

Bacterin International Holdings, Inc.
Form 10-Q
November 08, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2012

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) (I.R.S. Employer

of incorporation or organization) Identification No.)

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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 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 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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

Number of shares of common stock, \$0.000001 par value, of registrant outstanding at October 24, 2012: 42,600,844

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, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should” and “would,” as well as similar words, may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward looking. Forward-looking statements in this Form 10-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 efforts to innovate and develop new products;

£ our ability to engage and retain qualified technical personnel and members of our management team;

£ our reliance on our current facilities;

£ our ability to generate funds or raise capital to finance our growth;

£ our efforts to expand our sales force;

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

£ government regulations and additional taxes;

£ fluctuations in our operating results;

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

£ our ability to manage our growth;

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

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

£ product recalls and defects;

£ timing and results of clinical trials;

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

£ infringement and ownership of intellectual property;

£our ability to attract broker coverage;

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

£influence by our management; and

£our ability to issue preferred stock.

The forward-looking statements contained in this Form 10-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 our Annual Report on Form 10-K. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required under applicable securities laws.

PART I – FINANCIAL INFORMATION**Item 1. Financial Statements****BACTERIN INTERNATIONAL HOLDINGS, INC.****Condensed Consolidated Balance Sheets**

| | As of September 30, 2012 (unaudited) | December 31, 2011 |
|--|--|----------------------|
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | \$8,615,988 | \$751,111 |
| Trade accounts receivable, net of allowance for doubtful accounts of \$1,369,443 and \$1,232,806, respectively | 7,184,558 | 7,083,354 |
| Inventories, net | 13,409,540 | 8,479,710 |
| Prepaid and other current assets | 630,403 | 289,326 |
| Total current assets | 29,840,489 | 16,603,501 |
| Non-current inventories | 1,083,208 | 920,542 |
| Property and equipment, net | 4,883,231 | 3,774,140 |
| Intangible assets, net | 586,975 | 656,133 |
| Goodwill | 728,618 | 728,618 |
| Other assets | 1,324,338 | 486,914 |
| Total Assets | \$38,446,859 | \$23,169,848 |
| LIABILITIES & STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts payable | \$4,055,348 | \$2,654,263 |
| Accounts payable - related party | 429,081 | 513,193 |
| Accrued liabilities | 2,250,617 | 3,762,211 |
| Warrant derivative liability | 951,361 | 2,344,516 |
| Current portion of capital lease obligations | 175,175 | 33,791 |
| Current portion of royalty liability | 845,999 | - |
| Current portion of long-term debt | 44,465 | 1,632,978 |
| Total current liabilities | 8,752,046 | 10,940,952 |
| Long-term Liabilities: | | |
| Capital lease obligation, less current portion | 335,368 | 89,580 |
| Long term royalty liability, less current portion | 6,546,180 | - |
| Long-term debt, less current portion | 14,221,640 | 6,638,270 |

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| | | |
|---|--------------|---------------|
| Total Liabilities | 29,855,234 | 17,668,802 |
| Commitments and Contingencies | | |
| Stockholders' Equity (Deficit) | | |
| 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; 42,864,250 shares issued and outstanding as of September 30, 2012 and 40,841,218 shares issued and outstanding as of December 31, 2011 | 43 | 40 |
| Additional paid-in capital | 51,378,943 | 45,452,732 |
| Retained deficit | (42,787,361) | (39,951,726) |
| Total Stockholders' Equity | 8,591,625 | 5,501,046 |
| Total Liabilities & Stockholders' Equity | \$38,446,859 | \$23,169,848 |

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, | |
|--|-------------------------------------|------------------------|------------------------------------|---------------------|
| | 2012 | 2011 | 2012 | 2011 |
| Revenue | | | | |
| Tissue sales | \$ 8,643,299 | \$ 7,237,118 | \$ 24,427,853 | \$ 20,476,090 |
| Royalties and other | 236,466 | 302,383 | 430,185 | 572,690 |
| Total Revenue | 8,879,765 | 7,539,501 | 24,858,038 | 21,048,780 |
| Cost of tissue and medical devices sales | 2,600,452 | 1,318,606 | 6,788,606 | 4,048,049 |
| Gross Profit | 6,279,313 | 6,220,895 | 18,069,432 | 17,000,731 |
| Operating Expenses | | | | |
| General and administrative | 2,439,229 | 2,149,192 | 7,349,852 | 6,027,377 |
| Sales and marketing | 3,352,394 | 4,809,592 | 11,333,946 | 13,405,018 |
| Depreciation and amortization | 88,112 | 119,213 | 302,392 | 253,259 |
| Non-cash consulting expense | 186,867 | 708,530 | 491,051 | 1,097,005 |
| Total Operating Expenses | 6,066,602 | 7,786,527 | 19,477,241 | 20,782,659 |
| Income (Loss) from Operations | 212,711 | (1,565,632) | (1,407,809) | (3,781,928) |
| Other Income (Expense) | | | | |
| Interest expense | (867,894) | (541,163) | (1,276,946) | (1,039,703) |
| Change in warrant derivative liability | (125,972) | 245,024 | 1,393,155 | 7,471,409 |
| Other income (expense) | (1,738,202) | (1,302,533) | (1,544,035) | (1,302,533) |
| Total Other Income (Expense) | (2,732,068) | (1,598,672) | (1,427,826) | 5,129,173 |
| Net Income (Loss) Before (Provision) Benefit for Income Taxes | (2,519,357) | (3,164,304) | (2,835,635) | 1,347,245 |
| (Provision) Benefit for Income Taxes | | | | |
| Current | - | - | - | - |
| Deferred | - | - | - | - |
| Net Income (Loss) | \$ (2,519,357) | \$ (3,164,304) | \$ (2,835,635) | \$ 1,347,245 |
| Net income (loss) per share: | | | | |
| Basic | \$ (0.06) | \$ (0.08) | \$ (0.07) | \$ 0.04 |

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| | | | | |
|---------------------------------|------------|------------|------------|------------|
| Dilutive | \$ (0.06 |) \$ (0.08 |) \$ (0.07 |) \$ 0.03 |
| Shares used in the computation: | | | | |
| Basic | 42,796,244 | 39,574,952 | 42,341,796 | 38,378,027 |
| Dilutive | 42,796,244 | 39,574,952 | 42,341,796 | 43,204,930 |

See notes to unaudited condensed consolidated financial statements.

