

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

April 17, 2009

Kevin R. Davidson Chief Executive Officer 2060 Centre Pointe Boulevard, Suite 7 Mendota Heights, Minnesota 55120

Re: BioDrain Medical, Inc.

Amendment No. 3 to Registration Statement on Form S-1

Filed April 6, 2009 File No. 333-155299

Dear Mr. Davidson:

We have reviewed your filing and have the following comments. Where indicated, we think you should revise your document in response to these comments. If you disagree, we will consider your explanation as to why our comment is inapplicable or a revision is unnecessary. Please be as detailed as necessary in your explanation. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure. After reviewing this information, we may raise additional comments.

We welcome any questions you may have about our comments or any other aspect of our review. Feel free to call us at the telephone numbers listed at the end of this letter.

#### Prospectus Summary, page 1

#### The Offering, page 1

1. Tell us how the numbers in the bullet points account for the options and warrants granted to Ms. Doerfert pursuant to her employment agreement.

#### Because we are a development stage company..., page 3

2. Either expand the caption to also highlight the fact that your independent audit firm has issued a going concern opinion, or relocate that disclosure under a separately titled caption.

# Management's Discussion and Analysis, page 19

3. We see that you obtained FDA final clearance for your product on April 1, 2009. Please revise your disclosure to state when you expect to begin generating revenues from the sale of your product.

# Critical Accounting Policies and Estimates, page 20

4. We reference prior comment 9. Please revise the discussion of stock-based compensation to describe how you determined each of the individual assumptions used in the Black-Scholes-Merton option-pricing model. In addition, you should discuss how you determine measurement dates for non-employee stock transactions and the judgments involved in assessing probability when accounting for equity instruments with performance and service conditions.

# Results of Operations, page 22

5. We see that you discuss "general and administrative expense", "operations expense," and "sales and marketing expense," which do not reconcile to the line items on the statement of operations of "operating expenses" and "product development expenses." Please revise to reconcile your MD&A discussion with the line items presented on the statement of operations.

# General and Administrative expense, page 22

- 6. We reference the disclosure that the increase in stock based compensation expense resulted from using the "grant date fair value method." Clarify if this method is different from that used in prior years. If not, please revise to provide a substantive discussion of the underlying reasons for increased expense for stock-based compensation, such as a description of the underlying arrangements responsible for the increased expense in 2008.
- 7. Please reference the response to prior comment 10. To further assist us in understanding the accounting applied in the reduction of accrued salaries, please respond to the following:
  - Please tell us how much of the \$346,000 was accrued as of December 31, 2006. That is, clarify for us the dollar amount accrued in prior years that was later credited to expense in 2007.
  - In the third bullet you indicate that you accounted for the reduction of accrued shareholder salaries as an early extinguishment of debt under APB 26. Tell us why you believe, as stated in your response, that the forgiveness of amounts due to your shareholders for services previously rendered and accrued for is

- not a capital contribution to your business under footnote 1 of APB 26. That is, please explain the basis in GAAP for your view that the shareholders did not make a contribution to capital upon agreeing to waive the accrued amounts due them.
- In the fourth bullet you indicate that the equity instruments to be issued are
  compensation for past services. Accordingly, tell us why issuance of those
  instruments is linked to future financing, including why issuance of those
  instruments is dependent on your liquidity. Also, tell us the period when the
  underlying services were rendered.
- We refer to the fourth and sixth bullets. You indicate that the compensation expense for the equity instruments is being amortized over the derived service period. Please tell us that period and tell us how you determined that service period under the guidance from SFAS 123(R).
- As a related matter, if as indicated in the fourth bullet, the equity instruments are for past services, please tell us why the sixth bullet indicates that the value assigned to the equity instruments is being amortized over some future period. That is, if the equity instruments are for past services, please tell us why the full fair value was not expensed at the date of the agreements. In that regard, as previously requested please fully explain to us in a written response how the accounting for these instruments is consistent with SFAS 123(R).
- 8. We refer to your response to prior comment 10 and to the disclosure about the accrued salary reduction on pages 27 and F-12.
  - Please disclose, as indicated in your response, that accrued payroll after the reduction recorded in November 2007 was \$115,000 and disclose the financial caption statement where the accrued amount is presented.
  - Please disclose, as indicated in the fourth bullet of your response, that the cash amounts and equity instruments to be issued are for past services rendered by individuals and disclose the periods when the services were rendered. Please clarify, as indicated in your response, that the cash and equity payments are not compensation for obtaining the future funding on which payment is contingent.
  - As your response indicates that the equity instruments were earned for prior services, please disclose why issuance of those instruments is contingent on future funding.
  - Add disclosure that explains how the equity instruments are being accounted for and that provides sufficient context to clarify how the accounting is appropriate under SFAS 123(R).

