

Bacterin International Holdings, Inc.  
Form 10-Q  
May 06, 2015

**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 March 31, 2015**

**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.**



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Number of shares of common stock, \$0.000001 par value, of registrant outstanding at May 1, 2015: 7,044,426

**BACTERIN INTERNATIONAL HOLDINGS, INC.**

**FORM 10-Q**

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this Form 10-Q that are not purely historical are forward-looking statements within the meaning of applicable securities laws. Our forward-looking statements include, but are not limited to, statements regarding our “expectations,” “hopes,” “beliefs,” “intentions,” “plans,” or “strategies” regarding the future. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should” and “would,” as well as similar words and phrases, 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 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.

**PART I - FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****BACTERIN INTERNATIONAL HOLDINGS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

	As of March 31, 2015 (unaudited)	As of December 31, 2014
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$2,899,557	\$4,468,208
Trade accounts receivable, net of allowance for doubtful accounts of \$1,322,569 and \$1,392,989, respectively	5,495,667	4,427,081
Inventories, net	9,710,580	9,558,648
Prepaid and other current assets	885,359	654,140
Total current assets	18,991,163	19,108,077
Non-current inventories	1,787,061	1,934,258
Property and equipment, net	4,503,132	4,654,527
Intangible assets, net	621,126	655,490
Other assets	1,502,333	1,598,539
Total Assets	\$27,404,815	\$27,950,891
<b>LIABILITIES &amp; STOCKHOLDERS' (DEFICIT) EQUITY</b>		
Current Liabilities:		
Accounts payable	\$4,412,385	\$3,876,760
Accounts payable - related party	327,641	250,629
Accrued liabilities	2,645,346	1,921,301
Warrant derivative liability	1,782,579	1,320,371
Current portion of capital lease obligations	30,914	61,970
Current portion of royalty liability	1,109,750	1,000,750
Current portion of long-term debt	51,574	50,671
Total current liabilities	10,360,189	8,482,452
Long-term Liabilities:		
Capital lease obligation, less current portion	6,529	11,808
Long-term royalty liability, less current portion	6,228,293	6,361,216

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Long-term debt, less current portion	21,281,052	20,870,330
Total Liabilities	37,876,063	35,725,806
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; 7,044,426 shares issued and outstanding as of March 31, 2015 and 6,679,646 shares issued and outstanding as of December 31, 2014	7	7
Additional paid-in capital	64,572,987	63,091,620
Accumulated deficit	(75,044,242)	(70,866,542 )
Total Stockholders' Deficit	(10,471,248)	(7,774,915 )
Total Liabilities & Stockholders' Deficit	\$27,404,815	\$27,950,891

See notes to unaudited condensed consolidated financial statements.



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

	Quarter Ended March 31,	
	2015	2014
Revenue		
Tissue sales	\$9,277,047	\$8,751,345
Royalties and other	226,067	161,625
Total Revenue	9,503,114	8,912,970
Cost of sales	3,472,477	3,410,705
Gross Profit	6,030,637	5,502,265
Operating Expenses		
General and administrative	2,425,167	2,288,803
Sales and marketing	4,713,672	4,055,204
Research and development	433,561	254,583
Depreciation and amortization	124,111	75,148
Non-cash consulting expense	66,796	20,527
Total Operating Expenses	7,763,307	6,694,265
Loss from Operations	(1,732,670)	(1,192,000)
Other Income (Expense)		
Interest expense	(1,435,578)	(1,275,612)
Change in warrant derivative liability	(462,208 )	(1,485,729)
Non-cash consideration associated with stock purchase agreement	(558,185 )	-
Other income (expense)	11,837	(186,915 )
Total Other Income (Expense)	(2,444,134)	(2,948,256)
Net Loss from Operations	(4,176,804)	(4,140,256)
Net loss per share:		
Basic	\$(0.62 )	\$(0.77 )
Dilutive	\$(0.62 )	\$(0.77 )
Shares used in the computation:		
Basic	6,689,530	5,379,714
Dilutive	6,689,530	5,379,714

See notes to unaudited condensed consolidated financial statements.

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

(Unaudited)

	Quarter Ended March 31,	
	2015	2014
Operating activities:		
Net loss	\$(4,176,804)	\$(4,140,256)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	235,124	169,148
Non-cash interest	135,002	(13,285 )
Non-cash consideration associated with stock purchase agreement	558,185	-
Gain on sale of fixed assets	(16,415 )	-
Amortization of debt discount	424,387	359,087
Non-cash consulting expense/stock option expense	229,984	322,222
Provision for losses on accounts receivable and inventory	(209,891 )	168,120
Change in derivative warrant liability	462,208	1,485,729
Changes in operating assets and liabilities:		
Accounts receivable	(993,821 )	(836,581 )
Inventories	147,747	238,565
Prepaid and other assets	(152,026 )	(340,689 )
Accounts payable	610,718	1,444,605
Accrued liabilities	667,326	(1,045,554)
Net cash used in operating activities	(2,078,276)	(2,188,889)
Investing activities:		
Purchases of property and equipment and intangible assets	(48,768 )	(54,933 )
Proceeds from sale of fixed assets	16,415	36,073
Net cash used in investing activities	(32,353 )	(18,860 )
Financing activities:		
Proceeds from issuance of debt	-	4,000,000
Payments on long-term debt	(171,687 )	(29,193 )
Payments on capital leases	(36,335 )	(40,776 )
Net proceeds from issuance of stock	750,000	-
Net cash provided by financing activities	541,978	3,930,031
Net change in cash and cash equivalents	(1,568,651)	1,722,282
Cash and cash equivalents at beginning of period	4,468,208	3,046,340
Cash and cash equivalents at end of period	\$2,899,557	\$4,768,622

See notes to unaudited condensed consolidated financial statements.



