accounts receivable and inventory	2,320,955	636,704
Loss on disposal of assets	(500	) 7,902
Change in derivative warrant liability	(875,041	) (1,360,160
Reduction of contingent liability	(91,740	) (358,426
Changes in operating assets and liabilities:		
Accounts receivable	797,680	(414,860
Inventories	747,691	(5,271,950
Prepaid and other current assets	263,352	(1,049,458
Accounts payable	(1,001,228	) 1,249,255
Accrued liabilities	1,434,140	(602,300
Net cash used in operating activities	(5,620,924	) (10,792,332
Investing activities:		
Purchases of property and equipment	(623,045	) (1,825,614
Impairment of goodwill	728,618	-
Intangible asset additions	(70,255	) (11,163
Net cash provided by (used in) investing activities	35,318	(1,836,777
Financing activities:		
Proceeds from the issuance of long-term debt	-	22,741,719
Payments on long-term debt	(621,967	) (9,784,482
Payments on capital leases	(149,729	) (78,925
Proceeds from issuance of stock	4,450,001	3,879,749
Proceeds from exercise of options	27,575	46,003
Net cash provided by financing activities	3,705,880	16,804,064

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-K

Net change in cash and cash equivalents	(1,879,726	)	4,174,955
Cash and cash equivalents at beginning of period	4,926,066		751,111
Cash and cash equivalents at end of period	\$ 3,046,340		\$ 4,926,066

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 scaffolds and promote bone and soft 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, and 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.

## Concentrations and Credit Risk

The Company's accounts receivable are due from a variety of health care organizations and distributors throughout the world. Approximately 98% and 97% of sales were in the United States for 2013 and 2012, respectively. One customer accounted for approximately 4% and 5% of the Company's revenue for 2013 and 2012, respectively. One customer represented 5% and 22% of net accounts receivable at December 31, 2013 and 2012, 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, 2013.

Revenue by geographical region is as follows:

	Year ended December 31,	
	2013	2012
United States	\$32,488,822	\$31,947,757
Rest of World	584,592	1,032,142
	\$33,073,414	\$32,979,899

## 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 14, "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.

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



## **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 equity and 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 9, “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. The costs of patent filings and trademarks that have not been approved by regulatory authorities are not subject to amortization until such time that the filings are approved. During the period when a filing is denied or abandoned, all related costs are expensed.

## **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 RyMed and Bard Access Systems. Revenue under these agreements represented less than 1% of total revenue for 2013 and 2012.

## **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 \$47,000 and \$51,000 were expensed for the years ended December 31, 2013 and 2012, 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 and included in General and administrative expenses.

## **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 during the years ended December 31, 2013 and 2012. See Note 11, "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, 2013 or 2012.

## **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, 2013 and 2012 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 18,461,493 and 12,838,799 outstanding stock options and warrants for the twelve months ended December 31, 2013 and 2012, 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.

### **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, 2013 and 2012, 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, 2013 and December 31, 2012 that are measured at fair value on a recurring basis:

Accrued stock compensation

	As of December 31, 2013	As of December 31, 2012
Level 1	\$ 211,212	\$ 218,850
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, 2013	As of December 31, 2012
Level 1	\$ -	\$ -
Level 2	-	-
Level 3	1,594,628	984,356

Acquisition contingent consideration liability

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-K

	As of December 31, 2013	As of December 31, 2012
Level 1	\$ -	\$ -
Level 2	-	-
Level 3	-	91,740

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, 2013	\$984,356
New Issuance in 2013	1,485,313
Gain recognized in earnings	(875,041 )
Balance at December 31, 2013	\$1,594,628

*Acquisition contingent consideration liability*

Balance at January 1, 2013	\$91,740
Gain recognized in earnings	(91,740)
Balance at December 31, 2013	\$-

During the year ended December 31, 2013, 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 June 10, 2013, the Company issued approximately 8.51 million shares of common stock to new and existing investors at a price per share of \$0.57, which represented a 10% discount to the closing price on June 4, 2013. For each common share purchased in the offering, investors received a warrant providing the right to purchase 0.5 shares of Bacterin common stock at an exercise price of \$0.72, a 15% premium to the June 4, 2013 closing price. The warrants will be exercisable for seven years beginning 6 months from the date of issuance. The transaction resulted in net proceeds to the Company of approximately \$4.45 million, after deducting approximately \$400,000 of placement agent's fees and offering expenses. Proceeds from the transaction were used to fund the Company's operations and working capital requirements.

On November 14, 2013, the Company received a waiver from ROS for failure to achieve \$10.5 million of revenue in the third quarter of 2013. In exchange for the waiver and reduction of future quarterly minimum revenue thresholds, the Company issued 1,500,000 shares of restricted stock to an affiliate of ROS on November 25, 2013.

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. During the first quarter of 2012, we issued 1,472,537 shares of our common stock to LPC for net proceeds of \$3,879,749. We used the proceeds for working capital and general corporate purposes. The Purchase Agreement 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) Inventories

Inventories consist of the following:

	December 31,	
	2013	2012
Current inventories		
Raw materials	\$2,710,091	\$1,919,250
Work in process	3,333,672	4,991,032
Finished goods	5,775,813	7,350,332
	11,819,576	14,260,614
Reserve for obsolescence	(1,065,976)	(1,119,193)
Current inventories, total	10,753,600	13,141,421
Non-current inventories		
Finished goods	3,341,411	1,238,225
Reserve for obsolescence	(1,221,459)	-
Non-current inventories, total	2,119,952	1,238,225
Total inventories	\$12,873,552	\$14,379,646

## (4) Property and Equipment, Net

Property and equipment, net are as follows:

	December 31,	
	2013	2012
Buildings	\$1,653,263	\$1,653,263
Equipment	5,768,478	5,172,523
Computer equipment	312,650	312,650
Computer software	395,146	392,206
Furniture and fixtures	170,118	170,118
Leasehold improvements	1,808,461	1,793,756
Vehicles	41,099	78,306
Total cost	10,149,215	9,572,822
Less: accumulated depreciation	(4,968,659)	(4,337,955)
	\$5,180,556	\$5,234,867

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, 2013, the Company has recorded \$549,604 gross assets in Equipment, and \$159,722 of accumulated depreciation relating to assets under capital leases.

