

Bacterin International Holdings, Inc.
Form 10-Q
May 12, 2014

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
X ACT OF 1934**

For the quarterly period ended March 31, 2014

OR

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

For the transition period from to

Commission file number: 001-34951

BACTERIN INTERNATIONAL HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction)

20-5313323
(I.R.S. Employer)

of incorporation or organization) 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 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 May 6, 2014: 54,975,576

BACTERIN INTERNATIONAL HOLDINGS, INC.

FORM 10-Q

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1.	<u>Financial Statements</u>	
	<u>Condensed Consolidated Balance Sheets as of March 31, 2014 (unaudited) and December 31, 2013</u>	5
	<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2014 and 2013 (unaudited)</u>	6
	<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2014 and 2013 (unaudited)</u>	7
	<u>Notes to Consolidated Financial Statements</u>	8
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4.	<u>Controls and Procedures</u>	22

PART II. OTHER INFORMATION

Item 1.	<u>Legal Proceedings</u>	23
Item 1A.	<u>Risk Factors</u>	23
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	32
Item 3.	<u>Defaults Upon Senior Securities</u>	32
Item 4.	<u>Mine Safety Disclosures</u>	32
Item 5.	<u>Other Information</u>	32

Item 6. Exhibits

32

2

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:

- .. our ability to obtain financing on reasonable terms;
- .. our ability to increase revenue;
- .. our ability to remain listed on the NYSE MKT exchange;
- .. our ability to comply with the covenants in our credit facility;
- .. our ability to maintain sufficient liquidity to fund our operations;
- .. our ability to obtain shareholder approval to increase our authorized shares of common stock;
- .. the ability of our sales force to achieve expected results;
- .. our ability to remain competitive;
- .. government regulations;
- .. our ability to expand our production capacity;

- “ our ability to innovate and develop new products;
- “ our ability to obtain donor cadavers for our products;
- “ our ability to engage and retain qualified technical personnel and members of our management team;
- “ government and third-party coverage and reimbursement for our products;
- “ our ability to obtain regulatory approvals;
- “ 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 studies;
- “ our ability to obtain and protect our intellectual property and proprietary rights;
- “ infringement and ownership of intellectual property;
- “ 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 March 31, 2014 (unaudited)	As of December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	\$4,768,622	\$3,046,340
Trade accounts receivable, net of allowance for doubtful accounts of \$1,411,409 and \$1,309,859, respectively	5,528,865	4,793,834
Inventories, net	10,498,707	10,753,600
Prepaid and other current assets	981,535	574,910
Total current assets	21,777,729	19,168,684
Non-current inventories	2,069,710	2,119,952
Property and equipment, net	5,013,774	5,180,556
Intangible assets, net	616,746	586,965
Other assets	1,755,535	1,821,471
Total Assets	\$31,233,494	\$28,877,628
LIABILITIES & STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	\$4,249,574	\$2,767,639
Accounts payable - related party	610,514	647,844
Accrued liabilities	2,539,483	3,585,037
Warrant derivative liability	3,080,357	1,594,628
Current portion of capital lease obligations	170,241	171,926
Current portion of royalty liability	853,000	836,750
Current portion of long-term debt	48,447	47,727
Total current liabilities	11,551,616	9,651,551

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-Q

Long-term Liabilities:		
Capital lease obligation, less current portion	34,686	73,777
Long term royalty liability, less current portion	6,575,814	6,609,232
Long-term debt, less current portion	19,636,587	16,385,245
Total Liabilities	37,798,703	32,719,805
Commitments and Contingencies		
Stockholders' (Deficit) 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; 54,982,120 shares issued and outstanding as of March 31, 2014 and 53,432,820 shares issued and outstanding as of December 31, 2013	55	53
Additional paid-in capital	57,933,665	56,516,443
Accumulated deficit	(64,498,929)	(60,358,673)
Total Stockholders' (Deficit) Equity	(6,565,209)	(3,842,177)
Total Liabilities & Stockholders' (Deficit) Equity	\$31,233,494	\$28,877,628

See notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2014	2013
Revenue		
Tissue sales	\$ 8,751,345	\$ 8,523,348
Royalties and other	161,625	95,459
Total Revenue	8,912,970	8,618,807
Cost of tissue and medical devices sales	3,410,705	3,120,686
Gross Profit	5,502,265	5,498,121
Operating Expenses		
General and administrative	2,288,803	2,572,002
Sales and marketing	4,055,204	3,798,377
Research and development	254,583	285,080
Depreciation and amortization	75,148	106,378
Non-cash consulting expense	20,527	(30,297)
Total Operating Expenses	6,694,265	6,731,540
Loss from Operations	(1,192,000)	(1,233,419)
Other Income (Expense)		
Interest expense	(1,275,612)	(1,063,988)
Change in warrant derivative liability	(1,485,729)	635,355
Other (expense)	(186,915)	(7,206)
Total Other Income (Expense)	(2,948,256)	(435,839)
Net Loss	\$ (4,140,256)	\$ (1,669,258)
Net loss per share:		
Basic	\$ (0.08)	\$ (0.04)
Dilutive	\$ (0.08)	\$ (0.04)
Shares used in the computation:		
Basic	53,797,140	42,926,564
Dilutive	53,797,140	42,926,564

See notes to unaudited condensed consolidated financial statements.

BACTERIN INTERNATIONAL HOLDINGS, INC.**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

	Three Months Ended March 31,	
	2014	2013
Operating activities:		
Net loss	\$ (4,140,256)	\$ (1,669,258)
Noncash adjustments:		
Depreciation and amortization	169,148	200,378
Gain on sale of fixed assets	(13,285)	-
Amortization of debt discount	359,087	249,209
Non-cash consulting expense/stock option expense	322,222	29,310
Non-cash interest	-	(26,759)
Provision for losses on accounts receivable and inventory	168,120	85,388
Change in derivative warrant liability	1,485,729	(635,355)
Increase of contingent liability	-	7,206
Changes in operating assets and liabilities:		
Accounts receivable	(836,581)	(106,880)
Inventories	238,565	(455,773)
Prepaid and other assets	(340,689)	(302,808)
Accounts payable	1,444,605	(145,014)
Accrued liabilities	(1,045,554)	488,758
Net cash used in operating activities	(2,188,889)	(2,281,598)
Investing activities:		
Purchases of property and equipment and intangible assets	(54,933)	(477,837)
Proceeds from sale of fixed assets	36,073	-
Net cash used in investing activities	(18,860)	(477,837)
Financing activities:		
Proceeds from issuance of debt	4,000,000	-
Payments on long-term debt	(29,193)	(12,032)
Payments on capital leases	(40,776)	(35,520)
Net cash provided by (used in) financing activities	3,930,031	(47,552)
Net change in cash and cash equivalents	1,722,282	(2,806,987)
Cash and cash equivalents at beginning of period	3,046,340	4,926,066
Cash and cash equivalents at end of period	\$ 4,768,622	\$ 2,119,079

See notes to unaudited condensed consolidated financial statements.

7

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 bioactive coatings based on 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.

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 months ended March 31, 2014 and 2013 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, 2014.

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, 2013. 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% of sales were in the United States for the three months ended March 31, 2014 and 2013, respectively. One customer accounted for approximately 15% of the Company's revenue for the three months ended March 31, 2013. One customer represented 21% of accounts receivable at March 31, 2013. No single customer accounted for more than 10% of revenue or accounts receivable for the three months ended March 31, 2014. 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 March 31, 2014.

Revenue by geographical region is as follows:

	Three months ended March 31,	
	2014	2013
United States	\$8,742,073	\$8,433,834
Rest of World	170,897	184,973
	\$8,912,970	\$8,618,807

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; 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.

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.

After reviewing the full year product line sales associated with the goodwill asset and the fact that the sales were not meeting original projections, management engaged an independent third party to review the asset for impairment in accordance with and pursuant to ASC 350 and ASC 360-10. The implied fair value of the goodwill was determined in the same manner as the amount of goodwill recognized in a business combination, as determined under ASC 805. The Company and the independent third party concluded that the goodwill asset was impaired and recorded a goodwill impairment charge of \$728,618 as of December 31, 2013, which reduced the asset value to zero.

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 consolidated statement of operations during the period of change. See Note 9, “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.

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 13, “Related Party Transactions” below.

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 RyMed and Bard Access Systems. Revenue under these agreements represented less than 1% of total revenue for the three months ended March 31, 2014 and 2013.

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 advertising expense of \$26,711 and \$168,780 for the quarters ended March 31, 2014 and 2013, 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 Note 11, "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 quarters ended March 31, 2014 or 2013.

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 quarters ended March 31, 2014 and 2013 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. Dilutive earnings per share are not reported as their effects of including 18,418,493 and 11,985,029 outstanding stock options and warrants for the three months ended March 31, 2014 and 2013, respectively are anti-dilutive.