## Notes to Unaudited Condensed Consolidated Financial Statements

### (1) Business Description and Summary of Significant Accounting Policies

#### Business Description

The accompanying consolidated financial statements include the accounts of Bacterin International Holdings, Inc., a Delaware corporation, and its wholly owned subsidiary, Bacterin International, Inc., a Nevada corporation, (collectively, the “Company” or “Bacterin”). All intercompany balances and transactions have been eliminated in consolidation. Bacterin develops, manufactures and markets biologic products to domestic and international markets. Bacterin’s proprietary methods are used to process human derived allografts into scaffolds that 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 also develops and licenses coatings for various medical device applications. As of December 31, 2014, Bacterin made a strategic decision to discontinue the medical device coatings business which resulted in an impairment of related assets. See Note 4, “Impairment of Assets”.

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. Up until December 31, 2014, the Company operated two distinct lines of business consisting of the biologics and the device divisions. With the strategic exit from the device business as of December 31, 2014, the Company will be operating as a single business segment in 2015.

The Company's revenue is derived principally from the sale of its biologic products. 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 methods, 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 quarters ended March 31, 2015 and 2014 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, 2015.

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, 2014. 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 stock, stock options, 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 were used for working capital and general corporate purposes, including the continued expansion of the company's sales force, product development, 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 these warrants as a derivative liability (see "Derivative Instruments" below). Also, see Note 10, "Warrants" below.

### **Aspire Capital Transaction**

We entered into a Common Stock Purchase Agreement on March 16, 2015, as amended and restated on April 17, 2015 (the "Purchase Agreement"), with Aspire Capital Fund, LLC ("Aspire Capital"), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$10.0 million of our shares of common stock over the approximately 24-month term of the Purchase

Agreement. Pursuant to the terms of the Purchase Agreement, we issued 207,182 shares of our common stock to Aspire Capital for \$750,000 in aggregate proceeds. We also issued 154,189 shares of our common stock which were valued at \$3.62 per share and included as \$558,185 on the Statement of Operations to Aspire Capital as a commitment fee. See Note 2, "Equity" below.

### **Concentrations and Credit Risk**

The Company's accounts receivable are due from a variety of health care organizations and distributors throughout the world. Approximately 97% and 98% of sales were in the United States respectively for the first quarters ended 2015 and 2014. No single customer accounted for more than 10% of revenue or accounts receivable for the comparable periods. The Company provides for uncollectible amounts when specific credit issues arise. Management's estimates for uncollectible amounts have been adequate during prior periods, and management believes that all significant credit risks have been identified at March 31, 2015.

Revenue by geographical region is as follows:

	Quarter Ended	
	March 31,	
	2015	2014
United States	\$9,258,210	\$8,742,073
Rest of World	244,904	170,897
	\$ 9,503,114	\$8,912,970

### 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.



### **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. See Note 4, "Impairment of Assets".

### **Revenue Recognition**

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

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

The Company ships to certain customers under consignment arrangements whereby the Company's product is stored by the customer. The customer is required to report the use to the Company and upon such notice, the Company invoices the customer and revenue is recognized when above criteria 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 0.5% of total revenue for the quarters ended March 31, 2015 and 2014.

### **Advertising Costs**

The Company expenses advertising costs as incurred. The Company had advertising expense of \$2,658 and \$26,711 for the quarters ended March 31, 2015 and 2014, respectively.

### **Research and Development**

Research and development costs, which are principally related to internal costs for the development of new allograft technologies and processes are expensed as incurred.

### **Net Loss Per Share**

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. Diluted net income (loss) per share is computed in a manner consistent with that of basic earnings per share while giving effect to all potentially dilutive common shares outstanding during the period, which include the assumed exercise of stock options and warrants using the treasury stock method. Diluted net loss per share was the same as basic net loss per share for the quarters ended March 31, 2015 and 2014, 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 2,186,361 and 1,841,849 outstanding stock options and warrants for the quarters ended March 31, 2015 and 2014, respectively, are anti-dilutive.

### **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 quarters ended March 31, 2015 and 2014, there was no reclassification in financial assets or liabilities between Level 1, 2 or 3 categories.

