Bacterin International Holdings, Inc.
Form 10-Q
November 14, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2013

OR

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

For the transition period from to

Commission file number: 001-34951

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

Delaware	20-5313323
(State or other jurisdiction of incorporation or organization)	(I.R.S. 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)

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 (§232.405 of this chapter) 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 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

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

Number of shares of common stock, $0.000001 par value, of registrant outstanding at November 13, 2013: 51,744,136

BACTERIN INTERNATIONAL HOLDINGS, INC.
FORM 10-Q

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this Form 10-Q 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," "plans," or "strategies" regarding the future. In addition statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "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-Q may include, for example, statements about:

- the future performance and market acceptance of our products;
- our ability to maintain our competitive position;
- negative media publicity;
- our ability to obtain donor cadavers for our products;
- our ability to expand our production capacity;
- our efforts to innovate and develop new products;
- our ability to engage and retain qualified technical personnel and members of our management team;
- our reliance on our current facilities;
- our ability to generate funds or raise capital to finance our growth;
- the ability of our sales force to achieve expected results;
- government regulations and additional taxes;
- fluctuations in our operating results;
- government and third-party coverage and reimbursement for our products;
- our ability to manage our growth and our ability to scale expenses accordingly;
- our ability to meet the obligations of our secured lending facility;
- our ability to manage our cash flow and achieve profitability;
- our ability to successfully conclude government investigations;
- our ability to successfully integrate future business combinations or acquisitions;
- our ability to obtain regulatory approvals;
- product liability claims and other litigation to which we may be subjected;

- product recalls and defects;
- timing and results of clinical trials;
- our ability to obtain and protect our intellectual property and proprietary rights;

- infringement and ownership of intellectual property;
- our ability to attract broker coverage;
- the trading market, market prices and dilution of our common stock;
- our ability to remain listed on the NYSE MKT exchange;
- influence by our management; and
- our ability to issue preferred stock.

The forward-looking statements contained in this Form 10-Q 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 this Quarterly Report on Form 10-Q. 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 - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BACTERIN INTERNATIONAL HOLDINGS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	As of September 30, 2013 (Unaudited)	As of December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 3,437,549	$ 4,926,066
Trade accounts receivable, net of allowance for doubtful accounts of $1,297,335 and $1,576,955, respectively	4,633,067	7,154,065
Inventories, net	13,228,383	13,141,421
Prepaid and other current assets	486,685	353,271
Total current assets	21,785,684	25,574,823
Non-current inventories	1,238,225	1,238,225
Property and equipment, net	5,320,992	5,234,867
Intangible assets, net	563,524	592,378
Goodwill	728,618	728,618
Other assets	1,401,854	1,126,643
Total Assets	$ 31,038,897	$ 34,495,554
LIABILITIES & STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	$ 3,225,377	$ 3,997,789
Accounts payable - related party	555,361	418,922
Accrued liabilities	1,814,472	2,400,090
Warrant derivative liability	2,223,332	984,356
Current portion of capital lease obligations	165,844	149,729
Current portion of royalty liability	820,500	698,408
Current portion of long-term debt	47,018	45,135
Total current liabilities	8,851,904	8,694,429
Long-term Liabilities:		
Capital lease obligation, less current portion	119,543	245,703
Long term royalty liability, less current portion	6,639,435	6,839,935
Long-term debt, less current portion	16,064,064	14,483,102
Total Liabilities	31,674,946	30,263,169
Commitments and Contingencies		
Stockholders' Equity		
Preferred stock, $.000001 par value; 5,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock, $.000001 par value; 95,000,000 shares authorized; 51,781,044 shares issued and outstanding as of September 30, 2013 and	52	43

42,877,770 shares issued and outstanding as of December 31, 2012				
Additional paid-in capital		55,558,330		51,897,890
Accumulated deficit		(56,194,431)		(47,665,548)
Total Stockholders' (Deficit) Equity		(636,049)		4,232,385
Total Liabilities & Stockholders' (Deficit) Equity	$	31,038,897	$	34,495,554

See notes to unaudited condensed consolidated financial statements.

BACTERIN INTERNATIONAL HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Revenue				
Tissue sales	$ 7,710,256	$ 8,643,299	$ 24,430,158	$ 24,427,853
Royalties and other	219,727	236,466	385,480	430,185
Total Revenue	7,929,983	8,879,765	24,815,638	24,858,038
Cost of tissue and medical devices sales	3,318,327	2,600,452	10,011,687	6,788,606
Gross Profit	4,611,656	6,279,313	14,803,951	18,069,432
Operating Expenses				
General and administrative	2,764,328	2,439,229	7,877,697	7,349,852
Sales and marketing	4,053,679	3,352,394	12,057,389	11,333,946
Depreciation and amortization	97,923	88,112	304,771	302,392
Non-cash consulting expense	43,153	186,867	11,924	491,051
Total Operating Expenses	6,959,083	6,066,602	20,251,781	19,477,241
(Loss) Income from Operations	(2,347,427)	212,711	(5,447,830)	(1,407,809)
Other Income (Expense)				
Interest expense	(1,197,370)	(867,894)	(3,436,006)	(1,276,946)
Change in warrant derivative liability	(849,288)	(125,972)	246,337	1,393,155
Other income (expense)	17,551	(1,738,202)	108,616	(1,544,035)
Total Other Expense	(2,029,107)	(2,732,068)	(3,081,053)	(1,427,826)
Net Loss Before (Provision) Benefit for Income Taxes	(4,376,534)	(2,519,357)	(8,528,883)	(2,835,635)
(Provision) Benefit for Income Taxes				
Current	-	-	-	-
Deferred	-	-	-	-
Net Loss	$ (4,376,534)	$ (2,519,357)	$ (8,528,883)	$ (2,835,635)
Net loss per share:				
Basic	$ (0.08)	$ (0.06)	$ (0.18)	$ (0.07)
Dilutive	$ (0.08)	$ (0.06)	$ (0.18)	$ (0.07)
Shares used in the computation:				
Basic	51,616,319	42,796,244	46,611,358	42,341,796
Dilutive	51,616,319	42,796,244	46,611,358	42,341,796

See notes to unaudited condensed consolidated financial statements.

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BACTERIN INTERNATIONAL HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine months ended September 30,	
	2013	2012
Operating activities:		
Net income (loss)	$ (8,528,883)	$ (2,835,635)
Noncash adjustments:		
Depreciation and amortization	586,771	577,145
Amortization of debt discount	917,153	228,505
Write-off of debt discount	-	139,228
Non-cash consulting expense/stock option expense	603,058	1,114,846
Warrants issued for services	-	342,485
Non-cash interest	(78,408)	50,659
Provision for losses on accounts receivable and inventory	1,197,669	136,637
(Gain) loss on disposal of assets	(500)	7,902
Change in derivative warrant liability	(246,337)	(1,393,155)
Reduction of contingent liability	(91,740)	(358,426)
Changes in operating assets and liabilities:		
Accounts receivable	970,971	(237,841)
Inventories	265,396	(5,092,496)
Prepaid and other assets	291,375	(957,628)
Accounts payable	(635,973)	1,316,973
Accrued liabilities	(428,751)	(848,488)
Net cash used in operating activities	(5,178,199)	(7,809,289)
Investing activities:		
Purchases of property and equipment	(633,393)	(1,216,723)
Intangible asset additions	(10,149)	-
Net cash used in investing activities	(643,542)	(1,216,723)
Financing activities:		
Proceeds from the issuance of long-term debt	-	22,741,719
Payments on long-term debt	(34,308)	(9,773,075)
Payments on capital leases	(110,045)	(21,085)
Net proceeds from issuance of stock	4,450,002	3,899,996
Proceeds from exercise of options	27,575	43,334
Net cash provided by financing activities	4,333,224	16,890,889
Net change in cash and cash equivalents	(1,488,517)	7,864,877
Cash and cash equivalents at beginning of period	4,926,066	751,111
Cash and cash equivalents at end of period	$ 3,437,549	$ 8,615,988

See notes to unaudited condensed consolidated financial statements.

Notes to Unaudited Condensed Consolidated Financial Statements

(1) Business Description and Summary of Significant Accounting Policies

Business Description

The accompanying consolidated financial statements include the accounts of Bacterin International Holdings, Inc., a Delaware corporation, and its wholly owned subsidiary, Bacterin International, Inc., a Nevada corporation, (collectively, the "Company" or "Bacterin"). All intercompany balances and transactions have been eliminated in consolidation. Bacterin's biologics division develops, manufactures and markets biologics products to domestic and international markets. Bacterin's proprietary methods are used in human allografts to create cell scaffolds and promote bone and other tissue growth. These products are used in a variety of applications including enhancing fusion in spine surgery, relief of back pain with a facet joint stabilization, promotion of bone growth in foot and ankle surgery, promotion of skull healing following neurosurgery and regeneration in knee and other joint surgeries.

Bacterin's device division develops and licenses coatings for various medical device applications.

