Bacterin International Holdings, Inc.
Form 10-Q
November 07, 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 ACT OF 1934

For the quarterly period ended September 30, 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	**20-5313323**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

600 CRUISER LANE

BELGRADE, MONTANA 59714

(Address of principal executive offices) (Zip code)

(406) 388-0480 (Registrant s telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 November 3, 2014: 6,675,134

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BACTERIN INTERNATIONAL HOLDINGS, INC.

FORM 10-Q

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this Form 10-Q that are not purely historical are forward-looking statements within the meaning of applicable securities laws. Our forward-looking statements include, but are not limited to, statements regarding our expectations, hopes, beliefs, intentions, plans, or strategies regarding the future. In addition, ar 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, esti expect, intend, may, might, plan, possible, potential, predict, project, should and would, as wel 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 remain listed on the NYSE MKT exchange;
- our ability to increase revenue;
- our ability to obtain financing on reasonable terms;
- our ability to comply with the covenants in our credit facility;
- our ability to maintain sufficient liquidity to fund our operations;
- 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.

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BACTERIN INTERNATIONAL HOLDINGS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	As of September 30, 2014 (unaudited)	As of December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	$6,953,279	$3,046,340
Trade accounts receivable, net of allowance for doubtful accounts of $1,463,046 and $1,309,859, respectively	4,294,496	4,793,834
Inventories, net	11,139,471	10,753,600
Prepaid and other current assets	808,213	574,910
Total current assets	23,195,459	19,168,684
Non-current inventories	1,635,380	2,119,952
Property and equipment, net	4,767,137	5,180,556
Intangible assets, net	649,119	586,965
Other assets	1,566,059	1,821,471
Total Assets	$31,813,154	$28,877,628
LIABILITIES & STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	$3,893,250	$2,767,639
Accounts payable - related party	406,669	647,844
Accrued liabilities	1,947,328	3,585,037
Warrant derivative liability	2,018,234	1,594,628
Current portion of capital lease obligations	109,235	171,926
Current portion of royalty liability	951,500	836,750
Current portion of long-term debt	49,918	47,727
Total current liabilities	9,376,134	9,651,551
Long-term Liabilities:		
Capital lease obligation, less current portion	9,782	73,777

Long term royalty liability, less current portion	6,425,500	6,609,232
Long-term debt, less current portion	20,459,494	16,385,245
Total Liabilities	36,270,910	32,719,805
Commitments and Contingencies		
Stockholders' (Deficit) Equity		
Preferred stock, $0.000001 par value; 5,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock, $0.000001 par value; 95,000,000 shares authorized; 6,684,551 shares issued and outstanding as of September 30, 2014 and 5,343,282 shares issued and outstanding as of December 31, 2013	7	5
Additional paid-in capital	63,107,378	56,516,491
Accumulated deficit	(67,565,141)	(60,358,673)
Total Stockholders Deficit	(4,457,756)	(3,842,177)
Total Liabilities & Stockholders Deficit	$31,813,154	$28,877,628

See notes to unaudited condensed consolidated financial statements.

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BACTERIN INTERNATIONAL HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue				
Tissue sales	$ 8,246,325	$ 7,710,256	$ 25,712,586	$ 24,430,158
Royalties and other	207,179	219,727	537,821	385,480
Total Revenue	8,453,504	7,929,983	26,250,407	24,815,638
Cost of tissue and medical devices sales	3,017,734	3,318,327	9,718,952	10,011,687
Gross Profit	5,435,770	4,611,656	16,531,455	14,803,951
Operating Expenses				
General and administrative	2,282,386	2,726,586	6,664,982	7,652,958
Sales and marketing	3,927,028	4,053,679	12,387,459	12,057,389
Research and development	378,252	37,742	955,111	224,739
Depreciation and amortization	58,763	97,923	216,343	304,771
Non-cash consulting expense	39,697	43,153	81,924	11,924
Total Operating Expenses	6,686,126	6,959,083	20,305,819	20,251,781
Loss from Operations	(1,250,356)	(2,347,427)	(3,774,364)	(5,447,830)
Other Income (Expense)				
Interest expense	(1,498,508)	(1,197,370)	(4,216,109)	(3,436,006)
Change in warrant derivative liability	1,653,425	(849,288)	1,038,190	246,337
Other (expense)	(70,344)	17,551	(253,289)	108,616
Total Other Income (Expense)	84,573	(2,029,107)	(3,431,208)	(3,081,053)
Net Loss	$ (1,165,783)	$ (4,376,534)	$ (7,205,572)	$ (8,528,883)
Net loss per share:				
Basic	$ (0.19)	$ (0.85)	$ (1.26)	$ (1.83)
Dilutive	$ (0.19)	$ (0.85)	$ (1.26)	$ (1.83)
Shares used in the computation:				
Basic	6,233,751	5,161,631	5,711,452	4,661,135
Dilutive	6,233,751	5,161,631	5,711,452	4,661,135

See notes to unaudited condensed consolidated financial statements.

