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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended March 31, 2014

OR

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

For the transition period from to

Commission file number: 001-34951

BACTERIN INTERNATIONAL HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	20-5313323
(State or other jurisdiction	(I.R.S. Employer

of incorporation or organization) Identification No.)

600 CRUISER LANE

BELGRADE, MONTANA 59714

(Address of principal executive offices) (Zip code)

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

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

Yes þ No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes þ No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨		Accelerated filer	¨
Non-accelerated filer ¨	(Do not check if a smaller reporting company)	Smaller reporting company	þ

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

Yes ¨ No þ

Number of shares of common stock, $0.000001 par value, of registrant outstanding at May 6, 2014: 54,975,576

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,” “estimat “expect,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should” and “would,” as well as simi may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward looking. Forward-looking statements in this Form 10-Q may include, for example, statements about:

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

- our ability to innovate and develop new products;
- our ability to obtain donor cadavers for our products;
- our ability to engage and retain qualified technical personnel and members of our management team;
- government and third-party coverage and reimbursement for our products;
- our ability to obtain regulatory approvals;
- our ability to successfully integrate future business combinations or acquisitions;
- product liability claims and other litigation to which we may be subjected;
- product recalls and defects;
- timing and results of clinical studies;
- our ability to obtain and protect our intellectual property and proprietary rights;
- infringement and ownership of intellectual property;
- influence by our management; and
- our ability to issue preferred stock.

The forward-looking statements contained in this Form 10-Q are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties, or assumptions, many of which are beyond our control, which may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the "Risk Factors" section of this Quarterly Report on Form 10-Q. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required under applicable securities laws.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BACTERIN INTERNATIONAL HOLDINGS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

Long-term Liabilities:		
Capital lease obligation, less current portion	34,686	73,777
Long term royalty liability, less current portion	6,575,814	6,609,232
Long-term debt, less current portion	19,636,587	16,385,245
Total Liabilities	37,798,703	32,719,805
Commitments and Contingencies		
Stockholders' (Deficit) Equity		
Preferred stock, $.000001 par value; 5,000,000 shares authorized; no shares issued and Outstanding	-	-
Common stock, $.000001 par value; 95,000,000 shares authorized; 54,982,120 shares issued and outstanding as of March 31, 2014 and 53,432,820 shares issued and outstanding as of December 31, 2013	55	53
Additional paid-in capital	57,933,665	56,516,443
Accumulated deficit	(64,498,929)	(60,358,673)
Total Stockholders' (Deficit) Equity	(6,565,209)	(3,842,177)
Total Liabilities & Stockholders' (Deficit) Equity	$31,233,494	$28,877,628

See notes to unaudited condensed consolidated financial statements.

BACTERIN INTERNATIONAL HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

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

See notes to unaudited condensed consolidated financial statements.

BACTERIN INTERNATIONAL HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

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

See notes to unaudited condensed consolidated financial statements.

Notes to Consolidated Financial Statements

(1) Business Description and Summary of Significant Accounting Policies

Business Description

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

Bacterin's device division develops bioactive coatings based on proprietary knowledge of the phenotypical changes made by microbes as they sense and adapt to changes in their environment. Bacterin develops, employs, and licenses bioactive coatings for various medical device applications.

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

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

The accompanying interim condensed consolidated financial statements of Bacterin for the three months ended March 31, 2014 and 2013 are unaudited and are prepared in accordance with accounting principles generally accepted in the United States of America. They do not include all disclosures required by generally accepted accounting principles for annual financial statements, but in the opinion of management, include all adjustments, consisting only of normal recurring items, necessary for a fair presentation. Interim results are not necessarily indicative of results which may be achieved in the future for the full year ending December 31, 2014.

These financial statements should be read in conjunction with the financial statements and notes thereto which are included in Bacterin's Annual Report on Form 10-K for the year ended December 31, 2013. The accounting policies set forth in those annual financial statements are the same as the accounting policies utilized in the preparation of these financial statements, except as modified for appropriate interim financial statement presentation.

Concentrations and Credit Risk

The Company's accounts receivable are due from a variety of health care organizations and distributors throughout the world. Approximately 98% of sales were in the United States for the three months ended March 31, 2014 and 2013, respectively. One customer accounted for approximately 15% of the Company's revenue for the three months ended March 31, 2013. One customer represented 21% of accounts receivable at March 31, 2013. No single customer accounted for more than 10% of revenue or accounts receivable for the three months ended March 31, 2014. The Company provides for uncollectible amounts when specific credit issues arise. Management's estimates for uncollectible amounts have been adequate during prior periods, and management believes that all significant credit risks have been identified at March 31, 2014.

Revenue by geographical region is as follows:

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

Use of Estimates

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

Cash and Cash Equivalents

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

Accounts Receivable

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

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

Inventories

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

Property and Equipment

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

Goodwill

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

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

Derivative Instruments

The Company accounts for its derivative instruments in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 815 "Accounting for Derivative Instruments and Hedging Activities". The only derivative instruments presented in the accompanying consolidated financial statements relates to warrants issued in connection with certain debt financings. The Company has not designated its warrant derivative liability as a hedging instrument as described in ASC 815 and any changes in the fair market value of the warrant derivative liability is recognized in the consolidated statement of operations during the period of change. See Note 9, "Warrants" below.

Intangible Assets

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

Accounts Payable - Related Party

Accounts payable to a related party includes amounts due to American Donor Services, a supplier of donors to the Company. See Note 13, "Related Party Transactions" below.

Revenue Recognition

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

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

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

The Company also receives royalty revenue from third parties related to licensing agreements. The Company has royalty agreements with RyMed and Bard Access Systems. Revenue under these agreements represented less than 1% of total revenue for the three months ended March 31, 2014 and 2013.

Non-Cash Consulting Expense

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

Advertising Costs

The Company expenses advertising costs as incurred. The Company had advertising expense of $26,711 and $168,780 for the quarters ended March 31, 2014 and 2013, respectively.

Research and Development

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

Income Taxes

The Company accounts for income taxes under the asset and liability method of accounting for deferred taxes as prescribed under FASB ASC 740, Accounting for Income Taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. When applicable, a valuation allowance is established to reduce any deferred tax asset when it is determined that it is more likely than not that some portion of the deferred tax asset will not be realized. ASC 740 also requires reporting of taxes based on tax positions that meet a more-likely-than-not standard and that are measured at the amount that is more-likely-than-not to be realized. Differences between financial and tax reporting which do not meet this threshold are required to be recorded as unrecognized tax benefits. ASC 740 also provides guidance on the presentation of tax matters and the recognition of potential IRS interest and penalties. The Company classifies penalty and interest expense related to income tax liabilities as an income tax expense. There are no significant interest and penalties recognized in the statement of operations or accrued on the balance sheet. See Note 11, “Income Taxes” below.

Long-Lived Assets

Long-lived assets, including intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. No impairment was recorded during the quarters ended March 31, 2014 or 2013.

Net Loss Per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. Diluted net income (loss) per share is computed in a manner consistent with that of basic earnings per share while giving effect to all potentially dilutive common shares outstanding during the period, which include the assumed exercise of stock options and warrants using the treasury stock method. Diluted net loss per share was the same as basic net loss per share for the quarters ended March 31, 2014 and 2013 as shares issuable upon the exercise of stock options and warrants were anti-dilutive as a result of the net losses incurred for those periods. Dilutive earnings per share are not reported as their effects of including 18,418,493 and 11,985,029 outstanding stock options and warrants for the three months ended March 31, 2014 and 2013, respectively are anti-dilutive.

Stock-Based Compensation

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

Fair Value of Financial Instruments

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