Bacterin International Holdings, Inc.
Form POS AM
July 07, 2011
As filed with the Securities and Exchange Commission on July 7, 2011

File No. 333-169620

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

POST EFFECTIVE AMENDMENT NO. 2
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BACTERIN INTERNATIONAL HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	3841	20-5313323
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

600 Cruiser Lane
Belgrade, Montana 59714
(406) 388-0480
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

John P. Gandolfo
Chief Financial Officer
600 Cruiser Lane
Belgrade, Montana 59714
(406) 388-0480
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Jill Gilpin
VP and Legal Counsel
600 Cruiser Lane
Belgrade, Montana 59714
(406) 388-0480

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this

registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. þ

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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	¨ (Do not check if a smaller reporting company)	Smaller reporting company	þ

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)(2)	Proposed Maximum Offering Price Per Share (3)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, $0.000001 par value per share	11,296,112	$ 5.55	$ 62,693,421	$ 7,278.71(4)

(1) Pursuant to Rule 416 under the Securities Act, this registration statement also covers an indeterminate number of additional shares as may be issued as a result of adjustments by reason of any stock split, stock dividend, or similar transaction.

(2) Such shares are being registered for resale from time to time by certain selling stockholders and include 4,135,733 shares issuable upon the exercise of warrants.

(3) Estimated pursuant to Rule 457(c) solely for the purpose of calculating the amount of the registration fee based upon the average of the bid and asked prices of the registrant’s common stock on February 8, 2011 as reported on the OTCBB and OTCQB Marketplace.

(4) The registration fee was previously paid

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the

Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Explanatory Note

This Post Effective Amendment No. 2 to Registration Statement on Form S-1 (File No. 333-169620) contains updated information previously provided in periodic reports filed by the Registrant with the Securities and Exchange Commission.

The information in this prospectus is not complete and may be changed. The selling security holders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED _____, 2011

PROSPECTUS

11,296,112 Shares

Common Stock

The stockholders of Bacterin International Holdings, Inc. listed in this prospectus are offering for sale up to 11,296,112 shares of common stock, which includes up to 4,135,733 shares of common stock issuable upon the exercise of warrants.

We expect that sales made pursuant to this prospectus will be made through ordinary brokerage transactions, in privately negotiated sales or through any other means described in the section titled “Plan of Distribution.”

We will not receive any of the proceeds of sales by the selling stockholders. We will pay the expenses incurred to register the shares for resale, but the selling stockholders will pay any underwriting discounts, concessions, or brokerage commissions associated with the sale of their shares of common stock.

The selling stockholders will determine when they will sell their shares, and in all cases they will sell their shares at the current market price or at negotiated prices at the time of the sale. Securities laws and SEC regulations may require the selling stockholders to deliver this prospectus to purchasers when they resell their shares of common stock.

Our common stock is listed on the NYSE Amex under the symbol “BONE.” On June 30, 2011, the last reported asked price of our common stock was $2.84 per share.

Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page 4 of this prospectus for a discussion of information that should be considered in connection with an investment in our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2011

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

PROSPECTUS SUMMARY

This summary highlights certain information appearing elsewhere in this prospectus. For a more complete understanding of this offering, you should carefully read the entire prospectus and the registration statement of which this prospectus is a part, including the risk factors and the financial statements. Unless the context otherwise requires, "we," "our," "us," "our company" and similar expressions used in this prospectus refer to Bacterin International, Inc., a Nevada corporation, or Bacterin, prior to the closing of the Reverse Merger, as defined below, on June 30, 2010, and Bacterin International Holdings, Inc., f/k/a K-Kitz, Inc., a Delaware corporation, or the Company, as successor to the business of Bacterin, following the closing of the Reverse Merger transaction.

Bacterin International Holdings, Inc.

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.

The manufacturing and operations of the biologics and device divisions are organized separately while products from both are marketed through several channels including independent distributors, joint development projects and our direct sales network which we began to implement in the last half of 2009. To date, we have established 13 regions with a regional vice-president in charge of all activities within the region and have hired and trained 52 sales representatives. Our customers are located worldwide, with approximately 97% of our 2010 sales being derived from customers located in the United States. Our headquarters, laboratory and manufacturing facilities are located in Belgrade, Montana.

Recent Developments

On June 30, 2010, we completed a reverse merger transaction, or the Reverse Merger, in which we caused Bacterin to be merged with and into a wholly-owned Nevada subsidiary created for purposes of effecting the Reverse Merger, and the stockholders of Bacterin obtained control of the Company. 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 became our wholly owned subsidiary and we are now engaged, through Bacterin, in the business of biomaterials research, development, and commercialization.