The following table sets forth by level, within the fair value hierarchy, our liabilities as of March 31, 2015 and December 31, 2014 that are measured at fair value on a recurring basis:

Warrant derivative liability

	As of March 31, 2015	As of December 31, 2014
Level 1	-	-
Level 2	-	-
Level 3	\$ 1,782,579	\$ 1,320,371

The valuation technique used to measure fair value of the warrant liability is based on a valuation model and significant assumptions and inputs determined by us (See Note 10, "Warrants" below).

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 quarter ended March 31, 2015:

*Warrant derivative liability*

Balance at January 1, 2015	\$1,320,371
Loss recognized in earnings	462,208
Balance at March 31, 2015	\$1,782,579

During the quarter ended March 31, 2015, the Company did not change any of the valuation techniques used to measure its liabilities at fair value.

### **Recent Accounting Pronouncements**

In November 2014, FASB issued ASU No. 2014-08, Presentation of Financial Statements (Topic 201) and Property, Plant and Equipment (Topic 360) - Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity. The amendments in this Update are effective for the annual period ending after December 15, 2014, and interim periods within those years. Early adoption is permitted only for disposals (or classifications as held for sale) that have not been reported in financial statements previously issued or available for issuance. ASU 2014-08 is not expected to have a material impact on our consolidated financial position, results of operations, or cash flows.

### **(2) Equity**

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 8, "Long-term Debt" below.

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 were 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 these warrants as a derivative liability (See Note 1, "Fair Value of Financial Instruments" above). Also, see Note 10, "Warrants" below.

On March 16, 2015, we entered into a Purchase Agreement, as amended and restated April 17, 2015, with Aspire Capital which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$10.0 million of shares of our common stock over the 24-month term. The stock purchase transactions are at the Company's option. Pursuant to the terms and conditions in the Purchase Agreement, we also agreed to sell, and Aspire Capital agreed to buy, 207,182 shares of our common stock for \$750,000 in aggregate proceeds. We also issued 154,189 shares of our common stock to Aspire Capital as a commitment fee.

Under the Purchase Agreement, we have the right to sell up to an additional \$9,250,000 of our common stock in the aggregate to Aspire Capital over a 24-month period. More specifically, we have the right, at our sole discretion, to present Aspire Capital with purchase notices, directing Aspire Capital (as principal) to purchase up to 50,000 shares of our common stock, per trading day, provided that the aggregate price of each such purchase shall not exceed \$500,000 per trading day at a per share price equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, we also have the right to present Aspire Capital with volume-weighted average price purchase notices directing Aspire Capital to purchase an amount of our common stock equal to up to 30% of the aggregate shares of our common stock traded on the OTCQX marketplace on the next trading day, subject to the terms, conditions and limitations in the Purchase Agreement.

The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us. The Purchase Agreement also provides for customary events of default, upon the occurrence of which Aspire Capital may terminate the Purchase Agreement. Aspire Capital has agreed that neither it nor any of its agents, representatives or affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement. Any proceeds we receive under the Purchase Agreement are expected to be used for working capital and general corporate purposes.

**(3) Inventories**

Inventories consist of the following:

	March 31, 2015	December 31, 2014
Current inventories		
Raw materials	\$4,198,257	\$3,836,635
Work in process	2,444,393	2,484,635
Finished goods	4,911,679	5,163,458
	11,554,329	11,484,728
Reserve for obsolescence	(1,843,749 )	(1,926,080 )
Current inventories, total	9,710,580	9,558,648
Non-current inventories		
Finished goods	2,642,900	2,860,248
Reserve for obsolescence	(855,839 )	(925,990 )
Non-current inventories, total	1,787,061	1,934,258
Total inventories	\$11,497,641	\$11,492,906

**(4) Impairment of Assets**

During the fourth quarter of 2014, management decided to dispose of a group of components because of a shift in strategy for the Company. The component groups are the inventory and fixed assets associated with the Device Coatings and Cranial Maxillofacial Fixation (CMF) lines of business.

Sales for these product lines represented less than 1% of total revenue in both the 1st quarter of 2015 and 2014. Gross profit associated with these product lines were less than 1% of total gross profit for both periods.

Management has committed to a plan to sell the component assets and the assets are available for immediate sale in their present condition. Management has identified a potential buyer for the device coatings product line. And as noted below the CMF assets were sold during the first quarter of 2015.

Total assets associated with the two lines at December 31, 2014 included \$80,042 of related fixed assets, net of depreciation, and related inventory of \$832,507 for a total value of \$912,549. These assets were transferred to Assets held for Sale and are classified on the balance sheet at December 31, 2014 as part of "Prepaid and other current assets". After the impairment provision, the net balance of the Assets held for Sale is \$0 at December 31, 2014.



Because the device coatings agreement is in the early stage of negotiations and the sale of the CMF inventory during the first quarter of 2015 did not result in any tangible compensation, management decided to reserve for the entire amount and recorded a loss from impairment of assets of \$912,549 on the 2014 Consolidated Statement of Operations.

