

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): May 8, 2012

**Bacterin International Holdings, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-34951

(Commission File Number)

20-5313323

(IRS Employer Identification No.)

600 Cruiser Lane  
Belgrade, Montana

(Address of Principal Executive Offices)

59714

(Zip Code)

(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 7.01 Regulation FD Disclosure.**

New GPO Agreement: The Company has issued a press release entitled “Bacterin International Signs its Third National GPO Contract for OsteoSponge®, OsteoSelect® DBM Putty, OsteoWrap®, OsteoLock®, BacFast®, hMatrix®, Sports Medicine Allografts, and traditional allografts” which is attached as Exhibit 99.1 and incorporated herein.

Study Results: The results of a study comparing Bacterin’s OsteoSelect® DBM Putty to autogenous iliac crest bone graft in rabbit posterolateral lumbar spine arthrodesis is attached as Exhibit 99.2 and incorporated herein.

Update on 510(k) submission: We recently received comments from the FDA in response to our 510(k) submission for coated external fixation devices, and we are currently working with the FDA to proceed with the 510(k) submission process.

The information in this Item 7.01 and the document attached as Exhibit 99.1 are being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), nor otherwise subject to the liabilities of that section, nor incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No	Description
99.1	Press Release of Bacterin International Holdings, Inc. dated May 8, 2012 entitled “Bacterin International Signs its Third National GPO Contract for OsteoSponge®, OsteoSelect® DBM Putty, OsteoWrap®, OsteoLock®, BacFast®, hMatrix®, Sports Medicine Allografts, and traditional allografts”
99.2	Study results entitled “New Formulation of Demineralized Bone Matrix Putty Performs Substantially Equivalent to Iliac Bone Graft in Rabbit Posterolateral Lumbar Spine Arthrodesis”

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: May 8, 2012

**BACTERIN INTERNATIONAL HOLDINGS, INC.**

By: /s/ Guy S. Cook

Name: Guy S. Cook

Title: President and Chief Executive Officer

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## EXHIBIT INDEX

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## **Bacterin International Signs Its Third National GPO Contract with Novation**

BELGRADE, Mont. May 8, 2012 - Bacterin International Holdings, Inc. (NYSE Amex: BONE), a leader in the development of revolutionary bone graft material and antimicrobial coatings for medical applications, announces its third national GPO contract, a three-year agreement with Novation, a leading health care supply chain expert and contracting company. The agreement provides Bacterin's full biologic portfolio, including OsteoSponge®, OsteoSelect® DBM Putty, OsteoWrap®, OsteoLock®, BacFast®, hMatrix®, Sports Medicine Allografts, and traditional allografts to the nationwide network of hospitals and medical practices served by Novation. The group purchasing agreement became effective, after performing months of research and evaluation of the Bacterin product lines.

"We are pleased to partner with Novation, an organization which has developed an industry-wide reputation for innovative, technology-driven, results-oriented approaches to improving supply chain performance," said Guy Cook, Chairman and CEO of Bacterin International. "The inclusion of our products in Novation's network is a significant opportunity to create exposure and access for physicians to our broad portfolio of biologics. Our sales reps are excited to begin calling on their facilities."

### **About Novation, Winner of the Ethics Inside® Certification**

Founded in 1998, Novation is the leading health care supply chain expertise and contracting company for the more than 65,000 members of VHA Inc. and UHC, two national health care alliances, and Provista, LLC. Novation provides alliance members with sourcing services, as well as information and data services. Based in Irving, Texas, Novation develops and manages competitive contracts with more than 600 suppliers. VHA, UHC, and Provista members used Novation contracts to purchase more than \$40 billion in 2011. Novation recently earned the coveted Ethics Inside® Certification from Ethisphere Institute, a leading international think tank dedicated to the research and promotion of best practices in corporate ethics and compliance. Novation was also named on Ethisphere's World's Most Ethical Companies list, and is the only company in the health care industry to earn both distinctions.

### **About Bacterin International Holdings**

Bacterin International Holdings, Inc. (NYSE Amex: BONE) develops, manufactures and markets biologics products to domestic and international markets. Bacterin's proprietary methods optimize the growth factors in human allografts to create the ideal stem cell scaffold to promote bone, subchondral repair and dermal growth. These products are used in a variety of applications including enhancing fusion in spine surgery, relief of back pain, promotion of bone growth in foot and ankle surgery, promotion of cranial healing following neurosurgery and subchondral repair in knee and other joint surgeries.