BACTERIN INTERNATIONAL HOLDINGS, INC.**Condensed Consolidated Statements of Cash Flows**

(Unaudited)

| | Nine Months Ended September 30, | |
|---|---------------------------------|----------------|
| | 2012 | 2011 |
| Operating activities: | | |
| Net (loss) income | \$ (2,835,635 |) \$ 1,347,245 |
| Noncash adjustments: | | |
| Depreciation and amortization | 577,145 | 803,269 |
| Amortization of debt discount | 228,505 | |
| Write-off of debt discount | 139,228 | 1,307,933 |
| Non-cash consulting expense/stock option expense | 1,114,846 | 1,698,660 |
| Warrants issued for services | 342,485 | - |
| Non-cash interest | 50,659 | - |
| Provision for losses on accounts receivable and inventory | 136,637 | 163,616 |
| Loss on disposal of assets | 7,902 | - |
| Change in derivative warrant liability | (1,393,155 |) (7,471,409 |
| Reduction of contingent liability | (358,426 |) - |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (237,841 |) (2,921,285 |
| Accounts receivable - related party | - | (62,064 |
| Inventories | (5,092,496 |) (1,546,528 |
| Prepaid and other current assets | (957,628 |) (246,544 |
| Accounts payable | 1,316,973 | (200,047 |
| Accrued liabilities | (848,488 |) 704,918 |
| Net cash used in operating activities | (7,809,289 |) (6,422,236 |
| Investing activities: | | |
| Purchases of property and equipment | (1,216,723 |) (549,331 |
| Notes receivable from stockholder | - | 82,255 |
| Intangible asset additions | - | (131,967 |
| Net cash used in investing activities | (1,216,723 |) (599,043 |
| Financing activities: | | |
| Proceeds from the issuance of long-term debt | 22,741,719 | 9,579,687 |
| Payments on long-term debt | (9,773,075 |) (5,104,976 |
| Payments on capital leases | (21,085 |) (28,769 |
| Proceeds from issuance of stock | 3,899,996 | 3,224,017 |
| Proceeds from exercise of options | 43,334 | 698,776 |
| Proceeds from exercise of warrants | - | 139,738 |
| Net cash provided by financing activities | 16,890,889 | 8,508,473 |
| Net change in cash and cash equivalents | 7,864,877 | 1,487,194 |

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| | | |
|--|--------------|--------------|
| Cash and cash equivalents at beginning of period | 751,111 | 327,481 |
| Cash and cash equivalents at end of period | \$ 8,615,988 | \$ 1,814,675 |

See notes to unaudited condensed consolidated financial statements.

Notes to 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 stem 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 anti-microbial coatings to inhibit infection based upon proprietary knowledge of the phenotypical changes made by microbes as they sense and adapt to changes in their environment. Bacterin develops, employs, and licenses bioactive coatings for various medical device applications. Bacterin’s strategic coating initiatives include the inhibition of biofilm formation, local (as opposed to systemic) drug delivery, local (as opposed to systemic) pain management, and anti-thrombotic factors for medical device applications.

The accompanying interim condensed consolidated financial statements of Bacterin for the nine months ended September 30, 2012 and 2011 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, 2012.

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, 2011. 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.

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 the business.

Concentrations and Credit Risk

The Company's accounts receivable are due from a variety of health care organizations and distributors throughout the world. Approximately 97% and 98% of sales were in the United States for the first nine months of 2012 and 2011, respectively. One customer represented 6% and 9% of revenue for the first nine months of 2012 and 2011, respectively. One customer represented 21% and 30% of accounts receivable at September 30, 2012 and September 30, 2011, respectively. The Company provides for uncollectible amounts when specific credit issues arise. Management's estimates for uncollectible amounts have been adequate during prior periods, and management believes that all significant credit risks have been identified at September 30, 2012.

Revenue by geographical region is as follows:

| | Nine months ended September 30, | |
|---------------|------------------------------------|--------------|
| | 2012 | 2011 |
| United States | \$24,084,836 | \$20,639,609 |
| Rest of World | 773,202 | 409,171 |
| | \$24,858,038 | \$21,048,780 |

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 included amounts due to American Donor Services, a supplier of donors to the Company (See Note 15).

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 Long-term 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. See further discussion of goodwill in Note 3 below.

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 is recognized in the 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 and 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 first three quarters of 2012 and 2011.

Non Cash Consulting Expense

From time to time, the Company issues restricted stock awards to consultants and advisors to the Company. These awards are marked to market 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. Advertising costs of approximately \$50,000 and \$59,000 were expensed for the nine months ended September 30, 2012 and 2011, respectively.

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.

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 further discussion and disclosures in Note 12.

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 in the first three quarters of 2012 or 2011.

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. Dilutive shares were 4,826,903 for the nine months ended September 30, 2011. Diluted net loss per share was the same as basic net loss per share for the three months ended September 30, 2011 and three and nine months ended September 30, 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.