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BACTERIN INTERNATIONAL HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,	
	2014	2013
Operating activities:		
Net loss	$(7,205,572)	$(8,528,883)
Noncash adjustments:		
Depreciation and amortization	498,343	586,771
Non-Cash Interest	387,294	(78,408)
(Gain) loss on sale of fixed assets	33,373	(500)
Amortization of debt discount	1,207,859	917,153
Non-cash consulting expense/stock option expense	938,785	603,058
Provision for losses on accounts receivable and inventory	601,190	1,197,669
Change in derivative warrant liability	(1,038,190)	(246,337)
Increase of contingent liability	-	(91,740)
Changes in operating assets and liabilities:		
Accounts receivable	346,151	970,971
Inventories	(350,198)	265,396
Prepaid and other assets	22,109	291,375
Accounts payable	884,436	(635,973)
Accrued liabilities	(1,495,107)	(428,751)
Net cash used in operating activities	(5,169,527)	(5,178,199)
Investing activities:		
Purchases of property and equipment and intangible assets	(190,601)	(633,393)
Proceeds from sale of fixed assets	10,149	(10,149)
Net cash used in investing activities	(180,452)	(643,542)
Financing activities:		
Proceeds from issuance of debt	4,000,000	-
Payments on long-term debt	(492,695)	(34,308)
Payments on capital leases	(126,686)	(110,045)
Proceeds from the exercise of options	6,666	27,575
Net proceeds from issuance of stock	5,869,633	4,450,002
Net cash provided by financing activities	9,256,918	4,333,224
Net change in cash and cash equivalents	3,906,939	(1,488,517)
Cash and cash equivalents at beginning of period	3,046,340	4,926,066
Cash and cash equivalents at end of period	$6,953,279	$3,437,549

See notes to unaudited condensed consolidated financial statements.

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Notes to Unaudited Condensed Consolidated Financial Statements

(1) Business Description and Summary of Significant Accounting Policies

Business Description

The accompanying consolidated financial statements include the accounts of Bacterin International Holdings, Inc., a Delaware corporation, and its wholly owned subsidiary, Bacterin International, Inc., a Nevada corporation, (collectively, the Company or Bacterin). All intercompany balances and transactions have been eliminated in consolidation. Bacterin s biologics division develops, manufactures and markets biologics products to domestic and international markets. Bacterin s proprietary methods are used in human allografts to create 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 and nine months ended September 30, 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.

Reverse Stock Split

The Company completed a 1:10 reverse split of its common stock, effective at the close of business on Friday, July 25, 2014 and in effect for trading purposes on Monday, July 28, 2014. The reverse stock split was approved by the Company's shareholders at the 2014 Annual Meeting of Shareholders on June 11, 2014. All references to common shares, stock option, restricted stock units, warrants, and per share amounts have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Public Offering

In August 2014, the Company offered 1,143,000 shares of its common stock at $5.70 per share and warrants to purchase 571,500 shares of its common stock at an exercise price of $7.12 per share to the public. Gross proceeds of the offering were approximately $6.5 million. Net proceeds from the offering were approximately $5.9 million and will be used for working capital and general corporate purposes, including the continued expansion of the company's sales force and increasing inventory levels to support anticipated future growth. The offering closed on August 6, 2014.

The warrants have a five year term and expire on August 6, 2019. The Company utilizes a valuation model to determine the fair market value and accounts for the value as a warrant derivative liability (see "Derivative Instruments" below). Also, see Note 9, "Warrants" below.

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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 both the nine months ended September 30, 2014 and 2013. No single customer accounted for more than 10% of revenue or accounts receivable for the nine months ended September 30, 2014 and 2013. The Company provides for uncollectible amounts when specific credit issues arise. Management s estimates for uncollectible amounts have been adequate during prior periods, and management believes that all significant credit risks have been identified at September 30, 2014.

Revenue by geographical region is as follows:

	Nine months ended September 30 ,	
	2014	2013
United States	$25,792,878	$24,285,028
Rest of World	457,529	530,610
	$26,250,407	$24,815,638

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. Significant estimates include 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.

Reclassifications

Certain comparative balances for the three and nine months ended September 30, 2013 have been reclassified to make them consistent with the current year presentation. The reclassifications had no effect on the net income for 2013.

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

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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.

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 relate to warrants issued in connection with certain debt and equity financings. The Company has not designated its warrant derivative liability as a hedging instrument as described in ASC 815 and any change 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 and West Coast Tissue Services, as suppliers of donors to the Company for 2014 and 2013. 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 have 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 2% of total revenue for the three and nine months ended September 30, 2014 and 2013.

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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 $29,027 and $291,796 for the nine months ended September 30, 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 nine months ended September 30, 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 three and nine months ended September 30, 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 2,428,786 and 1,877,948 outstanding stock options and warrants after the 1:10 reverse split for the nine months ended September 30, 2014 and 2013, respectively, are anti-dilutive.

Stock-Based Compensation

The Company records stock-compensation expense according to the provisions of FASB ASC 718 Compensation Stock Compensation . 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

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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 nine months ended September 30, 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 September 30, 2014 and December 31, 2013 that are measured at fair value on a recurring basis:

Accrued stock compensation

	As of September 30, 2014	As of December 31, 2013
Level 1	$ -	$ 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

	As of September 30, 2014	As of December 31, 2013
Level 1	-	-
Level 2	-	-
Level 3	$ 2,018,234	$ 1,594,628

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

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Level 3 Changes

The following is a reconciliation of the beginning and ending balances for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the nine months ending September 30, 2014:

Warrant derivative liability

Balance at January 1, 2014	$1,594,628
Warrants issued with stock offering	1,461,796
Gain recognized in earnings	(1,038,190)
Balance at September 30, 2014	$2,018,234

During the nine months ended September 30, 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

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606). ASU 2014-09 supersedes the revenue recognition guidance in Topic 605, Revenue Recognition. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods and services to customers in an amount that reflects the consideration to which the entity expects to be entitled in the exchange for those goods or services. This standard is effective for annual reporting periods beginning after December 15, 2016. ASU 2014-09 is not expected to have a material impact on our consolidated financial position, results of operations, or cash flows.

