

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

October 26, 2010

John P. Gandolfo Chief Financial Officer 600 Cruiser Lane Belgrade, Montana 59714

Re: Bacterin International Holdings, Inc. Registration Statement on Form S-1 Filed September 28, 2010 File No. 333-169620

> Form 10-K Filed March 30, 2010 File No. 333-158426

Dear Mr. Gandolfo:

We have reviewed your registration statement on Form S-1 filed on September 28, 2010 and your Form 10-K filed on March 30, 2010 and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

#### General

1. Please note that where we provide examples to illustrate what we mean by our comments, they are examples and not complete lists. If our comments are applicable to portions of the filing that we have not cited as examples, please make the appropriate changes in accordance with our comments.

#### Cover Page

2. We note that Greenberg Traurig, LLP is no longer the company's outside counsel. Please revise the cover page of your filing to state your current outside counsel's contact information.

#### Bacterin International Holdings, Inc., pages 1

- 3. Please delete the word "leader" from your statement, "We develop, manufacture and market biologics products to domestic and international markets through our biologics division and believe we are emerging into a leader in the field of biomaterials research, device development and commercialization," in this section and elsewhere as applicable. Alternatively, provide us with the information justifying the characterization of your company as an emerging leader.
- 4. Please disclose the reasonable basis for the characterization of your products as set forth in the following statements:
  - "Our proprietary methods optimize the growth factors in human allografts to create the ideal stem cell scaffold and promote bone and other tissue growth;"
  - "Such coatings contain active agents and provide our products with several potential advantages over traditional medical devices. They offer a means of protecting the surface of a medical device from contamination by pathogenic organisms, thereby minimizing the potential for infection;" and
  - "Other coatings can serve as a reserve for local delivery of active agents, enhancing a variety of biological functions such as bone growth and pain management."

Alternatively, delete these statements from this section and elsewhere as applicable.

# Recent Developments, page 1

5. We note that the private placements through which the selling stockholders acquired the shares being registered are described on page 2 of the filing; however, it does not appear that the share amounts mentioned add up to the amount being registered through this registration statement. Please revise your disclosure to clarify when, and in what transactions, the entirety of the 11,352,479 shares (including 3,751,621 shares issuable upon the exercise of warrants) were placed with the selling stockholders.

#### **Risk Factors**

#### Our success will depend on our ability to engage and retain ..., page 5

6. To the extent that you have experienced problems engaging and retaining qualified technical personnel in the recent past, please revise your disclosure to describe these problems. Additionally, if any key technical personnel have plans to leave your company in the near future, please revise the discussion to disclose this information.

# Loss of key member of our management who we need to succeed..., page 5

7. To the extent that you have experienced problems attracting and retaining qualified key members of your management team in the recent past, please revise your disclosure to describe these problems. Additionally, if any key member of your management team has

plans to leave your company in the near future, please revise the discussion to disclose this information.

# We are highly dependent on the continued availability of our facilities..., page 5

8. Please disclose your level of business interruption insurance coverage and the cost to you of such coverage, if material.

#### We will be required to invest in facilities and equipment..., page 6

9. To the extent practicable, please provide the amounts, in this risk factor, that you have currently budgeted or anticipate spending to increase, expand or update your capabilities and facilities during the next five years and the extent to which you have identified sources of funding for this increase, expansion or update. In addition, please address this comment in more detail in the section entitled "Cash Requirements" in your Management's Discussion and Analysis.

# Future revenue will depend on our ability to develop new sales channels..., page 6

10. We note that you are engaging in a major initiative to build and further expand your direct sales force and that this effort will have significant costs. Please expand your disclosure in this risk factor to quantify, to the extent practicable, the amount of funds you will need to build and further expand your direct sales force. In addition, please quantify your funding requirements and sources of funding in greater detail in the section entitled "Cash Requirements" in your Management's Discussion and Analysis.

# Our revenues will depend upon prompt and adequate reimbursement from..., page 6

11. Please disclose any problems you have experienced with prompt and adequate reimbursement from public and private insurers and national health systems and quantify the effects of such problems on your company, if material.

# We may be subject to future product liability litigation..., page 7

- 12. Please disclose the level of insurance coverage that you carry relating to product liability claims and the cost to you of such coverage, if material.
- 13. Please disclose the level of reserves you maintain for product liability disbursements.

# We may not be able to obtain or protect our proprietary rights..., page 10

14. We note in your "Legal Proceedings" section that you have served complaints to Allosource and Advanced Biologics, Inc. Please discuss these claims and potential consequences in this risk factor discussion.

#### If we do not timely file and have declared effective the registration statement..., page 11

15. We note that you entered into a registration rights agreement where you "agreed to file and have declared effective this registration statement by a certain date." Please disclose the date that you agreed to file and have this registration statement declared effective.