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.

The Company follows 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 three months ended March 31, 2014 and 2013, 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 March 31, 2014 and December 31, 2013 that are measured at fair value on a recurring basis:

Accrued stock compensation

	As of March 31, 2014	As of December 31, 2013
Level 1	\$ 196,662	\$ 211,212
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

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-Q

	As of March 31, 2014	As of December 31, 2013
Level 1	-	-
Level 2	-	-
Level 3	\$3,080,357	\$ 1,594,628

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 three months ending March 31, 2013:

Warrant derivative liability

Balance at January 1, 2014	\$ 1,594,628
Loss recognized in earnings	1,485,729
Balance at March 31, 2014	\$3,080,357

During the quarter ended March 31, 2014, 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.

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

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 the Company of approximately \$4.45 million, after deducting approximately \$400,000 for placement agent's fees and offering expenses. Proceeds from the transaction were used to fund the Company's operations and working capital requirements.

On November 14, 2013, the Company received a waiver from ROS Acquisition Offshore LP ("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 issued 1,500,000 shares of restricted stock to an affiliate of ROS on November 25, 2013.

During the first quarter of 2014, we issued 1,500,000 shares of our common stock to an affiliate of ROS pursuant to a Sixth Amendment to our Credit Agreement with ROS whereby we borrowed an additional \$4 million under our Credit Agreement. This issuance has been accounted for as a debt discount and will be amortized over the life of the loan. See Note 7, "Long-Term Debt" below.

(3) Inventories

Inventories consist of the following:

	March 31, 2014	December 31, 2013
Current inventories		
Raw materials	\$2,859,196	\$2,710,091

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-Q

Work in process	3,144,738	3,333,672
Finished goods	5,586,405	5,775,813
	11,590,339	11,819,576
Reserve	(1,091,632)	(1,065,976)
Current inventories, total	10,498,707	10,753,600
Non-current inventories		
Finished goods	3,332,083	3,341,411
Reserve for obsolescence	(1,262,373)	(1,221,459)
Non-current inventories, total	2,069,710	2,119,952
Total inventories	\$12,568,417	\$12,873,552

(4) Property and Equipment, Net

Property and equipment, net are as follows:

	March 31, 2014	December 31, 2013
Buildings	\$1,658,396	\$1,653,263
Equipment	5,228,549	5,768,478
Computer equipment	312,650	312,650
Computer software	375,699	395,146
Furniture and fixtures	170,118	170,118
Leasehold improvements	2,335,690	1,808,461
Vehicles	41,099	41,099
Total cost	10,122,201	10,149,215
Less: accumulated depreciation	(5,108,427)	(4,968,659)
	\$5,013,774	\$5,180,556

The Company leases certain equipment under capital leases. For financial reporting purposes, minimum lease payments relating to the assets have been capitalized. As of March 31, 2014, the Company has recorded \$443,060 gross assets in Equipment, and \$119,157 of accumulated depreciation relating to assets under capital leases.

Maintenance and repairs expense for the first quarter of 2014 and 2013 was \$70,444 and \$83,846, respectively. Depreciation expense related to property and equipment, including property under capital lease for the first quarter of 2014 and 2013 was \$56,232 and \$181,461, respectively.

(5) Intangible Assets

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

The following table sets forth information regarding intangible assets:

	March 31, 2014	December 31, 2013
Intellectual Property		
Gross carrying value	\$939,731	\$ 891,034
Accumulated amortization	(322,985)	(304,069)
Net carrying value	\$616,746	\$ 586,965

Aggregate amortization expense: \$18,916 \$ 75,668

The following is a summary of estimated future amortization expense for intangible assets as of March 31, 2014:

Remainder of 2014	\$ 56,748
2015	75,664
2016	75,664
2017	75,664
2018	75,664
Thereafter	257,342
Total	\$ 616,746

(6) Accrued Liabilities

Accrued liabilities consist of the following:

	March 31, 2014	December 31, 2013
Accrued stock compensation	196,662	211,212
Wages/commissions payable	771,530	1,728,576
Other accrued expenses	1,571,291	1,645,249
	\$2,539,483	\$ 3,585,037