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Bacterin's Medical Device division develops, employs, and licenses bioactive coatings for various medical device applications. Bacterin's strategic coating initiatives include antimicrobial coatings designed to inhibit biofilm formation and microbial contamination. For further information, please visit [www.bacterin.com](http://www.bacterin.com).

#### Important Cautions Regarding Forward-looking Statements

This news release contains certain disclosures that may be deemed forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to significant risks and uncertainties. Forward-looking statements include statements that are predictive in nature, that depend upon or refer to future events or conditions, or that include words such as "continue," "efforts," "expects," "anticipates," "intends," "plans," "believes," "estimates," "projects," "forecasts," "strategy," "will," "goal," "target," "prospects," "potential," "optimistic," "confident," "likely," "probable" or similar expressions or the negative thereof. Statements of historical fact also may be deemed to be forward-looking statements. We caution that these statements by their nature involve risks and uncertainties, and actual results may differ materially depending on a variety of important factors, including, among others: the Company's ability to launch beta and full product releases, the Company's ability to obtain FDA concurrence use for anti-microbial coatings in a timely manner; the Company's ability to meet its obligations under existing and anticipated contractual obligations; the Company's ability to develop, market, sell and distribute desirable applications, products and services and to protect its intellectual property; the ability of the Company's sales force to achieve expected results; the ability of the Company's customers to pay and the timeliness of such payments, particularly during recessionary periods; the Company's ability to obtain financing as and when needed; changes in consumer demands and preferences; the Company's ability to attract and retain management and employees with appropriate skills and expertise; the impact of changes in market, legal and regulatory conditions and in the applicable business environment, including actions of competitors; and other factors. Additional risk factors are listed in the Company's Annual Report on Form 10-K under the heading "Risk Factors." The Company undertakes no obligation to release publicly any revisions to any forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events, except as required by law.

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## **New Formulation of Demineralized Bone Matrix Putty Performs Substantially Equivalent to Iliac Bone Graft in Rabbit Posterolateral Lumbar Spine Arthrodesis.**

Kiely PD, Breceovich A, Taher F, Cammisa FP, Abjornson C.

*Background Context:* Autogenous iliac crest bone graft (ABG) has long been considered the standard for grafting as it possesses three fundamental components: osteoconductivity, osteoinductivity, and osteogenic potential. Many new bone graft substitutes (BGS) have been developed over the past two decades as alternatives to autograft for posterolateral spine fusion with varying results. Demineralized bone matrix (DBM) is one class BGS that is derived from processed human bone and is mixed with a carrier material to enhance handling characteristics, while maintaining its osteoconductive and osteoinductive potential.

*Purpose:* To compare the efficacy of a new formulation of DBM putty (OsteoSelect DBM Putty, Bacterin International, Bozeman, MT) to that of ABG.

*Design:* A controlled rabbit model of lumbar posterolateral intertransverse process fusion was used.

*Materials and Methods:* Twenty four (24) male New Zealand White (NZW) rabbits, weight range at the start of the study 3.5-4.0 kg, underwent bilateral posterolateral spine arthrodesis of the L5- L6 intertransverse processes, using either ABG (control group, n= 12) or DBM (DBM made from rabbit bone) putty (test group, n =12) . The animals were killed 12 weeks after surgery and the lumbar spines were excised. Fusion success was evaluated by manual palpation of the motion segment and scoring high-resolution x-rays of the excised spine by the Lenke scale. Further analysis included 3-point bending in flexion, right and left bending, and extension to determine stiffness of fusion mass and micro-computed tomography (micro-CT) imaging to determine bone volume. Finally, undecalcified histologic analysis was performed.

*Results:* Manual palpation by three observers to assess fusion success in the explanted lumbar spines showed successful fusion in 81.8% (9/11) of the test group and 72.7% (8/11) of the control group which were equivalent ( $p = 0.99$ ). Fusion was assessed as solid (Lenke A score) in 10 of the DBM and 9 of the ABG specimens ( $p > 0.59$ ). Biomechanical testing showed no significant difference in stiffness between the control and test groups on flexion, extension, left lateral and right lateral bend, with  $p$  values accounting for 0.79, 0.42, 0.75 and 0.52, respectively. Bone volume/total volume was greater than 85% in DBM treated fusion masses. Histological evaluation revealed mature fusions with little remains of graft material in the DBM-treated group. The ABG-treated group was less mature with greater areas of graft material still present.

*Conclusion:* The OsteoSelect DBM putty proved equivalent to ABG in the posterolateral intertransverse rabbit model, and deserves consideration as an alternative to iliac crest autograft in spinal arthrodesis, avoiding donor site morbidities associated with bone graft harvesting.

*FDA device Status:* FDA approval.

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