An operating segment is a component of an enterprise whose operating results are regularly reviewed by the enterprise's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance. The primary performance measure used by management is net income or loss. The Company operates in two distinct lines of business consisting of the biologics and devices divisions. However, due to the immaterial revenue from devices to date, the Company reports as one segment.

The Company's revenue is derived principally from the sale or license of its medical products, coatings and device implants. The markets in which the Company competes are highly competitive and rapidly changing. Significant technological advances, changes in customer requirements, or the emergence of competitive products with new capabilities or technologies could adversely affect the Company's operating results. The Company's business could be harmed by a decline in demand for, or in the prices of, its products or as a result of, among other factors, any change in pricing or distribution model, increased price competition, changes in government regulations or a failure by the Company to keep up with technological change. Further, a decline in available tissue donors could have an adverse impact on our business.

The accompanying interim condensed consolidated financial statements of Bacterin for the three and nine months ended September 30, 2013 and 2012 are unaudited and are prepared in accordance with accounting principles generally accepted in the United States of America. They do not include all disclosures required by generally accepted accounting principles for annual financial statements, but in the opinion of management, include all adjustments, consisting only of normal recurring items, necessary for a fair presentation. Interim results are not necessarily indicative of results which may be achieved in the future for the full year ending December 31, 2013.

These financial statements should be read in conjunction with the financial statements and notes thereto which are included in Bacterin's Annual Report on Form 10-K for the year ended December 31, 2012. The accounting policies set forth in those annual financial statements are the same as the accounting policies utilized in the preparation of these financial statements, except as modified for appropriate interim financial statement presentation.

Concentrations and Credit Risk

The Company's accounts receivable are due from a variety of health care organizations and distributors throughout the world. Approximately 98% and 97% of sales were in the United States for the nine months ended September 30, 2013 and 2012, respectively. One customer accounted for approximately 5% and 6% of the Company's revenue for the nine months ended September 30, 2013 and 2012, respectively. One customer represented 19% and 21% of gross accounts

receivable at September 30, 2013 and 2012, respectively. The Company provides for uncollectible amounts when specific credit issues arise. Management believes its estimate for uncollectible amounts have been adequate during prior periods, and management believes that all significant credit risks have been identified at September 30, 2013.

Revenue by geographical region is as follows:

	Nine months ended September 30,	
	2013	2012
United States	$ 24,285,028	$ 24,084,836
Rest of World	530,610	773,202
	$ 24,815,638	$ 24,858,038

Use of Estimates

The preparation of the financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the period; the carrying amount of property and equipment and intangible assets; valuation allowances for trade receivables and deferred income tax assets; valuation of the warrant derivative liability; inventory reserve; contingent consideration from acquisitions; royalty liability; and estimates for the fair value of stock options grants and other equity awards upon which the Company determines stock-based compensation expense. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity date of three months or less to be cash equivalents. Cash equivalents are recorded at cost, which approximates market value. At times the Company maintains deposits in financial institutions in excess of federally insured limits.

Accounts Receivable

Accounts receivable represents amounts due from customers for which revenue has been recognized. Normal terms on trade accounts receivable are net 30 days and some customers are offered discounts for early pay. The Company performs credit evaluations when considered necessary, but generally does not require collateral to extend credit.

The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing receivables. The Company determines the allowance based on factors such as historical collection experience, customer's current creditworthiness, customer concentration, age of accounts receivable balance, general economic conditions that may affect a customer's ability to pay and management judgment. Actual customer collections could differ from estimates. Account balances are charged to the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. Provisions to the allowance for doubtful accounts are charged to expense. The Company does not have any off-balance sheet credit exposure related to its customers.

Accounts Payable - Related Party

Accounts payable to a related party includes amounts due to American Donor Services, a supplier of donors to the Company. See Note 14, “Related Party Transactions” below.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using the specific identification method and includes materials, labor and overhead. The Company calculates an inventory reserve for estimated obsolescence or excess inventory based on historical usage and sales, as well as assumptions about future demand for its products. These estimates for excess and obsolete inventory are reviewed and updated on a quarterly basis. Increases in the inventory reserves result in a corresponding expense, which is generally recorded to cost of tissue and medical devices sales. Inventories where the sales cycle is estimated to be beyond twelve months are classified as Non-current inventories.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally three to seven years for computers and equipment, and 30 years for buildings. Leasehold improvements are depreciated over the shorter of their estimated useful life or the remaining term of the lease. Repairs and maintenance are expensed as incurred.

Goodwill

Goodwill represents the excess of costs over fair value of assets of businesses acquired. Goodwill and intangible assets acquired in a purchase business combination and determined to have indefinite useful lives are not amortized, instead are tested for impairment at least annually and whenever events or circumstances indicate the carrying amount of the asset may not be recoverable. In its evaluation of goodwill, the Company performs an assessment of qualitative factors to determine if it is more-likely-than-not that goodwill might be impaired and whether it is necessary to perform the two-step goodwill impairment. The Company conducts its annual impairment test on December 31 of each year.

Derivative Instruments

The Company accounts for its derivative instruments in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 815 "Accounting for Derivative Instruments and Hedging Activities". The only derivative instruments presented in the accompanying consolidated financial statements relates to warrants issued in connection with certain debt financings. The Company has not designated its warrant derivative liability as a hedging instrument as described in ASC 815 and any changes in the fair market value of the warrant derivative liability are recognized in the consolidated statement of operations during the period of change. See Note 10, "Warrants" below.

Intangible Assets

Intangible assets with estimable useful lives must be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment whenever events or circumstances indicate their carrying amount may not be recoverable. Intangible assets include trademarks, customer lists and patents and include costs to acquire and protect Company patents. Intangible assets are carried at cost less accumulated amortization. The Company amortizes these assets on a straight-line basis over their estimated useful lives of five years for customer lists and 15 years for all other intangible assets.

Revenue Recognition

Revenue is recognized when all of the following criteria are met: a) the Company has entered into a legally binding agreement with the customer; b) the products or services have been delivered; c) the Company's fee for providing the products and services is fixed or determinable; and d) collection of the Company's fee is probable.

The Company's policy is to record revenue net of any applicable sales, use, or excise taxes. If an arrangement includes a right of acceptance or a right to cancel, revenue is recognized when acceptance is received or the right to cancel has expired.

The Company ships to certain customers under consignment arrangements whereby the Company's product is stored by the customer. The customer is required to report the use to the Company and upon such notice, the Company invoices the customer and revenue is recognized when above criteria has been met.

The Company also receives royalty revenue from third parties related to licensing agreements. The Company has royalty agreements with Nufix, RyMed and Bard Access Systems. Revenue under these agreements represented less than 1% of total revenue for the three and nine months ended September 30, 2013 and 2012.

Non-Cash Consulting Expense

From time to time, the Company issues restricted stock awards to consultants and advisors to the Company. These awards are measured at fair value at each reporting date, recognized ratably over the vesting period and are recorded in non-cash consulting expense.

Advertising Costs

The Company expenses advertising costs as incurred. The Company had no Advertising expense in the nine months ended September 30, 2013 and $50,000 for the nine months ended September 30, 2012.

Research and Development

Research and development costs, which are principally related to internal costs for the development of new technologies and processes for tissue and coatings, are expensed as incurred and included in general and administrative expenses.

Income Taxes

The Company accounts for income taxes under the asset and liability method of accounting for deferred taxes as prescribed under FASB ASC 740, Accounting for Income Taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. When applicable, a valuation allowance is established to reduce any deferred tax asset when it is determined that it is more likely than not that some portion of the deferred tax asset will not be realized. ASC 740 also requires reporting of taxes based on tax positions that meet a more-likely-than-not standard and that are measured at the amount that is more-likely-than-not to be realized. Differences between financial and tax reporting which do not meet this threshold are required to be recorded as unrecognized tax benefits. ASC 740 also provides guidance on the presentation of tax matters and the recognition of potential IRS interest and penalties. The Company classifies penalty and interest expense related to income tax liabilities as an income tax expense. There are no significant interest and penalties recognized in the statement of operations or accrued on the balance sheet. See Note 12, “Income Taxes” below.

Long-Lived Assets

Long-lived assets, including intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. No impairment was recorded during the nine months ended September 30, 2013 or 2012.

Net Loss Per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. Diluted net income (loss) per share is computed in a manner consistent with that of basic earnings per share while giving effect to all potentially dilutive common shares outstanding during the period, which include the assumed exercise of stock options and warrants using the treasury stock method. Diluted net loss per share was the same as basic net loss per share for the nine months ended September 30, 2013 and 2012 and the three months ended September 30, 2013 and 2012 as shares issuable upon the exercise of stock options and warrants were anti-dilutive as a result of the net losses incurred for those periods.