# Liquidity and Capital Resources, page 23

- 9. We note your response to prior comment 13:
  - We reissue the first bullet given the continued inconsistencies regarding your outstanding debt obligations on pages 23, 26 and 27. As one example, you disclose on page 23 that you owe Andcor \$50,000 but disclose on page 26 that the amount of such debt is \$10,000; and
  - Disclose the nature of the "other operating expenses" mentioned in the table on page 23. Also, your response implies that you believe such expenses are "insignificant." If so, tell us how you reached that conclusion, given that such expenses comprise almost half of your known capital requirements.

# Stock and Stock Options, page 31

10. We note the disclosure on page 32 regarding the vesting of options granted to Mr. Dauwalter. Given the terms of such vesting as noted in exhibit 10.38 and your disclosures regarding FDA clearance on April 1, 2009, it appears that a portion of those options have already vested. Please revise or advise.

#### Description of Business, page 34

#### Overview, page 34

- 11. We note your response to prior comment 4. If you will register a class of your securities under Section 12 of the Exchange Act concurrently with the effectiveness of this registration statement, then please revise to state so directly. The third paragraph under this caption implies that you will be subject to the reporting requirements of the Exchange Act solely because this registration statement will become effective.
- 12. We reissue prior comment 15. Contrary to your response, you have not disclosed on page 32 the exercise prices with respect to the June 16 and August 11, 2008 transactions.

#### Industry and Market Analysis, page 35

- 13. Regarding your response to prior comment 18:
  - Please furnish the staff with the Frost & Sullivan research report that contains the \$120 million estimate that you reference in the penultimate paragraph on page 35; and

- We reissue prior comment 18 with respect to the study cited in the first paragraph on page 48 and Outpatient Surgery Magazine article cite in the first paragraph on page 50.
- 14. Expand the table on page 38 to include the comparative information for the Cardinal disposal system.

# Corporate Strategy, page 43

15. Please clarify the meaning of the penultimate bullet point on page 44. The meaning of that sentence is unclear.

# Drainage Systems, page 45

16. Please revise the first paragraph on page 46. It appears words are missing.

# Handling Costs, page 47

17. We note your reliance on the research article referenced in the last paragraph. We also note that the article covers a total of 31 exposures, the majority of which are percutaneous exposures from needle sticks or cuts from sharp objects which are more severe and more costly for hospitals to address. We also note that the article concludes that the overall mean cost was \$1,687 per exposure, including the more serious percutaneous exposures. Please clarify this for investors and revise your cost estimate accordingly for non-percutaneous exposures.

# Engineering and Manufacturing, page 50

18. Please reconcile your response to prior comment 23 with your disclosure in this section, where you indicate that you "have not yet entered into agreements with any suppliers for there products." If you have entered "an exclusive licensing agreement with Oculus Innovative Research," as mentioned in your response, ensure that your disclosure describes the material terms of that agreement including, among other things, the duration and any minimum purchase requirements.

#### Employees, page 57

19. Reconcile your disclosure here with your disclosure on page 8. It appears your disclosure here regarding the number of your employees does not include Mr. Shuler.