(7) Long-term Debt

On August 24, 2012, the Company entered into a Credit Agreement with ROS, which provided for an initial \$20 million term loan. The Credit Agreement also provided for an additional \$5 million upon achievement prior to December 31, 2013 of certain revenue objectives, which were not achieved. On March 6, 2014, we entered into a Sixth Amendment to our Credit Agreement which allowed us to borrow an additional \$4 million the Credit Agreement in exchange for 1,500,000 shares of our common stock. 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 ten years. Upon the occurrence of a defined event of default, ROS has the option to require the Company to purchase from ROS all of its rights to the remaining royalty payments that will become due in accordance with the royalty agreement (the "ROS Put Option"). The ROS Put Option meets the definition of an embedded derivative and we concluded it had an immaterial value at March 31, 2014 and 2013. As such, the Company has not recorded a derivative liability related to the ROS Put Option and has not recognized any change in the fair value of this derivative liability in the consolidated financial statements because the impact is immaterial. Management will reassess the fair value of the embedded derivative instrument at each reporting period and record if and when it becomes material to the consolidated financial statements. Bacterin has the right to repurchase the loan and royalty interest at amounts to be determined based on the date of repurchase, less the amount of prior principal, interest and royalty payments. We will also have to pay fees, currently in the amount of 3.5% of the aggregate principal amount of the loan, as a result of waivers and modifications we have received in connection with the financial covenants in the Credit Agreement. 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.

On August 24, 2012, the Company received net proceeds from ROS 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.

In 2013, we entered into a number of waivers and amendments to our credit facility with ROS, including amendments that increased the amount payable to ROS. These waivers and amendments are summarized below.

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 in the amount of 1.5% of the aggregate amount of any principal payment, prepayment or repayment.

On August 12, 2013, we entered into a Waiver and Second Amendment to our Credit Agreement with ROS whereby we granted ROS Board observer rights in exchange for a waiver of our failure to replace our former Chief Executive

Officer within 90 days of his resignation.

On August 12, 2013, we also entered into a Waiver and Third Amendment to our Credit Agreement with ROS whereby we agreed to pay an additional fee in the amount of 2% (in addition to our prior fee of 1.5%, for a total of 3.5%) of the aggregate amount of any principal payment, prepayment or repayment in exchange for a waiver of our failure to achieve the minimum revenue required in the second quarter of 2013.

On August 30, 2013, we entered into a Fourth Amendment to our Credit Agreement with ROS to revise the Board observer rights we granted to ROS.

On November 14, 2013, we entered into a Waiver and Fifth Amendment to our Credit Agreement with ROS whereby we agreed to issue 1.5 million shares of common stock to an affiliate of ROS in exchange for a waiver of our failure to achieve the minimum required revenue for the third quarter of 2013 and a reduction of future quarterly minimum revenue thresholds.

On March 6, 2014, we entered into a Sixth Amendment to our Credit Agreement with ROS whereby we borrowed an additional \$4 million under of our Credit Agreement with ROS and agreed to issue 1.5 million shares to an affiliate of ROS. We plan to use the proceeds for working capital and general corporate purposes.

Long-term debt consists of the following:

	March 31, 2014	December 31, 2013
Loan payable to ROS Acquisition Offshore, LIBOR plus 12.13% maturing August 2019	\$24,000,000	\$ 20,000,000
Adjustment fee payable to ROS Acquisition Offshore, due in August 2019	700,000	700,000
6.00% loan payable to Valley Bank of Belgrade, \$10,746 monthly payments including interest, maturing December 24, 2030; secured by building	1,363,005	1,375,030
	26,063,005	22,075,030
Less: current portion	(48,447)	(47,727)
Debt discount	(6,377,971)	(5,642,058)
Long-term debt	\$ 19,636,587	\$ 16,385,245

The following is a summary of maturities due on the debt as of March 31, 2014:

Remainder of 2014	\$36,062
2015	50,671
2016	4,053,796
2017	8,057,114
2018	8,060,637
Thereafter	5,804,725
Total	\$26,063,005

The following is a summary of estimated future royalty payments as of March 31, 2014:

Remainder of 2014	\$639,750
2015	1,000,750
2016	1,229,250
2017	1,360,250
2018	1,462,750
Thereafter	7,201,575
Total	\$12,894,325

(8) 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, on occasion, independent 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. 9.0 million shares are authorized under the Plan and at March 31, 2014, we had approximately 516,000 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 quarters ended March 31, 2014 and 2013 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. An assumed forfeiture rate of 20% was used for the first quarter of 2014.

We also granted our Chief Executive Officer an option to purchase 2,000,000 shares of our common stock outside of the Plan (the “CEO Grant”).

