Bacterin International Holdings, Inc.
Form 10-K
April 11, 2011

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, 2010

or

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

For the transition period from to

Commission file number: 001-34951

Bacterin International Holdings, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	20-5313323
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
600 Cruiser Lane Belgrade, Montana	59714
(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 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. x

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, 2010, the last day of the registrants most recently completed second fiscal quarter, was $50,010,997 (based on the closing price of the Company's common stock on that date, as reported on the OTC.BB).

The number of shares of the Company's common stock, $0.000001 par value, outstanding as of March 17, 2011 was 37,659,410.

DOCUMENTS INCORPORATED BY REFERENCE

None

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 stateme 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," "estimat "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should" and "would," as well as sim 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 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;
- 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;
- 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;

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- 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 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.

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 we maintain an office at 8310 S. Valley Highway, No. 300, Englewood, Colorado 80112 and have sales employees located across the United States.

Our History

We began operations in 1998 as a sole proprietorship founded by Guy Cook, our President and 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 Holdings, 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 revenue sources including the following: sales from products developed and manufactured by us under our own label; 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 though we no longer generate revenue from any private label arrangements.

Recent Developments

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.

Pursuant to the terms of the Reverse Merger, the stockholders of Bacterin International, Inc. immediately preceding the Reverse Merger received one share of the Company's common stock for each two shares of Bacterin International, Inc. common stock such stockholder held prior to the Reverse Merger with the aggregate number of the Company's shares of common stock so issued to the Bacterin International, Inc. stockholders, being 28,257,133 shares (after rounding down fractional shares), representing approximately 96% of our outstanding common stock as of the closing

of the Reverse Merger on June 30, 2010, prior to taking into account the issuance of any shares of our common stock pursuant to the private placement described below. The remaining 4% of our common stock, or 1,180,596 shares, remained with the predecessor company's shareholders.

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.

Concurrently with the closing of the Reverse Merger, we completed an initial closing of a private placement to selected qualified investors of shares of our common stock at a purchase price of $1.60 per share and detachable warrants to purchase one-quarter share of our common stock for each share of our common stock purchased in the private placement (at an exercise price of $2.50 per share). In total, we sold 4,934,533 shares of our common stock and warrants to purchase 1,233,646 shares of common stock as part of this initial closing. We received gross proceeds of $7,508,329 in consideration for the sale of the shares of common stock and warrants, which consisted of (i) $4,026,000 in cash from investors in the private placement and (ii) $3,482,329 from note holders in two earlier Bacterin bridge financings (conducted to fund working capital and capital expenditures during the months prior to the Reverse Merger) who converted their outstanding principal and interest into the private placement at a 10% discount to the purchase price, being $1.44 per share, and received identical warrant coverage as the cash investors except that the exercise price of the converting note holders' warrants is $2.25 per share, a 10% discount to the exercise price of the warrants received by the cash investors. The note holders in the bridge financings also received warrants to purchase 1,482,256 shares of our common stock and our placement agent received warrants to purchase 328,125 shares of our common stock as part of our bridge financing.

In the second and final closing of this private placement on July 30, 2010, we sold a total of 1,102,500 additional shares of our common stock together with additional warrants to purchase an aggregate of 275,625 shares of our common stock for total gross cash proceeds of $1,764,000.

Our placement agents received an aggregate of $463,200 in cash fees in connection with the private placement ($322,080 from the initial closing and $141,120 from the second and final closing) and were reimbursed for their out-of-pocket-expenses. In addition, the placement agents received an aggregate of 106,217 shares of our common stock (84,167 shares from the initial closing and 22,050 shares from the second and final closing) and warrants to purchase 361,875 shares of our common stock (251,625 shares from the initial closing and 110,250 shares from the second and final closing) at an exercise price of $1.60 per share.

Following the private placement transaction, the Company has permitted an additional $450,000 in principal amount outstanding from the Bacterin bridge financings to convert into 316,823 shares of the Company's common stock and warrants to purchase 88,309 shares of the Company's common stock on the same terms as if such debt had actually converted in the private placement transaction. All other outstanding debt from those bridge financings that did not convert has been repaid.

In connection with the closing of the Reverse Merger, the Company repurchased 4,319,404 shares of its common stock from one of its stockholders for aggregate consideration of $100, as well as certain other good and valuable consideration, and Bacterin repurchased 77,029 shares of its common stock from certain of its stockholders for aggregate consideration of $123,245. Immediately after these repurchases, all of these shares were cancelled.

