Bacterin International Holdings, Inc.
Form 10-K
March 29, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2011

or

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

For the transition period from _____ to _____

Commission file number: 001-34951

Bacterin International Holdings, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or other jurisdiction of incorporation or organization)	20-5313323 (IRS Employer Identification No.)
600 Cruiser Lane Belgrade, Montana (Address of Principal Executive Offices)	59714 (Zip Code)

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the common stock held by non-affiliates as of June 30, 2011, the last day of the registrants most recently completed second fiscal quarter, was $69,258,526 (based on the closing price of the Company's common stock on that date, as reported on the NYSE Amex).

The number of shares of the Company's common stock, $0.000001 par value, outstanding as of March 13, 2012 was 42,076,553.

DOCUMENTS INCORPORATED BY REFERENCE

None

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

¨the ability of our sales force to achieve expected results;

¨government regulations;

¨fluctuations in our operating results;

¨government and third-party coverage and reimbursement for our products;

¨our ability to manage our growth;

¨our ability to successfully integrate future business combinations or acquisitions;

¨our ability to obtain regulatory approvals;

¨product liability claims and other litigation to which we may be subjected;

¨product recalls and defects;

¨timing and results of clinical trials;

¨our ability to obtain and protect our intellectual property and proprietary rights;

¨ infringement and ownership of intellectual property;

¨our ability to attract broker coverage;

¨ the trading market, market prices, dilution, and dividends of our common stock;

¨influence by our management; and

¨our ability to issue preferred stock.

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

PART I

Item 1. Business

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

Overview of Our Business

We develop, manufacture and market biologics products to domestic and international markets through our biologics division. Our products are used in a variety of applications including enhancing fusion in spine surgery, relief of back pain with a facet joint stabilization, promotion of bone growth in foot and ankle surgery, promotion of skull healing following neurosurgery and subcondral bone defect repair in knee and other joint surgeries.

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

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

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

Our Offices

Our headquarters, laboratory and manufacturing facilities are located at 600 Cruiser Lane, Belgrade, Montana 59714. Our telephone number is (406) 388-0480 and our fax number is (406) 388-0422. We also own a facility located at 664 Cruiser Lane, Belgrade, Montana 59714, and lease office space at 732 Cruiser Lane, Belgrade, Montana 59714 and 8310 S. Valley Highway, No. 300, Englewood, Colorado 80112.

Our History

We began operations in 1998 as a sole proprietorship founded by Guy Cook, our Chief Executive Officer, as a spinout of the Center for Biofilm Engineering at Montana State University, or the CBE. Mr. Cook is an expert in microbial testing methods and has been recognized by the U.S. Food and Drug Administration, or the FDA, industry, and academia for his contributions to the development of bioactive coatings. This sole proprietorship was eventually incorporated as "Bacterin, Inc." in the state of Montana in January 2000 to further Mr. Cook's work. In March 2004, Bacterin, Inc.'s stockholders completed the terms of a share exchange agreement with a company called Oil & Gas Seekers, Inc., a Nevada corporation, or OGS, which subsequently changed its name to "Bacterin International, Inc.", to effectively become a publicly-traded corporation. As a result of this transaction, the stockholders of Bacterin, Inc., the Montana corporation, became stockholders of Bacterin International, Inc., the Nevada corporation, and Bacterin, Inc., the Montana corporation, became a wholly owned subsidiary of Bacterin International, Inc., the Nevada corporation. At the end of 2004, management concluded that this transaction was problematic and did not deliver the expected result. Based on this determination, we entered into an agreement in 2005 to amend the terms of the exchange transaction with the former majority stockholder of OGS. In May 2005, we merged Bacterin, Inc., the Montana corporation, up and into Bacterin International, Inc., the Nevada corporation.

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

During 2008, we reached an important transition point in our history. Most of our business endeavors prior to that time had been devoted to developing our products with revenue generated from a variety of limited sources, including testing, government grants and unsubstantial product sales. In 2008, however, revenue from product sales either under our name or "private label" became our primary source of revenue. We no longer generate revenue from any private label arrangements.