Maintenance and repairs expense for 2013 and 2012 was \$244,398 and \$287,811, respectively. Depreciation expense related to property and equipment, including property under capital lease for 2013 and 2012 was \$677,856 and \$707,971, respectively.

(5) 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, 2013	December 31, 2012
Intellectual Property		
Gross carrying value	\$ 891,034	\$ 820,778
Accumulated amortization	(304,069 )	(228,400 )
Net carrying value	\$ 586,965	\$ 592,378

Aggregate amortization expense: \$ 75,668      \$ 74,918

Estimated amortization expense:

2014	\$ 75,668	\$ 74,918
2015	75,668	74,918
2016	75,668	74,918
2017	75,668	74,918
2018	75,668	74,918
Thereafter	208,625	217,788
Total	\$ 586,965	\$ 592,378

(6) Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2013	2012
Acquisition contingent liability	\$-	\$91,740
Accrued stock compensation	211,212	218,850
Wages/commissions payable	1,728,576	1,013,909
Other accrued expenses	1,645,249	1,075,591
	\$3,585,037	\$2,400,090

During 2013, management reviewed and adjusted the assumptions associated with the contingent liability which resulted in a reduction of the contingent liability to \$0 as of December 31, 2013.

(7) 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. The Credit Agreement also provided for an additional \$5 million upon achievement of certain revenue objectives prior to December 31, 2013, which were not achieved. On March 6, 2014, we entered into a Sixth Amendment to our Credit Agreement which allowed us to borrow an additional \$4 million in exchange for 1,500,000 shares of our common stock. The loan carries an interest rate of LIBOR plus 12.13%, subject to a LIBOR floor rate of 1.0%. Bacterin also entered into an agreement to pay a royalty of 1.75% on the first \$45,000,000 of net sales, plus 1.0% of net sales in excess of \$45,000,000 for ten years. Upon the occurrence of a defined event of default, ROS has the option to require the Company to purchase from ROS all of its rights to the remaining royalty payments that will become due in accordance with the royalty agreement (the "ROS Put Option"). The ROS Put Option meets the definition of an embedded derivative instrument in accordance with ASC 815. The Company used a Monte Carlo simulation model to determine the fair value of the embedded derivative and concluded it had an immaterial value at December 31, 2013 and 2012. As such, the Company has not recorded a derivative liability related to the ROS Put Option and has not recognized any change in the fair value of this derivative liability in the consolidated financial statements because the impact is immaterial. Management will reassess the fair value of the embedded derivative instrument at each reporting period and record if and when it becomes material to the consolidated financial statements. Bacterin has the right to repurchase the loan and royalty interest at amounts to be determined based on the date of repurchase, less the amount of prior principal, interest and royalty payments. The repurchase amounts, following the additional \$4 million we borrowed on March 6, 2014 and before deducting the amount of prior principal, interest and royalty payments, are as follows: (a) \$37,500,000 if we exercise the repurchase option before August 24, 2014; (b) \$40,000,000 if we exercise the repurchase option between August 24, 2014 and August 24, 2015; (c) \$45,000,000 if we exercise the repurchase option between August 24, 2015 and August 24, 2016; (d) \$52,500,000 if we exercise the repurchase option between August 24, 2016 and August 24, 2017; and (e) \$56,250,000 if we exercise the repurchase option after August 24, 2017. We will also have to pay fees, currently in the amount of 3.5% of the aggregate principal amount of the loan, as a result of waivers and modifications we have received in connection with the financial covenants in the Credit Agreement. The loan is secured by substantially all of our assets. The estimate of the royalty component of the facility over the life of the agreement resulted in a debt discount and a royalty liability of \$7,341,520. 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. The following table provides an approximation of the repurchase price based on revenue equal to the minimum revenue required pursuant to the financial covenants in our Credit Agreement and four years of interest only payments with principal and interest amortized over years five through seven. Any modification in the payment schedule or in actual revenue achieved would change the Net Buyout Amount in the table below. The estimated amounts in the table below do not include fees payable on the aggregate principal amount of the loan pursuant to waivers and modifications to the Credit

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-K

Agreement. The table below is for illustration purposes only and there can be no assurance that we will achieve the minimum revenue required by the financial covenants or that we will timely make all required payments.

Calculation of ROS Buyout	Repurchase Price	Interest/Principal Payments	Estimated Royalty on Minimum Revenue	Estimated Total Cumulative Payments	Net Buyout Amount
Before August 24, 2014	\$37,500,000	\$ 2,878,667	\$ 542,500	\$6,718,167	\$ 30,781,833
Between August 24, 2014 and August 24, 2015	\$40,000,000	\$ 3,151,200	\$ 638,750	\$10,508,117	\$ 29,491,883
Between August 24, 2015 and August 24, 2016	\$45,000,000	\$ 3,151,200	\$ 665,000	\$14,324,317	\$ 30,675,683
Between August 24, 2016 and August 24, 2017	\$52,500,000	\$ 9,721,896	\$ 665,000	\$24,711,213	\$ 27,788,787
After August 24, 2017	\$56,250,000	\$ 9,721,896	\$ 665,000	\$35,098,109	\$ 21,151,891

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 ROS.

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 used the net proceeds for working capital and general corporate purposes.

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

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

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

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

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

On November 14, 2013, we entered into a Waiver and Fifth Amendment to our Credit Agreement with ROS whereby we agreed to issue 1.5 million shares of common stock to an affiliate of ROS in exchange for a waiver of our failure to achieve the minimum required revenue for the third quarter of 2013 and a reduction of future quarterly minimum revenue thresholds.

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-K

On March 6, 2014, we entered into a Sixth Amendment to our Credit Agreement with ROS whereby we borrowed an additional \$4 million under the existing terms of our Credit Agreement with ROS and agreed to issue 1.5 million shares to an affiliate of ROS.