Management's Discussion and Analysis of Financial Condition and Results of Operations, page 16

Comparison of Twelve Months Ended December 31, 2009 and December 31, 2008..., page 18 Revenue, page 19

- 16. We note that the cost of tissue sales as a percentage to the tissue sales temporarily increased from 18% during the six months ended June 30, 2009 to 48% during the six months ended December 31, 2009, then decreased to 19% during the six months ended June 30, 2010. Please revise your discussion to identify which product temporarily increased demand and why. Quantify the sales volume and revenue by product to supplement your discussion.
- 17. We note that your largest customer accounted for 12% and 37% of the total consolidated revenues for the years ended 2009 and 2008, respectively. We also note that the relationship with the customer is governed by a contract, which indentifies prices for the services to be rendered and payments to be made by the customer, that expires in February 2011. Please disclose the name of this customer and describe, in the "Business" section, the material terms of the agreement including the pricing and payment, term and termination and any other material provisions of the agreement. Please note that the termination date should also include the day on which the contract terminates. Also, please file the contract as an exhibit, or alternatively, tell us the basis for your belief that you are not required to file the agreement pursuant to Item 601(b)(10)(ii)(B) of Regulation S-K.

# <u>Business, page 23</u> Overview of Our Business, page 23

- 18. We note that you will continue to use the proceeds from prior financings and the private placements to expand your direct sales network and your production capacity. To the extent practicable, please disclose the amount of funds you will allocate to each. Also, with respect to expanding your production capacity, please clarify whether you intend to use funds to open new facilities, increase the capacity of your current facility or both. If you intend to increase your current capacity and open new facilities, clarify the portion of funds you expect to allocate to each and indicate where you expect to open new facilities.
- 19. Please provide the basis for your statement that the Center for Biofilm Engineering at Montana State is "internationally acclaimed."
- 20. We note that you generate revenue from a number of revenue sources including the following: license fees and royalties from collaborative product development efforts,

sales from products developed and manufactured by you under your own label and contract revenue from analytical testing and development services provided to medical device manufacturer clients, which tailor your coating process to the client's specific product/medical application. Please disclose whether you have entered into any license or collaboration agreements or contracts with respect to these revenue generating sources and describe the material terms of these agreements or contracts including the obligations of the parties, term and termination, royalty rate and any other material provisions of the agreements or contracts. Also, please file the agreements or contracts as exhibits, or alternatively, tell us the basis for your belief that you are not required to file the agreements or contracts pursuant to Item 601(b)(10)(ii)(B) of Regulation S-K.

# Products and Services, page 24

- 21. We note that your discussion on products and services distinguishes between your Biologics Division and your Medical Device Products. However, we also note that products such as your OsteoSelect DBM putty appear in both sections. Please clarify which of your products are regulated as HCT and which are regulated as medical devices.
- 22. We note that you are beginning trials to establish the ability to market OsteoSponge SC as a cartilage re-generation scaffold, and that you are also initiating clinical studies to further support BacFast's effectiveness. Please specify in your disclosure what you and the FDA will have to do and, if applicable, have already done prior to clinically testing the products, and what you and the FDA will have to do to commercially market the products.
- 23. We note that you are using part of the proceeds of the private placements to fund your clinical trials for OsteoSponge SC and BacFast. To the extent practicable, please disclose the amount of funds you will allocate to the trials for each product.
- 24. We note that you are hoping to expand your product definition for certain of your products to claim cartilage regeneration capability. We also note that 15 patients have undergone knee, foot or ankle surgery for the purposes of the trial to make such claims, and that you plan to have 200 patients in the trial by year end. Lastly, we note that one of these products is OsteoSponge SC. Please disclose the other products for which you are hoping to expand your product definition to claim cartilage regeneration capability. Additionally, please disclose whether you are conducting trials for these products as well. If you are conducting trials for your other products, please specify in your disclosure what you and the FDA will have to do and, if applicable, have already done prior to clinically testing the products, and what you and the FDA will have to do to commercially market the products.
- 25. Please provide the basis for your statement, "We believe that the ultimate size of the market for wound drains is \$80 million per year." Alternatively, delete these statements from this section and elsewhere as applicable.

26. We note that in a joint development project between RyMed and your company, the InVision-Plus CS is treated with your patented antimicrobial technology. We also note that you will receive a royalty on all devices treated for RyMed. Please disclose whether you have entered into a collaboration agreement with RyMed and describe the material terms of the agreement including the obligations of the parties, term and termination, royalty rate and any other material provisions of the agreement. Also, please file the agreement as an exhibit, or alternatively, tell us the basis for your belief that you are not required to file the agreement pursuant to Item 601(b)(10)(ii)(B) of Regulation S-K.

#### Technology and Intellectual Property, page 26

27. We note your table containing your patent information. Under the section for your inlicensed intellectual property, please disclose the expiration date for these patents and the jurisdictions in which they were granted.

# Sales and Marketing, page 30

28. Please disclose the material terms of the contract with Broadlane, Inc., including the term and termination provisions, and file the contract as an exhibit, or alternatively, tell us the basis for your belief that you are not required to file the contract pursuant to Item 601(b)(10)(ii)(B) of Regulation S-K.