In August 2014, FASB issued Accounting Standards Update (ASU) No. 2014-15, Preparation of Financial Statements - Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Under GAAP, continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity's liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. If and when an entity's liquidation becomes imminent, financial statements should be prepared under the liquidation basis of accounting in accordance with Subtopic 205-30, Presentation of Financial Statements-Liquidation Basis of Accounting. Even when an entity's liquidation is not imminent, there may be conditions or events that raise substantial doubt about the entity's ability to continue as a going concern. In those situations, financial statements should continue to be prepared under the going basis of accounting, but the amendments in this Update should be followed to determine whether to disclose information about the relevant conditions and events. The amendments in this Update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company will evaluate the going concern considerations in this ASU, but has not elected early application.

(2) Equity

On June 10, 2013, the Company issued approximately 851,000 shares of common stock to new and existing investors at a price per share of $5.70, 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 $7.20, 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 150,000 shares of restricted stock to an affiliate of ROS on November 25, 2013.

During the first quarter of 2014, the Company issued 150,000 shares of 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.

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The Company recently completed a 1:10 reverse split of its common stock, effective at the close of business on Friday, July 25, 2014 and in effect for trading purposes on Monday, July 28, 2014. The reverse stock split was approved by the company's shareholders at the 2014 Annual Meeting of Shareholders held June 11, 2014.

In August 2014, the Company offered 1,143,000 shares of its common stock at $5.70 per share and warrants to purchase 571,500 shares of its common stock at an exercise price of $7.12 per share to the public. Gross proceeds of the offering were approximately $6.5 million. Net proceeds from the offering were approximately $5.9 million and are expected to be used for working capital and general corporate purposes including the continued expansion of the company's sales force and increasing inventory levels to support anticipated future growth. The offering closed on August 6, 2014.

The warrants have five year term and expire on August 6, 2019. The Company utilizes a valuation model to determine the fair market value and accounts for the value as a warrant derivative liability (See Note 1, Derivative Instruments" above). Aslo, see Note 9, "Warrants" below.

(3) Inventories

Inventories consist of the following:

	September 30, 2014	**December 31, 2013**
Current inventories		
Raw materials	$ 3,713,094	$2,710,091
Work in process	2,704,918	3,333,672
Finished goods	6,035,366	5,775,813
	12,453,378	11,819,576
Reserve for obsolescence	(1,313,907)	(1,065,976)
Current inventories, total	11,139,471	10,753,600
Non-current inventories		
Finished goods	3,056,910	3,341,411
Reserve for obsolescence	(1,421,530)	(1,221,459)
Non-current inventories, total	1,635,380	2,119,952
Total inventories	$ 12,774,851	$12,873,552

(4) Property and Equipment, Net

Property and equipment, net are as follows:

	September 30, 2014	**December 31, 2013**
Buildings	$1,658,396	$1,653,263
Equipment	5,154,048	5,768,478
Computer equipment	257,155	312,650
Computer software	291,732	395,146
Furniture and fixtures	153,834	170,118
Leasehold improvements	2,381,161	1,808,461
Vehicles	41,099	41,099
Total cost	9,937,425	10,149,215
Less: accumulated depreciation	(5,170,288)	(4,968,659)
	$4,767,137	$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 September 30, 2014, the Company has recorded $443,060 gross assets in Property and Equipment, and $172,815 of accumulated depreciation relating to assets under capital leases.

Maintenance and repairs expense for the first nine months of 2014 and 2013 was $233,547 and $198,986, respectively. Depreciation expense related to property and equipment, including property under capital lease for the first nine months of 2014 and 2013 was $440,397 and $530,020, respectively.

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(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:

	September 30, 2014	December 31, 2013
Intellectual Property		
Gross carrying value	$ 1,011,133	$ 891,034
Accumulated amortization	(362,014)	(304,069)
Net carrying value	$ 649,119	$ 586,965
Aggregate amortization expense for the nine months ended September 30, 2014 and 2013, respectively:	$ 57,946	$ 56,750

The following is a summary of estimated future amortization expense for intangible assets as of September 30, 2014:

Remainder of 2014	$32,424
2015	108,273
2016	62,130
2017	62,123
2018	61,069
Thereafter	323,100
Total	$649,119

(6) Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2014	December 31, 2013
Accrued stock compensation	$ -	$ 211,212
Wages/commissions payable	1,325,866	1,728,576
Other accrued expenses	621,462	1,645,249
	$1,947,328	$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 in exchange for 150,000 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 September 30, 2014 and 2013.

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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 $7,377,000. 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 150,000 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 150,000 shares to an affiliate of ROS. We plan to use the proceeds for working capital and general corporate purposes.

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Long-term debt consists of the following:

	September 30, 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	1,338,611	1,375,030
	26,038,611	22,075,030
Less: current portion	(49,918)	(47,727)
Debt discount	(5,529,199)	(5,642,058)
Long-term debt	$20,459,494	$16,385,245

The following is a summary of maturities due on the debt as of September 30, 2014:

Remainder of 2014	$12,201
2015	50,671
2016	4,053,796
2017	8,057,114
2018	8,060,637
Thereafter	5,804,192
Total	$26,038,611

The following is a summary of estimated future royalty payments as of September 30, 2014:

Remainder of 2014	$213,250
2015	1,000,750
2016	1,229,250
2017	1,360,250
2018	1,462,750
Thereafter	7,201,575
Total	$12,467,825

(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. 900,000 shares are authorized under the Plan and at September 30, 2014, we had approximately 58,000 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 nine months ended September 30, 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.