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, created for purposes of effecting the Reverse Merger, and the stockholders of Bacterin International, Inc. obtained control of Bacterin International Holdings, Inc., f/k/a K-Kitz Incorporated, a Delaware corporation. 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, our corporate name was K-Kitz, Incorporated, and our trading symbol was KKTZ.OB. On June 29, 2010, we changed our corporate name to "Bacterin International Holdings, Inc." which name change became effective for trading purposes on July 1, 2010. Effective July 21, 2010, our trading symbol was changed from KKTZ.OB to BIHI.OB. On March 7, 2011, our common stock began trading on the NYSE Amex under the ticker symbol "BONE."

Recent Developments

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

Pursuant to the Purchase Agreement and Registration Rights agreement with LPC, we filed an S-3 Registration Statement which became effective on July 19, 2011, and we have the right to require LPC to purchase up to an additional $30 million of our common stock at prevailing market prices in limited daily amounts as specified under the terms of the Purchase Agreement. Although we did not draw on our equity line with LPC in 2011, during the first quarter of 2012, we issued approximately 1,475,037 shares of our common stock to LPC for aggregate proceeds of approximately $3,899,994. We intend to use the proceeds for working capital and general corporate purposes.

In consideration for entering into the Purchase Agreement, we issued 128,506 shares of our common stock to LPC as initial commitment shares and we agreed to issue up to 164,675 additional commitment shares on a pro rata basis when LPC purchases additional shares. We may terminate the Purchase Agreement at any time at our sole discretion without any cost to us.

On July 11, 2011, we acquired substantially all of the assets of Robinson MedSurg, LLC ("RMS") for $1 million of our common stock. In addition, we agreed to pay RMS an additional $500,000 in common stock if gross revenue from the sale of products resulting from the purchased assets equals or exceeds $1 million, and an additional $500,000 in common stock if gross revenue from the sale of products equals or exceeds $2 million, provided that such gross revenue thresholds are achieved within 2 years. The Company also engaged the sole member of RMS as a consultant.

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 initially, and gave us the ability to borrow up to an additional $8 million through December 31, 2011 in connection with a permitted acquisition (which did not occur). We also issued warrants to purchase 192,157 shares of the Company's common stock at an exercise price of $2.55 per share in connection with this transaction.

Industry and Market Overview

The orthopedic biomaterials market consists of materials that are organic, inorganic or synthetic in nature. These materials are implanted or applied in or near the indicated bone to facilitate healing, encourage bone tissue augmentation, compensate in areas where bone tissue is depleted and restore structure to allow for repair. Orthopedic biomaterials are capable of producing specific biological action or regenerative responses that are beyond what is observed in normal healing. These materials are often used as substitutes to autograft materials, which are taken from a harvest site in the patient to patch or repair the wounded or unhealthy site.

Bone is a biologically active tissue and may or may not regenerate depending on the condition of the patient. The damage may be significant enough that a scaffold to help regenerate the surgical site may be necessary. In 2009, the orthopedic biomaterials market was valued at almost $3.5 billion. This market is expected to grow at a CAGR of 8.9% by 2016. (Idata Research Inc. 2010, U.S. Market for Orthopedic Biomaterials).

Products and Services

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

Biologics Division

Our biologics products include OsteoSponge®, OsteoSponge®SC, OsteoWrap®, OsteoLock®, BacFast® and hMatrix® as well as certain other allograft products which are briefly described below:

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

- OsteoSponge®SC is a form of OsteoSponge® designed to be used in joint surgery. Bacterin has shown, in goat studies, the ability to re-generate cartilage in joint repair and believes that this product has the potential to significantly change the standard of care in human joint surgery. We have received permission from the FDA to market this product as a subchondral bone void filler and are currently marketing it as such. In order to market OsteoSponge®SC as a cartilage re-generation scaffold, we would need to obtain FDA approval to begin marketing for that indication. Surgeons are using the product and we have begun trials to establish the ability to market it as a cartilage re-generation scaffold. These trials are likely to take two years. There can be no assurance that these trials will be successful or lead to any FDA action.