## (5) Property and Equipment, Net

Property and equipment, net are as follows:

	March 31, 2015	December 31, 2014
Buildings	\$1,657,579	\$ 1,657,579
Equipment	4,711,916	4,724,608
Computer equipment	225,009	225,009
Computer software	359,046	345,039
Furniture and fixtures	153,834	153,834
Leasehold improvements	2,381,413	2,380,617
Vehicles	10,000	41,099
Total cost	9,498,797	9,527,785
Less: accumulated depreciation	(4,995,665)	(4,873,258 )
	\$4,503,132	\$ 4,654,527

The Company leases certain equipment under capital leases. For financial reporting purposes, minimum lease payments relating to the assets have been capitalized. As of March 31, 2015, the Company has recorded \$443,060 gross assets in Equipment, and \$209,542 of accumulated depreciation relating to assets under capital leases.

Maintenance and repairs expense for the first quarters of 2015 and 2014 was \$99,523 and \$70,444, respectively. Depreciation expense related to property and equipment, including property under capital lease for the first quarters of 2015 and 2014 was \$165,403 and \$150,232, respectively.

## (6) Intangible Assets

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

The following table sets forth information regarding intangible assets:

	March 31, 2015	December 31, 2014
Intellectual Property		
Gross carrying value	\$ 1,021,350	\$ 1,036,580
Accumulated amortization	(400,224 )	(381,090 )
Net carrying value	\$621,126	\$ 655,490
Aggregate amortization expense:	\$52,709	\$ 77,022

The following is a summary of estimated future amortization expense for intangible assets as of March 31, 2015:

Remainder of 2015	\$ 65,875
2016	56,972
2017	56,972
2018	56,972
2019	54,405
Thereafter	329,930
Total	\$ 621,126

**(7) Accrued Liabilities**

Accrued liabilities consist of the following:

	March 31, 2015	December 31, 2014
Accrued stock compensation	\$56,824	\$ -
Wages/commissions payable	1,795,005	1,434,743
Other accrued expenses	793,517	486,558
	\$2,645,346	\$ 1,921,301

**(8) Long-term Debt**

On March 6, 2014, we entered into a Sixth Amendment to our Credit Agreement with ROS whereby we borrowed an additional \$4.0 million under our Credit Agreement with ROS and agreed to issue 150,000 shares to an affiliate of ROS. We used the proceeds for working capital and general corporate purposes.

Long-term debt consists of the following:

	March 31, 2015	December 31, 2014
Loan payable to ROS Acquisition Offshore, LIBOR plus 12.13% maturing August 2019	\$24,000,000	\$ 24,000,000
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	1,313,051	1,325,814
	26,013,051	26,025,814
Less: current portion	(51,574 )	(50,671 )
Debt discount	(4,680,425 )	(5,104,813 )
Long-term debt	\$21,281,052	\$ 20,870,330

The following is a summary of maturities due on the debt as of March 31, 2015:

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Remainder of 2015	\$37,846
2016	2,112,064
2017	8,290,378
2018	8,293,897
2019	6,239,295
Thereafter	1,039,571
Total	\$26,013,051

The following is a summary of estimated future royalty payments as of March 31, 2015:

2015	\$787,500
2016	1,229,250
2017	1,360,250
2018	1,462,750
2019	1,575,250
Thereafter	5,626,325
Total	\$12,041,325

**(9) Stock-Based Compensation**

Our Amended and Restated 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 March 31, 2015, we had approximately 103,000 shares available for issuance. Shares issued under the Plan may be authorized, but unissued or reacquired shares.

Stock compensation expense recognized in the statement of operations for the quarters ended March 31, 2015 and 2014 is based on awards ultimately expected to vest and reflects an estimate of awards that will be forfeited. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The estimated fair value of stock options granted is done using the Black-Sholes-Merton method applied to individual grants. Key assumptions used to estimate the fair value of stock awards are as follows:

	Quarter Ended March 31, 2015		Quarter Ended March 31, 2014	
Risk-free interest rate	2.38	%	0.91	%
Expected volatility	64	%	64	%
Expected term	6.1 Years		6.6 Years	
Expected forfeiture rate	20	%	20	%
Dividend yield	0	%	0	%

In July 2014, the Company granted our President an option to purchase 55,000 shares of our common stock outside of the Plan, and 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 (collectively the "Non-Plan Grants").

Stock option activity under the Plan, plus the Non-Plan Grants, was as follows:

	2015			2014		
	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	695,336	\$ 11.09	\$ 5.35	758,328	\$ 14.90	\$ 8.60
Granted	-	-	-	-	-	-
Exercised	-	-	-	-	-	-
Cancelled or expired	-	-	-	(300 )	14.70	9.00
Outstanding at March 31	695,336	\$ 11.09	\$ 5.35	758,028	\$ 14.90	\$ 7.40
Exercisable at March 31	322,381	\$ 14.97	\$ 6.89	263,971	\$ 21.00	\$ 7.40

The aggregate intrinsic value of options outstanding as of March 31, 2015 is approximately \$35,653. The aggregate intrinsic value of exercisable options as of March 31, 2015 is approximately \$35,650. As of March 31, 2015, there were 372,955 unvested options with a weighted average fair value at the grant date of \$4.26 per option. As of March 31, 2015, there is approximately \$938,085 of compensation expense related to unvested awards not yet recognized.