Long-term debt consists of the following:

	December 31, 2013	December 31, 2012
Loan payable to ROS Acquisition Offshore, LIBOR plus 12.13% maturing August 2019	\$ 20,000,000	\$ 20,000,000
Adjustment fee payable to ROS Acquisition Offshore August 2019	700,000	-
6.00% loan payable to Valley Bank of Belgrade, \$10,746 monthly payments including interest, maturing December 24, 2030; secured by building	1,375,030	1,421,420
	22,075,030	21,421,420
Less: Current portion	(47,727 )	(45,135 )
Debt discount	(5,642,058 )	(6,893,183 )
Long-term debt	\$ 16,385,245	\$ 14,483,102

The following is a summary of maturities due on the debt as of December 31, 2013:

2014	\$47,727
2015	50,671
2016	1,778,797
2017	6,957,114
2018	6,960,637
Thereafter	6,280,084
Total	\$22,075,030

The following is a summary of estimated future royalty payments as of December 31, 2013:

2014	\$836,750
2015	1,000,750
2016	1,229,250
2017	1,360,250
2018	1,462,750
Thereafter	7,951,250
Total	\$ 13,841,000



(8) Stock-Based Compensation

Our Equity Incentive Plan ("The Plan") provides for stock awards, including options and performance stock awards, to be granted to employees, consultants, independent contractors, officers and directors. The purpose of the Plan is to enable us to attract, retain and motivate key employees, directors and, on occasion, independent consultants, by providing them with stock options and restricted stock grants. Stock options granted under the Plan may be either incentive stock options to employees, as defined in Section 422A of the Internal Revenue Code of 1986, or non-qualified stock options. The Plan is administered by the compensation committee of our Board of Directors. The administrator of the Plan has the power to determine the terms of any stock options granted under the Plan, including the exercise price, the number of shares subject to the stock option and conditions of exercise. Stock options granted under the Plan are generally not transferable, vest in installments over the requisite service period and are exercisable during the stated contractual term of the option only by such optionee. The exercise price of all incentive stock options granted under the Plan must be at least equal to the fair market value of the shares of common stock on the date of the grant. 9 million shares are authorized under the Plan and at December 31, 2013, we had approximately 1,006,648 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, 2013 and 2012 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 1.16% for year ended December 31, 2013.

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

**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, 2013.

**Dividend Yield:** The dividend yield assumption is based on our history and expectation of dividend payouts and was 0% as of December 31, 2013 and 2012.

Activity under the Plan was as follows:

	2013			2012		
	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	5,266,535	\$ 2.02	\$ 1.03	4,828,910	\$ 2.14	\$ 1.01
Granted	3,331,250	0.63	0.53	1,716,250	1.79	1.03
Exercised	(230,000 )	0.10	0.06	(39,375 )	0.87	0.37
Cancelled or expired	(784,500 )	1.76	0.89	(1,239,250)	2.17	0.39
Outstanding at December 31	7,583,285	\$ 1.49	\$ 0.86	5,266,535	\$ 2.02	\$ 1.03
Exercisable at December 31	2,642,718	\$ 2.10	\$ 1.03	2,565,301	\$ 1.83	\$ 0.80

The total intrinsic value of options exercised in 2013 was \$109,000. The aggregate intrinsic value of options outstanding as of December 31, 2013 is \$72,666. The aggregate intrinsic value of exercisable options as of December 31, 2013 is \$72,666. As of December 31, 2013, there were 4,940,567 unvested options with a weighted average fair value at the grant date of \$0.77 per option. As of December 31, 2013, there is no compensation related to nonvested awards not yet recognized.

On May 24, 2013, the Company issued 335,000 restricted stock awards to certain employees. These restricted shares vest after one year and were issued when the stock price was \$0.68 per share. The total expense of \$227,800 is recognized ratably over the vesting period in General and Administrative and Sales and Marketing Expenses.

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

Total share based compensation for employees and consultants was \$975,905 and \$1,554,657 for the years ending December 31, 2013 and 2012, respectively.

The following table summarizes restricted stock award activity during the year ended December 31, 2013:

	Shares
Outstanding at Jan. 1, 2013	733,900
Cancelled	(278,676)
Vested	(146,724)
Outstanding at December 31, 2013	308,500

The restricted stock awards generally vest over three to five year periods. The Company recognized non cash consulting expense of a negative \$5,117 and a positive \$427,787 for the years ended December 31, 2013 and 2012, respectively. As of December 31, 2013, the total expense related to nonvested restricted stock awards not yet recognized is \$101,362 and is expected to be recognized over three years.

(9) Warrants

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, 2013:

	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
Issued	4,352,215	0.72
Expired	(795,674 )	2.00
Exercised	-	-
Outstanding at December 31, 2013	10,878,208	\$ 1.62

We utilize a lattice model to determine the fair market value of the warrants accounted for as liabilities. The warrants issued in the second quarter of 2013 resulted in the issuance of 4,254,387 warrants and a warrant derivative liability of \$1,485,313. There was 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 and an additional 97,828 related to the second quarter of 2013 equity financing. The lattice model accommodates the probability of exercise price adjustment features as outlined in the warrant agreements. We recorded an unrealized gain of \$875,041 resulting from the change in the fair value of the warrant derivative liability for 2013. 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,			
	2013		2012	
Value of underlying common stock (per share)	\$0.50		\$1.25	
Risk free interest rate	0.89	%	0.24	%
Expected term	5.56 years		3.83 years	
Dividend yield	0		0	
Volatility	65	%	72	%

The following table summarizes our activities related to number of warrants used in the derivative liability for the period ended December 31, 2013 and 2012:

	2013	2012
Balance at January 1	1,649,707	1,506,007
Derivative warrants issued	4,352,215	143,700
Derivative warrants exercised	-	-
Balance at December 31	6,001,922	1,649,707

(10) Commitments and Contingencies

**Operating Leases**

We lease two office facilities under non-cancelable operating lease agreements with expiration dates in 2019 and 2023. We have the option to extend both the leases for another ten year term and for one facility, we have the right of first refusal on any sale. We lease an additional office facility under a month-to-month arrangement. Future minimum payments for the next five years and thereafter as of December 31, 2013, under these leases, are as follows:

2014	\$269,400
2015	269,400
2016	269,400
2017	269,400
2018	269,400
Thereafter	727,864
Total	\$2,074,864

Rent expense was approximately \$283,000 and \$298,000 for the years ended December 31, 2013 and 2012, 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.

### **Indemnification**

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

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

### **Pending and Threatened Litigation**

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

Lacuna Hedge Fund LLLP ("Lacuna") has asserted various claims against our former CEO, Guy Cook, in connection with financing Lacuna provided to Holgan, LLC, a former stocking distributor. Holgan failed to fully pay for the products it received from Bacterin and defaulted under its credit agreement with Lacuna. We are currently in settlement negotiations with Lacuna regarding this matter, and we are also negotiating with Holgan on its unpaid obligation, which we wrote off in 2013.



