

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)

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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

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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

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this Form 10-K that are not purely historical are forward-looking statements within the meaning of applicable securities laws. Our forward-looking statements include, but are not limited to, statements regarding our “expectations,” “hopes,” “beliefs,” “intentions,” or “strategies” regarding the future. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should” and “would,” as well as 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 mater