From time to time we may grant stock options and 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 Company recognized non-cash consulting expense for the quarters ended March 31, 2015 and 2014 as \$66,796 and \$20,527.

Total share based compensation recognized for employees, directors and consultants was \$229,984 and \$322,222 for the quarters ended March 31, 2015 and 2014, respectively.

On November 10, 2014, the company issued 39,312 shares of restricted stock to the independent Directors of the Company. These restricted shares vest on July 1, 2015 and were issued when the stock price was \$4.07 per share. The total expense of \$160,000 is going to be recognized ratably over the period in General and Administrative expense.

## (10) Warrants

The following table summarizes our warrant activities for the period ended March 31, 2015:

	Shares	Weighted Average Exercise Price
Outstanding as of January 1, 2014	1,087,820	\$ 16.20
Issued	571,500	7.12
Expired	(4,000 )	20.00
Outstanding at January 1, 2015	1,655,320	\$ 13.06
Issued	-	-
Expired	(164,295 )	17.90
Outstanding at March 31, 2015	1,491,025	\$ 12.52

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 loss of \$462,208 resulting from the change in the fair value of the warrant derivative liability for first quarter of 2015. Under the terms of some of our warrant agreements, 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 valuation model with the following weighted-average assumptions:

	Quarter ended			
	March 31,			
	2015	2014		
Value of underlying common stock (per share)	\$3.03	\$8.40		
Risk free interest rate	1.30	1.92	%	%
Expected term	4.75 years	5.46 years		
Dividend yield	0	0		
Volatility	64	64	%	%

The following table summarizes our activities related to warrants accounted for as a derivative liability for the quarters ended March 31, 2015 and 2014:

	2015	2014
Balance at January 1,	1,171,692	600,192
Derivative warrants issued	-	-
Derivative warrants exercised	-	-
Balance at March 31,	1,171,692	600,192

## (11) Commitments and Contingencies

### Operating Leases

We lease two office facilities under non-cancelable operating lease agreements with expiration dates in 2019 and 2023. We have the option to extend both the leases for another ten year term and for one facility, we have the right of first refusal on any sale. We lease additional office space under a month-to-month arrangement. Future minimum payments for the next five years and thereafter as of March 31, 2015, under these leases, are as follows:

Remainder of 2015	\$243,300
2016	283,448
2017	280,527
2018	286,754
2019	166,940
Thereafter	559,000
Total	\$1,819,969

Rent expense was \$83,613 and \$78,466 for the quarters ended March 31, 2015 and 2014, 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 indemnification provisions 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.

## **(12) Income Taxes**

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

The 2011 through 2014 tax years remain open to examination by the Internal Revenue Service and the 2009 to 2014 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 quarters ended March 31, 2015 and 2014.

**(13) Supplemental Disclosure of Cash Flow Information**

Supplemental cash flow information is as follows:

	Quarter Ended March 31,	
	2015	2014
Supplemental disclosure of cash flow information		
Cash paid during the period for:		
Interest	\$801,844	\$930,547
Non-cash activities:		
Issuance of shares related to debt issuance	\$-	\$1,094,999

**(14) Related Party Transactions**

Darrel Holmes, our Chief Operating Officer, and Mitchell Godfrey, a former director, 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 recovers tissue from donors and we reimburse them for their recovery fees, which are comprised primarily of labor costs. The approximate aggregate amount of all transactions with ADS for the quarters ended March 31, 2015 and 2014 was \$452,874 and \$610,514 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.

**(15) Subsequent Event**

On April 8, 2015, we received a notice indicating that the NYSE MKT denied our appeal of their delisting determination. We were also notified that trading of our common stock would be suspended on the NYSE MKT. Beginning April 9, 2015, our stock began trading on the OTCQX marketplace.

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

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

You should read the following discussion of our financial condition and results of operations in conjunction with our financial statements and related notes set forth in this report.

**Results of Operations**

**Comparison of Quarters Ended March 31, 2015 and March 31, 2014**

*Revenue*

Total revenue for the quarter ended March 31, 2015 increased approximately 6.6% to \$9,503,114 compared to \$8,912,970 in the prior year. The increase of \$590,144 is due to improved sales force productivity realized from increased sales headcount and manufacturer representatives.

*Cost of sales*

Costs of tissue sales consist primarily of tissue manufacturing costs. Costs of tissue sales increased by 0.1% or \$1,772 to \$3,472,477 for the quarter ended March 31, 2015 from \$3,410,705 for the quarter ended March 31, 2014. As a percentage of tissue sales, cost of tissue sales was 36.5% of revenues for the first quarter of 2015 compared to 38.3% in the first quarter of 2014. The decrease is the result of improved manufacturing efficiencies and a change in product and customer mix between the two periods.

### *Operating Expenses*

Operating expenses include general and administrative expenses, selling and marketing expenses, depreciation, research and development expenses, and compensation costs, including incentive compensation. Operating expenses increased 16.0%, or \$1,069,042 for the quarter ended March 31, 2015 compared to the quarter ended March 31, 2014, primarily due to the reasons set forth below.