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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 nine months of 2014.

In August 2013, the Company granted our Chief Executive Officer an option to purchase 200,000 shares of our common stock outside of the Plan, and in July 2014, the Company granted our President an option to purchase 55,000 shares of our common stock outside of the Plan (collectively the Non-Plan Grants).

Stock option activity under the Plan, plus the Non-Plan Grants, 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	758,328	$ 14.90	$ 8.60	526,653	$ 20.20	$ 10.30
Granted	169,200	5.78	5.00	333,125	6.30	5.30
Exercised	(6,666)	10.00	0.04	(23,000)	1.00	0.60
Cancelled or expired	(147,396)	19.95	9.20	(72,900)	17.80	9.00
Outstanding at September 30	773,466	$ 11.99	$ 7.10	763,878	$ 14.90	$ 8.60
Exercisable at September 30	297,962	$ 17.03	$ 6.50	253,153	$ 20.30	$ 9.80

The aggregate intrinsic value of options outstanding as of September 30, 2014 is approximately $73,000. The aggregate intrinsic value of exercisable options as of September 30, 2014 is approximately $73,000. As of September 30, 2014, there were 218,774 unvested options with a weighted average fair value at the grant date of $8.41 per option. As of September 30, 2014, there is approximately $861,000 of compensation expense related to unvested awards not yet recognized.

On May 24, 2013, the Company issued 33,500 restricted stock awards to certain employees. These restricted shares vested after one year and were issued when the stock price was $6.80 per share. The total expense of $227,800 was 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 for the first nine months of 2014 and 2013 was $81,924 and $11,924 respectively.

Total share based compensation recognized for employees and consultants were $938,785 and $603,058 for the nine months ended September 30, 2014 and 2013, respectively.

The following table summarizes restricted stock award activity during the nine months ended September 30, 2014:

	Shares
Outstanding at January 1, 2014	30,850
Awarded	-
Cancelled	(7,000)
Vested	(8,484)
Outstanding at September 30, 2014	15,366

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(9) Warrants

The following table summarizes our warrant activities for the nine months ended September 30, 2014:

	Shares	Weighted Average Exercise Price
Outstanding at January 1, 2014	1,087,820	$ 16.20
Issued	571,500	7.12
Exercised	-	-
Expired	(4,000)	20.00
Outstanding at September 30, 2014	1,655,320	$13.06

We utilize a valuation model to determine the fair market value of the warrants accounted for as liabilities. The valuation model accommodates the probability of exercise price adjustment features as outlined in the warrant agreements. We recorded an unrealized gain of $1,038,190 resulting from the change in the fair value of the warrant derivative liability for the first nine months 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 a common stock equivalent that is lower than the exercise price per share as stated in the warrant agreement.

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

	Nine months ended September 30, 2014	2013
Value of underlying common stock (per share)	$4.48	$ 6.80
Risk free interest rate	1.81%	0.72 %
Expected term	5.25 years	5. 96 years
Dividend yield	0%	0 %
Volatility	58%	63 %

The following table summarizes our activities related to warrants accounted for as a derivative liability for the nine months ended September 30, 2014 and 2013:

	2014	2013
Balance at January 1	600,192	164,971
Derivative warrants issued	571,500	435,221
Derivative warrants exercised	-	-
Balance at September 30	1,171,692	600,192

(10) Commitments and Contingencies

Operating Leases

We lease two office facilities under non-cancelable operating lease agreements with expiration dates in 2019 and 2023. We have the option to extend both the leases for another ten year term and for one facility, we have the right of first refusal on any sale. We lease an additional office facility under a month-to-month arrangement. Future minimum payments for the next five years and thereafter as of September 30, 2014, under these leases, are as follows:

Remainder of 2014	$	85,577
2015		300,236
2016		269,400
2017		269,400
2018		269,400
Thereafter		725,940
Total	$	1,919,953

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Rent expense was $245,884 and $204,180 for the nine months ended September 30, 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.

On July 9, 2014, a complaint was served on the Company in the following action in the United States District Court, District of New Jersey: Middlebury Securities, LLC v. Bacterin International, Inc., Case Number 2:14-CV-03905-WJM-MF. The complaint alleges that Bacterin owes Middlebury an $80,000 fee, along with $80,000 in warrants, in connection with the March 6, 2014 extension of credit by ROS. Bacterin believes this case lacks merit because there is no agreement between the parties regarding the transaction in question.

On July 14, 2014, a complaint was served on the Company in the following action in the United States Bankruptcy Court, Southern District of New York, In re: Rodman & Renshaw, LLC, Debtor, Case No. 13-10087 (REG): YANN GERON, Chapter 7 Trustee of the Estate of Rodman & Renshaw, LLC, Plaintiff, against Bacterin International Holdings, Inc. The complaint alleges that Bacterin owes a $150,000 investment banking fee in connection with Bacterin s April 2012 accounts receivable credit facility with MidCap Financial LLC. Bacterin believes this case lack merit because the accounts receivable credit facility was not a debt or equity security covered by the engagement

letter.

NYSE MKT Deficiency Notice

On May 13, 2013, we received a deficiency notice from the NYSE MKT 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. If we fail to achieve $6,000,000 in shareholder equity by the end of the extension period, our common stock will most likely be delisted from the NYSE MKT. We continue to evaluate various opportunities that may increase our shareholder equity, and we understand there is an appeal process, but as of the date of this filing, we are not in compliance with the NYSE MKT continued listing requirements, and we do not expect to achieve compliance with the NYSE MKT continued listing requirements by November 13, 2014.