Stock-Based Compensation

The Company records stock-compensation expense according to the provisions of ASC 718. Under ASC 718, stock-based compensation costs are recognized based on the estimated fair value at the grant date for all stock-based awards. The Company estimates grant date fair values using the Black-Scholes-Merton option pricing model, which requires assumptions of the life of the award and the stock price volatility over the term of the award. The Company records compensation cost of stock-based awards using the straight line method, which is recorded into earnings over the vesting period of the award. Pursuant to the income tax provisions included in ASC 718-740, the Company has elected the “short cut method” of computing its hypothetical pool of additional paid-in capital that is available to absorb future tax benefit shortfalls.

Fair Value of Financial Instruments

The carrying values of financial instruments, including trade accounts receivable, accounts payable, other accrued expenses and long-term debt, approximate their fair values based on terms and related interest rates.

We follow a framework for measuring fair value. The framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy are described below:

Level 1: Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets.

Level 2: Inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.

Level 3: Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. During the nine months ended September 30, 2013 and 2012, there was no reclassification in financial assets or liabilities between Level 1, 2 or 3 categories.

The following tables set forth by level, within the fair value hierarchy, our assets and liabilities as of September 30, 2013 and December 31, 2012 that are measured at fair value on a recurring basis:

Accrued stock compensation

	As of September 30, 2013	As of December 31, 2012
Level 1	$ 171,174	$ 218,850
Level 2	-	-
Level 3	-	-

The valuation technique used to measure fair value of the accrued stock compensation is based on quoted stock market prices.

Warrant derivative liability

	As of September 30, 2013	As of December 31, 2012
Level 1	-	-
Level 2	-	-
Level 3	$ 2,223,332	$ 984,356

Acquisition contingent consideration liability

	As of September 30, 2013	As of December 31, 2012
Level 1	-	-
Level 2	-	-
Level 3	$ -	$ 91,740

The valuation technique used to measure fair value of the warrant liability is based on a lattice model and significant assumptions and inputs determined by the Company.

Level 3 Changes

The following is a reconciliation of the beginning and ending balances for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the nine months ending September 30, 2013:

Warrant derivative liability	
Balance at January 1, 2013	$984,356
Gain recognized in earnings	(246,337)
New warrants issued	1,485,313
Balance at September 30, 2013	$2,223,332

Acquisition contingent consideration liability	
Balance at January 1, 2013	$91,740
Gain recognized in earnings	(91,740)
Balance at September 30, 2013	$-

During the nine months ended September 30, 2013, the Company did not change any of the valuation techniques used to measure its liabilities at fair value.

Items measured at fair value on a non-recurring basis:

The Company’s royalty liability is carried at its estimated fair value based upon the discounted present value of the payments using an estimated discount rate. The Company did not have access to a readily traded market for similar credit risks and the estimated interest rate was based upon the Company’s estimate of a market interest rate to obtain similar financing. The Company originally discounted the $16.8 million of estimated payments at an interest rate of 16.7%. This was adjusted to an estimated royalty total of $13.8 million as of December 31, 2012 and was not adjusted in the first nine months of 2013. Accordingly, these inputs are classified as Level 3 inputs.

Recent Accounting Pronouncements

There are no recently issued accounting standards for which the Company expects a material impact to its consolidated financial statements.

(2) Equity

During the first quarter of 2012, we issued 1,475,037 shares of our common stock to Lincoln Park Capital for aggregate proceeds of $3,899,996. We used the proceeds for working capital and general corporate purposes.

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

(3) Acquisition

In 2011, the Company acquired the assets of a medical devices company. As part of the purchase agreement, we agreed to pay an additional $500,000 in common stock if gross revenue from the sale of products resulting from the purchased assets equaled or exceeded $1 million, and an additional $500,000 in common stock if gross revenue from the sale of products resulting from the purchased assets equaled or exceeded $2 million, provided that such gross revenue thresholds were achieved within 2 years. The revenue thresholds were not achieved within 2 years of the asset acquisition, so no additional stock issuances were required.

The initial valuation of the contingent consideration was based upon management's estimates of the probability of reaching the milestones that would trigger the requirement to pay the contingent amounts. During 2013, management reviewed and adjusted the assumptions associated with the contingent liability which resulted in an elimination of the contingent liability as of June 30, 2013.

(4) Inventories

Inventories consist of the following:

	September 30, 2013	December 31, 2012
Current inventories		
Raw materials	$ 2,223,978	$ 1,919,250
Work in process	4,176,764	4,991,032
Finished goods	8,004,314	7,350,332
	14,405,056	14,260,614
Reserve	(1,176,673)	(1,119,193)
Current inventories, total	$ 13,228,383	$ 13,141,421
Non-current inventories		
Finished goods	$ 1,238,225	$ 1,238,225
Non-current inventories, total	$ 1,238,225	$ 1,238,225
Total inventories	$ 14,466,608	$ 14,379,646

(5) Property and Equipment, Net

Property and equipment, net are as follows:

	September 30, 2013	December 31, 2012
Buildings	$ 1,653,263	$ 1,653,263
Equipment	5,761,079	5,172,523
Computer equipment	312,650	312,650
Computer software	395,146	392,206
Furniture and fixtures	170,118	170,118
Leasehold improvements	1,808,461	1,793,756
Vehicles	41,099	78,306
Total cost	10,141,816	9,572,822
Less: accumulated depreciation	(4,820,824)	(4,337,955)
	$ 5,320,992	$ 5,234,867

The Company leases certain equipment under capital leases. For financial reporting purposes, minimum lease payments relating to the assets have been capitalized. As of September 30, 2013, the Company has recorded $549,603 gross assets in Equipment, and $142,307 of accumulated depreciation relating to assets under capital leases.

Maintenance and repairs expense for the first nine months of 2013 and 2012 was $198,986 and $204,947, respectively. Depreciation expense related to property and equipment, including property under capital lease for the first nine months of 2013 and 2012 was $530,020 and $516,162 respectively.

(6) Intangible Assets

Bacterin has applied for various patents with regards to processes for its products.

The following table sets forth information regarding intangible assets:

	September 30, 2013	December 31, 2012
Intellectual Property		
Gross carrying value	$ 848,675	$ 820,778
Accumulated amortization	$ (285,151)	$ (228,400)
Net carrying value	$ 563,524	$ 592,378
Aggregate amortization expense:	$ 56,750	$ 74,918
Estimated amortization expense:		
Remainder of 2013		$ 18,729
2014		$ 74,918
2015		$ 74,918
2016		$ 74,918
2017		$ 74,918
Thereafter		$ 245,123
Total		$ 563,524

(7) Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2013	December 31, 2012
Acquisition contingent liability	$ -	$ 91,740
Accrued stock compensation	171,174	218,850
Wages/commissions payable	1,129,555	1,013,909
Other accrued expenses	513,743	1,075,591
	$ 1,814,472	$ 2,400,090

(8) Long-term Debt

On April 23, 2012, the Company secured an accounts receivable credit facility with Midcap Financial LLC and Silicon Valley Bank. The revolving loan credit facility allowed Bacterin to borrow up to $5 million through January 1, 2015. The facility allowed borrowings based upon a predetermined formula of up to 80% of Bacterin's eligible accounts receivable, as defined in the credit and security agreement. The Company also amended its existing Loan and Security Agreement with MidCap to allow the Company to borrow up to an additional $3 million in connection with a permitted acquisition. The credit facility carried an interest rate of LIBOR plus 4%, subject to a LIBOR floor rate of 2.5%. The Company also agreed to pay a 0.5% collateral management fee on the average outstanding balance of the facility and 1% of the average unused portion of the facility, as well as a 1% origination fee. We repaid the outstanding balance owed on this credit facility in full with the proceeds from our credit facility with ROS Acquisition Offshore LP (“ROS”) on August 24, 2012.

On August 24, 2012, the Company entered into a Credit Agreement with ROS, whereby ROS agreed to provide an initial $20 million term loan and Bacterin may also borrow an additional $5 million upon achievement of certain revenue objectives prior to December 31, 2013. The loan carries an interest rate of LIBOR plus 12.13%, subject to a LIBOR floor rate of 1.0%. Bacterin also agreed to pay a royalty of 1.75% on the first $45,000,000 of net sales, plus

1.0% of net sales in excess of $45,000,000 for each of the next ten years. Bacterin has the right to repay the loan and royalty interest at amounts to be determined based on the date of repayment and the amount of prior principal, interest and royalty payments. The loan is secured by substantially all of our assets. The estimate of the royalty component of the facility over the life of the agreement resulted in a debt discount and a royalty liability of $7,341,520. The debt discount will be amortized to interest expense over the seven year term of the loan using the effective interest method. The royalty liability will be accreted to $13.8 million through interest expense over the ten year term of the royalty agreement using the effective interest method. Payments made under the royalty agreement, per the table below, will directly reduce the royalty liability.

The Company received net proceeds of approximately $10 million following repayment of the existing term loan and accounts receivable credit facility with MidCap Financial, including prepayment penalties. The Company used the net proceeds for working capital and general corporate purposes.

On May 16, 2013, we entered into an amendment to our Credit Agreement with ROS, whereby ROS agreed to reduce our minimum liquidity requirement from $1,500,000 to $750,000 until September 30, 2013. In exchange, we agreed to pay a fee of $300,000 required to be paid pursuant to the Credit Agreement or other loan documents which is recorded in Long-term debt and in Other long term assets which will be amortized to interest expense over the term of the debt.