### *General and Administrative*

General and administrative expenses consist principally of corporate personnel, cash based and stock option compensation related costs and corporate expenses for legal, accounting and other professional fees as well as occupancy costs. General and administrative expenses increased 6.0%, or \$136,364, to \$2,425,167 for the quarter ended March 31, 2015 compared to the same period of 2014.

### *Selling and Marketing*

Selling and marketing expenses primarily consist of costs for sales and marketing personnel, sales commissions, costs for trade shows, sales conventions and meetings, travel expenses, advertising and other sales and marketing related costs. In addition, stock option compensation expense associated with our sales force is also included in sales and marketing expenses. Selling and marketing expenses increased 16.2%, or \$658,468, to \$4,713,672 for the quarter ended March 31, 2015 compared to the same period of 2014. The increase is due to increased commissions tied to increased revenues. As a percentage of revenue, selling and marketing expenses increased to 49.6% in the first quarter of 2015 from 45.5% in the prior year first quarter.

*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 \$158,978 or 62.4% from \$254,583 for the quarter ended March 31, 2014 to \$413,561 for the same period of 2015. The increase is due to increased spending on research and development projects.

*Depreciation*

Depreciation expense consists of depreciation of long-lived property and equipment. Depreciation expense increased 65.2% to \$124,111 for the quarter ended March 31, 2015 from \$75,148 in the same period in 2014.

*Non-cash Consulting Expense*

Non-cash consulting expense consists of non-cash expense associated with granting restricted stock and stock to consultants and directors. Non-cash consulting expense increased \$46,269 to \$66,796 for the quarter ended March 31, 2015 from \$20,527 in the same period in the prior year.

*Interest Expense*

Interest expense is from our debt instruments. Interest expense for the first quarter of 2015 increased \$159,966 to \$1,435,578 as compared to \$1,275,612 in the first quarter of 2014.

*Change in Warrant Derivative Liability*

For the first quarter of 2015, the Company recorded a loss from a increase in its non-cash warrant derivative liability of \$462,208 which was primarily driven by the increase in the closing price of the Company's common stock March 31, 2015 compared to December 31, 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 and the Company's 2014 equity financing



which contain certain provisions requiring the Company to record a change in the warrant derivative liability from period to period.

*Other Income/Expense*

Other Income for the first quarter of 2015 was \$11,837 as compared to an expense of \$186,915 in the same period in 2014. The change is related to payments made in connection with a legal settlement in 2014.

### *Liquidity and Capital Resources*

Since our inception, we have historically financed our operations through operating cash flows, as well as the private placement of equity securities and convertible debt, an equity credit facility and other debt transactions. In March 2015 we received \$750,000 from the sale of our common stock to Aspire Capital pursuant to a Purchase Agreement. See Note 2, "Equity", describing the Purchase Agreement with Aspire Capital. At March 31, 2015, we had \$8,395,224 of cash and cash equivalents and accounts receivables.

Net cash used in operating activities for the first quarter of 2015 was \$2,078,276, primarily related to funds required to finance the Company's operations. For comparable period of 2014, net cash used in operating activities was \$2,188,889.

Net cash used in investment activities for the first quarter of 2015 was \$32,354 due to the sale/retirement of property and equipment offset by increases in intangible assets.

Net cash provided by financing activities was \$541,978 for the first quarter of 2015, primarily due to proceeds from the sale of equity securities. See Note 2, "Equity" above.

### *Off Balance Sheet Arrangements*

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

### *Cash Requirements*

We believe that our March 31, 2015 cash on hand and accounts receivable balance of \$8,395,224 along with anticipated cash receipts from sales expected from operations and from the Aspire Capital financing will be sufficient to meet our anticipated cash requirements through March 31, 2016. We incurred approximately \$17 million in sales and marketing expenses in 2014 and expect to incur \$19 million in 2015 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.

### **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 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 Rule 13a-15(e) under the Exchange Act) as of March 31, 2015. Based upon that evaluation, our chief executive officer and chief financial officer concluded that as of March 31, 2015, our disclosure controls and procedures were effective.

#### **Management's Report on Internal Control over Financial Reporting**

Management is responsible for establishing and 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 (2013) 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 (2013), management concluded that our internal control over financial reporting was effective as of March 31, 2015.

This report does not include an attestation report of the Company's independent public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

### **Changes in Internal Control over Financial Reporting**

There were no changes in the Company's internal control over financial reporting during the quarter ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **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 Acquisition Offshore LP, a Cayman Islands Exempted Limited Partnership. 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.