Stock option activity under the Plan, plus the CEO Grant, was as follows:

	2014			2013		
	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	7,583,285	\$ 1.49	\$ 0.86	5,266,535	\$ 2.02	\$ 1.03
Granted	-	-	-	-	-	-
Exercised	-	-	-	-	-	-
Cancelled or expired	(3,000)	1.47	0.90	(70,000)	\$ 2.89	\$ 1.45
Outstanding at March 31	7,580,285	\$ 1.49	\$ 0.74	5,196,535	\$ 2.01	\$ 1.03
Exercisable at March 31	2,639,718	\$ 2.10	\$ 0.74	2,672,301	\$ 1.83	\$ 0.83

The aggregate intrinsic value of options outstanding as of March 31, 2014 is \$834,695. The aggregate intrinsic value of exercisable options as of March 31, 2014 is \$134,985. As of March 31, 2014, there were 4,940,567 unvested options with a weighted average fair value at the grant date of \$0.74 per option. As of March 31, 2014, there is no compensation related to nonvested awards not yet recognized.

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 restricted stock awards generally vest over three to five year periods. The Company recognized non-cash consulting expense of \$20,527 for the first quarter of 2014 and a reduction of expense of \$30,297 for the quarter ended March 31, 2013. As of March 31, 2014, the total expense related to nonvested restricted stock awards not yet recognized is \$189,720 and is expected to be recognized over three years.

Total share based compensation for employees and consultants was \$322,222 and \$29,310 for the three months ended March 31, 2014 and 2013, respectively.

The following table summarizes restricted stock award activity during the quarter ended March 31, 2014:

	Shares
Outstanding at Jan. 1, 2014	308,500
Awarded	-
Cancelled	-
Vested	(29,500)
Outstanding at March 31, 2014	279,000

(9) Warrants

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-Q

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 period ended March 31, 2014:

	Shares	Weighted Average Exercise Price
Outstanding at January 1, 2014	10,878,208	\$ 1.62
Issued	-	-
Exercised	-	-
Expired	(40,000)	\$ 2.00
Outstanding at March 31, 2014	10,838,208	\$ 1.62

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 and 375,000 warrants issued in connection with a 2010 debt financing were accounted for as derivative liabilities in connection with the price protection provisions of the warrants in compliance with ASC 815. 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. The lattice model accommodates the probability of exercise price adjustment features as outlined in the warrant agreements. We recorded an unrealized loss of \$1,485,729 resulting from the change in the fair value of the warrant derivative liability for the first quarter of 2014. 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:

	Three months ended			
	March 31,			
	2014	2013		
Value of underlying common stock (per share)	\$0.84	\$0.83		
Risk free interest rate	1.92	% 0.24	%	%
Expected term	5.46 years	3.58 years		
Dividend yield	0	% 0	%	%
Volatility	64	% 72	%	%

The following table summarizes our activities related to number of warrants used in the derivative liability for the period ended March 31, 2014 and 2013:

	2014	2013
Balance at January 1	6,001,922	1,649,707
Derivative warrants issued	-	-
Derivative warrants exercised	-	-
Balance at March 31	6,001,922	1,649,707

(10) Commitments and Contingencies

Operating Leases

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-Q

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 March 31, 2014, under these leases, are as follows:

Remainder of 2014	\$217,764
2015	269,400
2016	269,400
2017	269,400
2018	269,400
Thereafter	725,940
Total	\$2,021,304

Rent expense was \$78,466 and \$69,311 for the quarters ended March 31, 2014 and 2013, 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.

Pending and Threatened Litigation

On March 17, 2014, a complaint was served on the Company in the following state court action in the District Court for the County of Arapahoe, State of Colorado: Robert Taggart v. Guy Cook, Bacterin International, Inc. a Nevada Corporation and Bacterin International Holdings, Inc., a Delaware corporation, Civil Action No. 14CV30401. The complaint involves claims under an employment agreement between plaintiff and the Company seeking commissions on Company sales, a commission on funds obtained by the Company as a result of a reverse merger and vesting of certain stock options. Plaintiff seeks damages in excess of \$5 million. The Company believes this case lacks legal merit and has filed counterclaims for plaintiff's breach of his employment agreement and breach of his duty of loyalty to the Company, asserting the right to recover all compensation paid to Plaintiff during his employment as well as other damages.

Lacuna Hedge Fund LLLP ("Lacuna") asserted various claims against our former CEO, Guy Cook, in connection with financing Lacuna provided to Holgan, LLC, a former stocking distributor. Holgan failed to fully pay for the products it received from Bacterin and defaulted under its credit agreement with Lacuna. We recently reached a settlement with Lacuna regarding this matter whereby we paid Lacuna \$350,000. We expect our D&O insurance carrier to reimburse 50% of the settlement amount plus applicable attorney fees after deducting the \$100,000 retention amount for this claim. We are still in discussions with Holgan on its unpaid obligation to the Company.