# Directors, Executive Officers, Promotors and Control Persons, page 58

- 20. Please tell us why you deleted information regarding Mr. Gerald Rice from this section. We note that according to the signatures page, he is a member of your board of directors.
- 21. Given your disclosure on page 8, please disclose the information required by Item 401 of Regulation S-K with respect to Mr. Alan Shuler. Please also file as an exhibit your employment agreement with Mr. Shuler.

# Summary Compensation Table, page 62

- 22. We note your response to prior comment 31:
  - Your disclosure in the notes to the summary compensation table continues to be inconsistent with your disclosure on pages 64-65 and response to the third bullet of prior comment 34 regarding the amounts Messrs. Davidson and Rice were entitled to receive pursuant to their employment agreements. For example, your response to prior comment 34 states that Mr. Davidson was entitled to receive \$185,000 under his employment agreement; however, your disclosure here states he was entitled to \$160,000 and your disclosure on page 64 states he was entitled to receive \$170,000. Similarly, you disclose here that in 2008, Mr. Rice was entitled to receive \$114,250 but disclose on page 64 that he was entitled to receive \$118,500. Please reconcile;
  - As a result of the inconsistencies noted above, the numbers in the notes following this table are difficult to follow. For example, you state that Mr. Davidson was entitled to receive \$160,000 in 2008. You then state that he was paid \$126,650, including a bonus, and waived payment of \$58,250. The amounts he was paid and waived do not appear to add to \$160,000. Similarly, you state that Mr. Davidson was entitled to receive \$150,000 in 2007. You then state that he was paid \$59,375 and waived \$70,000 in compensation for 2007 and prior years. As a result, it appears the amounts he was paid and waived in 2007 do not add to \$150,000. Please reconcile; and
  - Disclose the reasons for awarding Mr. Davidson a \$25,000 bonus in 2008, given your disclosures regarding shortage of cash and liquidity issues.

# Outstanding Equity Awards at Fiscal Year End, page 63

23. Your response to prior comment 78 indicates that you will issue the 80,000 and 160,000 options to Messrs. Davidson and Rice, respectively, when you have raised an additional \$3 million. Your table here, including note 1, indicates that you have issued those options and that vesting, rather than issuance, of those options is contingent on raising an additional \$3 million. Please reconcile.

# Employment Agreements . . ., page 64

- 24. Refer to the third full paragraph on page 67 regarding the vesting of options granted to Mr. Ruwe. Given your disclosure that you have requested and received FDA clearance, it appears that a portion of those options have vested and are now exercisable. If so, please revise to disclose that fact. Also ensure that your disclosure in the tables appearing on pages 71-73 and 77 account for any changes in the number of vested and exercisable options held by Mr. Ruwe.
- 25. Discuss the material terms of Ms. Doerfert's employment agreement.

# Certain Relationships and Related Transactions, page 70

26. Regarding your reference to a verbal agreement in response 32, please refer to Regulation S-K Compliance and Disclosure Interpretation Question 146.04 available on our web site at <a href="http://www.sec.gov/divisions/corpfin/guidance/regs-kinterp.htm">http://www.sec.gov/divisions/corpfin/guidance/regs-kinterp.htm</a>.

# Selling Security Holders, page 70

27. We note your response to prior comment 38. However, the first bullet on page 71 continues to refer to shares underlying a "convertible debenture" while notes 11-17 and 24 refer to shares underlying a "convertible promissory note." You also refer on page 79 to outstanding convertible notes. Please reconcile.

#### Security Ownership of Certain Beneficial Owners and Management, page 76

28. Please disclose your response to prior comment 39. Also revise your disclosure on page 34 under the caption "Private Placement Financing" and on page 79 where you state that the warrants "are immediately exercisable."

# Common Stock, page 78

29. Please provide current disclosure. We note the references in the first paragraph to the number of shares outstanding and number of shareholders as of November 1, 2008.

