Bacterin International Holdings, Inc.
Form 8-K
February 01, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT

TO SECTION 13 OR 15(D) OF THE

SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): January 29, 2013

Bacterin International Holdings, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-34951	20-5313323
	(IRS Employer Identification No.)
(Commission File Number)	
600 Cruiser Lane	
	59714
Belgrade, Montana	
	(Zip Code)
(Address of Principal Executive Offices)	

(406) 388-0480
(Registrant’s Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

¨Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

On January 29, 2013, we received two warning letters from the FDA related to our procedures to ensure compliance with regulatory requirements. The concerns include (i) procedures for implementing corrective and preventative action; (ii) procedures for receiving, reviewing and evaluating complaints; (iii) procedures related to changes to a specification, method, process or procedure; (iv) procedures to ensure that purchased or otherwise received products or services conform to specified requirements; (v) procedures to control documents; (vi) procedures to identify training needs and to ensure all personnel are trained to adequately perform assigned responsibilities; (vii) procedures related to medical device reporting; (viii) procedures to control product that does not conform to specified requirements; (ix) procedures for finished device acceptance; and (x) marketing materials related to our Elutia wound drain.

The warning letters relate to the July 2012 inspection of our facilities and procedures. Following the July 2012 inspection, the FDA issued two Form 483s identifying certain observations regarding our procedures to ensure compliance with regulatory requirements. We established a schedule to respond to the FDA's observations, and we have provided timely responses. Although the FDA acknowledged receipt of our response, the content of our response was not considered in the warning letters.

The company is committed to actively working with the FDA to address their concerns. The warning letters do not restrict our ability to continue manufacturing and selling our products, nor do they require the withdrawal of any product from the marketplace. The issuance of the warning letters has no impact on patient safety. We take this matter very seriously, and we are committed to fully resolving any issues or concerns.

SIGNATURE

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 hereunto duly authorized.

Dated: January 31, 2013 **BACTERIN INTERNATIONAL HOLDINGS, INC**.

By: /s/ Guy S. Cook
Name: Guy S. Cook
Title: President and Chief Executive Officer