# Legal Proceedings, pages 32-33

29. Please disclose the relief sought in your lawsuits with Yanaki and Activatek, Allosource and minSURG.

#### Potential Payments Upon termination or Change-in-Control, page 40

30. We note that you state, "Except for Mr. Gandolfo's employment agreement described below, we currently have no employment agreements with any of our named executive officers..." However, on page 38 of your filing, you state that you intend to keep the current employment agreements between Bacterin and Guy Cook, Mitchell Godfrey, Jesus Hernandez and Darrel Holmes, and that these employment agreements are set forth as exhibits to the registration statement. Please revise your disclosure to reconcile this apparent discrepancy.

### Director Independence, page 41

31. We note your statement that during the year ended December 31, 2009, you did not have any independent directors on your board. However, in your discussion on board committees, for example, you list Mr. Swanson as a member of your audit and compensation committees and state that he is an independent director of your company under Nasdaq listing standards as well as under rules adopted by the SEC. Mr. Swanson was a director as of the year ended December 31. 2009. Please revise your disclosure to

reconcile this apparent discrepancy to explain whether you did or did not have any independent directors on your board during the year ended December 31, 2009.

# Selling Stockholders, page 45

32. Please revise your disclosure to indicate the nature of any position, office, or other material relationship which the selling security holders have had within the past three years with the company or any of its predecessors or affiliates. Please refer to Item 507 of Regulation S-K for guidance.

### Other Rights To Acquire Our Common Stock, page 57

33. We note that you are contractually obligated to issue shares of your common stock to one of your stockholders. Please disclose the name of such stockholder and file as an exhibit the contract underlying such obligation or alternatively, tell us the basis for your belief that you are not required to file the agreement pursuant to Item 601(b)(10) of Regulation S-K.

### Legal Matters, page 58

34. We note that Greenberg Traurig, LLP is no longer your outside legal counsel. Please revise your disclosure to state who will pass a legal opinion regarding the validity of the securities in this offering.

# <u>Financial Statements for the Quarterly Period Ended June 30, 2010</u> (1) Business Description and Summary of Significant Accounting Policies Reverse Merger Transaction, page F-8

35. Please revise your disclosure to describe what happened to the operations of K-Kitz. If K-Kitz's operations were terminated (e.g. through sales or discontinuation), also disclose the timing of termination. If K-Kitz's operations were not terminated prior to or at the time of your reverse merger, please explain to us why you qualify for the recapitalization accounting.

# <u>Financial Statements for the Year Ended December 31, 2009</u> General

36. Your "de facto one-for-two reverse stock split" effective June 30, 2010 should be retroactively reflected throughout your document, including your financial statements for the year ended December 31, 2009. Please revise your document to discuss share counts and per share pricing information in a consistent manner.

#### Statements of Operations, page F-22

37. Your operating expense captions on the 2009 and 2010 statements of operation are not the same and do not allow for comparability. Please revise to use the same captions for

all periods. If the caption "Stock options compensation expense" is retained, disclose on the face of the statement of operations which other captions each amount would be included in if it were non-stock compensation. Disclose why depreciation is not included in cost of sales or parenthetically disclose in the caption "cost of sales" that that caption excludes depreciation presented below.

# (1) Business Description and Summary of Significant Accounting Policies Grants, page F-26

38. Please quantify the amount of grants you awarded and received during the periods presented. In addition, please revise your disclosure to describe how you account for the grants you awarded and received.

#### Revenue Recognition, page F-27

39. On page F-25, you disclose that you principally derive revenues from sale or license of medical products, coatings and device implants. Since your obligations may be different under sales and license transactions, please disclose your accounting policy separately and disclose the line item under which the license revenues are presented on your statements of operations. If you recognize revenues from licenses upon delivery, rather than over the license term, provide additional discussion to support your accounting.

# Net Income (Loss) Per Share, page F-27

40. Please disclose the number of common stock equivalents that were excluded in the calculation of earnings per share for the reason that they were anti-dilutive.

#### (8) Convertible Notes Payable, page F-30

41. The conversion price of your notes appears adjustable based on your future qualified financing. Please tell us how you have accounted for the conversion feature and provide us a scope analysis under ASC 815-40-15. If the conversion feature is included within the scope of ASC 815-40, please also provide us an analysis under ASC 815-40-25 to support your accounting.

#### **Exhibits**

42. Please file your remaining exhibits, including the legal opinion, as soon as practicable. We will need time to review these exhibits prior to granting effectiveness of the registration statement.

\* \* \* \* \*

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Act of 1933 and all applicable Securities Act rules require. Since the company and its management are in

possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event you request acceleration of the effective date of the pending registration statement please provide a written statement from the company acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please refer to Rules 460 and 461 regarding requests for acceleration. We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Keira Ino at (202) 551-3659 or Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Johnny Gharib at (202) 551-3170 or me at (202) 551-3715 with any other questions.

Sincerely,

Jeffrey Riedler Assistant Director