(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.

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The 2010 through 2013 tax years remain open to examination by the Internal Revenue Service and the 2008 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 nine months ended September 30, 2014 and 2013.

(12) Supplemental Disclosure of Cash Flow Information

Supplemental cash flow information is as follows:

	Nine Months Ended September 30,	
	2014	2013
Supplemental disclosure of cash flow information		
Cash paid during the period for:		
Interest	$2,379,439	$3,436,006
Non-cash activities:		
Net shares issued for non-cash consulting expense	$81,924	$157,561
Issuance of shares related to debt issuance	$1,095,000	$-
Issuance of restricted stock to employees	$142,601	$-

(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 was indebted to us in the amount of approximately $33,468, which was paid.

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), formerly 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 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.

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 185,000 shares of Bacterin stock as collateral for loans made for the benefit of Silver Forest.

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 former director, also serve on the board of ADS, and Mr. Godfrey also serves as secretary and treasurer for ADS. Mssrs. Godfrey and Holmes receive $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 nine months ended September 30, 2014 and 2013 was $98,600 and $577,200, respectively, and the approximate aggregate amount of all transactions with ADS for the nine months ended September 30, 2014 and 2013 was $1,900,952 and $1,558,360, 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.

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(14) Subsequent Event

The Company evaluated events up to the filing date of these interim financial statements and determined that no subsequent activity required 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 our ability to remain listed on the NYSE MKT, our ability to comply with the covenants in our credit facility, our ability to obtain financing on reasonable terms, 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.

Results of Operations

Comparison of Three Months Ended September 30, 2014 and September 30, 2013

Revenue

Total revenue for the third quarter ended September 30, 2014 increased 6.6% to $8,453,504 compared to $7,929,983 for the third quarter of 2013. The increase of $523,521 was due to an increase in volume of sales.

Cost of Tissue Sales

Costs of tissue sales consist primarily of tissue and device manufacturing costs. Costs of tissue sales decreased by 9.1% or $300,593 to $3,017,734 for the third quarter of 2014 from $3,318,327 for the third quarter of 2013. As a percentage of sales, cost of sales was 35.7% of revenues for the third quarter of 2014 compared to 41.8% for the third quarter of 2013. The decrease was largely the result of write-offs of expired inventory in 2013 and improved processes.

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 3.9%, or $272,958, for the three months ended September 30, 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 16.3%, or $444,200, to $2,282,386, for the third quarter of 2014 compared to the third quarter 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. In addition, stock option compensation expense associated with our sales force is also included in sales and marketing expenses. Selling and marketing expenses decreased 3.1%, or $126,651, to $3,927,028 for the three months ended September 30, 2014 from $4,053,679 for the comparable prior year period. As a percentage of revenue, selling and marketing expenses decreased to 46.5% in the third quarter of 2014 from 51.1% in the third quarter of 2013. The decreases were primarily the result of lower commission costs.

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Research and Development

Research and Development expenses primarily consist of personnel costs and disbursements related to research and development projects. Research and Development expenses increased 902% or $340,510 from $37,742 in the third quarter of 2013 to $378,252 for the third quarter of 2014. The increase is due to increased spending on research and development projects and the transfer of research and development personnel expenses from General and Administrative to Research and Development.

Depreciation

Depreciation expense consists of depreciation of long-lived property and equipment. Depreciation expense decreased 40% to $58,763 for the three months ended September 30, 2014 from $97,923 for the three months ended September 30, 2013. The decrease reflects more assets being fully depreciated as of September 30, 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 decreased $3,456 to $39,697 for the third quarter of 2014 from $43,153 in the third quarter of 2013. The decrease is due to fluctuations and changes in the stock price.

Other Income (Expense)

Other expenses include interest, warrant derivative liability changes and other miscellaneous items. Other expenses decreased 104.2%, or $2,113,680, for the quarter ended September 30, 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 third quarter of 2014 increased $301,138 to

$1,498,508 as compared to $1,197,370 in the third quarter of 2013. The increase was the result of a higher average debt balance.

Change in Warrant Derivative Liability

For the third quarter of 2014, the Company recorded income from a decrease in its warrant derivative liability of $1,653,425 based upon the decrease in the closing price of the Company s common stock at September 30, 2014 compared to June 30, 2014. The liability is associated with the issuance of warrants as part of the Company s prior convertible debt financing, the Company s 2010 financing, the Company s 2013 equity financing, which contain anti dilution adjustment provisions, and the Company's 2014 equity financing, which contain adjustment provisions requiring the Company to record a change in the warrant derivative liability from period to period.

Other Income-Other Expense

Other Expense for the third quarter of 2014 increased by $87,895 to $70,344 as compared to Other Income of $17,551 in the third quarter of 2013.

Comparison of Nine Months Ended September 30, 2014 and September 30, 2013

Revenue

Total revenue for the nine months ended September 30, 2014 increased 5.8% compared to $26,250,407 for the first nine month of 2014 compared to $24,815,638 for the first nine months of 2013. This increase in revenue is due to improved sales force productivity realized through a restructuring of the sales function.

Cost of Tissue Sales

Costs of tissue sales consist primarily of tissue and device manufacturing costs. Costs of tissue sales decreased by 2.9% or $292,735 to $9,718,952 for the first nine months of 2014 from $10,011,687 for the first nine months of 2013. As a percentage of sales, cost of sales was 37.0% of revenues for the first nine months of 2014 compared to 40.3% for the first nine months of 2013. The decrease was largely the result of write-offs of expired inventory in 2013 and improved processes.