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, 2012 and September 30, 2011, 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, 2012 and December 31, 2011 that are measured at fair value on a recurring basis:

Warrant derivative liability

| | As of September 30, 2012 | As of December 31, 2011 |
|---------|--------------------------------|-------------------------------|
| Level 1 | - | - |
| Level 2 | - | - |
| Level 3 | \$ 951,361 | \$ 2,344,516 |

Acquisition contingent consideration liability

| | As of September 30, 2012 | As of December 31, 2011 |
|---------|--------------------------------|-------------------------------|
| Level 1 | - | - |
| Level 2 | - | - |
| Level 3 | \$ 91,740 | 450,166 |

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

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 period ending September 30, 2012:

Warrant derivative liability

| | |
|-------------------------------|-------------|
| Balance at January 1, 2012 | \$2,344,516 |
| Gain recognized in earnings | (1,393,155) |
| Balance at September 30, 2012 | \$951,361 |

Acquisition contingent consideration liability

| | |
|----------------------------------|-----------|
| Balance at January 1, 2012 | \$450,166 |
| Reduction recognized in earnings | (358,426) |
| Balance at September 30, 2012 | \$91,740 |

During the nine months ended September 30, 2012, the Company did not change any of the valuation techniques used to measure its liabilities at fair value.

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 discounted the \$16.8 million of estimated payments at an interest rate of 16.7%. Accordingly, these inputs are classified as Level 3 inputs.

Recent Accounting Pronouncements

In September 2011, the FASB issued ASU 2011-08 on testing goodwill for impairment that will become effective for the Company in the first quarter of 2012; however, early adoption is permitted. Under the new guidance, an entity has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the entity determines that this threshold is not met, then performing the two-step impairment test is unnecessary. The Company elected to early adopt this pronouncement in 2011.

Reclassification of Prior Year Amounts

We have reclassified certain prior year amounts to conform to the current year presentation.

(2) Equity

In the second quarter of 2011, we raised \$3,027,504 in a private placement transaction under Rule 506 of Regulation D. The transaction resulted in the issuance of 939,377 shares of our common stock and warrants to purchase 375,747 shares of our common stock.

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

In consideration for entering into the Purchase Agreement, we issued 128,506 shares of our common stock to LPC as initial commitment shares and we agreed to issue up to 164,675 additional commitment shares on a pro rata basis when LPC purchases additional shares. The Purchase Agreement allowed us to require LPC to purchase up to \$30 million of our common stock from time to time, and also allowed us to terminate the Purchase Agreement for any reason or for no reason with one business day's notice to LPC.

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

On May 3, 2012, we terminated the LPC Purchase Agreement.

(3) Acquisition

On July 11, 2011, we signed an Asset Purchase Agreement (“Agreement”) with Robinson MedSurg, LLC (“Seller”), a company engaged in the manufacture, distribution and sale of implantable medical devices for maxillofacial, craniofacial and orthopedic uses. These products are used by many of our current customers and therefore represents an opportunity to expand our product offerings to these customers. Under the terms of the Agreement, we purchased certain assets from Seller, as described in the Agreement, for \$1 million in common stock. In addition, we agreed to pay Seller an additional \$500,000 in common stock when gross revenue from the sale of products resulting from the

purchased assets (“Products”) equals or exceeds \$1 million, and an additional \$500,000 in common stock when gross revenue from the sale of Products equals or exceeds \$2 million, provided that such gross revenue thresholds are achieved within 2 years. We also engaged the sole member of Seller as a consultant. We accounted for this business combination under the acquisition method in accordance with ASC 805 – Business Combinations, which requires the acquiring entity in a business combination to recognize all (and only) the assets acquired and liabilities assumed in the transaction; establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed; and requires the acquirer to disclose to investors and other users all of the information they need to evaluate and understand the nature and financial effect of the business combination.

The purchase price was allocated as follows:

| | |
|----------------------|--------------|
| Finished inventory | \$ 504,827 |
| Customer list | 157,077 |
| Trademark | 59,644 |
| Goodwill | 728,618 |
| | |
| Total purchase price | \$ 1,450,166 |

Goodwill is primarily made up of business synergies expected from the additional product offerings through our established distribution network. Goodwill is not expected to be deductible for tax purposes.

The consideration for the purchase price was made up of the following components:

| | |
|--------------------------|--------------|
| Stock issued | \$ 1,000,000 |
| Contingent consideration | 450,166 |
| Total consideration | \$ 1,450,166 |

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 the first nine months of 2012, management reviewed and adjusted the assumptions associated with the contingent liability which resulted in a reduction of the contingent liability to \$91,740 as of September 30, 2012.

The useful lives of the Customer List and the Trademark are 5 years and 15 years, respectively resulting in the following amortization schedule:

| | |
|----------------|------------|
| Remaining 2012 | 8,848 |
| 2013 | 35,392 |
| 2014 | 35,392 |
| 2015 | 35,392 |
| 2016 | 35,392 |
| Thereafter | 22,065 |
| Total | \$ 172,481 |

(4) Inventories

Inventories consist of the following:

| | September 30, 2012 | December 31, 2011 |
|--------------------------------|-----------------------|----------------------|
| Current inventories | | |
| Raw materials | \$ 2,397,958 | \$ 1,612,901 |
| Work in process | 4,867,762 | 2,586,047 |
| Finished goods | 6,980,008 | 5,107,400 |
| | 14,245,728 | 9,306,348 |
| Reserve | (836,188) | (826,638) |
| Current inventories, total | \$ 13,409,540 | \$ 8,479,710 |
| Non-current inventories | | |
| Finished goods | \$ 1,083,208 | \$ 920,542 |
| Non-current inventories, total | \$ 1,083,208 | \$ 920,542 |
| Total inventories | \$ 14,492,748 | \$ 9,400,252 |