There were two compliance violations of covenants in the ROS Credit Agreement in the second quarter of 2013. The Company did not achieve the $8.5 million revenue in the second quarter of 2013 for which we received a waiver, in exchange, the Company agreed to pay a fee of $400,000 when the Company pays, prepays or is required to pay any principal amount of the loan. In addition, the Company did not hire a Chief Executive Officer within 90 days of the resignation of the prior Chief Executive Officer for which we received a waiver in exchange for Board observer rights.

Long-term debt consists of the following:

	September 30, 2013	December 31, 2012
Loan payable to ROS Acquisition Offshore, LIBOR plus 12.13% maturing August 2019	$ 20,000,000	$ 20,000,000
Adjustment fee payable to ROS Acquisition Offshore August 2019	700,000	-
6.00% loan payable to Valley Bank of Belgrade, $10,746 monthly payments including interest, maturing December 24, 2030; secured by building	1,387,112	1,421,420
	22,087,112	21,421,420
Less: Current portion	(47,018)	(45,135)
Debt discount	(5,976,030)	(6,893,183)
Long-term debt	$ 16,064,064	$ 14,483,102

The following is a summary of maturities due on the debt as of September 30, 2013:

Remainder of 2013	11,357
2014	47,727
2015	50,670
2016	1,720,463
2017	6,723,781
Thereafter	13,533,114
Total	$22,087,112

The following is a summary of estimated future royalty payments as of September 30, 2013:

Remainder of 2013	197,000
2014	853,000
2015	1,050,000
2016	1,289,000
2017	1,384,000
Thereafter	8,477,000
Total	$13,250,000

(9) Stock-Based Compensation

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

are authorized under the Plan and at September 30, 2013, we had approximately 622,648 shares available for issuance. Shares issued under the Plan may be authorized, but unissued, or reacquired shares.

Stock compensation expense recognized in the statement of operations for the nine months ended September 30, 2013 and 2012 is based on awards ultimately expected to vest and reflects an estimate of awards that will be forfeited. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The estimated fair value of stock options granted is done using the Black-Sholes-Merton method applied to individual grants. The Company utilizes historical employee termination behavior to determine the estimated forfeiture rates. If the actual forfeitures differ from those estimated by management, adjustments to compensation expense will be made in future periods. Assumed forfeiture rates range from 17.00% to 20.00% for the first nine months of 2013.

Key assumptions used to estimate the fair value of stock awards are as follows:

- Risk-Free Rate: The risk-free rate is determined by reference to U.S. Treasury yields at or near the time of grant for time periods similar to the expected term of the award. We used a weighted-average rate of 1.68% for the nine months ended September 30, 2013.

- Expected Term: We do not have adequate history to estimate an expected term of stock-based awards, and accordingly, we use the short-cut method as prescribed by Staff Accounting Bulletin 107 to determine an expected term. We used a weighted-average expected term of 6.4 years for the nine months ended September 30, 2013.

- Volatility: We estimate expected volatility based on peer-companies as prescribed by ASC 718. We used a weighted-average volatility rate of 62.6% for the nine months ended September 30, 2013.

- Dividend Yield: The dividend yield assumption is based on our history and expectation of dividend payouts and was 0% for the nine months ended September 30, 2013.

Activity under our stock option plans was as follows:

	2013			2012		
	Shares	Weighted Average Exercise Price	Weighted Average Fair Value at Grant Date	Shares	Weighted Average Exercise Price	Weighted Average Fair Value at Grant Date
Outstanding at January 1	5,266,535	$ 2.02	$ 1.03	4,828,910	$ 2.14	$ 1.01
Granted	3,331,250	0.63	0.53	1,105,000	2.00	1.19
Exercised	(230,000)	0.10	0.06	(39,375)	0.87	0.37
Cancelled or expired	(729,000)	1.78	0.90	(1,152,250)	2.01	0.78
Outstanding at September 30	7,638,785	$ 1.49	$ 0.86	4,742,285	$ 2.11	$ 1.04
Exercisable at September 30	2,531,534	$ 2.03	$ 0.98	2,242,118	$ 1.77	$ 0.76

The aggregate intrinsic value of options outstanding as of September 30, 2013 is $799,941. The aggregate intrinsic value of exercisable options as of September 30, 2013 is $132,766. As of September 30, 2013, there were 5,107,251 unvested options with a weighted average fair value at the grant date of $0.80 per option. As of September 30, 2013, compensation expense related to nonvested awards not yet recognized was $667,175.

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

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

The following table summarizes restricted stock award activity during the period ended September 30, 2013:

	Shares
Outstanding at Jan. 1, 2013	733,900
Awarded	-
Cancelled	(112,500)
Vested	(164,500)
Outstanding at September 30, 2013	456,900

The restricted stock awards generally vest over three to five year periods. The Company recognized reduction of non-cash consulting expense of $11,924 for the first nine months of 2013 and expense of $491,051 for the nine months ended September 30, 2012. As of September 30, 2013, the total expense related to nonvested restricted stock awards not yet recognized is $160,021 and is expected to be recognized over three years.

(10) Warrants

In the fourth quarter of 2012, the Company issued 297,991 warrants with an exercise price of $2.30 to a broker in conjunction with the August 24, 2012 financing arrangement with ROS. These were recorded in “Other Assets” and will be amortized over the life of the financing term. In addition, on July 23, 2012 the Company issued 300,895 warrants with an exercise price of $1.03 to a private party resulting in $342,485 recorded in “Other Expense”.

The following table summarizes our warrant activities for the nine months ended September 30, 2013:

	Shares	Weighted Average Exercise Price
Outstanding at January 1, 2013	7,321,667	$ 2.20
Issued	4,352,215	0.72
Exercised	-	-
Expired	(533,173)	2.00
Outstanding at September 30, 2013	11,140,709	$ 1.63

We utilize a lattice model to determine the fair market value of the warrants accounted for as liabilities. The 1,570,565 warrants issued in connection with a 2010 bridge financing, the 375,000 warrants issued in connection with a 2010 debt financing and the 4,254,387 warrants issued in connection with the second quarter 2013 equity financing were accounted for as derivative liabilities in connection with the price protection provisions of the warrants in compliance with ASC 815. The warrants issued in the second quarter of 2013 resulted in a warrant derivative liability of $1,485,313 as of the issuance on June 5, 2013. There were an additional 143,700 warrants in the first quarter of 2012 as a result of the LPC share issuance triggering the anti-dilution clause in the original warrant agreement and an additional 97,828 related to the second quarter of 2013 equity financing. The lattice model accommodates the probability of exercise price adjustment features as outlined in the warrant agreements. We recorded an unrealized gain of $246,337 resulting from the change in the fair value of the warrant derivative liability for the first nine months of 2013. Under the terms of the warrant agreement, at any time while the warrant is outstanding, the exercise price per share can be reduced to the price per share of future subsequent equity sales of our common stock or common stock equivalents that is lower than the exercise price per share as stated in the warrant agreement.

The estimated fair value was derived using the lattice model with the following weighted-average assumptions:

	Nine months ended September 30, 2013		2012	
Value of underlying common stock (per share)	$ 0.68		$ 1.55	
Risk free interest rate	0.72	%	0.38	%
Term to expiration/implied expected life	5.96 years		4.15 years	
Dividend yield	0	%	0	%
Volatility	63	%	62	%

The following table summarizes our activities related to number of warrants used in the derivative liability for the nine months ended September 30, 2013 and 2012:

	2013	2012
Balance at January 1	1,649,707	1,506,007
Derivative warrants issued	4,352,215	143,700
Derivative warrants exercised	-	-
Balance at September 30	6,001,922	1,649,707

(11) Commitments and Contingencies

Operating Leases

We lease two office facilities under non-cancelable operating lease agreements with expiration dates in 2019 and 2023. We have the option to extend both the leases for another ten year term and for one facility, we have the right of first refusal on any sale. We lease an additional office facility under a month-to-month arrangement. Future minimum payments for the next five years and thereafter as of September 30, 2013, under these leases, are as follows:

Remainder of 2013	$61,599
2014	$269,400
2015	$263,136
2016	$263,136
2017	$263,136
Thereafter	$823,730
Total	$1,944,137

Rent expense was $204,180 and $234,316 for the nine months ended September 30, 2013 and 2012, respectively. Rent expense is determined using the straight-line method of the minimum expected rent paid over the term of the agreement. We have no contingent rent agreements.