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Operating Expenses

Operating expenses include general and administrative expenses, selling and marketing expenses, depreciation, research and development expenses, and compensation costs, including incentive compensation. Operating expenses increased by $54,039 for the nine months ended September 30, 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 12.9%, or $987,976, to $6,664,982, for the first nine months of 2014 compared to the first nine months 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 2.7%, or $330,070, to $12,387,459 for the nine months ended September 30, 2014 from $12,057,389 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 decreased to 47.2% in the first nine months of 2014 from 48.6% in the first nine months 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 increased $730,372 or 325% from $224,739 for the nine months ended September 30, 2013 to $955,111 for the same period of 2014. The increase is due to increased spending on research and development projects and the transfer of research and development personnel expenses from General and Administrative to Research and Development.

Depreciation

Depreciation expense consists of depreciation of long-lived property and equipment. Depreciation expense decreased 29% or $88,428 to $216,343 for the nine months ended September 30, 2014 from $304,771 for the nine months ended September 30, 2013. The decrease reflects more assets being fully depreciated as of September 30, 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 $70,000 to $81,924 for the first nine months of 2014 from an expense of $11,924 in the first nine months of 2013..

Other Income (Expense)

Other expenses include interest, warrant derivative liability changes and other miscellaneous items. Other expenses increased 11.4%, or $350,155, for the nine months ended September 30, 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 and capital leases. Interest expense for the first nine months of 2014 increased $780,103 to $4,216,109 as compared to $3,436,006 in the first nine months of 2013. The increase was the result of a higher average debt balance in 2014.

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Change in Warrant Derivative Liability

For the first nine months of 2014, the Company recorded a gain in its non cash warrant derivative liability of $1,038,190, which was primarily driven by the decrease in the closing price of the Company s common stock at September 30, 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 the Company's 2014 equity financing which contain adjustment provisions requiring the Company to record changes in warrant derivative liability from period to period.

Other Income-Other Expense

Other Expense for the first nine months of 2014 increased $361,905 to $253,289 as compared to Other Income of $108,616 in the first nine months of 2013.

Liquidity and Capital Resources

At September 30, 2014, we had $11,247,775 of cash and cash equivalents and accounts receivables.

In March 2014, we borrowed an additional $4 million from 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. 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.

In August 2014, the Company offered 1,143,000 shares of its common stock at $5.70 per share and warrants to purchase 571,500 shares of its common stock at an exercise price of $7.12 per share to the public. Gross proceeds of the offering were approximately $6.5 million. Net proceeds from the offering were approximately $5.9 million and are expected to be used for working capital and general corporate purposes including the continued expansion of the company's sales force and increasing inventory levels to support anticipated future growth. The offering closed on August 6, 2014.

Net cash used in operating activities the first nine months of 2014 was $5,169,527. 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 $5,178,199.

Net cash used in investing activities for the first nine months of 2014 was $180,452, primarily due to the purchase of property and equipment.

Net cash provided by financing activities was $9,256,918 for the first nine months of 2014, which was primarily related to the extension of credit by ROS in the first quarter of 2014 and the common stock offering in the third 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 September 30, 2014 cash on hand and accounts receivable balance of $11,247,775 along with anticipated cash receipts from sales expected from operations will be sufficient to meet our anticipated cash requirements through September 30, 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.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our senior management with the participation of our chief executive officer and chief financial officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a 15(e) under the Exchange Act) as of September 30, 2014. Based upon that evaluation, we concluded that as of September 30, 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 September 30, 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.

On July 9, 2014, a complaint was served on the Company in the following action in the United States District Court, District of New Jersey: Middlebury Securities, LLC v. Bacterin International, Inc., Case Number 2:14-CV-03905-WJM-MF. The complaint alleges that Bacterin owes Middlebury an $80,000 fee, along with $80,000 in warrants, in connection with the March 6, 2014 extension of credit by ROS. Bacterin believes this case lacks merit because there is no agreement between the parties regarding the transaction in question.

On July 14, 2014, a complaint was served on the Company in the following action in the United States Bankruptcy Court, Southern District of New York, In re: Rodman & Renshaw, LLC, Debtor, Case No. 13-10087 (REG): YANN GERON, Chapter 7 Trustee of the Estate of Rodman & Renshaw, LLC, Plaintiff, against Bacterin International Holdings, Inc. The complaint alleges that Bacterin owes a $150,000 investment banking fee in connection with Bacterin s April 2012 accounts receivable credit facility with MidCap Financial LLC. Bacterin believes this case lack merit because the accounts receivable credit facility was not a debt or equity security covered by the engagement letter.

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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.

Our Common Stock may be delisted from the NYSE MKT exchange in the near future.

Our common stock may be delisted from the NYSE MKT in the near future. On May 13, 2013, we received a deficiency notice from the NYSE MKT 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. If we fail to achieve $6,000,000 in shareholder equity by the end of the extension period, our common stock will most likely be delisted from the NYSE MKT. We continue to evaluate various opportunities that may increase our shareholder equity, and we understand there is an appeal process, but as of the date of this filing, we are not in compliance with the NYSE MKT continued listing requirements, and we do not expect to achieve compliance with the NYSE MKT continued listing requirements by November 13, 2014. Therefore, we expect the NYSE MKT to initiate the delisting process in the near future. If our common stock is delisted from the NYSE MKT, our stock price might be negatively affected, some shareholders may sell their shares, and we may not be able to attract institutional investors in future financing transactions.