On August 6, 2010, we paid certain of Bacterin's former stockholders, who held approximately 743,940 shares of Bacterin common stock in the aggregate (or the equivalent of 371,970 shares of our common stock post-Reverse Merger), the fair value for such shares in connection with the exercise of their dissenters' rights. As a result, and pursuant to the terms of the agreement governing the Reverse Merger, the former Bacterin stockholders (excluding the dissenting shareholders) were issued 371,970 shares of our common stock (i.e. , the same number of shares that the dissenting stockholders would have received had they not exercised their dissenters rights) in proportion to such stockholders' pre-Reverse Merger share holding percentages in Bacterin.

On November 19, 2010, the Company entered into financing arrangement with two subsidiaries of Western Technology Investment ("WTI"), whereby WTI, through its subsidiaries, agreed to provide a credit facility which allows the Company to draw down $2.5 million initially, and gives the Company the ability to draw down an additional $2.5 million through April 30, 2011 provided the Company has achieved 90% of performance based milestones for the next two quarters. In addition, upon the mutual agreement of Bacterin and WTI, WTI has agreed to an additional commitment through December 31, 2011 of up to 25% of the next new round of equity financing or up to $3.0 million. The credit facility is secured by the Company's personal property and carries an all-in interest rate of 12.5%. Repayment of the initial $2.5 million will be interest only for the first six months, with principal and interest for the subsequent 30 months. The WTI facility also allows the company to obtain separate accounts receivable financing. In connection with the financing, WTI also received warrants to purchase up to 375,000 shares of the Company's common stock. The warrants have an exercise price of the lower of $4.00 per share or the price at which shares of the Company's stock are sold in the next qualified financing, if applicable prior to the date of exercise. The WTI warrants expire on April 30, 2018. WTI also has the right to receive additional warrants to purchase 125,000 shares of the Company's common stock at the same exercise price if the Company draws down the second $2.5 million tranche of the facility. In January 2011, Middlebury Securities LLC also received warrants to purchase 25,000 shares of our common stock for placement agent services in connection with the WTI transaction.

The Company also issued warrants to purchase a total of 489,710 shares of the Company's common stock to a limited group of existing investors who exercised existing warrants. The new warrants have an exercise price of $4.00 per share and expire on November 19, 2015. The Company received a total of $1,172,696 from the cash payments of the exercise price of the existing warrants.

The Company also issued 30,000 shares to a former executive in connection with a settlement agreement and converted the former executive's 100,000 stock options to an equivalent number of warrants.

Effective January 14, 2011, the Company entered into a Loan and Security Agreement with Bridge Bank, National Association ("Bridge Bank") whereby Bridge Bank agreed to provide a two year revolving credit facility which allows the Company to borrow up to the lesser of (i) 80% of the Company's accounts receivable, or (ii) $3 million, increasing to $5 million if the Company achieves two consecutive quarters of profitability of at least $4 million in the aggregate. Amounts advanced will carry interest at the Bridge Bank prime rate plus 2.25% (subject to a minimum prime rate of 4%) and will be secured by the Company's accounts receivable and other personal property.

Beginning March 7, 2011, the Company's 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 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, into 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® and BacFast®, 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 will need to obtain FDA approval to begin marketing for that indication. Surgeons are using the product and we are beginning trials to establish the ability to market it as a cartilage re-generation scaffold. These trials are likely to take two years and we will likely publish preliminary results of the study at six months and one year. There can be no assurance that these trials will be successful or lead to any FDA action. We have allocated approximately $750,000 to fund this clinical trial.

- 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. While this product is currently in production and use, Bacterin is initiating clinical studies to further support its effectiveness and we have allocated approximately $100,000 to fund these clinical trials. There can be no assurance of the success of these trials.

¨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 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 plans on releasing a second generation product called the Elutia® surgical drains which will be performance enhanced via an antimicrobial coating to help reduce the incidence of surgical site infection.

Our wound drain product is gaining attention at the VA Hospitals. During August 2010, we received notice that the Brook Army Medical Hospital in Texas, a level 1 trauma facility, will begin using our wound drain product system wide. This hospital currently reports that over fifty percent (50%) of post operative infections occur due to an uncoated wound drain that it is currently using. We are hopeful that over the next several months, our wound drain product will be distributed throughout the VA Hospital system. Our wound drain products sell into hospitals for $40 and cost us approximately $6 to produce.