# Warrants and Convertible Notes, page 79

- 30. Regarding your response to prior comment 41:
  - Your response to prior comment 61 in our letter dated January 29, 2009 stated that "the convertible note financing that was closed in July 2007 was considered a bridge loan to allow sufficient time to arrange a subsequent

- financing which was finalized in October 2008." If so, please disclose that fact. Your current disclosure is unclear regarding how the convertible note financing relates to the October 2008 financing; and
- Disclose the identities of the seven bridge loan holders mentioned in your response to prior comment 41. That comment requested disclosure of those identities, not simply identifying them in your response letter.

# Legal Matters and Interests of Named Experts, page 85

31. We note your response to prior comment 42. Given your response to prior comment 41 regarding the identities of the bridge loan holders, it is unclear how you concluded that the \$150,000 debt to Richardson & Patel mentioned on page 23 is "consistent with the convertible notes." For example, we note the different amounts of the debts you owe and the different identities of the holders of those debts. Please revise or advise.

# **Financial Statements**

- 32. Please update the financial statements when required by Rule 8-08 of Regulation S-X.
- 33. Please tell us where you have made disclosure about pending accounting standards under SAB Topic 11M. In that regard, for instance, it appears that EITF 07-05 (which is effective for the first quarter of 2009) may be applicable to your non-employee stock options and warrants where those instruments include provisions that provide for reduction of the exercise price based on strike prices of future instruments that you may issue.

# Balance Sheet, page F-4

- 34. We refer to your response to prior comment 44. Please add footnote disclosure that describes the terms and conditions for release of the restricted cash.
- 35. Please revise to label the \$10,000 notes payable as "convertible."

# Statements of Cash Flows, page F-7

36. We refer to your response to prior comment 46. While we understand that once released the restricted cash from your recent financing maybe used in operating activities, the restricted cash was not derived from nor was it actually used in operating activities in 2008. In a written response, please tell us why classification of the restricted cash as an operating activity is consistent with the guidance from SFAS 95. We may have further comment upon review of your response.

# Note 1. Product Development, page F-8

37. Your response to prior comment 72 indicates that \$75,000 of the amount due Mr. Ryan is presented as professional fees (operating expense) in 2007 and that the remaining \$100,000 is presented as product development expense in 2008. Please tell us why the two amounts accrued under the arrangement with Mr. Ryan are not similarly classified in your statement of operations. Please cite a basis in GAAP for your view.

# Note 1. Patent and Intellectual Property, page F-8

- 38. Refer to prior comment 73. Your former disclosures states that you were informed in 2007 that the cost of the product development work performed in prior years would be \$100,000 and that you accrued that amount as of December 31, 2007. The responses to prior comments 72 and 73 state that you accrued \$75,000 at December 31, 2007 for exclusive ownership of the patent in June 2008 and that \$100,000 was due in June 2009 for past services, which was accrued during 2008. Please reconcile the timing of the amounts accrued with the date(s) the agreement(s) with Mr. Ryan were executed and when you became aware of the amounts due for prior services. The disclosure in your amendment should be consistent with your response to this comment.
- 39. We see the disclosure added in response to prior comments 47 and 48. Please also revise the disclosure to clarify that the value assigned to the warrants issued to Mr. Ryan was expensed during fiscal year 2008.

# Note 3. Stockholders' Deficit, Stock Options and Warrants, page F-9

# Valuation and accounting for options and warrants, page F-9

- 40. In your response to prior comment 75 you state that "We did not vary the volatility estimate from year to year or in the interim periods because that would imply a level of precision in our estimate that is not present." Under SFAS 123(R) volatility is intended to represent expected volatility over the expected term of the instrument being valued. It appears that you have granted options and warrants at varying times and with varying terms. Accordingly, tell how your approach which has apparently applied a fixed volatility assumption for all issuances of options and warrants for all periods is consistent with the requirements of SFAS 123(R). We may have further comment upon review of your response.
- 41. We refer to your response to prior comment 75. You previously disclosed that you applied a volatility factor of zero for stock options and warrants. You now

disclose that you applied a volatility assumption of 45%, apparently for all periods. It is not clear why the change in the volatility factor did not impact the fair values assigned to the options and warrants. In response to this comment, quantify the impact of the change in the volatility assumption on the assigned fair value of the relevant instruments and tell us why you have not reported a correction of an error for this matter. If there was no change in fair value, please explain and support your position with reference to SFAS 123(R).