### **Item 1A. Risk Factors**

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

*common stock could decline and investors in our common stock could lose all or part of their investment.*

***We recently moved from the NYSE MKT to the OTCQX marketplace.***

On April 8, 2015, we received a notice indicating that the NYSE MKT denied our appeal of their delisting determination. We were also notified that trading of our common stock would be suspended on the NYSE MKT. Beginning April 9, 2015, our common stock began trading on the OTCQX marketplace. As a result, some shareholders may sell their shares, and we may not be able to attract institutional investors in future financing transactions. In addition, because our common stock is no longer listed on a national securities exchange, we will not be eligible to utilize a Form S-3 registration statement (i) for a primary offering, if our public float is not at least \$75.0 million as of a date within 60 days prior to the date of filing the Form S-3, or a re-evaluation date, whichever is later, and (ii) to register the resale of our securities by persons other than us (i.e., a resale offering). Because we are unable to utilize a Form S-3 registration statement for primary and secondary offerings of our common stock, we will be required to file a Form S-1 registration statement, which could delay our ability to raise funds in the future, may limit the type of offerings of common stock we could undertake, and could increase the expenses of any offering, as, among other things, registration statements on Form S-1 are subject to SEC review and comments whereas take downs pursuant to a previously effective Form S-3 are not. In addition, we are no longer subject to NYSE MKT shareholder approval requirements, which formerly required us to obtain shareholder approval before issuing 20% or more of our common stock in an acquisition or financing transaction, unless the transaction satisfied certain pricing requirements or was considered a “public offering” by the NYSE MKT staff. Since we are no longer subject to such shareholder approval requirements, we could issue shares in excess of 20% of our outstanding shares in acquisitions or financing transactions without shareholder approval. Any such issuance would dilute the ownership of our current stockholders. In addition, we will no longer be subject to the NYSE MKT rules requiring us to meet certain corporate governance standards, which could decrease investor interest in our common stock.

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

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

***We may need to use 50% of the net proceeds from future offerings to make a mandatory prepayment on our loan to ROS Acquisition Offshore LP***

Subject to the discretion of our lender, our credit agreement with ROS includes an obligation on our part to use 50% of the net proceeds from equity offerings above \$15 million in the aggregate to make a mandatory prepayment on our loan to ROS. 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 may be obligated to apply 50% of the net proceeds of any such future offering to make a prepayment on our loan 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.



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 OsteoSelect<sup>®</sup> 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.

***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.

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

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

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

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

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

Media reports or other negative publicity concerning both improper methods of tissue recovery from donors and disease transmission from donated tissue may limit widespread acceptance of our allografts. Unfavorable reports of

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

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

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

***We will need to continue to innovate and develop new products to be desirable to our customers.***

The markets for our products and services are characterized by rapid technological change, frequent new introductions, changes in customers' demands and evolving industry standards. Accordingly, we will need to continue to innovate and develop additional products. These efforts can be costly, subject to long development and regulatory delays and may not result in products approved for sale. These costs may hurt operating results and may require additional capital. If additional capital is not available, we may be forced to curtail development activities. In addition, any failure on our behalf to react to changing market conditions could create an opportunity for other market participants to capture a critical share of the market within a short period of time.

***Our success will depend on our ability to engage and retain qualified technical personnel who are difficult to attract.***

Our success will depend on our ability to attract and retain qualified technical personnel to assist in research and development, testing, product implementation, low-scale production and technical support. The demand for such personnel is high and the supply of qualified technical personnel is limited. A significant increase in the wages paid by competing employers could result in a reduction of our technical work force and increases in the wage rates that we must pay or both. If either of these events were to occur, our cost structure could increase and our growth potential could be impaired.

***Loss of key members of our management who we need to succeed could adversely affect our business.***

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

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

Any failure in the physical infrastructure of our facilities or services could lead to significant costs and disruptions that could reduce our revenues and harm our business reputation and financial results. We are highly reliant on our Belgrade, Montana facilities. Any natural or man-made event that impacts our ability to utilize these facilities could have a significant impact on our operating results, reputation and ability to continue operations. The regulatory process for approval of facilities is time-consuming and our ability to rebuild facilities would take a considerable

amount of time and expense and cause a significant disruption in service to our customers. Further, the FDA or some other regulatory agency could identify deficiencies in future inspections of our facilities or our supplies that could disrupt our business, reducing profitability.

*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.

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

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

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

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

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

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

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

Although we are not currently subject to any product liability proceedings, we have no reserves for product liability disbursements, and we may incur material liabilities relating to product liability claims in the future, including product liability claims arising out of the use 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.

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 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 the 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 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 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, Montana (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 2, 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 believe addressed all of the FDA's concerns. While we have implemented a corrective action strategy that we believe addresses all of the FDA's concerns, there is a chance that the FDA will not agree with our proposed corrective actions. If the FDA does not agree with our proposed actions, they could issue another warning letter, request that we take additional actions, or take additional enforcement actions. The 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 the FDA will conduct an additional follow up inspection. In addition, from July 22, 2013 to August 2, 2013, the 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 the 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, the 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, would 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 the 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.

***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 the 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.

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 EU 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.

***Loss of AATB Accreditation would have a Material Adverse Effect***

We are accredited with the American Association of Tissue Banks (“AATB”), a private non-profit organization that accredits tissue banks and sets industry standards. Although AATB accreditation is voluntary and not required by law, as a practical matter, many of our customers would not purchase our products if we failed to maintain our AATB accreditation. Although we make every effort to maintain our AATB accreditation, the accreditation process is somewhat subjective and lacks regulatory oversight. There can be no assurance that we will continue to remain accredited with the AATB.