**NYSE MKT Deficiency Notice**

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

(11) 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,	
	2013	2012
United States	\$(12,693,125)	\$(7,713,822)
	\$(12,693,125)	\$(7,713,822)

The components of the income tax provision are as follows:

	Year Ended December 31,	
	2013	2012



Edgar Filing: Bacterin International Holdings, Inc. - Form 10-K

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,	
	2013	2012
Statutory Federal tax rate	\$(4,442,594)	\$(2,699,838)
Valuation allowance	4,112,338	2,789,646
State income taxes, net of Federal benefit	(528,034 )	(443,236 )
Change in state income tax rate	574,964	823,665
Change in Warrant Derivative Liability	(342,666 )	(554,211 )
Stock issued in exchange for debt waiver	581,649	-
Nondeductible meals & entertainment expense	44,343	83,974
	\$-	\$-

Deferred tax components are as follows:

	At December 31,	
	2013	2012
Deferred tax assets:		
Current deferred tax assets		
Accrued liability for vacation	\$85,599	\$75,442
Bad debt reserve	512,941	642,546
Charitable contributions carryforward	19,746	19,686
Inventory reserve	895,760	456,026
Restricted stock compensation	82,640	94,212
Total current deferred tax assets	1,596,686	1,287,912
Valuation Allowance	(1,596,686 )	(1,287,912 )
Net current deferred tax assets	-	-
Noncurrent deferred tax assets		
Net operating loss carryovers	14,863,919	11,963,305
Stock warrants	134,117	139,549
Stock option compensation	1,307,998	1,023,192
Debt discount and waiver amortization	455,916	-
Goodwill amortization	90,868	-
Depreciation	97,492	-
Amortization	25,797	-
Total noncurrent deferred tax assets	16,976,107	13,126,046
Valuation allowance	(16,976,107)	(13,172,543)
Net noncurrent deferred tax assets	-	(46,497 )
Deferred tax liabilities:		
Goodwill Amortization	-	(11,346 )
Depreciation	-	31,055
Amortization	-	26,788
Total deferred tax liabilities	-	46,497
Net deferred tax assets	\$-	\$-

The ultimate realization of deferred tax assets is dependent upon the existence, or generation, of taxable income in the periods when those temporary differences and net operating loss carryovers are deductible. Management considers the scheduled reversal of deferred tax liabilities, taxes paid in carryover years, projected future taxable income, available tax planning strategies, and other factors in making this assessment. Based on available evidence, management does not believe it is more likely than not that all of the deferred tax assets will be realized. Accordingly, the Company has established a valuation allowance equal to the net realizable deferred tax assets. The valuation allowance increased by \$4,112,338 and \$2,789,646 in 2013 and 2012, respectively.

At December 31, 2013 and 2012, the Company had total domestic Federal and state net operating loss carryovers of approximately \$37,956,891 and \$29,360,685, respectively. Federal net operating loss carryovers expire at various dates between 2025 and 2033, while state net operating loss carryovers expire between 2025 and 2033.

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 2013 or 2012.

The 2010 through 2012 tax years remain open to examination by the Internal Revenue Service and the 2008 to 2012 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, 2013 and 2012. There were no material changes to uncertain tax positions for the years ended December 31, 2013 and 2012.

#### (12) Employee Benefit Plans

The Company has a 401(k) retirement plan. Qualified employees may defer their salary and the deferrals are matched up to 2%. The plan covers substantially all full-time employees. Under the terms of the plan, participants may contribute up to the lower of \$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.

#### (13) Supplemental Disclosure of Cash Flow Information

Supplemental cash flow information is as follows:

Supplemental disclosure of cash flow information	Year ended	
	December 31, 2013	2012
Cash paid during the period for:		
Interest	\$2,681,459	\$1,873,155
Income taxes	\$-	\$-
Non-cash activities:		
Non-cash consulting expense	\$(5,117 )	\$401,395
Settlement of SeaArk accounts receivable	\$1,829,647	\$-
Inventory received in SeaArk settlement	\$409,838	\$-
Write-off of SeaArk allowance for doubtful accounts	\$1,419,809	\$-
Warrants issued with debt	\$-	\$220,872
Capital lease acquisition	\$-	\$350,986
Issuance of warrants	\$1,485,313	\$220,872
Increase in long term debt, ROS adjustment fee	\$700,000	\$-
Issuance of common stock, ROS adjustment fee	\$630,000	\$-
Debt discount related to financing	\$-	\$7,341,520
Royalty liability related to financing	\$-	\$7,341,520

#### (14) Related Party Transactions

Guy Cook was our President, Chief Executive Officer and Chairman of our Board of Directors until April 5, 2013, when he resigned. Mr. Cook has advised us that he is currently an owner and executive officer of Lattice Biologics, Inc., a competitor of ours that was formerly known as International Biologics, LLC. International Biologics, LLC was a former customer of Bacterin and is indebted to us in the amount of approximately \$32,974, which we are currently attempting to collect.

Mr. Cook assisted unrelated parties in the initial capitalization of Holgan, LLC, a former stocking distributor that purchased a bulk shipment of products from Bacterin at a discount in 2012 (“Holgan”). Holgan subsequently obtained financing from Lacuna Hedge Fund LLLP (“Lacuna”), which is a significant Bacterin shareholder. Holgan failed to fully pay for the products it acquired from Bacterin and defaulted under its credit agreement with Lacuna. The parties are currently in settlement negotiations and we understand that Mr. Cook’s new company Lattice may be purchasing substantially all of the Bacterin products held by Holgan, with the proceeds to be paid to Lacuna. We are continuing to negotiate with Lacuna on possible settlement arrangements and with Holgan on its unpaid obligation, which we wrote off in 2013.

Mr. Cook’s spouse was employed by Bacterin as the Director of Human Resources until April 9, 2013. Mr. Cook, together with his adult children, owned and operated Silver Forest Fund, LP (“Silver Forest”), a former distributor of Bacterin products. We terminated the contractual relationship with Silver Forest on October 24, 2013. In 2012, Silver Forest purchased Bacterin products from an unaffiliated former distributor and subsequently exchanged some of those products for different Bacterin products of equivalent value. Other than product exchanges and payment of amounts owed by the non-affiliated distributor, there were no other direct transactions between Bacterin and Silver Forest. In 2012, Mr. Cook pledged 1,850,000 shares of Bacterin stock as collateral for loans made for the benefit of Silver Forest.