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 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 may need to split the proceeds from future offerings with ROS Acquisition Offshore LP

Our credit agreement with ROS includes an obligation on our part to split the net proceeds from equity offerings evenly with ROS above $15 million in the aggregate. So far we have not exceeded the $15 million threshold; however, future offerings may, when combined with previous offerings, take us above the $15 million threshold in the aggregate, at which point we would be obligated to split the net proceeds of any such future offering evenly with ROS. This would reduce the net proceeds to us, which may affect our ability to raise capital in the future.

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.

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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.

The impact of United States healthcare reform legislation remains uncertain.

In 2010 federal legislation, the Patient Protection and Affordable Care Act (PPACA), 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 PPACA imposes a 2.3 percent excise tax on medical devices, 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.

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.

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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

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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.

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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.

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.

If we fail to maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market these products could suffer.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval application, or PMA unless the device is specifically exempt from those requirements.

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The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other 510(k)-cleared products. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA s satisfaction the safety and efficacy of the device for its intended use.

Our failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

Modifications to our products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.

Modifications to our products may require new regulatory approvals or clearances, including 510(k) clearances, premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer s decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application. Where we determine that modifications to our products require a new 510(k) clearance or premarket approval, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining clearances and approvals can be a time consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

Future products may require FDA clearance of a 510(k) or approval of a PMA. In addition, future products may require clinical trials to support regulatory approval and we may not successfully complete these clinical trials. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new products. Failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

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 generally required to support a PMA application and are sometimes required for 510(k) clearance. Such trials generally require an investigational device exemption application, or IDE, approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a nonsignificant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board, or IRB, for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the patients informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. In addition, the commencement or completion of any clinical trial may be delayed or halted for numerous reasons, including, but not limited to 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. Clinical trials often take several years to execute. The outcome of any

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trial is uncertain and may have a significant impact on the success of our current and future products and future profits. 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. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the United States.

Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with FDA s Quality System Regulations, or QSR, and International Standards Organization, or ISO, regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

unanticipated expenditures to address or defend such actions;

customer notifications for repair, replacement, refunds;

recall, detention or seizure of our products;

operating restrictions or partial suspension or total shutdown of production;

refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;

operating restrictions;

withdrawing 510(k) clearances or HDE or PMA approvals that have already been granted;

refusal to grant export approval for our products; or

criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated

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adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

We face risks and uncertainties relating to an ongoing inspection and Warning Letter.

We received a Warning Letter from the FDA on January 28, 2013 concerning the facility located at 600 Cruiser Lane, Belgrade, MT (Site 600). The Warning Letter addressed issues regarding aspects of Bacterin s quality system with a focus on OsteoSelect DBM Putty which is both a tissue and a device. We responded to the Warning Letter on February 22, 2013, and provided periodic response updates on March 20, 2013, April 15, 2013 and May 20, 2013. We developed and implemented a corrective action strategy that we believed addressed all of FDA s concerns. While we believe that we have developed and have implemented a corrective action strategy that we believe addresses all of FDA s concerns, there is a chance that FDA will not agree with our completed corrective actions. If FDA does not agree with our actions, they could issue another Warning Letter, request that we take additional actions, or take additional enforcement actions. FDA conducted a re-inspection of Site 600 from July 8, 2013 to July 12, 2013, which evaluated the completion of the corrective actions and resulted in the issuance of an unrelated FDA-Form 483 on July 12, 2013. We responded to the FDA-Form 483 on August 1, 2013, and provided periodic response updates on August 13, 2013, September 26, 2013, October 31, 2013 and December 4, 2013. On October 29, 2013, we received an Establishment Inspection Report (EIR) for this re-inspection. At this time, we do not know whether or when FDA will conduct an additional follow up inspection. In addition, from July 22, 2013 to August 2, 2013, FDA conducted a tissue-focused inspection of Site 600 which resulted in an FDA-Form 483. We responded to the FDA-Form 483 on August 22, 2013. At this time, we do not know whether this inspection will lead to an enforcement action or when FDA will close out this inspection.

If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. Under FDA HCT/P reporting regulations, we are required to report all adverse reactions involving a communicable disease if it is fatal, life threatening, or results in permanent impairment of a body function or permanent damage to body structure. If we fail to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

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 FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or off-label uses.

Our promotional materials and training methods for physicians must comply with FDA and other applicable laws and regulations. We believe that the specific surgical procedures for which our products are marketed fall within the scope of the surgical applications that have been cleared by the FDA. However, the FDA could disagree and require us to stop promoting our products for those specific procedures until we obtain FDA clearance or approval for them. In addition, if the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

If we or our suppliers fail to comply with ongoing FDA or other regulatory authority requirements pertaining to Human Tissue Products, these products could be subject to restrictions or withdrawal from the market.

Human tissues intended for transplantation have been regulated by the FDA since 1993. Over the course of several years, the FDA issued comprehensive regulations that address manufacturer 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. This set of regulations also includes the criteria that must be met in order for the HCT/P to be eligible for marketing solely under Section 361 of the PHS Act and the regulations in 21 CFR Part 1271, rather than under the drug or device provisions of the FD&C Act or the biological product licensing provisions of the PHS Act. The second set of regulations 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 these regulations 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. The FDA periodically inspects tissue processors to determine compliance with these requirements. Violations of applicable regulations noted by the FDA during facility inspections could adversely affect the continued marketing of our products. We believe we comply with all aspects of the Current Good Tissue Practices, although there can be no assurance that we will comply, or will comply on a timely basis, in the future. Entities that provide us with allograft bone tissue are responsible for performing donor recovery, donor screening and donor testing and our compliance with those aspects of the Current Good Tissue Practices regulations that regulate those functions

are dependent upon the actions of these independent entities. If our suppliers fail to comply with applicable requirements, our products and our business could be negatively affected. If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions from public warning letters, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure of our products, total or partial shutdown of our production, withdrawal of approvals, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us.