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

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

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

In addition, we make and sell (i) sports allografts which are processed specifically for anterior and posterior cruciate ligament repairs, anterior cruciate ligament reconstruction and meniscal repair, (ii) milled allografts which are comprised of cortical bone milled to desired shapes and dimensions, also called milled spinal allografts, and (iii) traditional allografts for multi-disciplinary applications including orthopedics, neurology, podiatry, oral/maxillofacial, genitourinary and plastic/reconstructive.

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

Medical Device Products

Our medical devices division researches, tests and develops coatings for medical devices, particularly antimicrobial-based coatings. This division also produces and distributes OsteoSelect® DBM putty, an osteoinductive product used by surgeons as a bone void filler in the extremities and pelvis.

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

Our medical devices division also develops custom surgical instrument kits for use with allografts processed by our biologics division. These kits offer state-of-the-art instrumentation that is designed based upon the needs and inputs of surgeons who desire to use the most minimally invasive techniques. The instrumentation is intended to be an optimal delivery system for the proper placement of our proprietary allografts. Objectives of allograft use include pain relief, aid in the regeneration of tissue, and to provide a scaffold for bone fusion in spinal and sports medicine procedures. We currently sell a surgical drain series called ViaTM, which is used to drain exudate from a surgical site. Building upon the ViaTM platform, Bacterin created a second generation product called Elutia® surgical drains which are performance enhanced via an antimicrobial coating to help reduce the incidence of surgical site infection.

In a joint development project with RyMed, we treat RyMed's InVision-Plus CS™ with our patented antimicrobial technology. The InVision-Plus CS™ is the only needleless IV connector to offer the combined antibacterial protection of chlorhexidine and silver. The device is designed to reduce potentially deadly, catheter-related bloodstream infections. We receive a fixed price for each InVision-Plus CS™ unit sold by RyMed on all devices treated for RyMed.

Technology and Intellectual Property

Patents

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

- The delivery of bioactive agents impregnated into or onto metals, polymers or tissues which, when activated by bodily fluids, release the agent into the surrounding environment; and

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

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

Title	Business Purpose	First Inventor	Serial or Patent Number	Date Filed or Granted	Status
1. Pending U.S. Applications					
MEDICAL DEVICE INCLUDING A BIOACTIVE IN A NON-IONIC AND AN IONIC FORM AND METHODS OF PREPARATION THEREOF	This application arose out of a now defunct project. We retained rights as the technology may prove useful in the future. The patent describes the modification of elution profiles via active agent equilibration; it is potentially applicable to many coated products.	Mike Johnson	11/864,360	9/28/2007	Pending
ANTIMICROBIAL COATING FOR INHIBITION OF BACTERIAL ADHESION AND BIOFILM FORMATION	This application describes the coating used for the Elutia wound drain and for the Bard BioBloc coating on their HemoStar hemodialysis catheter. The efficacy period can be varied according to the desired outcome; the coating has shown in-vitro efficacy for between 7 and 21 days.	Guy Cook	10/891,885	7/15/2004	Pending

PROCESS FOR DEMINERALIZATION OF BONE MATRIX WITH PRESERVATION OF NATURAL GROWTH FACTORS	This application is intended to protect OsteoSponge, a core Bacterin product. OsteoSponge is a novel form of demineralized bone matrix which provides a natural scaffold for cellular growth and exposes bone growth inducing proteins to the healing environment in orthopedic applications.	Nancy J. Shelby	12/130,384	5/30/2008	Pending
SURGICAL KIT AND METHOD FOR BONE REPAIR	This application is intended to support the OsteoSponge SC Surgical Kit and Instruments. This surgical kit contains instruments that facilitate the placement of OsteoSponge in the subchondral region of articulating joints for the purpose of repairing defects.	Guy Cook	To Be Assigned	7/19/2011	Pending
COMPOSITION OF DEMINERALIZED BONE MATRIX WITH CONTRAST AGENT AND/OR BIOGLASS ADDITIVE	This application is intended to expand the potential applications for and enhance the performance of Bacterin's demineralized bone matrix products.	Gregory Juda	To Be Assigned	12/30/2011	Pending