Indemnifications

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

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

Litigation

On January 29, 2013, we received two warning letters from the Food and Drug Administration (“FDA”): one related to our procedures to ensure compliance with regulatory requirements regarding the production of medical devices; and one related to our procedures to ensure compliance with regulatory requirements regarding the production of human tissue cellular products (H/TCP). We responded to both warning letters and, on April 17, 2013, we received two letters from FDA in which the agency stated that it was in receipt of our response letters and found that the corrective actions in those letters appeared to be adequate. The letters also stated, however, that the corrections would be further evaluated in conjunction with our operations during the next inspection of our facilities. FDA conducted two follow-up inspections as a result of the warning letters of our facilities in July 2013: one inspection focused on our production of medical devices and one inspection focused on our production of H/TCPs. At the conclusion of the inspection focused on medical devices, no Form 483 was issued. At the conclusion of the inspection focused on H/TCPs, FDA issued a one-item Form 483, to which we responded, and we are in the process of providing further updates to FDA. FDA also conducted a routine inspection focused on H/TCPs in July 2013 and issued two observations on a Form 483. We have fully responded to that Form 483. On September 19, 2013, we received a letter from FDA indicating that, based on a review of our corrective actions, it appears we have addressed the violations contained in the warning letter regarding our production of medical devices.

Market Exchange Notification

On May 13, 2013, we received a deficiency notice from the New York Stock Exchange (“Exchange”) notifying us that we are not in compliance with Section 1003(a)(iii) of the Company Guide with stockholders’ equity of less than $6,000,000 and net losses in five of our most recent fiscal years and Section 1003(a)(ii) with stockholders’ equity of less than $4,000,000 and net losses in three of our four most recent fiscal years. On June 12, 2013 we submitted a plan to regain compliance with the continued listing requirements, and on June 21, 2013 the Exchange informed us of the acceptance of our plan and gave us an extension until November 13, 2014 to regain compliance with the continued listing standards. We will be subject to periodic review by Exchange staff during the extension period and failure to make progress consistent with our Plan or to regain compliance with the continued listing standards by the end of the extension period could result in our delisting from the Exchange.

(12) Income Taxes

In evaluating the realizability of the net deferred tax assets, we take into account a number of factors, primarily relating to the ability to generate taxable income. Where it is determined that it is likely that we will be unable to realize deferred tax assets, a valuation allowance is established against the portion of the deferred tax asset. Because it cannot be accurately determined when or if we will become profitable, a valuation allowance was provided against the entire deferred income tax asset balance.

The 2008 through 2012 tax years remain open to examination by the Internal Revenue Service and the 2006 to 2012 tax years remain open to the Montana Department of Revenue. These taxing authorities have the authority to examine those tax years until the applicable statute of limitations expire.

The Company did not recognize any interest or penalties related to income taxes for the nine months ended September 30, 2013 and 2012.

(13) Supplemental Disclosure of Cash Flow Information

Supplemental cash flow information is as follows:

	Nine months ended September 30, 2013	2012
Supplemental disclosure of cash flow information		
Cash paid during the period for:		
Interest	$ 3,436,006	$ 815,031
Income taxes	-	-
Non-cash activities:		
ROS adjustment fee	$ 700,000	$ -
Settlement of SeaArk accounts receivable	$ 1,829,647	$ -
Inventory received in SeaArk settlement	$ 409,838	$ -
Write-off of SeaArk allowance for doubtful accounts	$ 1,419,809	$ -
Net shares issued for non-cash consulting expense	$ 157,561	$ -
Capital lease acquisition	$ -	$ 408,257
Issuance of warrants	$ -	$ 220,872
Non-cash accrued compensation	$ -	$ 304,680
Debt discount related to financing	$ -	$ 7,341,520
Royalty liability related to financing	$ -	$ 7,341,520

(14) Related Party Transactions

Guy Cook, our former President and Chief Executive Officer, formerly served as a board member of West Coast Tissue Services (“WCTS”) and American Donor Services (“ADS”). Mr. Cook did not received any compensation for his board service for either entity as of the date of his resignation. Mitchell Godfrey, a director, is on the board of ADS and also serves as secretary and treasurer for ADS. Mr. Godfrey receives $5,000 annually for his service to ADS.

ADS and WCTS recover tissue from donors. We reimburse them for their recovery fees, which are comprised primarily of labor costs. The approximate aggregate amount of all transactions with WCTS for the first nine months of 2013 and 2012 was $577,200 and $389,500, respectively, and the approximate aggregate amount of all transactions with ADS for the first nine months of 2013 and 2012 was $1,558,360 and $1,004,036, respectively. These relationships benefit us as these entities provide us with donors, thus insuring that we have a pipeline of current and future donors, which is necessary to our success. As of September 30, 2013, we had an accounts payable balance of $555,361 to American Donor Services.

On June 27, 2012, the Board of Directors granted a waiver of certain provisions of the Company’s Code of Conduct to allow an entity controlled by two of our former CEO’s adult children to become a distributor of the Company’s products. This entity acquired inventory from Allograft Tissue Management, a non-affiliated distributor that had previously acquired inventory from the Company. The affiliated distributor, Silver Forest Fund, LP, exchanged products initially purchased from the non-affiliated distributor with Bacterin for different Bacterin products of equivalent value. Other than product exchanges and payment of amounts owed by the non-affiliated distributor, there have been no other direct transactions between Bacterin and the affiliated distributor. Mr. Cook pledged 1,850,000 of his shares of Bacterin stock as collateral for loans made to the affiliated distributor by independent third parties.

On April 5, 2013, Guy Cook resigned from his roles of Chief Executive Officer, President and Chairman of the Board effective immediately. The Board unanimously voted to have Kent Swanson, an existing independent director, serve as Acting Chairman of the Board. Our current Chief Financial Officer, John Gandolfo, and our Chief Operating

Officer, Darrel Holmes, served as interim Co-Chief Executive Officers until the Board appointed Daniel Goldberger as the new Chief Executive Officer on August 14, 2013. Mr. Goldberger received inducement grant stock options to purchase up to 2,000,000 shares of the Company's common stock, with a per share exercise price of $0.60, which was the closing price of the Company's common stock on the August 14, 2013 grant date. The option will vest over five years, with 20% of the underlying shares vesting after one year and the remaining eighty percent (80%) vesting in forty-seven (47) equal monthly installments as to 33,334 underlying shares, beginning September 15, 2014, and one final installment as to 33,302 underlying shares.

(15) Subsequent Events

On November 5, 2013, the United States Patent and Trademark Office issued US Patent No. 8,574,825 entitled "Process for Demineralization of Bone Matrix with Preservation of Natural Growth Factors" to the Company. The issued claims in the patent are for a method to produce a demineralized cancellous bone matrix, such as Bacterin's OsteoSponge® product line. Bacterin has a pending divisional application in the United States to pursue protection on other aspects of its bone demineralization technology and is pursuing protection on related applications in Canada, Europe, and Korea.

On November 14, 2013, the Company received a waiver from ROS for failure to achieve $10.5 million of revenue in the third quarter of 2013. In exchange for the waiver and reduction of future quarterly minimum revenue thresholds, the Company agreed to issue 1,500,000 shares of restricted stock to ROS by December 2, 2013. If the Company does not or is unable to issue the restricted shares by December 2, 2013, the Company agreed to pay an additional exit fee in the amount equal to 3.5% of the aggregate principal amount of the loan.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operation

This Management's Discussion and Analysis of Financial Condition and Results of Operations contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include statements relating to the intended usage and markets for our products and services, the market for our common stock, the ability of our sales force to achieve expected results; and our liquidity, results of operations, and ability to meet our anticipated cash requirements. Actual results could differ materially from those currently anticipated as a result of a number of factors, including those set forth under "Risk Factors" in this Quarterly Report on Form 10-Q.

You should read the following discussion of our financial condition and results of operations in conjunction with our financial statements and related notes set forth in this report. Unless the context otherwise requires, “we,” “our,” “us” and similar expressions used in this Management’s Discussion and Analysis of Financial Condition and Results of Operation section refer to Bacterin International, Inc., a Nevada corporation (“Bacterin”).

Comparison of Three Months Ended September 30, 2013 and September 30, 2012

Revenue

Total revenue for the third quarter ended September 30, 2013 decreased 11% to $7,929,983 compared to $8,879,765 for the third quarter of 2012. The decrease of $949,782 was due to the 2012 period including a stocking order of approximately $1.5 million. Net of that one time stocking order, total revenue for the quarter ended September 30, 2013 increased 14% compared to the quarter ended September 30, 2102.

Cost of tissue sales

Costs of tissue sales consist primarily of tissue and device manufacturing costs. Costs of tissue sales increased by 28% or $717,875 to $3,318,327 for the third quarter of 2013 from $2,600,452 for the third quarter of 2012. As a percentage of sales, cost of sales was 41.8% of revenues for the third quarter of 2013 compared to 29.3% for the third quarter of 2012. This increase was largely the result of lower revenue per item sold due to pricing pressure, write-offs of contaminated inventory related to our dermis production process and an increase in expired product in the 2013 period.

Operating Expenses

Operating expenses include general and administrative expenses, selling and marketing expenses, depreciation, research and development expenses, and compensation costs, including incentive compensation. Operating expenses increased 15%, or $892,481, for the three months ended September 30, 2013 compared to the same period of 2012, primarily due to the reasons set forth below.