In addition, the FDA could disagree with our conclusion that some of our HCT/Ps meet the criteria for marketing solely under Section 361 of the PHS Act, and therefore do not require approval or clearance of a marketing application. For our HCT/Ps that are not combined with another article, the FDA could conclude that the tissue is more than minimally manipulated, that the product is intended for a non-homologous use, or that the product has a systemic effect or is dependent on the metabolic activity of living cells for its effect. If the FDA were to draw these conclusions, it would likely require the submission and approval or clearance of a marketing application in order for us to continue to market the product. Such an action by the FDA could cause negative publicity, decreased or discontinued product sales, and significant expense in obtaining required marketing approval or clearance.

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.

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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.

Many companies to which we supply our products also are subject to extensive regulation by the U.S. Food and Drug Administration. Their failure to meet strict regulatory requirements could adversely affect our business.

Medical devices that incorporate coatings technology are subject to extensive regulation by the FDA and equivalent foreign regulatory authorities. Generally, any medical device manufacturer that wishes to incorporate our coatings technology into its products will be responsible for obtaining FDA clearance or approval for the medical devices it intends to market though we will assist in the 510(k) or PMA filing submitted by licensees. Some of these products may require clinical trials to support regulatory approval and we may not successfully complete these clinical trials. 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 not approve or clear these customer products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our licensees requests for 510(k) clearance or premarket approval of their products. Failure to receive clearance or approval for our licensees products would have an adverse effect on our ability to expand our business.

Approval or clearance may place substantial restrictions on the indications for which the licensees products 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.

In addition, modifications to our licensees products may require new regulatory approvals or clearances, including 510(k) clearances or premarket approvals, or require them to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA may not approve or clear these product modifications for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our licensees requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products. Failure of our licensees to receive clearance or approval for new or modified products would have an

adverse effect on our ability to supply our product.

Finally, FDA and equivalent foreign regulatory authorities may conduct periodic audits or inspections of our licensees facilities to monitor their compliance with applicable regulatory standards. If the FDA finds that a facility has failed to comply with applicable regulations, the agency can institute a wide variety of enforcement actions, ranging from warning letters or untitled letters; fines and civil penalties; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, products; withdrawal or suspension of approval of products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; orders for physician notification or device repair, replacement or refund; interruption of production; operating restrictions; injunctions; and criminal prosecution. Any adverse action by an applicable regulatory agency could impair our licensees ability to produce products and thus could significantly increase our costs and impact our ability to provide our products to them.

Federal regulatory reforms may adversely affect our ability to sell our products profitably.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

For example, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. For example, in 2011, the FDA initiated a review of the premarket

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clearance process in response to internal and external concerns regarding the 510(k) program, announcing 25 action items designed to make the process more rigorous and transparent. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, or the FDASIA, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. The FDA has implemented, and continues to implement, these reforms, which could impose additional regulatory requirements upon us and delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. For example, the FDA recently issued guidance documents intended to explain the procedures and criteria the FDA will use in assessing whether a 510(k) submission meets a minimum threshold of acceptability and should be accepted for review. Under the Refuse to Accept guidance, the FDA conducts an early review against specific acceptance criteria to inform 510(k) submitters if the submission is administratively complete, or if not, to identify the missing element(s). Submitters are given the opportunity to provide the FDA with the identified information, but if the information is not provided within a defined time, the submission will not be accepted for FDA review. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

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.

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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.

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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.

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 securities.

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

announcements of technological innovations or new commercial products by us, our collaborative partners or our present or potential competitors;

our issuance of debt, equity or other securities, which we need to pursue to generate additional funds to cover our operating expenses;

our quarterly operating results;

developments or disputes concerning patent or other proprietary rights;

developments in our relationships with employees, suppliers or collaborative partners;

acquisitions or divestitures;

litigation and government proceedings;

adverse legislation, including changes in governmental regulation;

third-party reimbursement policies;

changes in securities analysts recommendations;

short selling;

changes in health care policies and practices;

halting, suspension of trading or delisting of our common stock by the 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.

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Because we became public through a reverse merger, 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.

If securities or industry analysts publish inaccurate or unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who covers us downgrades our common stock, changes their opinion of our shares or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease and we could lose visibility in the financial markets, which could cause our stock price and trading volume to decline.

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.

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, if any, 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 September 5, 2014, we issued 4,000 shares of our common stock to Cameron Beckman in exchange for a release to settle a claim. The transaction was exempt from the registration requirements of the Securities Act of 1933 under Section 4(2) of the Securities Act as a transaction by an issuer not involving any public offering.

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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		Restated Certificate of Incorporation (filed as Exhibit 3.1 to Form 10-Q filed November 14, 2011, incorporated by reference herein); Amendment to Restated Certificate of Incorporation (filed as Exhibit 3.1 to Form 8-K filed July 25, 2014)
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

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* 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.

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SIGNATURES

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

BACTERIN INTERNATIONAL
HOLDINGS, INC.

Date: November 7, 2014 By: /s/ John P. Gandolfo
Name: John P. Gandolfo
Title: Chief Financial Officer

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