Mr. Cook remains our largest stockholder with beneficial ownership of approximately 19.4% of our outstanding capital according to Amendment No. 4 to his Schedule 13D filed on February 25, 2014 with the Securities and Exchange Commission (the “Schedule 13D”). In the Schedule 13D, Mr. Cook indicated that he believed Bacterin would be better able to realize its full value as a private entity, and that he planned to engage legal and financial advisors to assist him in evaluating alternatives for taking Bacterin private. To date, Mr. Cook has not made any formal offer to our Board of Directors.

Mr. Cook also formerly served as a board member of West Coast Tissue Services (“WCTS”) and American Donor Services (“ADS”). Mr. Cook did not receive any compensation for his board service from either entity. Darrel Holmes, our Chief Operating Officer, and Mitchell Godfrey, a director, also serve on the board of ADS, and Mr. Godfrey also serves as secretary and treasurer for ADS. Mr. Godfrey receives \$5,000 per year for his service to ADS. Mr. Holmes does not receive any compensation for serving on the board of ADS. ADS and WCTS recover tissue from donors. We reimburse them for their recovery fees, which are comprised primarily of labor costs. The approximate aggregate amount of all transactions with WCTS was \$840,100 for 2013 and \$525,900 for 2012, and the approximate aggregate amount of all transactions with ADS was \$2,055,523 for 2013 and \$1,472,949 for 2012. These relationships have benefited us, as these entities provide us with donors, thus insuring that we have a pipeline of current and future donors, which is necessary to our success.

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



(15) Subsequent Events

On March 6, 2014, we borrowed an additional \$4 million from ROS under the same terms that the Company received in its original August 2012 financing with ROS. As additional consideration for the loan, we issued 1.5 million shares of our common stock to an affiliate of ROS.

**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, 2013. Based upon that evaluation, we concluded that as of December 31, 2013, our disclosure controls and procedures were adequate.

**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 adequate as of December 31, 2013.



**Item 9B. Other Information**

None

48

### **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:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Daniel Goldberger	55	Director, Chief Executive Officer and President
Kent Swanson	69	Chairman of the Board
Mitchell Godfrey	68	Director
Michael Lopach	65	Director
Jon Wickwire	70	Director
John Deedrick	51	Director
John Gandolfo	53	Chief Financial Officer
Darrel Holmes	60	Chief Operating Officer
Nicholas Navarro	34	Vice President of Sales
Gregory Juda	38	Chief Scientific Officer

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

**Daniel Goldberger, Director, Chief Executive Officer and President**, has more than 25 years of experience as a leader of both publicly traded and privately held medical technology companies, with a proven track record of building revenue and profits through the introduction of market changing product innovations. He was most recently CEO and a director of Sound Surgical Technologies from April 2007 through its merger with Solta Medical (Nasdaq

SLTM) in February 2013. Previously, he was President/CEO and a director of Xcorporeal (Amex XCR) an innovator in portable dialysis and Glucon (private) a developer of glucose measurement technology and several other successful enterprises. Mr. Goldberger is a named inventor on more than 60 US patents. He holds a BS in Mechanical Engineering from the Massachusetts Institute of Technology and an MS in Mechanical Engineering from Stanford University.

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

**Mitchell 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 to the Company and is also on the Board of Directors of American Donor Services, one of our recovery partners.

**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 Gandolfo, Chief Financial Officer**, joined Bacterin as its interim Chief Financial Officer on a part-time basis, effective June 4, 2010, and filled this position full time commencing on July 6, 2010. Mr. Gandolfo also served as Interim Co-Chief Executive Officer from April 5, 2013 to August 14, 2013, and as a Director from July 9, 2013 to August 14, 2013. Mr. Gandolfo has 25 years of experience as chief financial officer of rapidly growing private and publicly held companies with a primary focus in the life sciences, healthcare and medical device areas. Mr. Gandolfo has had direct responsibility over capital raising, including four public offerings, financial management, mergers and acquisition transactions and SEC reporting throughout his professional career. Prior to joining Bacterin, Mr. Gandolfo served as the Chief Financial Officer for Progenitor Cell Therapy LLC, a leading manufacturer of stem cell therapies. Prior to joining Progenitor, Mr. Gandolfo served as the Chief Financial Officer for Power Medical Interventions, Inc., a publicly held developer and manufacturer of computerized surgical stapling and cutter systems, from January 2007 to January 2009. Prior to joining PMI, Mr. Gandolfo was the Chief Financial Officer of Bioject Medical Technologies, Inc., a publicly held supplier of needle-free drug delivery systems to the pharmaceutical and biotechnology industries, from September 2001 to May 2006, and served on the Bioject's Board of Directors from September 2006 through May 2007. Prior to joining Bioject, Mr. Gandolfo was the Chief Financial Officer of Capital Access Network, Inc., a privately held specialty finance company, from 2000 through September 2001, and Xceed, Inc., a publicly held Internet consulting firm, from 1999 to 2000. From 1994 to 1999, Mr. Gandolfo was Chief Financial Officer and Chief Operating Officer of Impath, Inc., a publicly held, cancer-focused healthcare information

company. From 1987 through 1994, he was Chief Financial Officer of Medical Resources, Inc., a publicly held manager of diagnostic imaging centers throughout the United States. A graduate of Rutgers University, Mr. Gandolfo is a certified public accountant (inactive status) who began his professional career at Price Waterhouse.

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

**Nicholas Navarro, National Sales Manager**, has ten years of sales and management experience in the orthopedic industry. As the Vice President of Sales, 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.

**Gregory Juda, Chief Scientific Officer**, joined Bacterin in 2005 and has played an integral role in the growth of Bacterin's orthobiologics business. During his time with the company, Dr. Juda has been responsible for guiding the development, commercialization, and marketing of 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. A majority of our board members and all of our board committee members are independent directors. All directors hold office for staggered three year terms and until the election and qualification of their successors. Officers are elected by, and serve at the discretion of, the board of directors.

### **Board Committees**

We have established an audit committee, compensation committee and nominations and corporate governance committee, in compliance with applicable corporate governance requirements.

#### *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 John Deedrick, Kent Swanson and Michael Lopach, each of whom is an independent director. Mr. Deedrick serves as the Chairman of the Compensation Committee.