On August 10, 2010, we announced that the FDA has cleared RyMed Technologies, Inc.'s InVision-Plus® CS™ needleless IV connector for commercialization. In a joint development project between RyMed and our company, the InVision-Plus CS™ is treated 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 will 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	Undergoing further examination
ANTIMICROBIAL COATING FOR INHIBITION OF BACTERIAL ADHESION AND BIOFILM FORMATION®	This application relates to 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	Non-final Office Action mailed 9/15/09; response submitted 12/15/09
PROCESS FOR DEMINERALIZATION OF BONE MATRIX WITH PRESERVATION OF NATURAL GROWTH FACTORS	This application is intended to protect OsteoSponge®, a core product produced by our Biologics division. OsteoSponge® is a novel form of demineralized bone matrix which	Nancy J. Shelby	12/130,384	5/30/2008	First examination: November 2010 (estimated)

	provides a natural scaffold for cellular growth and exposes bone growth inducing proteins to the healing environment.				

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	Preliminary Report on Patentability generated 3/13/09

ANTIMICROBIAL COATING FOR INHIBITION OF BACTERIAL ADHESION AND BIOFILM FORMATION	This application relates to 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	Entered National Phase in: Europe, Australia, Canada, Japan
PROCESS FOR DEMINERALIZATION OF BONE MATRIX WITH PRESERVATION OF NATURAL GROWTH FACTORS	This application is intended to protect OsteoSponge®, a core product produced by our Biologics division. 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.	Nancy J. Shelby	PCT/US2008/ 006942	6/2/2008	Entered national Phase in: Europe, Canada, Mexico, Korea
AN ELASTOMERIC ARTICLE INCORPORATED WITH A BROAD SPECTRUM ANTIMICROBIAL	This application was generated as a means of protecting the technology used for a forthcoming product. We have observed long term (over 30 days) in vitro efficacy with this technology.	Benjamin P. Luchsinger	PCT/US2009/ 005103	9/11/2009	Awaiting International Search Report (this application will enter the US through PCT)

3. In-Licensed Intellectual Property

SWOLLEN DEMINERALIZED BONE PARTICLES, FLOWABLE OSTEOGENIC COMPOSITION CONTAINING SAME AND USE OF THE COMPOSITION IN THE REPAIR OF OSSEOUS DEFECTS	This patent protects OsteoSelect®, Bacterin's DBM putty. OsteoSelect® has exceptional handling characteristics and can easily be molded into any shape and compressed into bony voids. Bacterin employs a low-dose, low-temperature sterilization process to provide maximum osteoinductive potential while maintaining device-level sterility.	Simon Bogdansky	5,284,655	2/8/1994	Granted - US Expires April 2011

FLOWABLE DEMINERALIZED BONE POWDER COMPOSITION AND ITS USE IN BONE REPAIR	This patent protects OsteoSelect®, Bacterin's DBM putty. OsteoSelect® has exceptional handling characteristics and can easily be molded into any shape and compressed into bony voids. Bacterin employs a low-dose, low-temperature sterilization process to provide maximum osteoinductive potential while maintaining device-level sterility.	Robert K. O'Leary	5,290,558	3/1/1994	Granted - US Expires April 2011

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®, and Elutia® and have recently applied to register 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 implemented our biologics division, among other reasons, to secure and process our own tissue, which posed initial challenges and associated operational disadvantages. At the time we embarked on this plan, we lacked donor sources, manufacturing capabilities, and distribution channels. We also lacked the vertical integration of an in-house tissue processing laboratory and were thus constrained by sub-contracting tissue processing to outside processors. These same sub-contractors are essentially suppliers of their own tissue to the marketplace and are hence ultimately our competitors. We have since successfully secured rights of first refusal of human tissue with multiple recovery agencies. Concurrent with this initiative, we also sought to secure future allograft production capability by constructing our own tissue processing facility. We have now begun efforts to expand our network for donor tissue in anticipation of increased production and believe that this effort, along with our current network of procurement agencies, will be sufficient to supply enough donors to meet our forecasted revenue volume through 2011 and beyond. We expect to be able to continue to build the network for donor tissue as the needs arise.

Sales and Marketing

We are committed to building our direct sales channel into the primary method of distributing our products. We have promoted three regional vice presidents to the role of executive vice-president to lead the North, South and West thirds of the United States and 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 and 2010, it is our expectation that this investment in the direct sales network will lead to higher revenue in 2011 and beyond. No assurance can be given that these efforts will be successful.