(5) Property and Equipment, Net

Property and equipment, net are as follows:

| | September 30, 2012 | December 31, 2011 |
|-----------|-----------------------|----------------------|
| Buildings | \$ 1,653,263 | \$ 1,653,263 |

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| | | |
|--------------------------------|--------------|--------------|
| Equipment | 5,223,261 | 3,597,471 |
| Computer equipment | 328,907 | 392,375 |
| Computer software | 392,223 | 228,054 |
| Furniture and fixtures | 170,118 | 171,418 |
| Leasehold improvements | 1,200,936 | 1,357,218 |
| Vehicles | 78,306 | 68,306 |
| Total cost | 9,047,014 | 7,468,105 |
| Less: accumulated depreciation | (4,163,783) | (3,693,965) |
| | \$ 4,883,231 | \$ 3,774,140 |

The Company leases certain equipment under capital leases. As of September 30, 2012, the Company has recorded \$656,319 gross assets in Equipment, and \$55,695 of accumulated depreciation relating to assets under capital leases.

Maintenance and repairs expense for the nine months ended September 30, 2012 and 2011 was \$204,947 and \$71,652, respectively. Depreciation expense related to property and equipment, including property under capital lease for the nine months ended September 30, 2012 and 2011 was \$516,162 and \$499,607, respectively.

(6) Intangible Assets

Bacterin has been issued various patents with regards to processes for its products and acquired trademarks and customer lists.

The following table sets forth information regarding intangible assets:

| | September 30, 2012 | December 31, 2011 |
|--------------------------|--------------------------|----------------------|
| Intellectual Property | | |
| Gross carrying value | \$809,615 | \$ 809,615 |
| Accumulated amortization | \$(222,640) | \$ (153,482) |
| Net carrying value | \$586,975 | \$ 656,133 |

Aggregate amortization expense: \$69,158 \$ 53,638

Estimated amortization expense:

| | |
|-------------------|------------|
| Remainder of 2012 | \$ 5,718 |
| 2013 | \$ 74,921 |
| 2014 | \$ 74,921 |
| 2015 | \$ 74,921 |
| 2016 | \$ 74,921 |
| Thereafter | \$ 281,573 |

(7) Accrued Liabilities

Accrued liabilities consist of the following:

| | September 30, 2012 | December 31, 2011 |
|----------------------------------|-----------------------|----------------------|
| Acquisition contingent liability | \$ 91,740 | \$ 450,166 |
| Accrued stock compensation | 306,881 | 608,933 |
| Wages/commissions payable | 1,329,197 | 1,289,827 |
| Other accrued expenses | 522,799 | 1,413,285 |
| | \$ 2,250,617 | \$ 3,762,211 |

(8) Long-term Debt

On July 29, 2011, we entered into Loan and Security Agreement with MidCap Funding III, LLC (“MidCap”), whereby MidCap and Silicon Valley Bank (“SVB”) agreed to provide a \$15 million credit facility which allowed us to borrow \$7 million and up to an additional \$8 million in connection with a permitted acquisition through December 31, 2011. The \$8 million portion expired unused as of December 31, 2011. The credit facility was secured by substantially all of our assets and carried an interest rate of LIBOR plus 7.5%, subject to a LIBOR floor rate of 3% and contained covenants based upon revenue thresholds. Repayment was interest only for the first nine months, with principal and interest for the subsequent 33 months. In the second quarter of 2012, the interest only period was extended through December 31, 2012. We repaid this loan in full with the proceeds from our credit facility with ROS Acquisition Offshore LP on August 24, 2012.

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 for the next nine months 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. The Company repaid this accounts receivable credit facility in full with the proceeds from the credit facility with ROS Acquisition Offshore LP on August 24, 2012.

On August 24, 2012, the Company entered into a Credit Agreement with ROS Acquisition Offshore LP (“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. Bacterin has the right to repurchase the loan and royalty interest at amount to be determined based on the date of repurchase 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 over the seven year term of the loan and royalty liability will be amortized over the ten year term of the royalty agreement.

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 plans to use the net proceeds for working capital and general corporate purposes.

Long-term debt consists of the following:

| | September 30, 2012 | December 31, 2011 |
|--|-----------------------|----------------------|
| Loan payable to ROS Acquisition Offshore, LIBOR plus 12.13% maturing August 2019 | \$ 20,000,000 | \$ - |
| Loan payable to MidCap, LIBOR plus 7.5% maturing January 2015 | - | 4,666,667 |
| Loan payable to SVB, LIBOR plus 7.5% maturing January 2015 | - | 2,333,333 |
| 6.00% loan payable to Valley Bank of Belgrade, \$10,746 monthly payments including interest, maturing December 24, 2030; secured by building | 1,432,827 | 1,464,183 |
| | 21,432,827 | 8,464,183 |
| Less: Current portion | (44,465) | (1,632,978) |
| Debt discount | (7,166,722) | (192,935) |
| Long-term debt | \$ 14,221,640 | \$ 6,638,270 |

The following is a summary of maturities due on the debt as of September 30, 2012:

| | |
|-------------------|--------------|
| Remainder of 2012 | 11,538 |
| 2013 | 45,135 |
| 2014 | 47,919 |
| 2015 | 50,875 |
| 2016 | 1,720,679 |
| Thereafter | 19,556,681 |
| Total | \$21,432,827 |

(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 incentive compensation plan is to enable us to attract, retain and motivate key employees, directors and, on occasion, independent consultants, by providing them with stock options and restricted stock grants. Stock options granted under the incentive compensation 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 currently 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 incentive plan, including the exercise price, the number of shares subject to the stock option and conditions of exercise. Stock options granted under the incentive 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 incentive plan must be at least equal to the fair market value of the shares of common stock on the date of the grant. The Plan has 9 million shares authorized and at September 30, 2012, we had approximately 2,518,065 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, 2012 and 2011 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. 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 1.25% for the nine months ended September 30, 2012.