COMPOSITION OF AND METHOD FOR FORMING REDUCED VISCOSITY POLYMERIC COATINGS	This application is intended to describe and protect several of our coating technologies, including those used on our orthopedic devices. These technologies are highly biocompatible and demonstrate excellent elution characteristics.	Mark Schallenberger	To Be Assigned	2/17/2012	Pending
ADJUSTABLE BIOACTIVE AGENT DISPERSION WITHIN A POLYMERIC COATING	This application is intended to describe and protect several of our coating technologies, including those used on our orthopedic devices. These technologies are highly biocompatible and demonstrate excellent elution characteristics.	Mark Schallenberger	To Be Assigned	2/17/2012	Pending
SURGICAL KIT WITH MULTIPLE POP-UP PRE-LOADABLE DRIVERS	This application describes a unique strategy for enhanced accessibility of pre-loaded surgical screw/driver units. This kit will drive our craniomaxillofacial business by providing a highly efficient means of accessing and implanting the surgical screws required in such procedures.	Mike Schneider	To Be Assigned	3/2/2012	Pending

2. Pending Foreign Applications					
MEDICAL DEVICE INCLUDING A BIOACTIVE IN A NON-IONIC AND AN IONIC FORM AND METHODS OF PREPARATION THEREOF	This application arose out of a now defunct project. We retained rights as the technology may prove useful in the future. The patent describes the modification of elution profiles via active agent equilibration and is potentially applicable to many coated products.	Mike Johnson	PCT/US2007/079924	9/28/2007	Pending
ANTIMICROBIAL COATING FOR INHIBITION OF BACTERIAL ADHESION AND BIOFILM FORMATION	This application describes the coating used for the Elutia wound drain and for the Bard BioBloc coating on their HemoStar hemodialysis catheter. The efficacy period can be varied according to the desired outcome; the coating has shown in-vitro efficacy for between 7 and 21 days.	Guy Cook	PCT/US2005/015162	4/28/2005	Issued in Australia, otherwise pending

PROCESS FOR DEMINERALIZATION OF BONE MATRIX WITH PRESERVATION OF NATURAL GROWTH FACTORS	This application is intended to protect OsteoSponge, a core Bacterin product. OsteoSponge is a novel form of demineralized bone matrix which provides a natural scaffold for cellular growth and exposes bone growth inducing proteins to the healing environment in orthopedic applications.	Nancy J. Shelby	PCT/US2008/006942	6/2/2008	Pending
AN ELASTOMERIC ARTICLE INCORPORATED WITH A BROAD SPECTRUM ANTIMICROBIAL	This application was generated as a means of protecting the technology used for impregnation of elastomeric medical devices. We have observed long term (over 30 days) in vitro efficacy with this technology.	Benjamin P. Luchsinger	PCT/US2009/005103	9/11/2009	Pending

We believe our patent filings and patent position will facilitate growth and enhance our proprietary core competencies, enabling us to protect and expand revenue growth and stockholder value in the future. We expect that additional patent applications will be filed and prosecuted as inventions are discovered, technological improvements and processes are developed and specific applications are identified. The status of individual patents and patent jurisdiction is maintained in our internal records. We anticipate, however, that there may be instances in which we enter into collaborative research and development agreements with medical device companies under such terms that the medical device company may or will retain a right to make future patent filings arising from such cooperative development agreement. In such instances, we will attempt to protect our overall patent use rights by agreements which limit the right of the collaborative party to an exclusive right only as it pertains to the field of use, as defined by the applicable project's scope of work. In this manner, we anticipate that we will receive future benefit and use of such intellectual property outside the field of use, as defined by any given scope of work. There can be no assurance that we will be able to obtain final approval of any patents.

Trademarks

We believe in the superiority of our technology and products. As a result, we have invested in the development and protection 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 registered trademarks to the following brand names of certain of our products: OsteoSponge®, OsteoWrap®, OsteoLock®, BacFast®, OsteoSelect®, Elutia® and hMatrix®.