- 42. We note your response to prior comment 76. As required by paragraph A240 of SFAS 123(R), please revise your footnote to disclose how you determined each of the individual assumptions applied in valuing stock options and warrants under SFAS 123(R). In that regard, also clearly disclose how you selected comparable companies for purposes estimating volatility and how you determined the expected term assumption and disclose why you believe your assumptions are appropriate under SFAS 123(R).
- 43. As a related matter, tell us how you determined the expected term assumption for non-employee stock options and warrants. If you used other than the contractual term, please tell us how you considered the guidance from footnote 7 of SAB Topic 14.
- 44. Regarding your response to prior comment 50, please provide us with an analysis under SAB 108 that the impact of the error that resulted in an understatement of your expenses in 2007 is not material to your financial statements.
- 45. In addition, we do not see where you have made disclosure about the warrants issued with the \$170,000 convertible debt, including all relevant terms and conditions. Please revise.

## Warrants, page F-11

46. We refer to your response to prior comment 51. Please expand the narrative to describe the all of the 5.7 million warrants issued in 2008. Ensure that you disclose all significant terms and provisions of each grant, the fair value assigned and how you accounted for that fair value.

#### Stock and Stock Options, page F-11

47. We refer to your response to prior comment 52. Please expand this footnote to disclose the components of the 2.3 million shares issued in 2008 to "finders, agents and attorneys." Please also expand this footnote to describe how those shares were valued and accounted for the financial statements. To the extent the shares were accounted for as a cost of raising capital under SAB Topic 5-A, please add narrative that explains how the shares issued are connected to an actual

offering and how the issuances are a specific incremental cost of that offering as defined in the SAB.

- 48. The disclosure added in response to prior comment 53 states that Mr. McGoldrick and Mr. Reding will receive options to purchase 5,985 shares of common stock each year. Please clarify in your disclosure if options were also issued to these directors in 2007 and 2008. If so, please also disclose the terms of those options and any expense recorded in the related periods.
- 49. We do not see where you have revised your filing to disclose how you accounted for the fair value assigned to the equity instruments issued as a finder's fee, as requested in prior comment 54. Please expand the referenced narrative.
- 50. We reissue prior comment 55. Please expand the referenced paragraph to describe how you accounted for the \$87,500 fair value assigned to the 250,000 shares issued for the investor relations arrangement with Kulman.
- 51. We refer to your response to prior comment 56. You disclose that Namaste Financial is "entitled" to receive 125,000 shares and a warrant to purchase 125,000 shares of common stock for consulting services. Please revise the referenced disclosure to state whether you have actually issued the equity instruments. Disclose the fair value assigned to the arrangement and how you are accounting for that fair value. Your disclosure should clarify how the accounting is compliant with GAAP, including SFAS 123(R), EITF 96-18 and EITF 00-18, as relevant
- 52. As a related matter, you disclose that the Namaste arrangement is for "business, strategic and growth advisory services." However, your response to prior comment 56 indicates that the shares were issued in connection with an equity financing. Please describe to us and clearly disclose the nature of the services rendered. If the shares were accounted for as a cost of raising capital under SAB Topic 5-A, explain to us and disclose your rationale.
- We note your response to prior comment 57 that the 50,000 shares granted to Mr. Davidson in 2006 is actually 29,927 shares on a post-split basis. Please revise the disclosure to state the shares granted on a split-adjusted basis. Please ensure that share disclosures in your financial statements have been updated for all splits.
- 54. We reissue prior comment 58. Please revise the referenced disclosure to disclose the fair value assigned to the 543,292 options granted to Mr. Davidson on September 12, 2008 and the accounting for that fair value. Also disclose the assumptions specific to that grant.