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 6.34 years for the nine months ended September 30, 2012.

Volatility: We estimate expected volatility based on peer-companies as prescribed by ASC 718. We used a weighted-average volatility rate of 66% for the nine months ended September 30, 2012.

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, 2012.

Activity under our stock option plans was as follows:

| | September 30, 2012 | | | September 30, 2011 | | |
|-----------------------------|--------------------|---------------------------------|---|--------------------|---------------------------------|---|
| | 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 | 4,828,910 | \$ 2.14 | \$ 1.01 | 3,850,743 | \$ 1.38 | \$ 0.83 |
| Granted | 1,105,000 | 2.00 | 1.19 | 1,710,500 | 2.92 | 1.35 |
| Exercised | (39,375) | 0.87 | 0.37 | (509,833) | 1.37 | 0.68 |
| Cancelled or expired | (1,152,250) | 2.01 | 0.78 | (361,750) | 2.94 | 1.54 |
| Outstanding at September 30 | 4,742,285 | \$ 2.11 | \$ 1.04 | 4,689,660 | \$ 1.98 | \$ 0.92 |
| Exercisable at September 30 | 2,242,118 | \$ 1.77 | \$ 0.76 | 2,081,910 | \$ 1.34 | \$ 0.60 |

Stock option expense was \$623,565 and \$708,704 for the nine months ended September 30, 2012 and September 30, 2011, respectively. The total intrinsic value of options exercised in the first nine months of 2012 was \$41,778. The aggregate intrinsic value of options outstanding and exercisable as of September 30, 2012 is \$688,846. As of September 30, 2012, there were 2,500,167 unvested options with a weighted average fair value at the grant date of \$1.27 per option. As of September 30, 2012, the total compensation related to nonvested awards not yet recognized is \$3,183,994 and is expected to be recognized over 3.6 years.

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 nine months ended September 30, 2012:

| | Shares |
|-----------------------------------|------------|
| Outstanding at January 1, 2012 | 1,632,900 |
| Awarded | 84,992 |
| Vested | (368,992) |
| Outstanding at September 30, 2012 | 1,348,900 |

The restricted stock awards generally vest over three to five year periods. The Company recognized non cash consulting expense of \$491,051 and \$1,097,005 for the nine months ended September 30, 2012 and 2011, respectively. As of September 30, 2012, the total expense related to nonvested restricted stock awards not yet recognized is \$1,036,759 and is expected to be recognized over four years.

(10) Warrants

Associated with the second quarter of 2011 private placement of common stock, 375,747 warrants with exercise prices ranging from \$2.95 to \$3.52 were issued to the participants. Warrants issued with common stock under this private placement were recorded as additional paid in capital at their estimated fair market value of \$312,285 during the second quarter of 2011.

In connection with the July 29, 2011 MidCap financing described above, MidCap and SVB received 192,157 warrants to purchase shares of our common stock equal to 7% of the amount drawn on the credit facility divided by the exercise price of \$2.55 per share. The warrants have a seven year term. MidCap and SVB also have the right to receive additional warrants if additional amounts are drawn under the facility. The fair value of these warrants, \$227,388, was recorded as a discount to the underlying debt and additional paid in capital.

In the third quarter of 2012, the Company accounted for 297,991 warrants with an exercise price of \$2.30 earned by the broker in 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. These warrants were issued in the fourth quarter of 2012. 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 period ended September 30, 2012:

| | Shares | Weighted Average Exercise Price |
|-----------------------------------|------------|--|
| Outstanding at January 1, 2012 | 6,967,529 | \$ 2.22 |
| Issued | 742,586 | 1.79 |
| Exercised | (146,184) | 1.57 |
| Outstanding at September 30, 2012 | 7,563,931 | \$ 2.19 |

The exercise of 146,184 warrants in the first nine months of 2012 resulted in the issuance of 129,972 shares of common stock as the warrants were exercised using the cashless feature of the warrants.

We utilize a lattice model to determine the fair market value of the warrants. The 1,570,565 warrants issued in connection with our 2010 bridge financings and the 375,000 warrants issued in connection with our 2010 WTI financing were accounted for as derivative liabilities in connection with the price protection provisions of the warrants in compliance with ASC 815. There were 133,474 additional warrants issued to WTI in the first quarter of 2011 and 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. The lattice model accommodates the probability of exercise price adjustment features as outlined in the warrant agreements. We recorded an unrealized gain of \$1,393,155 resulting from the change in the fair value of the warrant derivative liability for the nine months ended September 30, 2012, respectively. 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:

| | | |
|--|---------|-------|
| Value of underlying common stock (per share) | \$ 1.55 | |
| Risk free interest rate | 0.38 | % |
| Expected term | 4.15 | years |
| Dividend yield | 0 | % |
| Volatility | 62 | % |

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

| | |
|-------------------------------|-----------|
| Balance at January 1, 2012 | 1,506,007 |
| Derivative warrants issued | 143,700 |
| Balance at September 30, 2012 | 1,649,707 |