General and Administrative

General and administrative expenses consist principally of corporate personnel cash based and stock option compensation related costs and corporate expenses for legal, accounting and other professional fees as well as occupancy costs. General and administrative expenses increased 13%, or $325,099, to $2,764,328, for the third quarter of 2013 compared to the third quarter of 2012. The increase is primarily due to bad debt expense of approximately $642,000 recorded in the 2013 period associated with a stocking order placed in 2012. General and administrative expenses, net of the bad debt adjustment, decreased 13% for the quarter ended September 30, 2013 compared to the quarter ended September 30, 2012.

Selling and Marketing

Selling and marketing expenses primarily consist of costs for trade shows, sales conventions and meetings, travel expenses, advertising and other sales and marketing related costs. In addition, stock option compensation expense associated with our sales force is also included in sales and marketing expenses. Selling and marketing expenses increased 21%, or $701,285, to $4,053,679 for the three months ended September 30, 2013 from $3,352,394 for the comparable prior year period. As a percentage of revenue, selling and marketing expenses increased to 51.1% in the third quarter of 2013 from 37.8% in the third quarter of 2012. The increases were primarily the difference of commissions not being earned on the 2012 stocking orders as compared to commissions being earned on the higher core revenues in the 2013 period.

Depreciation

Depreciation expense consists of depreciation of long-lived property and equipment. Depreciation expense increased 11% to $97,923 for the three months ended September 30, 2013 from $88,112 for the three months ended September 30, 2012. The increase reflects the depreciation of fixed assets acquired over the past twelve months in connection with equipment required to increase manufacturing capacity.

Non-cash Consulting Expense

Non-cash consulting expense consists of non-cash expense associated with granting restricted stock to consultants. Non-cash consulting expense decreased $143,714 to $43,153 for the third quarter of 2013 from $186,867 in the third quarter of 2012. The decrease is due to a combination of fewer contracts in 2013 and a reduced stock price at the end of the third quarter.

Other Income (Expense)

Other expenses include interest, warrant derivative liability changes and other miscellaneous items. Other expenses decreased 26%, or $702,961, for the quarter ended September 30, 2013 compared to the same period of 2012, primarily due to the reasons set forth below.

Interest Expense

Interest expense for the third quarter of 2013 increased $329,476 to $1,197,370 as compared to $867,894 in the third quarter of 2012. The increase was the result of a higher average debt balance in 2013 and the higher interest rate related to the debt financing entered into with ROS Acquisition Offshore LP during the third quarter of 2012.

Change in Warrant Derivative Liability

For the third quarter of 2013, the Company recorded expense from an increase in the warrant derivative liability of $849,288 based upon the increase in the closing price of the Company's common stock at September 30, 2013 compared to June 30, 2013. The liability is associated with the issuance of warrants as part of the Company's prior convertible debt financing, the Company's 2010 financing and the Company's 2013 equity financing which contain anti dilution adjustment provisions requiring the Company to record a change in the warrant derivative liability from period to period.

Other Income (Expense)

Other income for the third quarter of 2013 was $17,551 as compared to expense of $1,738,202 in the third quarter of 2012. The expense in 2012 was primarily related to the write-off of the debt discount and prepayment penalties related to termination of the MidCap financing in the third quarter of 2012.

Comparison of Nine months Ended September 30, 2013 and September 30, 2012

Revenue

Total revenue for the first nine months ended September 30, 2013 decreased $42,400 to $24,815,638 compared to $24,858,038 for the first nine months of 2012.

Cost of tissue sales

Costs of tissue sales consist primarily of tissue and device manufacturing costs. Costs of tissue sales increased by 47% or $3,223,081 to $10,011,687 for the first nine months of 2013 from $6,788,606 for the first nine months of 2012. As a percentage of sales, cost of sales was 40.3% of revenues for the first nine months of 2013 compared to 27.3% for the first nine months of 2012. This increase was largely the result of lower revenue per item sold due to pricing pressure, write-offs of contaminated inventory related to our dermis production process and an increase in expired product and inventory reserves to cover future expiring product in the 2013 period.

Operating Expenses

Operating expenses include general and administrative expenses, selling and marketing expenses, depreciation, research and development expenses, and compensation costs, including incentive compensation. Operating expenses increased 4%, or $774,540, for the nine months ended September 30, 2013 compared to the same period of 2012, primarily due to the reasons set forth below.

General and Administrative

General and administrative expenses consist principally of corporate personnel cash based and stock option compensation related costs and corporate expenses for legal, accounting and other professional fees as well as occupancy costs. General and administrative expenses increased $527,845, or 7% to $7,877,697, compared to the first nine months of 2012. The increase is primarily due to an increase in bad debt expense of approximately $990,000 in

2013, primarily associated with large stocking orders to distributors, a strategy which the Company is no longer pursuing. General and administrative expenses, net of the bad debt adjustment, decreased 6% for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012.

Selling and Marketing

Selling and marketing expenses primarily consist of costs for trade shows, sales conventions and meetings, travel expenses, advertising and other sales and marketing related costs. In addition, stock option compensation expense associated with our sales force is also included in sales and marketing expenses. Selling and marketing expenses increased by $723,443, or 6%, for the nine months ended September 30, 2013 compared to the prior year period. As a percentage of revenue, selling and marketing expenses increased to 48.6% in the first nine months of 2013 from 45.6% in the first nine months of 2012. The increases were primarily the difference of commissions not being earned on the 2012 stocking orders as compared to commissions being earned on the higher core revenues in 2013.

Depreciation

Depreciation expense consists of depreciation of long-lived property and equipment. Depreciation expense remained relatively flat at $304,771 for the nine months ended September 30, 2013 from $302,392 for the nine months ended September 30, 2012.

Non-cash Consulting Expense

Non-cash consulting expense consists of non-cash expense associated with granting restricted stock to consultants. Non-cash consulting expense decreased $479,127 to $11,924 for the first nine months of 2013 from an expense of $491,051 in the first nine months of 2012. The decrease is due to a combination of fewer contracts in 2013 and a reduced stock price at the end of the third quarter.

Other Income (Expense)

Other expenses include interest, warrant derivative liability changes and other miscellaneous items. Other expenses increased 116%, or $1,653,227, for the nine months ended September 30, 2013 compared to the same period of 2012, primarily due to the reasons set forth below.

Interest Expense

Interest expense for the first nine months of 2013 increased $2,159,060 to $3,436,006 as compared to $1,276,946 in the first nine months of 2012. The increase was the result a higher average debt balance in 2013 and the higher interest rate related to the debt financing with ROS Acquisition Offshore LP.

Change in Warrant Derivative Liability

For the first nine months of 2013, the Company recorded income from a decrease in its non cash warrant derivative liability of $246,337 based upon the decrease in the closing price of the Company’s common stock at September 30, 2013 compared to December 31, 2012 which was partially offset by the issuance of additional derivative warrants in 2013. The liability is associated with the issuance of warrants as part of the Company’s prior convertible debt financing, the Company’s 2010 financing and the Company’s 2013 equity financing which contain anti dilution adjustment provisions requiring the Company to record a change in the warrant derivative liability from period to period.

Other Income (Expense)

Other income for the first nine months of 2013 was $108,616 as compared to expense of $1,544,035 in the first nine months of 2012. The expense in 2012 was primarily related to the write-off of the debt discount and prepayment penalties related to termination of the MidCap financing in the third quarter of 2012.

Liquidity and Capital Resources

Since our inception, we have historically financed our operations through operating cash flows, as well as the private placement of equity securities and convertible debt, an equity credit line and other debt transactions. In August 2012, we closed on a $20 million term loan transaction with ROS Acquisition Offshore LP. The net proceeds were used to pay off the previous loans with MidCap Financial LLC and Silicon Valley Bank of approximately $9.3 million with the remainder adding to our working capital. In addition, on June 10, 2013, the Company issued approximately 8.51 million shares of common stock to new and existing investors with net proceeds to Bacterin International of approximately $4.45 million. Proceeds from the transaction will be used to fund the Company's operations and

working capital requirements. At September 30, 2013, we had $8,070,616 of cash and cash equivalents and accounts receivables.

Net cash used in operating activities the first nine months of 2013 was $5,178,199. For the comparable period of 2012, net cash used in operating activities was $7,809,289. The decrease was primarily due to a reduction in cash used in purchases of inventory.

Net cash used in investing activities for the first nine months of 2013 was $643,542 due to the purchase of property and equipment and intangible assets.

Net cash provided by financing activities was $4,333,224 for the nine months ended September 30, 2013 primarily due to the equity capital raise in the second quarter of 2013.

On November 14, 2013, we entered into a Waiver and Fifth Amendment to our Credit Agreement with ROS Acquisition Offshore LP (“ROS”) whereby ROS (i) waived our failure to achieve the revenue required by Section 8.4.1 of the Credit Agreement for the quarter ended September 30, 2013, and (ii) agreed to revise our future revenue requirements as described in Part II, Item 3 of this 10-Q. In exchange, we agreed to issue 1,500,000 shares (the “Shares”) of our common stock to ROS. If we do not issue the Shares by December 2, 2013, we will be required to pay an additional fee in the amount of 3.5% of any principal payment required to be paid pursuant to the Credit Agreement or other loan documents.