NYSE MKT Deficiency Notice

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. On November 19, 2013, we received another letter from the NYSE MKT notifying us that we are not in compliance with Section 1003(a)(i) of the Company Guide with stockholders' equity of less than \$2,000,000 as of September 30, 2013 and net losses in two of three of our most recent fiscal years, and we submitted an amended plan to regain compliance. We will continue to be subject to periodic review by the NYSE MKT during the extension period and failure to make progress consistent with our plan to regain compliance by the end of the extension period

could result in our delisting from the exchange.

(11) 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 2009 through 2013 tax years remain open to examination by the Internal Revenue Service and the 2007 to 2013 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 three months ended March 31, 2014 and 2013.

(12) Supplemental Disclosure of Cash Flow Information

Supplemental cash flow information is as follows:

	Quarter ended March 31,	
	2014	2013
Supplemental disclosure of cash flow information		
Cash paid during the period for:		
Interest	\$930,547	\$1,873,155
Income taxes	\$-	\$-
Non-cash activities:		
Net shares issued for non-cash consulting expense	\$20,527	\$95,115
Issuance of shares related to debt issuance	\$1,095,000	\$-

(13) Related Party Transactions

Guy Cook was our President, Chief Executive Officer and Chairman of our Board of Directors until April 5, 2013, when he resigned. Mr. Cook has advised us that he is currently an owner and executive officer of Lattice Biologics, Inc., a competitor of ours that was formerly known as International Biologics, LLC. International Biologics, LLC was a former customer of Bacterin and is indebted to us in the amount of approximately \$33,468, which we are currently attempting to collect.

Mr. Cook assisted unrelated parties in the initial capitalization of Holgan, LLC, a former stocking distributor that purchased a bulk shipment of products from Bacterin at a discount in 2012 (“Holgan”). Holgan subsequently obtained financing from Lacuna Hedge Fund LLLP (“Lacuna”), which is a significant Bacterin shareholder. Holgan failed to fully pay for the products it acquired from Bacterin and defaulted under its credit agreement with Lacuna. We recently reached a settlement with Lacuna whereby we paid Lacuna \$350,000 in exchange for a release of all claims Lacuna may have against Bacterin and its current and former directors and officers, and we understand that Mr. Cook’s new company Lattice purchased substantially all of the Bacterin products held by Holgan, with the proceeds to be paid to Lacuna. We are still in discussions with Holgan regarding its unpaid obligations.

Mr. Cook’s spouse was employed by Bacterin as the Director of Human Resources until April 9, 2013. Mr. Cook, together with his adult children, owned and operated Silver Forest Fund, LP (“Silver Forest”), a former distributor of Bacterin products. We terminated the contractual relationship with Silver Forest on October 24, 2013. In 2012, Silver Forest purchased Bacterin products from an unaffiliated former distributor and subsequently exchanged some of those products for different Bacterin products of equivalent value. Other than product exchanges and payment of amounts owed by the non-affiliated distributor, there were no other direct transactions between Bacterin and Silver Forest. In 2012, Mr. Cook pledged 1,850,000 shares of Bacterin stock as collateral for loans made for the benefit of Silver Forest.

Mr. Cook remains our largest stockholder with beneficial ownership of approximately 19.4% of our outstanding capital according to Amendment No. 4 to his Schedule 13D filed on February 25, 2014 with the Securities and Exchange Commission (the “Schedule 13D”). In the Schedule 13D, Mr. Cook indicated that he believed Bacterin would be better able to realize its full value as a private entity, and that he planned to engage legal and financial advisors to assist him in evaluating alternatives for taking Bacterin private. To date, Mr. Cook has not made any formal proposal to our Board of Directors.

Mr. Cook also formerly served as a board member of West Coast Tissue Services (“WCTS”) and American Donor Services (“ADS”). Mr. Cook did not receive any compensation for his board service from either entity. Darrel Holmes, our Chief Operating Officer, and Mitchell Godfrey, a director, also serve on the board of ADS, and Mr. Godfrey also serves as secretary and treasurer for ADS. Messrs. Godfrey and Holmes received \$5,000 per year for their 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 quarter of 2014 and 2013 was \$98,600 and \$232,000, respectively, and the approximate aggregate amount of all transactions with ADS for the first quarter of 2014 and 2013 was \$610,514 and \$308,536, respectively. These relationships have benefited 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.