After 7 months of testing by Broadlane, Inc., the largest operator of healthcare supply chains in the United States, and its clients, we were accepted in May 2010 as an authorized vendor in its group purchasing program, which enables Broadlane's customers to purchase products from us. Our contract with Broadlane has a three year term and may be terminated by either party for breach of contract and Broadlane may terminate the agreement if Bacterin or any of Bacterin's key personnel is convicted of an offense related to health care or listed by a federal agency as being debarred, excluded, or otherwise in eligible for federal program participation. Broadlane manages approximately $10 billion in contract volume with over 6,000 medical facilities and 33,000 physician practices in its network. In June 2010, Broadlane issued a newsletter to its entire network showcasing and introducing Bacterin to all of its hospitals, independent delivery networks, ambulatory care and surgery centers. As a result of this contract, our sales force can now proceed to sell our products to this expansive network of doctors. We have already received our first order from Tenet Hospitals, which runs over 40 hospitals, and Advocates in Illinois, which manages approximately 25 hospitals.

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.

Within the medical devices division, our marketing strategy is to develop product development alliances with multinational medical device companies at the same time as we develop our own new products in fields or applications outside of the rights of our collaborative partners. We have implemented this strategy and are pursuing contract opportunities with other medical device companies.

Although we are in the process of discontinuing it, we also have a physician compensation program that compensates physicians for referring our products to other surgeons and medical care providers with whom they do not have a disqualifying "financial relationship" under applicable laws. These physicians, at our direction, refer us to other physicians and are paid a commission on all revenue generated by the referred physicians' use of our products. We have established procedures that are designed to prevent abuses involving these physicians and others with whom they have financial relationships and been advised by counsel that this program complies with the Stark laws and applicable anti-kickback regulations.

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. We have spent months preparing the business to capitalize on our core markets, as well as new market opportunities. In particular, 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 3 executive vice presidents, 13-15 regional vice presidents, and 52 sales representatives. We strive to hire sales representatives with deep industry experience and pre-existing contacts. 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, insurers and other purchasing organizations. To this end, we have already entered into agreements with Banner Hospitals, the Hospital for Special Surgery, Broadlane (a purchasing organization for 1,200 hospitals and other medical facilities), and Access Mediquip (a national purchasing organization for ambulatory

surgery centers). 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 held 27.1% of the market in 2009. Medtronic's lead is based on the strength of their Infuse® growth factor product. However, the growth potential of this product 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 that 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 29, 2011, we had 117 full-time employees, of whom 33 were in production, 66 were in sales, 2 were in marketing, and 16 were in administrative. In addition, we make use of a varying number of temporary employees and outsourced services to manage normal business cycles. None of these employees is covered by a collective bargaining agreement and our 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. In addition to our corporate headquarters, this space also 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 October 2013 and has a monthly lease payment of $10,000. The lease also has a ten-year renewal option.

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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 office space in Englewood, Colorado, where certain of our administrative and sales 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 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.

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

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

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

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

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

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

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

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

Future revenue will depend on our ability to develop new sales channels and there can be no assurance that these efforts will result in significant sales.

We are in the process of developing sales channels for our products but there can be no assurance that these channels can be developed or that we will be successful in selling our products. We currently sell our products through direct sales by our employees and indirectly through distributor relationships. We recently engaged in a major initiative to build and further expand our direct sales force. In 2010, we incurred sales and marketing expenses of approximately $8 million and expect this amount to be approximately $20 million in 2011. The increased sales and marketing expenses are anticipated to be funded from operating cash flow. The incurrence of these additional expenses may impact our operating results and there can be no assurance of their effectiveness. Many of our competitors have well-developed sales channels and it may be difficult for us to break through these competitors to take market share. If we are unable to develop these sales channels, we may not be able to grow revenue or maintain our current level of revenue generation.

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

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

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

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

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

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

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

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

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

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

We recently entered into a non-binding letter of intent to acquire substantially all of the assets of Robinson MedSurg LLC. There can be no assurance that we will complete this transaction or that the integration of this acquisition will be successful.

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

Although we are not currently subject to any product liability proceedings, and we have no reserves for product liability disbursements, we may incur material liabilities relating to product liability claims in the future, including product liability claims arising out of the usage of our products. We currently carry product liability insurance of up to $10 million at an annual premium cost of approximately $140,000, however, our insurance coverage and any reserves we may maintain in the future for product related liabilities may not be adequate and our business could suffer material adverse consequences.

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

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

Risks Related to the Regulatory Environment in which We Operate