Off Balance Sheet Arrangements

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

Cash Requirements

We believe that our September 30, 2013 cash on hand and accounts receivable balance of $8,070,616, combined with anticipated cash receipts from sales expected from operations, expense reductions and access to addition capital resources will be sufficient to meet our anticipated cash requirements through September 30, 2014; however there can be no assurance that we will achieve expected sales results, raise additional capital, reduce expenses or collect our accounts receivable.We incurred approximately $16 million in sales and marketing expenses in 2012 and expect to incur $18 million in 2013 based upon our current sales estimates. The sales and marketing expenses are largely variable expenses and are anticipated to be funded from operating cash flow. An increase of these expenses may impact our operating results and there can be no assurance of their effectiveness. If we do not meet our revenue objectives over that period, we may need to sell additional equity securities, which could result in dilution to our stockholders, or seek additional loans. The incurrence of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. Financing may not be available in amounts or on terms acceptable to us, if at all. Any failure by us to raise additional funds on terms favorable to us, or at all, could limit our ability to expand our business operations and could harm our overall business prospects.

In addition, we currently anticipate that we will need to spend between $4 and $5 million over the next 5 years in order to increase, expand or update our existing facilities to meet our expected growth over that period.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our senior management with the participation of our chief executive officer and chief financial officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a - 15(e) under the Exchange Act) as of September 30, 2013. Based upon that evaluation, we concluded that as of September 30, 2013, our disclosure controls and procedures were ineffective due to the material weakness in our internal controls over financial reporting detailed below that have not been fully remediated as of September 30, 2013.

Management's Report on Internal Control over Financial Reporting

Management is responsible for maintaining adequate internal control over financial reporting as such term is defined in rule 13a-15 (f) under the Securities and Exchange Act of 1934 as amended. Under the supervision and with the participation of senior and executive management, we conducted an evaluation of our internal controls over financial reporting based upon the Internal Control - Integrated Framework as outlined by COSO, the Committee of Sponsoring Organizations of the Treadway Commission. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of an evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Based on our evaluation under the framework Internal Control - Integrated Framework, management concluded that our internal control over financial reporting was ineffective as of September 30, 2013 due to material weaknesses in our internal control over financial reporting that have not been fully remediated as of September 30, 2013 as detailed below:

1) At December 31, 2012, the Company had an insufficient number of personnel with the appropriate level of experience and technical expertise to appropriately resolve account reconciliations while completing the financial statement close process. Until this design deficiency in our internal control over financial reporting is remediated, there is a reasonable possibility that a material misstatement in our annual or interim financial statements could occur and not be corrected or prevented by our internal control system in a timely manner. Since December 31, 2012, we have expanded the training of qualified accounting and finance personnel and included an additional level of management review to the financial close process. The Company plans on performing an additional detailed evaluation of the internal controls surrounding financial reporting as of December 31, 2013 in connection with the year end financial close process.

2) The documentation surrounding equity transactions for employees and consultants needs to be strengthened to comply with procedures outlined by the Company to ensure that all equity related transactions are properly recorded in the appropriate periods. In 2013, the Company improved the approval process for grants of equity securities. The approval process includes approval by the Compensation Committee or the Board of Directors, review by our Human Resources department on all stock option vestings and cancellations and additional review by in house legal counsel on all stock option and equity grants. We anticipate that all of the above initiatives will be implemented by December 31, 2013 when we re-evaluate our internal review of financial controls.

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PART II - OTHER INFORMATION

Item 1. Legal Proceedings

On January 29, 2013, we received two warning letters from the Food and Drug Administration ("FDA"): one related to our procedures to ensure compliance with regulatory requirements regarding the production of medical devices; and one related to our procedures to ensure compliance with regulatory requirements regarding the production of human tissue cellular products (H/TCP). We responded to both warning letters and, on April 17, 2013, we received two letters from FDA in which the agency stated that it was in receipt of our response letters and found that the corrective actions in those letters appeared to be adequate. The letters also stated, however, that the corrections would be further evaluated in conjunction with our operations during the next inspection of our facilities. FDA conducted two follow-up inspections as a result of the warning letters of our facilities in July 2013: one inspection focused on our production of medical devices and one inspection focused on our production of H/TCPs. At the conclusion of the inspection focused on medical devices, no Form 483 was issued. At the conclusion of the inspection focused on H/TCPs, FDA issued a one-item Form 483, to which we responded, and we are in the process of providing further updates to FDA. FDA also conducted a routine inspection focused on H/TCPs in July 2013 and issued two observations on a Form 483, to which we have fully responded. On September 19, 2013, we received a letter from FDA indicating that, based on a review of our corrective actions, it appears we have addressed the violations contained in the warning letter regarding our production of medical devices.

Item 1A Risk Factors

Our business and an investment in our securities are subject to a variety of risks. The following risk factors describe some of the most significant events, facts or circumstances that could have a material adverse effect upon our business, financial condition, results of operations, ability to implement our business plan and the market price for our securities. Many of these events are outside of our control. If any of these risks actually occurs, our business, financial condition or results of operations may be materially adversely affected. In such case, the trading price of our common stock could decline and investors in our common stock could lose all or part of their investment.

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

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

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

We have substantial operating expenses associated with the sales and marketing of our products. The sales and marketing expenses are anticipated to be funded from operating cash flow. An increase of these expenses may impact

our operating results and there can be no assurance of their effectiveness. There can be no assurance that we will have sufficient access to liquidity or cash flow in the future to meet our operating expenses and other obligations. If we do not increase our revenue or reduce our expenses, we will need to raise additional capital, which would result in dilution to our stockholders, or seek additional loans. The incurrence of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. Financing may not be available in amounts or on terms acceptable to us, if at all. Any failure by us to raise additional funds on terms favorable to us, or at all, could limit our ability to expand our business operations and could harm our overall business prospects.

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

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

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

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

The impact of United States healthcare reform legislation remains uncertain.

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

We face risks and uncertainties relating to FDA warning letters and an OIG subpoena.

On January 29, 2013, we received two warning letters from the Food and Drug Administration (“FDA”): one related to our procedures to ensure compliance with regulatory requirements regarding the production of medical devices; and one related to our procedures to ensure compliance with regulatory requirements regarding the production of human tissue cellular products (H/TCP). We responded to both warning letters and, on April 17, 2013, we received two letters from FDA in which the agency stated that it was in receipt of our response letters and found that the corrective actions in those letters appeared to be adequate. The letters also stated, however, that the corrections would be further evaluated in conjunction with our operations during the next inspection of our facilities. FDA conducted two follow-up inspections as a result of the warning letters of our facilities in July 2013: one inspection focused on our production of medical devices and one inspection focused on our production of H/TCPs. At the conclusion of the inspection focused on medical devices, no Form 483 was issued. At the conclusion of the inspection focused on H/TCPs, FDA issued a one-item Form 483, to which we responded, and we are in the process of providing further updates to FDA. FDA also conducted a routine inspection focused on H/TCPs in July 2013 and issued two observations on a Form 483, to which we have fully responded. On September 19, 2013, we received a letter from FDA indicating that, based on a review of our corrective actions, it appears we have addressed the violations contained in the warning letter regarding our production of medical devices. We are committed to working with the FDA to address their concerns; however, there can be no assurance that the FDA will be satisfied with our corrective actions or that the FDA will not have additional concerns.

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

We cannot assure you that the government will find our efforts to resolve the FDA warning letter or the investigation initiated by the OIG subpoena to be satisfactory. We may be unable to implement corrective actions within a timeframe or in a manner satisfactory to the FDA. Failure to do so could result in enforcement proceedings by the government, which could potentially include civil or criminal fines and penalties, including disgorgement of amounts earned on any legally-adulterated products; injunctive relief, which could limit, modify or constrain our ability to manufacture, market and sell our products; and exclusion from participation in government healthcare programs, such as Medicare and Medicaid. The investigation initiated by the OIG subpoena could result in civil or criminal fines or penalties, increased supervision of our business operations by the OIG, or exclusion from participation in government healthcare programs, such as Medicare and Medicaid. We are unable to predict when these matters will be resolved or what action, if any, the government will take in connection with these matters. The issues arising out of the FDA inspection and OIG subpoena may be expanded to cover other matters. We could also face product liability, third-party payer, shareholder, or other litigation. Any of these risks and uncertainties could adversely affect our revenues, results of operations, cash flows and financial condition.

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

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

Future regulatory action remains uncertain.

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

Competition from former Chief Executive Officer

We believe our former Chief Executive Officer, Guy Cook, has acquired an ownership interest in a tissue bank that sells competitive products. Because our former CEO has in depth knowledge about our customers, employees, consultants, products, policies, practices and prospects, we may be adversely affected by increased competition with that business.

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

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

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

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

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

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

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

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

Our success is dependent on our ability to remain accredited with the AATB.