Trade Secrets

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

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 are committed to building our direct sales channel into the primary method of distributing our products. We have one National Sales Manager and two executive vice-presidents to lead this effort and we have established 13 regions with a regional vice president in charge of all activities within the region. We have hired and trained 52 sales

representatives toward a near term goal of establishing four to five sales representatives in each region. While we incurred significant costs due to this initiative in 2009 through 2011, it is our expectation that this investment in the direct sales network will lead to higher revenue in 2012 and beyond. No assurance can be given that these efforts will be successful.

We also market our products through independent distributors who receive a discount off of our list price and then sell to their customer base. Because we have experienced a decline in revenue from this sales channel, we expect it will continue to represent a smaller portion of our overall revenue as our direct distribution channel grows.

Growth Strategy

After multiple years of product development, we believe that our technology has been largely market tested, and since 2009, we have been transitioning our focus to appropriately market and distribute our products. In preparing the business 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 the infrastructure of what we believe will grow into a formidable sales force, refined the message to our market and started gathering proof points on how to scale our revenue in these markets.

As discussed in “Sales and Marketing” above, we began implementing a direct sales network in July 2009. We have met our goal of growing this sales force to one National Sales Manager, two executive vice presidents, 13 regional vice presidents, and 52 sales representatives. In addition, we plan to utilize small independent sales representatives with entrenched physician relationships. We expect revenue to move towards 50% by employed sales representatives and 50% by independent sales representatives.

We are working on developing and implementing a high-level, national effort to present our products as a value proposition to hospital chains and other purchasing organizations. To this end, we have entered into agreements with Banner Hospitals, the Hospital for Special Surgery, MedAssets, ROi, and Access Mediquip. These agreements are paving the way for our sales representatives to call on physicians, as the hospital process has already been approved.

Competition

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

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

Specific competitors in the orthopedic biomaterials markets are: Medtronic, DePuy, Synthes, Arthrex, Smith & Nephew, Nuvasive, OrthoFix, Biomet, Osteotech, Orthovita, MTF, Stryker, RTI, AlloSource, Lifenet Health, Integra, ConMed/Linvatec, Wright, Exactech, ArthroCare, Harvest, and Arteriocyte. (Idata Research Inc. 2010, U.S. Market for Orthopedic Biomaterials).

Government Regulation

We produce human allografts that are regulated and comply with all the criteria under both Sections 361 and 351 of the Public Health Service Act. Compliance is determined by the FDA during the inspection of our production facility. To date, we have successfully completed all of our FDA inspections. We are registered with the FDA as a

manufacturer of human cellular and tissue products (HCT/Ps) as well as medical devices. We are an accredited member of the American Association of Tissue Banks in good standing. We meet all licensing requirements for the distribution of HCT/Ps in the States of Florida, California, Maryland and New York. We cannot predict the impact of future regulations on either us or our customers.

Human Tissue

Our human tissue products, which are sold through our biologics division, have been regulated by the FDA since 1993. In May 2005, three new, comprehensive regulations went into effect that address manufacturing activities associated with HCT/Ps. The first requires that companies that produce and distribute HCT/Ps register with the FDA. The second provides criteria that must be met for donors to be eligible to donate tissues and is referred to as the "Donor Eligibility" rule. The third rule governs the processing and distribution of the tissues and is often referred to as the "Current Good Tissue Practices" rule. Together, they are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients. Our HCT/P products such as OsteoSponge® are regulated by the Center for Biologics Evaluation and Research. Our OsteoSponge® and OsteoWrap® products are regulated as a HCT/P as determined by the Tissue Reference Group and regulated solely under Section 361 of the Public Health Service Act and 21 CFR Part 1271.