(11) Commitments and Contingencies

Operating Leases

We lease two office facilities under non-cancelable operating lease agreements with expiration dates in 2013 and 2019. 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, 2012, under these leases, are as follows:

| | |
|-------------------|-----------|
| Remainder of 2012 | \$43,675 |
| 2013 | \$93,000 |
| 2014 | \$113,400 |
| 2015 | \$113,400 |
| 2016 | \$113,400 |
| Thereafter | \$236,250 |

Rent expense was \$234,316 and \$141,394 for the nine months ended September 30, 2012 and 2011, 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

In November 2009, a complaint was served on the Company in connection with the following court action filed in Utah state court: Yanaki and Activatek, Inc. v. Cook and Bacterin International, Inc., Case Number 090912772. The complaint involves attempts by one of the plaintiffs, Yanaki, to sell shares of the Company's common stock to a third party in a private sale. Plaintiffs claimed, as their primary allegation, that the Company intentionally interfered with the sales contract. Yanaki sought \$300,000, 358,904 shares of the Company's common stock, attorneys fees, costs and punitive damages. On July 17, 2012, the parties entered into a confidential settlement agreement which resolved this dispute.

On March 2, 2012, Bacterin International, Inc. ("Bacterin") filed a Complaint and Jury Demand in the United States District Court for the District of Colorado in Civil Action No. 12cv558-REB-MEH against Tissue Transplant Technology, Ltd, a Texas Limited Partnership and its general partner T-TOT, LLC, a Texas Limited Liability Company; and Transplant Technologies of Texas, Ltd, a Texas Limited Partnership, and its general partners TTT, LLC, a Texas Limited Liability Company and JWL Management, LLC, a Texas Limited Liability Company. Defendant Tissue Transplant Technology, LTD is using the trademark "Sterisponge" to identify various allograft products in the marketplace. In view of Bacterin's prior and established rights in the mark "Osteosponge," Bacterin asserted against Tissue Transplant Technology, LTD claims for trademark infringement under federal law, unfair competition under federal law, trademark infringement under Colorado common law, and unfair competition under Colorado common law. In addition, Bacterin also asserted against Transplant Technologies of Texas, LTD a claim for cancellation of a Federal Registration for "Sterisponge". Bacterin sought injunctive relief, damages and exemplary damages to be determined at trial. The parties entered into a settlement agreement whereby Tissue Transplant Technologies has agreed to discontinue use of their SteriSponge mark.

On April 4, 2012, Bacterin International, Inc. filed suit against SeaArk Capital, LLC and its principal, Mark Bartosh, seeking recovery of \$1,648,993.58 for product delivered to SeaArk in 2011. The case is pending in the United States District Court of the Eastern District of Pennsylvania.

On April 19, 2012, Bacterin International, Inc. filed a lawsuit in federal court in Dallas, Texas, seeking injunctive relief and damages against Shantal Howell, a former regional vice president of the company. The suit arises out of the former employee's breach of contract, breach of fiduciary duties, interference with Bacterin's business relationships, and misappropriation of Bacterin's trade secrets. On June 8, 2012, Howell asserted a counterclaim against Bacterin for

breach of contract and defamation, seeking damages for allegedly owed commissions and loss of business. The case is currently in the pre-trial phase and trial is scheduled for October 2013.

(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 2011 tax years remain open to examination by the Internal Revenue Service and the 2006 to 2011 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, 2012 and 2011.

(13) Employee Benefit Plans

As of January 1, 2011, we switched from a SIMPLE IRA to a 401(k) retirement plan. Qualified employees may defer their salary and the deferrals are matched up to 2%. The plan covers substantially all full-time employees. Under the terms of the plan, participants may contribute up to the lower of \$16,500 of their salary or the statutorily prescribed limit to the plan. Employees are eligible after six months of employment and may enroll twice a year in January and July.

(14) Supplemental Disclosure of Cash Flow Information

Supplemental cash flow information is as follows:

| | Nine months ended September 30, | |
|---|------------------------------------|-------------|
| | 2012 | 2011 |
| Supplemental disclosure of cash flow information | | |
| Cash paid during the period for: | | |
| Interest | \$815,031 | \$1,039,703 |
| Income taxes | - | - |
| Non-cash activities: | | |
| Capital lease acquisition | \$408,257 | \$- |
| Issuance of warrants | \$220,872 | \$227,388 |
| Non-cash accrued compensation | \$304,680 | \$- |
| Debt discount related to financing | \$7,341,520 | \$- |
| Royalty liability related to financing | \$7,341,520 | \$- |
| Acquisition contingent consideration | \$- | \$450,166 |
| Issuance of stock for business acquisition | \$- | \$1,000,000 |
| Conversion of accounts payable into common stock | \$- | \$600,000 |
| Decrease in warrant derivative liability due to warrant | \$- | \$968,554 |

(15) Related Party Transactions

Our Chief Executive Officer (“CEO”) serves as a Board member of West Coast Tissue Services. In addition, one of our directors, Mitchell Godfrey, serves as a Board member of American Donor Services. Both of these entities recover tissues from donors and we reimburse them for recovery fees including labor costs. These relationships benefit us, thus insuring we have a pipeline of current and future donors which is necessary for our success. As of September 30, 2012, we had an accounts payable balance of \$429,081 to American Donor Services. No compensation is paid to our CEO or our director for their services to those entities.

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 the CEO’s adult children to become a distributor of the Company’s products. This entity acquired inventory from Allograft Tissue Management, a distributor that had previously acquired inventory from the Company.

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 our Annual Report on Form 10-K filed with the SEC on March 29, 2012.