Our success is dependent on our ability to remain accredited with the American Association of Tissue Banks (“AATB”). Although AATB accreditation is voluntary, many participants in our industry would not do business with us if we lost our AATB accreditation. Although we make every effort to meet and exceed AATB standards, the AATB has broad discretionary power when reviewing members for accreditation, and there can be no assurance that we will continue to remain accredited with the AATB.

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

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

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

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

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

Future revenue will depend on our ability to increase sales.

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

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

Significant annual and quarterly fluctuations in our results of operations may be caused by, among other factors, our volume of revenues, the timing of new product or service announcements, releases by us and our competitors in the marketplace of new products or services, 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.

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

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

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

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

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

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

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

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

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

not be adequate and our business could suffer material adverse consequences.

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

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

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

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

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

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

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

Medical devices that incorporate coatings technology are subject to FDA regulation and compliance. Generally, any medical device manufacturer that wishes to incorporate our coatings technology into its products will be responsible for obtaining FDA approval for the medical devices it intends to market though we will assist in the 510(k) filing submitted by licensees. The FDA process can take several months to several years in the United States. The time required to obtain approval for international sales may be longer or shorter, depending on the laws of the particular country. There can be no assurance that our licensees will be able to obtain FDA or international approval on a timely basis. The FDA may also require the more extensive Premarket Approval Application, or PMA, process for certain products, which 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 human cells, tissues and cellular and tissue-based products, or HCT/Ps. The first requires that companies that produce and distribute HCT/Ps register with the FDA. The second provides criteria that must be met for donors to be eligible to donate tissues and is referred to as the "Donor Eligibility" rule. The third rule governs the processing and distribution of the tissues and is often referred to as the "Current Good Tissue Practices" rule. The "Current Good Tissue Practices" rule covers all stages of allograft processing, from procurement of tissue to distribution of final allografts. Together they are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of

communicable disease transmission to recipients. These regulations increased regulatory scrutiny within the industry in which we operate and have lead to increased enforcement action which affects the conduct of our business. In addition, these regulations can increase the cost of tissue recovery activities.

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

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

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

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

The commencement or completion of any clinical trial may be delayed or halted for numerous reasons, including, but not limited to, a regulatory body placing clinical trials on hold, patients not enrolling in clinical trials at the rate we expect, patients experiencing adverse side effects, third party contractors failing to perform in accordance with our anticipated schedule or consistent with good clinical practices, inclusive or negative interim trial results or our inability to obtain sufficient quantities of raw materials to produce our products. Our development costs may increase if we have material delays in clinical trials or if we need to perform more or larger clinical trials than planned. If this occurs, our financial results and the commercial prospects for our products may be harmed.

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

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

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

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

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

We may not be able to obtain, maintain and protect certain proprietary rights necessary for the development and commercialization of our products or product candidates. Our commercial success will depend in part on obtaining and maintaining patent protection on our products and successfully defending these patents against third-party challenges. Our ability to commercialize our products will also depend in part on the patent positions of third parties, including those of our competitors. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict with certainty the

scope and breadth of patent claims that may be afforded to other companies' patents. We could incur substantial costs in litigation if we are required to defend against patent suits brought by third parties, or if we initiate suits to protect our patent rights.

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

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

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

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

- we were the first to make the inventions covered by each of our patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;

- any of our pending patent applications will result in issued patents;
- any of our issued patents or those of our licensors will be valid and enforceable;
- any patents issued to us or our collaborators will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies that are patentable;
- the patents of others will not have a material adverse effect on our business rights; or
- the measures we rely on to protect the intellectual property underlying our products may not be adequate to prevent third parties from using our technology, all of which could harm our ability to compete in the market.

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

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

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

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

The result of litigation may result in financial loss and/or impact our ability to sell our products going forward.

We intend to vigorously defend any future intellectual property litigation that may arise but there can be no assurance that we will prevail in these matters. An unfavorable judgment may result in a financial burden on us. An unfavorable

judgment may also result in restrictions on our ability to sell certain products and therefore may impact future operating results.

We have found material weaknesses in our system of internal controls over financial reporting that have not been fully remediated as of September 30, 2013, which could adversely affect our ability to record, process, summarize and report certain financial data.

In connection with the evaluation of the effectiveness of our internal controls over financial reporting as of September 30, 2013, management discovered the following deficiencies: (i) insufficient number of personnel with the appropriate level of experience and technical expertise to appropriately resolve account reconciliations, while completing the financial statement close process; and (ii) the documentation surrounding equity transactions for employees and consultants needs to be strengthened to comply with procedures outlined by the Company to ensure that all equity transactions are properly recorded in the appropriate periods. In light of these material weaknesses, management has concluded that we did not maintain effective internal control over our disclosure controls and procedures as of September 30, 2013, which constituted a material weakness in our internal controls over financial reporting because they resulted in a reasonable possibility that a material misstatement could occur in our annual or interim financial statements which could not be prevented or detected. Although we are working to remediate these deficiencies as outlined in Item 4 of this Quarterly Report on Form 10-Q, there can be no assurance that our remediation efforts will resolve all of our internal control deficiencies or that we will not discover additional material weaknesses or significant deficiencies as we evaluate and test such controls in the future. Such material weaknesses or deficiencies could adversely affect our ability to record, process, summarize and report our financial information, which could cause current and potential stockholders to lose confidence in our financial reporting which could have a negative effect on the trading price of our common stock.

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

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

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

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

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

- announcements of technological innovations or new commercial products by us, our collaborative partners or our present or potential competitors;
- our issuance of debt, equity or other securities, which we need to pursue to generate additional funds to cover our operating expenses;
- our quarterly operating results;
- developments or disputes concerning patent or other proprietary rights;
- developments in our relationships with employees, suppliers or collaborative partners;
- acquisitions or divestitures;
- litigation and government proceedings;
- adverse legislation, including changes in governmental regulation;
- third-party reimbursement policies;
- changes in securities analysts' recommendations;
- short selling;

- changes in health care policies and practices;
- halting or suspension of trading in our common stock by NYSE MKT;
- economic and other external factors; and
- general market conditions.

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

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

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

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

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

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

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

We currently intend to retain our future earnings to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

We could issue "blank check" preferred stock without stockholder approval with the effect of diluting then current stockholder interests and impairing their voting rights, and provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable.

Our certificate of incorporation provides for the authorization to issue up to 5,000,000 shares of "blank check" preferred stock with designations, rights and preferences as may be determined from time to time by our board of directors. Our board of directors is empowered, without stockholder approval, to issue one or more series of preferred stock with dividend, liquidation, conversion, voting or other rights which could dilute the interest of, or impair the voting power of, our common stockholders. The issuance of a series of preferred stock could be used as a method of discouraging, delaying or preventing a change in control. For example, it would be possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company. In addition, we have a staggered board of directors and advanced notice is required prior to stockholder proposals, which might further delay a change of control.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Nothing to report for the quarterly period ended September 30, 2013.

Item 3. Defaults Upon Senior Securities

On November 14, 2013, we entered into a Waiver and Fifth Amendment to our Credit Agreement with ROS Acquisition Offshore LP ("ROS") whereby ROS (i) waived our failure to achieve the revenue required by Section 8.4.1 of the Credit Agreement for the quarter ended September 30, 2013, and (ii) agreed to revise our future revenue requirements as follows:

December 31, 2013	$7,500,000
March 31, 2014	$7,500,000
June 30, 2014	$8,000,000
September 30, 2014	$8,000,000
December 31, 2014	$8,000,000
March 31, 2015 and thereafter	$9,500,000

In exchange, we agreed to issue 1,500,000 shares (the "Shares") of our common stock to ROS. If we do not issue the Shares by December 2, 2013, we will be required to pay an additional fee in the amount of 3.5% of any principal payment required to be paid pursuant to the Credit Agreement or other loan documents.

The foregoing description of the amendment to our Credit Agreement is qualified in its entirety by reference to the full text of the amendment, which is attached hereto as Exhibit 10.27 and incorporated by reference herein.

Item 4 Mine Safety Disclosures

Not Applicable

Item 5. Other Information

None

Item 6. Exhibits

3.1		Certificate of Incorporation (filed as Exhibit 3.1 to Form 10-Q filed November 14, 2011, incorporated by reference herein)
3.2		Amended and Restated Bylaws (filed as Exhibit 3.2 to Form 8-K filed July 11, 2013, incorporated by reference herein)
10.26	*	Indemnification Agreement with Daniel Goldberger
10.27	*	Waiver and Fifth Amendment to Credit Agreement
31.1	*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	*	Section 1350 Certification of Chief Executive Officer

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

* Filed herewith

** Furnished herewith
XBRL (eXtensible Business Reporting Language) information is furnished and not filed as part of any registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these Sections.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BACTERIN INTERNATIONAL HOLDINGS, INC.

Date: November 14, 2013

By: /s/ John P. Gandolfo
Name: John P. Gandolfo
Title: Chief Financial Officer