***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 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, 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 of our Information Technology Systems could disrupt our Business.***

Our operations depend on the continued performance of our information technology systems. Despite security measures and other precautions we have taken, our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptions. Sustained failure of our information technology systems could disrupt our business operations. In addition, some of our contracts impose obligations related to information we may have in physical or electronic formats, and any breach or failure of our information technology systems could result in breach of contract claims and other damages.

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

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

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

We may not be able to obtain, maintain and protect certain proprietary rights necessary for the development and commercialization of our products or product candidates. Our commercial success will depend in part on obtaining and maintaining patent protection on our products and successfully defending these patents against third-party challenges. Our ability to commercialize our products will also depend in part on the patent positions of third parties, including those of our competitors. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict with certainty the scope and breadth of patent claims that may be afforded to other companies' patents. We could incur substantial costs in litigation if we are required to defend against patent suits brought by third parties, or if we initiate suits to protect our patent rights.

In addition to the risks involved with patent protection, we also face the risk that our competitors will infringe on our trademarks. Any infringement could lead to a likelihood of confusion and could result in lost sales. There can be no assurance that we will prevail in any claims we make to protect our intellectual property.

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

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

- we were the first to make the inventions covered by each of our patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;
- any of our issued patents or those of our licensors will be valid and enforceable;

any patents issued to us or our collaborators will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties;

- we will develop additional proprietary technologies that are patentable;
- the patents of others will not have a material adverse effect on our business rights; or

the measures we rely on to protect the intellectual property underlying our products will be adequate to prevent third parties from using our technology, all of which could harm our ability to compete in the market.

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

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

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

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

***Litigation may result in financial loss and/or impact our ability to sell our products going forward.***

We intend to vigorously defend any future intellectual property litigation that may arise but there can be no assurance that we will prevail in these matters. An unfavorable judgment may result in a financial burden on us. An unfavorable judgment may also result in restrictions on our ability to sell certain products and therefore may impact future operating results.

*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:

- o announcements of technological innovations or new commercial products by us, our collaborative partners or our present or potential competitors;
- o our issuance of debt, equity or other securities, which we need to pursue to generate additional funds to cover our operating expenses;
  - o our quarterly operating results;
- o developments or disputes concerning patent or other proprietary rights;
- o developments in our relationships with employees, suppliers or collaborative partners;
  - o acquisitions or divestitures;
  - o litigation and government proceedings;

- o adverse legislation, including changes in governmental regulation;
  - o third-party reimbursement policies;
- o changes in securities analysts' recommendations;
  - o short selling;
- o changes in health care policies and practices;
- o suspension of trading of our common stock;
- o economic and other external factors; and
  - o 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, 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.

***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 March 16, 2015, we entered into a Common Stock Purchase Agreement, as amended and restated on April 17, 2015 (the “Purchase Agreement”), with Aspire Capital Fund, LLC (“Aspire Capital”), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$10.0 million of shares of our common stock (the “Purchase Shares”) over the 24-month term of the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, on March 30, 2015, we issued 207,182 initial purchase shares to Aspire Capital for \$750,000 and 154,189 commitment shares as a commitment fee.

The Purchase Shares may be sold by the Company to Aspire Capital on any business day the Company selects in two ways: (1) through a regular purchase of up to 50,000 shares at a known price based on the market price of our common stock prior to the time of each sale, and (2) through a VWAP purchase of a number of shares up to 30% of the volume traded on the purchase date at a price equal to the lesser of the closing sale price or 97% of the volume weighted average price for such purchase date.



The issuance of the Initial Purchase Shares, the Commitment Shares and all other shares of common stock that may be issued from time to time to Aspire Capital under the Purchase Agreement is exempt from registration under the Securities Act of 1933, as amended (the “Securities Act”), pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act.

On April 17, 2015, we filed a registration statement on Form S-1 to register up to 2,000,000 shares of our common stock that may be sold by Aspire Capital from time to time. The registration statement was declared effective on April 27, 2015.

**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, incorporated by reference herein)
- 3.2 Amended and Restated Bylaws (filed as Exhibit 3.2 to Form 8-K filed July 11, 2013, incorporated by reference herein)
- 31.1 \* Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
- 31.2 \* Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
- 32.1 \*\* Section 1350 Certification of Chief Executive Officer
- 32.2 \*\* Section 1350 Certification of Chief Financial Officer
- 101.INS \* XBRL INSTANCE DOCUMENT
- 101.SCH \* XBRL TAXONOMY EXTENSION SCHEMA
- 101.CAL \* XBRL TAXONOMY EXTENSION CALCULATION LINKBASE
- 101.DEF \* XBRL TAXONOMY EXTENSION DEFINITION LINKBASE
- 101.LAB \* XBRL TAXONOMY EXTENSION LABEL LINKBASE
- 101.PRE \* XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE

\* Filed herewith

\*\* Furnished herewith

SIGNATURES

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

BACTERIN INTERNATIONAL  
HOLDINGS, INC.

Date: May 6, 2015 By: /s/ John P. Gandolfo  
Name: John P. Gandolfo  
Title: Chief Financial Officer