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, 2012 and September 30, 2011

Revenue

Total revenue for the three months ended September 30, 2012 increased 18% to \$8,879,765 compared to \$7,539,501 in the comparable prior year period. The increase of \$1,340,264 was largely the result of increased sales generated from our direct sales force and independent distributors compared to the third quarter of 2011. Since 2009, we have been transitioning from a 100% distributor based sales model to a hybrid model which includes sales from our direct sales force as well as independent distributors which has increased the market penetration of our products.

Cost of tissue and medical devices sales

Costs of tissue sales consist primarily of tissue and medical device manufacturing costs. Costs of sales increased by 97% or \$1,281,846 to \$2,600,452 from \$1,318,606 for the three months ended September 30, 2011. As a percentage of tissue sales, cost of tissue sales was 29% of revenues for the third quarter of 2012 compared to 17% in the comparable prior year period. In the last quarter of 2011, we experienced an increase to the percentage of our overhead expense allocated to cost of tissue sales based upon increased production which resulted in a higher cost of tissue sales than the prior year period.

Operating Expenses

Operating expenses include general and administrative expenses, selling and marketing expenses, depreciation and amortization, and compensation costs, including incentive compensation. Operating expenses decreased 22%, or \$1,719,925, for the three months ended September 30, 2012 compared to the three months ended September 30, 2011. Fluctuations are discussed 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 \$290,037, to \$2,439,229, for the three months ended September 30, 2012 compared to the same period of 2011. The increase is primarily due to higher administrative costs supporting the higher revenue in addition to added rental and maintenance expense for increased operational space.

Selling and Marketing

Selling and marketing expenses primarily consist of costs for commissions, sales wages, 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 decreased 30%, or \$1,457,198, to \$3,352,394 for the three months ended September 30, 2012 from \$4,809,592 for the comparable prior year period. As a percentage of revenue, selling and marketing expenses decreased to 38% in the third quarter of 2012 from 64% in the third quarter of 2011. The decreases were primarily the result of more variable compensation paid to our direct sales force compared to salaries earned in the comparable period of 2011 and a lower corporate sales commission structure.

Depreciation and Amortization

Depreciation expense consists of depreciation of long-lived property and equipment while amortization expense consists of amortization of intangible assets. Depreciation and amortization expense decreased 26% to \$88,112 for the three months ended September 30, 2012 from \$119,213 in the comparable prior year period. The decrease is due to certain assets reaching the end of their accounting useful lives thereby reducing the depreciation expense.

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 \$521,663 to \$186,867 of expense in the third quarter of 2012. The decrease is due to a lower closing price of the Company's common stock as of September 30, 2012 resulting in lower expense associated with the consulting contracts.

Interest Expense

Interest expense is from our promissory notes and capital leases. Interest expense for the third quarter of 2012 increased \$326,731 to \$867,894, as compared to \$541,163 in the third quarter of 2011. The increase was the result of the higher debt balance and interest rate relating to the new \$20 million credit facility entered into in the third quarter of 2012.

Change in Warrant Derivative Liability

For the third quarter of 2012, the Company recorded an increase in its non cash warrant derivative liability of \$125,972 based upon the slight increase in the closing price of the Company's common stock at September 30, 2012 compared to June 30, 2012. The liability is associated with the issuance of warrants as part of its convertible debt financing, and WTI financing which contain anti dilution adjustment provisions requiring the Company to record a change in the warrant derivative liability from period to period.

Other Expense

Other expense was \$1,738,202 for the three months ended September 30, 2012, up \$435,669 or 33% from the same period in 2011. The increase was due to the prepayment penalties expensed and the write-off of capitalized debt issuance costs resulting from terminating the MidCap financing agreement in the third quarter of 2012.

Comparison of Nine Months Ended September 30, 2012 and September 30, 2011

Revenue

Total revenue for the nine months ended September 30, 2012 increased 18% to \$24,858,038 compared to \$21,048,780 in the comparable prior year period. The increase of \$3,809,258 was largely the result of increased sales generated from our direct sales force and independent distributors compared to the first nine months of 2011. Since 2009, we have been transitioning from a 100% distributor based sales model to a hybrid model which includes sales from our direct sales force as well as independent distributors which has increased the market penetration of our products.

Cost of tissue and medical devices sales

Costs of tissue sales consist primarily of tissue and medical device manufacturing costs. Costs of sales increased by 68% or \$2,740,557 to \$6,788,606 for the first nine months of 2012 from \$4,048,049 for comparable period of 2011. The increase was largely the result of increased costs associated with our higher sales. As a percentage of tissue sales, cost of tissue sales was 27% of revenues for the first three quarters of 2012 compared to 19% in the comparable prior year period. In the last quarter of 2011, we experienced an increase to the percentage of our overhead expense allocated to cost of tissue sales based upon increased production which resulted in a higher cost of tissue sales than the prior year period.

Operating Expenses

Operating expenses include general and administrative expenses, selling and marketing expenses, depreciation and amortization, and compensation costs, including incentive compensation. Operating expenses decreased 6%, or \$1,305,418, for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. Fluctuations are discussed 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 22%, or \$1,322,475, to \$7,349,852, for the nine

months ended September 30, 2012 compared to the same period of 2011. The increase is primarily due to higher administrative costs supporting the higher revenue in addition to added rental and maintenance expense for increased operational space.

Selling and Marketing

Selling and marketing expenses primarily consist of costs for commissions, sales wages, 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 decreased 15%, or \$2,071,072, to \$11,333,946 for the nine months ended September 30, 2012 from \$13,405,018 for the comparable prior year period. As a percentage of revenue, selling and marketing expenses decreased to 46% in the first nine months of 2012 from 64% in the first nine months of 2011. The decreases were primarily the result of more variable compensation paid to our direct sales force compared to salaries earned in the comparable period of 2011 and a lower corporate sales commission structure.