#### *Nominations and Corporate Governance Committee*

The purposes of the Nominations and Corporate Governance Committee include the selection or recommendation to our Board of Directors of nominees to stand for election as directors 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, Swanson and Deedrick, 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:

o 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;

o convicted in a criminal proceeding or is subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);

o 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.

Except as described in Item 13 below and in Note 10 to our financial statements, 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: Daniel Goldberger filed a Form 4 one day late due to a delay in receipt of trade confirmations.

#### **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](http://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 named executive officers other than the Chief Executive Officer. The Company had two Chief Executive Officers and two Interim Co-Chief Executive Officers during 2013.

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards (1)	Change in Pension Value and Non-Equity Deferred Compensation			Total
						Plan Compensation	Accrual	Change	
Daniel Goldberger Chief Executive Officer From August 14, 2013 to present	2013	143,077	-	-	1,098,055	-	-	-	1,241,132
Guy S. Cook Chief Executive Officer Until April 5, 2013	2013	\$156,065	\$46,960	\$-	\$-	\$-	\$-	\$-	\$203,025
	2012	500,000	100,000	-	138,180	-	-	-	738,180
John Gandolfo Chief Financial Officer Interim Co-Chief Executive Officer from April 5 2013 to August 14, 2013	2013	321,462	100,800	68,340	34,745	-	-	-	525,347
	2012	299,947	50,000	-	96,726	-	-	-	446,673
Darrel Holmes Chief Operating Officer Interim Co-Chief Executive Officer from April 5 2013 to August 14, 2013	2013	254,615	84,000	68,340	34,745				441,700
	2012	199,231	50,000		197,467				
Nick Navarro National Sales Manager	2013	240,000	70,500	22,780	34,745				368,025
	2012	233,077			261,005			13,344 (2)	507,426
Gregory Juda Chief Scientific Officer	2013	200,000	71,128	22,780	34,745				328,653
	2012	179,807			110,482				290,289

(1) Key assumptions used to estimate the grant date fair value of restricted stock and option awards are contained in Note 8 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 and Inducement Grant to our Chief Executive Officer**

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

The purpose of the Plan is to enable us to attract, retain and motivate key employees, directors and independent consultants, by providing them with stock options and restricted stock grants. Stock options granted under the Plan may be either incentive stock options to employees, as defined in Section 422A of the Internal Revenue Code of 1986, or non-qualified stock options. The Plan is administered by 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 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, 2013, we had outstanding options to purchase 5,583,285 shares and 643,500 shares of restricted stock issued, to directors, executives, employees and consultants, leaving approximately 1,006,648 shares available for issuance thereunder.

We also granted stock options to our Chief Executive Officer outside of our Plan as an inducement material to entering into employment with the company pursuant to Section 711(a) of the NYSE MKT Company Guide. The inducement grant to our Chief Executive Officer was approved by the Compensation Committee of our Board of Directors. The inducement grant consists of a stock option to purchase up to 2,000,000 shares of the Company's common stock, with a per share exercise price of \$0.60, which was the closing price of the Company's common stock on the August 14, 2013 grant date. The option vests over five years, with 20% of the underlying shares vesting after one year and the remaining eighty percent (80%) vesting in forty-seven (47) equal monthly installments as to 33,334 underlying shares, beginning September 15, 2014, and one final installment as to 33,302 underlying shares.

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

**Outstanding Equity Awards at Fiscal Year-End (December 31, 2013)**

Name	Option Awards				Stock Awards	
	Equity Incentive Number of Plan Awards: Securities Underlying Unexercised Options	Number of Securities Underlying Unexercised Unearned	Option Exercise Price	Option Expiration Date	Number of shares or units of stock that  <b>have not vested</b>	Market value of shares or units of stock that have  <b>not vested</b>
Daniel Goldberger	-	2,000,000	\$ 0.60	8/14/23		
Guy Cook	-	-	\$ -	-		
John Gandolfo	150,000	100,000	\$ 1.60	6/3/20	100,500	50,250
	14,000	56,000	\$ 2.36	3/27/22		
		70,000	\$ 0.68	5/24/23		
Darrel Holmes	30,000		\$ 1.34	10/9/16	100,500	50,250
	18,287		\$ 1.50	12/29/18		
	11,712		\$ 1.50	12/29/18		
	15,000		\$ 1.50	12/29/18		
	15,000		\$ 1.50	12/29/18		
	15,000		\$ 1.50	12/29/18		
	14,000	56,000	\$ 2.36	3/27/22		
	33,000	67,000	\$ 1.65	9/6/22		
		70,000	\$ 0.68	5/24/23		
Nick Navarro	36,000	24,000	\$ 1.60	4/1/20	33,500	16,750
	24,000	36,000	\$ 2.36	3/27/22		
	80,000	120,000	\$ 1.48	5/8/22		
		70,000	\$ 0.68	5/24/23		
Gregory Juda	2,500		\$ 1.34	8/22/15	33,500	16,750
	3,750		\$ 1.34	2/8/17		
	14,999		\$ 1.34	8/21/17		
	25,000		\$ 6.90	11/17/20		
	24,000	96,000	\$ 1.47	5/8/22		
		70,000	\$ 0.68	5/24/23		

**Potential Payments Upon Termination or Change-in-Control**

Both our Chief Executive Officer and our Chief Financial Officer have employment agreements that provide for payment of twelve months base salary if they are terminated in connection with a change in control.

**Retirement Plans**

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

**Director Compensation**

Name	Fees Earned or Paid in Cash <sup>(1)</sup>	Stock Awards	Option Awards <sup>(2)</sup>	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Mitch Godfrey <sup>(3)</sup>	\$ -	\$ -	\$41,500	\$ -	\$ -	\$ 95,000	\$ 136,500
Kent Swanson	\$ 50,000	\$ -	\$41,500	\$ -	\$ -	\$ -	\$ 91,500
Michael Lopach	\$ 50,000	\$ -	\$41,500	\$ -	\$ -	\$ -	\$ 91,500
Jon Wickwire	\$ 50,000	\$ -	\$41,500	\$ -	\$ -	\$ -	\$ 91,500
John Deedrick	\$ 50,000	\$ -	\$41,500	\$ -	\$ -	\$ -	\$ 91,500

Our independent Board members receive an annual retainer of \$40,000 per year, and our Committee Chairs (1) receive an additional \$10,000 per year. Beginning in 2014, our independent Board Chair will receive an additional \$20,000 per year.