Pursuant to the terms of the Reverse Merger, the stockholders of Bacterin immediately preceding the Reverse Merger received one share of the Company's common stock for each two shares of Bacterin 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 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, and the holders of 180,596 of those shares are included as selling stockholders in this registration statement.

Before the Reverse Merger, our corporate name was K-Kitz, Inc., 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.

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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 79,206 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) are entitled to be 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. 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 the fifth anniversary of the date of issuance. 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 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."

The Company recently raised $3,027,504 in a private placement transaction, which resulted in the issuance of 939,377 shares of the Company's common stock and warrants to purchase 375,742 shares of the Company's common stock. The transaction was funded in three tranches and priced at market value on the date each tranche was submitted to NYSE Amex for approval. The warrants have a market value exercise price and are exercisable over the next five years, subject to a six month holding period. Middlebury Securities LLC received $20,000 in connection with the participation of certain investors.

On May 27, 2011, we signed a Purchase Agreement with Lincoln Park Capital Fund, LLC ("LPC") whereby, following the effectiveness of a registration statement we plan to file with the SEC covering the shares that may be issued to LPC under the Purchase Agreement, we have the right, in our sole discretion, over a 36-month period to sell up to $30 million of our common stock to LPC.

Our Offices

Our executive offices are located at 600 Cruiser Lane, Belgrade, Montana 59714 and our telephone number is (406) 388-0480. Our website is located at www.bacterin.com . The information contained on our website does not constitute part of this prospectus.

Through our website, we make available free of charge our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section

13(a) or 15(d) of the Securities Exchange Act of 1934. These reports are available as soon as reasonably practicable after we electronically file those materials with the Securities and Exchange Commission, or SEC. When available, we also expect to post on our website investor presentations and webcast earnings calls and transcripts, in addition to the charters of our committees of our Board of Directors; our Corporate Governance Guidelines, our Code of Ethics, and any amendments or waivers thereto; and any other corporate governance materials contemplated by SEC regulations. The documents are available in print by contacting our corporate secretary at our executive offices.

The Offering

Common stock offered by the selling stockholders	11,296,112 shares, which includes up to 4,135,733 shares of common stock issuable upon the exercise of warrants.
Use of proceeds	We will not receive any of the proceeds of sales of common stock by the selling stockholders. To the extent we receive any proceeds from the exercise of warrants by the selling stockholders, we expect to use such proceeds for working capital and other general corporate purposes. However, such warrants contain a “cashless” exercise provision, so there can be no assurance that we will receive any proceeds upon the exercise of warrants.
Risk factors	See “Risk Factors” and other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in shares of our common stock.
NYSE Amex Symbol	BONE

RISK FACTORS

Before you invest in our common stock, you should be aware that there are risks, including those set forth below. You should carefully consider these risk factors, together with all the other information included in this prospectus, before you decide to purchase shares of our common stock.

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.

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

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

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

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

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

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

Medical devices that incorporate coatings technology are subject to FDA regulation and compliance. Generally, any medical device manufacturer that wishes to incorporate our coatings technology into its products will be responsible for obtaining FDA approval for the medical devices it intends to market though we will assist in the 510(k) filing submitted by licensees. The FDA process can take several months to several years in the United States. The time required to obtain approval for international sales may be longer or shorter, depending on the laws of the particular country. There can be no assurance that our licensees will be able to obtain FDA or international approval on a timely basis. The FDA may also require the more extensive Premarket Approval Application, or PMA, process for certain products, which results, in effect, in a private license being granted to the applicant for marketing a particular medical device and requires an additional level of FDA scientific review to ensure the safety and effectiveness of such

devices. Approval or clearance may place substantial restrictions on the indications for which the product may be marketed or to whom it may be marketed, warnings that may be required to accompany the product or additional restrictions placed on the sale and/or use of the product. Changes in regulations or adoption of new regulations could also cause delays in obtaining product approval. In addition, regulatory approval is subject to continuing compliance with regulatory standards, and product approval is subject to withdrawal if a licensee fails to comply with standards, or if an unforeseen event should occur concerning a product. Significant delays in obtaining product approval could have a significantly detrimental impact on our business.

Human tissues intended for transplantation have been regulated by the FDA since 1993. In May 2005, three new comprehensive regulations went into effect that address manufacturing activities associated with