Medical Devices

Because our medical devices incorporate coating technologies, they are subject to regulation by the FDA. These medical devices require the approval of the FDA prior to sale within the United States. The manufacturers and licensees who use our coating technology in their medical devices will have the burden of demonstrating the safety and efficacy of the medical devices, a burden which we will assist such manufacturers and licensees in demonstrating to the extent our coating technologies are at issue. Sales of medical devices using our coating technology in the European Union will require the CE Mark certification and sales of such medical devices in Canada will 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, be made to the FDA to demonstrate that the medical device is safe and effective and is substantially equivalent to a legally marketed device that is not subject to pre-market approval. Applicants must compare the device to one or more similar devices that are commercially available in the U.S. (known as the "predicate device"), and make and support a claim of substantial equivalency to such predicate device. Support for such claims must include descriptive data and, when necessary, performance data. In some cases, data from clinical trials must also be submitted in support of a 510(k) Submission. The FDA must then issue an order finding substantial equivalency before the devices may be commercially distributed in the U.S. This process can take anywhere from three months to two or three years, and can be extremely expensive. The Center for Devices and Radiological Health regulates medical devices, including our OsteoSelect® DBM putty.

ISO Certification

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

Employees

As of March 5, 2012, we had 179 full-time employees and 184 total employees, of whom 72 were in production, 68 were in sales, 5 were in marketing, and 39 were in administrative functions. In addition, we make use of a varying number of outsourced services to manage normal business cycles. None of these employees is covered by a collective bargaining agreement and management considers relations with employees and services partners to be good.

Facilities

We lease approximately 16,000 square feet in a building located at 600 Cruiser Lane, Belgrade, Montana 59714. This space includes a clean room, fully equipped diagnostics laboratory, microbiology laboratory and testing laboratory. We lease the building under a ten-year operating lease which runs through August 2013 and has a monthly lease payment of $10,000. The lease also has a ten-year renewal option.

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 5 “Class 1,000” clean rooms 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 products, including our surgical drains (ViaTM and Elutia®), as well as production requirements for coated medical devices from our medical device partners. The facility is registered with the FDA for device design, device manufacture, and contract manufacture, as well as for screening, testing, storing, and distributing biological tissues.

We also lease space at 732 Cruiser Lane, Belgrade, Montana 59714 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.

Risks Related to Our Business and Our Industry

Our products are relatively new and long-term results are incomplete, thus, the future of our business still remains uncertain.

Many of our current products are relatively new and have been in use for a relatively short period of time. The results of the use of these products will be monitored for many years. While preliminary results have been good, there can be no assurance that any or all of these products will perform well over longer periods of time. Future product issues may expose us to legal actions, removal of regulatory approvals or products being pulled from use. If we become subject to product or general liability or errors and omissions claims, they could be time-consuming and costly. The U.S. Food and Drug Administration, or the FDA, and foreign regulatory authorities may impose significant restrictions on the use or marketing of our products or impose additional requirements. Later discovery of previously unknown problems with any of these products or their manufacture may result in further restrictions, including withdrawal of the product from the market. Any such restrictions or withdrawals could materially affect our ability to execute our business plan. In addition, governmental authorities could seize our inventory of products, or force us to recall any product already in the market if we, or any of our tissue bank suppliers, fail to comply with FDA or other governmental regulations.

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

Our business is in a very competitive and evolving field. Rapid new developments in this field have occurred over the past few years, and are expected to continue to occur. Other companies already have competing products available or about to be available or may develop products to compete with ours.

Many of these products may have short regulatory timeframes and our competitors, many with more substantial development resources, may be able to develop competing products that are equal to or better than ours. This may make our products obsolete or undesirable by comparison and reduce our revenue. Our success will depend, in large part, on our ability to maintain a competitive position concerning our intellectual property, and to develop new technologies and new applications for our technologies. Many of our competitors have substantially greater financial and technical resources, as well as greater production and marketing capabilities, than us.

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

Members of the medical community and the general public may perceive synthetic materials and growth factors as safer than our allograft-based bone tissue products.

Our products may be incapable of competing successfully with synthetic bone graft substitutes and growth factors developed and commercialized by others, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

We are highly dependent on the services of Guy Cook, our President and Chief Executive Officer, and other key members of our management team and the loss of his or any of their services could have an adverse effect on our future operations. We do not currently maintain a key-man life insurance policy insuring the life of Mr. Cook or any other member of our management team.

We are highly dependent on the continued availability of our facilities and would be harmed if they we