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

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

**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, 2013, 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 and Address of Beneficial Owner	Number of Shares Beneficially Owned <sup>(2)</sup>	Percentage of Shares Beneficially Owned <sup>(3)</sup>
<i>Directors and Named Executive Officers</i> <sup>(1)</sup> :		
Daniel Goldberger	100,100	*
Kent Swanson	676,509 <sup>(4)</sup>	1.3 %
Mitchell Godfrey	1,112,133 <sup>(5)</sup>	2.1 %
Michael Lopach	181,185 <sup>(6)</sup>	*
Jon Wickwire	503,764 <sup>(7)</sup>	0.9 %
John Deedrick	50,000 <sup>(8)</sup>	*
John P. Gandolfo	177,920 <sup>(9)</sup>	*
Darrel Holmes	152,332 <sup>(10)</sup>	*
Nick Navarro	170,000 <sup>(11)</sup>	*
Gregory Juda	90,249 <sup>(12)</sup>	*
All executive officers and directors as a group (10 persons)	3,214,192	6.0 %
Five Percent Shareholders:		
Guy S. Cook 246 Painted Hills Rd. Bozeman, MT 59714	10,305,441 <sup>(13)</sup>	19.3 %
Rawleigh Hazen Ralls, IV c/o Lacuna, LLC 1100 Spruce Street, Suite 202 Boulder, Colorado 80302	3,100,550 <sup>(14)</sup>	5.8 %



Edgar Filing: Bacterin International Holdings, Inc. - Form 10-K

OrbiMed Advisors LLC 601 Lexington Ave., 54 <sup>th</sup> Floor New York, NY 10022	4,131,579 (15)	7.8	%
Perkins Capital Management, Inc. 730 East Lake Street Wayzata, MN 55391	3,316,273 (16)	6.2	%

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

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

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 (2) the right to acquire those shares within 60 days after December 31, 2013, 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 53,338,658 shares of common stock outstanding on December 31, 2013. 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) 350,000 shares of our common stock held directly, (b) 200,000 shares held by a family limited partnership, (c) warrants to purchase 66,509 shares of our common stock, and (d) options to purchase 60,000 shares of our common stock.

(5) Includes (a) 711,467 shares of our common stock, (b) 250,666 shares of common stock owned by Mr. Godfrey's spouse, and (c) vested options to purchase 150,000 shares of our common stock.

(6) 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.

(7) 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.

(8) Includes vested options to purchase 50,000 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 164,000 shares of our common stock.

(10) Includes vested options to purchase 152,332 shares of our common stock.

(11) Includes vested options to purchase 170,000 shares of our common stock.

(12) Includes (a) 20,000 shares of our common stock, and (b) vested options to purchase 70,249 shares of our common stock.

(13) Includes (a) 4,871,029 shares of our common stock held directly, (b) 5,300,000 shares of our common stock held by trusts for the benefit of Mr. Cook's children, and (c) warrants to purchase 134,412 shares of our common stock.

(14) Based on Schedule 13G filed with the SEC on February 14, 2014. Includes 1,990,550 shares held indirectly by a fund for which Mr. Ralls may be deemed to have shared power to vote and dispose of the shares, and 110,000 shares held indirectly by Mr. Ralls' spouse. Mr. Ralls disclaims beneficial ownership of shares held indirectly, except to the extent of his pecuniary interest therein.

(15)

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-K

Based on Schedule 13G filed with the SEC on February 13, 2014. Includes 3,254,386 shares of our common stock and warrants to purchase 877,193 shares of our common stock held by an entity managed by OrbiMed Advisors LLC.

(16) Based on Schedule 13G filed with the SEC on February 7, 2014. Includes 2,965,393 shares of our common stock and warrants to purchase 350,880 shares of our common stock.

*Economic Ownership; Stock Ownership Guidelines*

Because the table above is limited to shares that are owned or which the person has the right to acquire within 60 days, it does not present a complete view of the economic exposure our directors and executive officers have to the Company's common stock. Excluded from the table above are unvested stock options and unvested warrants which will become vested more than 60 days from December 31, 2013.

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

### **Transactions with Related Persons, Promoters and Certain Control Persons**

Guy Cook was our President, Chief Executive Officer and Chairman of our Board of Directors until April 5, 2013, when he resigned. Mr. Cook has advised us that he is currently an owner and executive officer of Lattice Biologics, Inc., a competitor of ours that was formerly known as International Biologics, LLC. International Biologics, LLC was a former customer of Bacterin and is indebted to us in the amount of approximately \$32,974, which we are currently attempting to collect.

Mr. Cook assisted unrelated parties in the initial capitalization of Holgan, LLC, a former stocking distributor that purchased a bulk shipment of products from Bacterin at a discount in 2012 (“Holgan”). Holgan subsequently obtained financing from Lacuna Hedge Fund LLLP (“Lacuna”), which is a significant Bacterin shareholder. Holgan failed to fully pay for the products it acquired from Bacterin and defaulted under its credit agreement with Lacuna. The parties are currently in settlement negotiations and we understand that Mr. Cook’s new company Lattice may be purchasing substantially all of the Bacterin products still held by Holgan, with the proceeds to be paid to Lacuna. We are continuing to negotiate with Lacuna on possible settlement arrangements and with Holgan on its unpaid obligation, which we wrote off in 2013.

Mr. Cook’s spouse was employed by Bacterin as the Director of Human Resources until April 9, 2013. Mr. Cook, together with his adult children, owned and operated Silver Forest Fund, LP (“Silver Forest”), a former distributor of Bacterin products. We terminated the contractual relationship with Silver Forest on October 24, 2013. In 2012, Silver Forest purchased Bacterin products from an unaffiliated former distributor and subsequently exchanged some of those products for different Bacterin products of equivalent value. Other than product exchanges and payment of amounts owed by the non-affiliated distributor, there were no other direct transactions between Bacterin and Silver Forest. In 2012, Mr. Cook pledged 1,850,000 shares of Bacterin stock as collateral for loans made for the benefit of Silver Forest.