Depreciation and Amortization

Depreciation expense consists of depreciation of long-lived property and equipment while amortization expense consists of amortization of intangible assets. Depreciation and amortization expense increased 19% to \$302,392 for the nine months ended September 30, 2012 from \$253,259 in the comparable prior year period. The increase reflects increased equipment purchases made since September 30, 2011 and a full nine months of depreciation in 2012 on the assets acquired in the second quarter of 2011 acquisition of Robinson MedSurg.

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 \$605,954 to \$491,051 of expense in the first nine months of 2012 from \$1,097,005 for the comparable period of 2011. The decrease is due to the lower closing price of the Company's common stock at September 30, 2012 which was partially offset by more contracts in place in 2012.

Interest Expense

Interest expense is from our promissory notes and capital leases. Interest expense for the first nine months of 2012 increased \$237,243 to \$1,276,946, as compared to \$1,039,703 in the first nine months of 2011. The increase was the result of the higher debt balance and interest rate relating to the new \$20 million credit facility entered into in the third

quarter of 2012.

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Change in Warrant Derivative Liability

For the first nine months of 2012, the Company recorded a decrease in its non cash warrant derivative liability of \$1,393,155 based upon the decrease in the closing price of the Company's common stock at September 30, 2012 compared to December 31, 2011. The liability is associated with the issuance of warrants as part of its convertible debt financing, and WTI financing which contain anti dilution adjustment provisions requiring the Company to record a change in the warrant derivative liability from period to period.

Other Expense

Other expense was \$1,544,035 for the nine months ended September 30, 2012, up \$241,502 or 19% from the same period in 2011. The increase was due to the prepayment penalties expensed and the write-off of capitalized debt issuance costs resulting from terminating the MidCap financing agreement 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 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. At September 30, 2012, we had approximately \$15,800,546 of cash and cash equivalents and accounts receivables.

Net cash used in operating activities for the first nine months of 2012 was \$7,948,517. This was primarily related to cash used to fund our operations as well as an increase in our inventory balance of \$5,092,496. For the first nine months of 2011, net cash used in operating activities was \$7,809,289.

Net cash used in investing activities for the nine months ended September 30, 2012 was \$1,216,723 due to the purchase of property and equipment.

Net cash provided by financing activities was \$17,030,117 for the first nine months of 2012 which was primarily due to the net proceeds of the new term loan in addition to cash raised through the issuance of 1,475,037 shares of our

common stock to Lincoln Park Capital for aggregate proceeds of approximately \$3,899,996.

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, 2012 cash on hand and accounts receivable balance of \$15,800,546 and anticipated cash receipts from sales expected from operations will be sufficient to meet our anticipated cash requirements through September 30, 2013. We incurred approximately \$19 million in sales and marketing expenses in 2011 and expect to incur \$16 million in 2012. 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, 2012. Based upon that evaluation, we concluded that as of September 30, 2012, 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, 2012.

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 framework 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, 2012 due to material weaknesses in our internal control over financial reporting that have not been fully remediated as of September 30, 2012 as detailed below:

1) During 2011, the Company kept its inventory records under a separate operating system than its accounting system. Accordingly, duplicate input was required for both systems, increasing the risk of errors in recording inventory transactions while requiring numerous reconciliations to be performed by Company personnel. In addition, the inventory system did not have the capability to generate historical detailed inventory reports which limited our ability to reconcile discrepancies between the accounting system and the inventory system.

Our efforts to remediate the weakness include the following:

During 2011, we purchased an integrated accounting operating and inventory system, and on December 28, 2011, -we switched over to the new system. We believe our new system will substantially improve our ability to track our inventory.

2) Insufficient number of personnel with the appropriate level of experience and technical expertise to appropriately resolve routine, including monthly and quarterly sales and accounts payable cutoff timing, as well as complex accounting matters 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.

Our efforts to remediate this weakness include the following:

-We hired an outside consultant to advise us on certain technical accounting issues.

-We hired an accounting manager in the second quarter of 2012.

3) 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.

Our efforts to remediate the weakness include the following:

Development of a standard operating procedure for the grant of all equity securities including the approval process by the Compensation Committee and the Board of Directors.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

On April 4, 2012, Bacterin International, Inc. filed suit against SeaArk Capital, LLC and its principal, Mark Bartosh, seeking recovery of \$1,648,993.58 for product delivered to SeaArk in 2011. The case is pending in the United States District Court of the Eastern District of Pennsylvania.

On April 19, 2012, Bacterin International, Inc. filed a lawsuit in federal court in Dallas, Texas, seeking injunctive relief and damages against Shantal Howell, a former regional vice president of the company. The suit arises out of the former employee's breach of contract, breach of fiduciary duties, interference with Bacterin's business relationships, and misappropriation of Bacterin's trade secrets. On June 8, 2012, Howell asserted a counterclaim against Bacterin for breach of contract and defamation, seeking damages for allegedly owed commissions and loss of business. The case is currently in the pre-trial phase and trial is scheduled for October 2013.

Item 1A Risk Factors

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

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

Nothing to report for the quarterly period ended September 30, 2012.

Item 3. Defaults Upon Senior Securities

None

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 January 12, 2011, incorporated by reference herein)

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

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Filed herewith

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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 8, 2012 By: /s/ Guy Cook
Name: Guy Cook
Title: President and Chief Executive Officer

Date: November 8, 2012 By: /s/ John P. Gandolfo
Name: John P. Gandolfo
Title: Chief Financial Officer