Unless delegated to the Compensation Committee by the Board of Directors, the Audit Committee or the disinterested members of the full Board of Directors reviews and approves all related party transactions.

(14) Subsequent Events

There were no subsequent events that require disclosure.

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 March 31, 2014 and March 31, 2013

Revenue

Total revenue for the first quarter ended March 31, 2014 increased 3% to \$8,912,970 compared to \$8,618,807 for the first quarter of 2013. The first quarter of 2013 revenue included approximately \$1,300,600 associated with a non-recurring stocking order sale. This increase in core recurring revenues is due to improved sales force productivity realized through a reorganization of the sales function, as well as increase revenues derived from our independent distributors.

Cost of tissue sales

Costs of tissue sales consist primarily of tissue and device manufacturing costs. Costs of tissue sales increased by 9% or \$290,019 to \$3,410,705 for the first quarter of 2014 from \$3,120,686 for the first quarter of 2013. As a percentage of sales, cost of sales was 38.2% of revenues for the first quarter of 2014 compared to 36.2% for the first quarter of 2013. The increase is the result of a change in product and customer mix between the two periods.

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 decreased, \$37,275 for the three months ended March 31, 2014 compared to the same period of 2013, 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 decreased 11%, or \$283,199, to \$2,288,803, for the first quarter of 2014 compared to the first quarter of 2013. The decrease is primarily due to headcount reductions made in March and May of 2013.

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. Stock option compensation expense associated with our sales force is also included in sales and marketing expenses. Selling and marketing expenses increased 6%, or \$256,827, to \$4,055,204 for the three months ended March 31, 2014 from \$3,798,377 for the comparable prior year period. The increase is due to higher commissions earned by our direct sales force and independent distributors compared to the comparable prior period. As a percentage of revenue, selling and marketing expenses increased to 45.5% in the first quarter of 2014 from 44.1% in the first quarter of 2013 but decreased sequentially from 48.0% in the fourth quarter of 2013.

Research and development

Research and development expenses consist primarily of internal costs for the development of new technologies and processes for tissue and coatings. Research and development expenses decreased \$30,497 or 11% from \$285,080 for the three months ended March 31, 2013 to \$254,583 for the same period of 2014.

Depreciation

Depreciation expense consists of depreciation of long-lived property and equipment. Depreciation expense decreased 29% to \$75,148 for the three months ended March 31, 2014 from \$106,378 for the three months ended March 31, 2013. The decrease reflects more assets being fully depreciated as of March 31, 2014.

Non-cash Consulting Expense

Non-cash consulting expense consists of non-cash expense associated with granting restricted stock to consultants. Non-cash consulting expense increased \$50,824 to \$20,527 for the first quarter of 2014 from income of \$30,297 in the

first quarter of 2013. The increase is due to the higher closing price of the Company's common stock at for the three months ended March 31, 2014.

Other Income (Expense)

Other expenses include interest, warrant derivative liability changes and other miscellaneous items. Other expenses increased 576%, or \$2,512,417, for the three months ended March 31, 2014 compared to the same period of 2013, primarily due to the reasons set forth below.

Interest Expense

Interest expense is from our promissory notes. Interest expense for the first three months of 2014 increased \$211,624 to \$1,275,612 as compared to \$1,063,988 in the first three months of 2013. The increase was the result of a higher average debt balance in 2014.

Change in Warrant Derivative Liability

For the first quarter of 2014, the Company recorded a loss in its non cash warrant derivative liability of \$1,485,729, which was primarily driven by the increase in the closing price of the Company's common stock at March 31, 2014 compared to December 31, 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 and are accounted for as derivative instruments with any changes in fair value is recognized in the consolidated statement of operations during the period of change.

Other Income (Expense)

Other expense for the first three months of increased \$179,709 to \$186,914 as compared to expense of \$7,206 in the first three months of 2013. The increase was a result of legal settlement costs accrued as of the end of the quarter. See Note 10, "Commitments and Contingencies" above.

Liquidity and Capital Resources

Edgar Filing: Bacterin International Holdings, Inc. - Form 10-Q

In March 2014, we borrowed an additional \$4 million from ROS Acquisition Offshore LP under our Credit Agreement with ROS. In June 2013, the Company closed on a \$4.5 million equity financing with existing and new investors. In August 2012, we closed on a \$20 million term loan transaction with ROS Acquisition Offshore LP. The proceeds of the term loan transaction 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 March 31, 2014, we had \$10,297,487 of cash and cash equivalents and accounts receivables.