Mr. Cook remains our largest stockholder with beneficial ownership of approximately 19.4% of our outstanding capital according to Amendment No. 4 to his Schedule 13D filed on February 25, 2014 with the Securities and Exchange Commission (the “Schedule 13D”). In the Schedule 13D, Mr. Cook indicated that he believed Bacterin would be better able to realize its full value as a private entity, and that he planned to engage legal and financial advisors to assist him in evaluating alternatives for taking Bacterin private. To date, Mr. Cook has not made any formal offer to our Board of Directors.

Mr. Cook also formerly served as a board member of West Coast Tissue Services (“WCTS”) and American Donor Services (“ADS”). Mr. Cook did not receive any compensation for his board service from either entity. Darrel Holmes,

our Chief Operating Officer, and Mitchell Godfrey, a director, also serve on the board of ADS, and Mr. Godfrey also serves as secretary and treasurer for ADS. Mr. Godfrey receives \$5,000 per year for his service to ADS. Mr. Holmes does not receive any compensation for serving on the board of ADS. ADS and WCTS recover tissue from donors. We reimburse them for their recovery fees, which are comprised primarily of labor costs. The approximate aggregate amount of all transactions with WCTS was \$840,100 for 2013 and \$525,900 for 2012, and the approximate aggregate amount of all transactions with ADS was \$2,055,523 for 2013 and \$1,472,949 for 2012. These relationships have benefited us, as these entities provide us with donors, thus insuring that we have a pipeline of current and future donors, which is necessary to our success.

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

### 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, 2013 and December 31, 2012. The following table presents the aggregate fees billed for professional services rendered by EKS&H for the years ended December 31, 2013 and December 31, 2012.

	2013	2012
Audit fees	\$ 138,500	\$ 85,000
Audit-related fees	\$ 11,073	\$ 39,500
Tax fees	\$-	\$-
All other fees	\$-	\$ 5,288

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/ Daniel Goldberger  
Name: Daniel Goldberger  
Title: Chief Executive Officer  
Date: March 27, 2014

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, 2014.

<b>Signature</b>	<b>Title</b>
/s/ Daniel Goldberger Daniel Goldberger	Chief Executive Officer, President and Director (Principal Executive Officer)
/s/ John Gandolfo John Gandolfo	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
/s/ Kent Swanson Kent Swanson	Director
/s/ Mitchell Godfrey Mitchell Godfrey	Director
/s/ Michael Lopach Michael Lopach	Director
/s/ Jon Wickwire Jon Wickwire	Director
/s/ John Deedrick John Deedrick	Director





**Exhibit Index**

**Exhibit**

<b>No.</b>	<b>Description</b>
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. <sup>(1)</sup>
3.1	Restated Certificate of Incorporation <sup>(5)</sup>
3.2	Amended and Restated Bylaws <sup>(3)</sup>
4.1	Form of Warrant to Purchase Common Stock <sup>(1)(17)</sup>
4.2	Form of Common Stock Certificate <sup>(6)</sup>
10.1	Form of Indemnification Agreement for the officers and directors <sup>(2)</sup>
10.2	Amended and Restated Bacterin International Equity Incentive Plan <sup>(7)</sup>
10.3	Form of Stock Option Agreement <sup>(14)</sup> •
10.4	Daniel Goldberger Employment Agreement <sup>(8)</sup> •
10.5	Daniel Goldberger Stock Option Agreement <sup>(9)</sup> •
10.6	Daniel Goldberger Indemnification Agreement <sup>(10)</sup>
10.7	John Gandolfo Employment Agreement <sup>(2)</sup> •
10.8	Nicholas Navarro Employment Agreement <sup>(11)</sup> •
10.9	Darrel Holmes Employment Agreement <sup>(2)</sup> •
10.10	Greg Juda Employment Agreement <sup>(14)</sup> •
10.11	Mitchell Godfrey Consulting Agreement <sup>(11)</sup> •
10.12	Credit Agreement dated August 24, 2012 by and between Bacterin and ROS Acquisition Offshore LP <sup>(12)</sup>
10.13	First Amendment to Credit Agreement dated May 16, 2013 by and between Bacterin and ROS Acquisition Offshore LP <sup>(15)</sup>
10.14	Waiver and Second Amendment to Credit Agreement dated August 12, 2013 by and between Bacterin and ROS Acquisition Offshore LP <sup>(16)</sup>
10.15	Waiver and Third Amendment to Credit Agreement dated August 12, 2013 by and between Bacterin and ROS Acquisition Offshore LP <sup>(16)</sup>
10.16	Fourth Amendment to Credit Agreement dated August 30, 2013 by and between Bacterin and ROS Acquisition Offshore LP <sup>(17)</sup>
10.17	Waiver and Fifth Amendment to Credit Agreement dated August 12, 2013 by and between Bacterin and ROS Acquisition Offshore LP <sup>(10)</sup>
10.18	Sixth Amendment to Credit Agreement dated March 6, 2014 by and between Bacterin and ROS Acquisition Offshore LP <sup>(18)</sup>
10.19	Royalty Agreement dated August 24, 2012 by and between Bacterin and ROS Acquisition Offshore LP <sup>(12)</sup>
10.20	First Amendment to Royalty Agreement dated August 12, 2013 by and between Bacterin and ROS Acquisition Offshore LP <sup>(16)</sup>
10.21	Form of Securities Purchase Agreement <sup>(13)</sup>
10.22	Form of Registration Rights Agreement <sup>(13)</sup>
14.1	Code of Conduct <sup>(4)</sup>
14.2	Code of Ethics for the CEO and Senior Financial Officials <sup>(4)</sup>
21.1	Subsidiaries of the Registrant <sup>(2)</sup>
23.1*	Consent of Independent Accounting Firm, EKS&H LLLP
31.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer

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

- Compensation Agreement
- \* Filed herewith
- \*\*Furnished herewith

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 July 11, 2013.
- (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 August 15, 2013.
- (9) Incorporated by reference to the Registrant's Registration Statement on Form S-8 filed with the SEC on September 19, 2013.
- (10) Incorporated by reference to the Registrant's Form 10-Q filed with the SEC on November 14, 2013.
- (11) Incorporated by reference to the Registrant's Form 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 August 28, 2012.
- (13) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on June 5, 2013.
- (14) Incorporated by reference to the Registrant's Form 10-Q filed with the SEC on May 4, 2012.
- (15) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on May 22, 2013.
- (16) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on August 13, 2013.

- (17) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on September 4, 2013.
  
- (18) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on March 10, 2014.