Net cash used in operating activities the first quarter of 2014 was \$2,188,889. This was primarily related to cash used to fund our operations offset by changes in accounts payable. For the comparable period of 2013, net cash used in operating activities was \$2,281,598.

Net cash used in investing activities for the first quarter of 2014 was \$18,860, primarily due to the purchase of property and equipment.

Net cash provided by financing activities was \$3,930,031 for the first quarter of 2014, which was primarily related to the extension of credit by ROS in the first quarter of 2014.

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 March 31, 2014 cash on hand and accounts receivable balance of \$10,297,487 and anticipated cash receipts from sales expected from operations will be sufficient to meet our anticipated cash requirements through March 31, 2015. We incurred approximately \$16 million in sales and marketing expenses in 2013 and expect to incur \$17 million in 2014 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 March 31, 2014. Based upon that evaluation, we concluded that as of March 31, 2014, our disclosure controls and procedures were adequate.

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 adequate as of March 31, 2014.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

On March 17, 2014, a complaint was served on the Company in the following state court action in the District Court for the County of Arapahoe, State of Colorado: Robert Taggart v. Guy Cook, Bacterin International, Inc., a Nevada Corporation and Bacterin International Holdings, Inc., a Delaware corporation, Civil Action No. 14CV30401. The complaint involves claims under an employment agreement between plaintiff and the Company seeking commissions on Company sales, a commission on funds obtained by the Company as a result of a reverse merger and vesting of certain stock options. Plaintiff seeks damages in excess of \$5 million. The Company believes this case lacks legal merit and has filed counterclaims for plaintiff's breach of his employment agreement and breach of his duty of loyalty to the Company, asserting the right to recover all compensation paid to Plaintiff during his employment as well as other damages.

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.

Our debt agreements with ROS Acquisition Offshore LP ("ROS") 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 credit 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. There can be no assurance that we will have sufficient access to liquidity or cash flow 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 result in our inability to pay our expenses as they come due, limit our ability to expand our business operations, and harm our overall business prospects.

We may not be able to raise 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, disposition of assets, debt financings or restructuring, bank borrowing 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 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. On November 19, 2013, we received another letter from the NYSE MKT notifying us that we are not in compliance with Section 1003(a)(i) of the Company Guide with stockholders' equity of less than \$2,000,000 as of September 30, 2013 and net losses in two of three of our most recent fiscal years, and we submitted an amended plan to regain compliance. We will continue to be subject to periodic review by the NYSE MKT during the extension period and failure to make progress consistent with our Plan or to regain compliance by the end of the extension period could result in our delisting from the Exchange.

In order to regain compliance, we will either need to increase our market capitalization or shareholders' equity. In order to increase our shareholder's equity, we may need to raise substantial equity capital, which would be dilutive to existing shareholders and may require shareholder approval. We currently have approximately 20,000,000 shares available for issuance on a fully diluted basis. To raise sufficient equity capital to achieve \$6 million in shareholder equity, we may need to increase the number of authorized shares available for issuance, which requires shareholder approval. There can be no assurance that we will obtain any necessary shareholder approval or raise sufficient equity capital to regain compliance with the NYSE MKT continued listing standards.

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 an OIG subpoena.

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. Although it does not appear that the OIG is actively pursuing the investigation at the present time, we cannot assure you that the OIG will not resume the investigation in the future. Any further investigation by the OIG could divert management’s attention from business demands and subject us to significant legal expenses.

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

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, and is not bound by a non-compete agreement, 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.

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. 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, seasonality and general economic conditions. There can be no assurance that the level of revenues 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 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 led 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. 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 will 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.

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.

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;
- .. 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, consultants and employees. We expect to grant restricted stock and 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

On March 11, 2014, we issued 1,500,000 shares of our common stock to Royalty Opportunities S.A. R.L. as consideration for the Sixth Amendment to Credit Agreement whereby we borrowed an additional \$4 million under our credit facility with ROS Acquisition Offshore LP. The issuance was exempt from the registration requirements of the Securities Act under Section 4(2) of the Securities Act as a transaction by an issuer not involving any public offering. We plan to use the loan proceeds for working capital and general corporate purposes.

Item 3. Defaults Upon Senior Securities

Not applicable.

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)
- 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: May 12, 2014 By: /s/ John P. Gandolfo
Name: John P. Gandolfo
Title: Chief Financial Officer