# Other Securities For Issuance Upon Certain Contingencies, page F-12

- 55. We note your response to prior comment 59; however, your response fails to address the issues raised in the comment. Accordingly, we re-issue prior comment 59. With respect to the options granted to Mr. Ruwe and Mr. Dauwalter please:
  - Tell us and fully disclose (in the referenced footnote) the underling performance conditions. Refer to paragraph A240 of SFAS 123(R).
  - · In a complete written response, tell us how your accounting considers the guidance about stock options with performance conditions as described in paragraphs 47, 48 and Appendix A of SFAS 123(R). Your written response should fully demonstrate that you have appropriately applied the accounting guidance relevant to stock options with performance conditions.

We may have further comment on disclosure upon resolution of the accounting issue.

- We refer to your response to prior comment 61. With respect to the agreements with Andcor and Taylor please expand the referenced paragraph to disclose whether individuals have been hired under the employee search arrangements, and, if so, the expected vesting dates for the 150,000 warrants.
- 57. While we acknowledge your response to prior comment 62, the response does not address how your accounting considers the requirements of the relevant underlying literature and your disclosures do not address the accounting applied for the warrants. As the counter-parties appear to be non-employees as defined in SFAS 123(R), in a written response tell us how your accounting for each of the three arrangements considers the specific relevant guidance from EITF 96-18. Please also expand the referenced footnote disclosure to explain how you are accounting for the instruments and the basis in GAAP for that accounting.
- 58. We refer to your response to comment 63. We have continuing concerns about the referenced disclosure (currently appearing as the first paragraph of page F-13). In the first sentence, if the word "valuation" is referring to the exercise price, please revise to clarify. Otherwise please explain to us what you mean by "valuation" in the context in which you are using that word.

Your disclosure also indicates that "valuation" is subject to change due to downward pressure from various factors cited in the disclosure. The term "valuation" appears to refer to the exercise price of currently outstanding options and warrants. Changes in exercise prices can significant impact the valuation of and accounting for outstanding options and warrants under SFAS 123(R).

Accordingly, please disclose which actual instruments are subject to downward "valuation" and describe the accounting implications under SFAS 123(R) and related literature. Please be specific.

#### Item 26. Recent Sales of Unregistered Securities, page II-4

- 59. Your response to prior comment 79 and disclosure on page F-4 indicates that you had 8,130,841 shares outstanding as of December 31, 2008. Your response to prior comment 79 also indicates that you had 8,255,841 shares outstanding as of March 31, 2009. Therefore, it appears you issued 125,000 shares between December 31, 2008 and March 31, 2009. However, those issues do not appear to be described here. Please revise or advise.
- 60. Tell us why this section does not disclose the information required by Item 701 of Regulation S-K with respect to the options and warrants mentioned in paragraph 4.c. of Exhibit 10.48.
- 61. We note the disclosure on page II-7 regarding what Mr. Sachs "would" receive upon reaching FDA clearance. Given your disclosures regarding FDA clearance on April 1, 2009, please revise to clarify what securities Mr. Sachs received.

# Item 27. Exhibits, page II-8

- 62. Your response to prior comment 2 states that the warrants were issued on February 24, 2009. Your disclosure on page II-6 states "The Company will issue the warrants in February 2009." Please reconcile.
- We note that you have requested confidential treatment for portions of exhibits 10.46 and 10.47 to your registration statement. We will review and provide any comments on your request separately. Please resolve all comments regarding your request prior to requesting effectiveness of this registration statement.

#### Signatures, page II-12

64. We reissue the last sentence of prior comment 81 because it continues to be unclear which individual signed in the capacity of principal accounting officer or controller. If Mr. Davidson signed in that capacity, as suggested by your response, then please make that clear.

\* \* \* \* \* \* \*

As appropriate, please amend your registration statement in response to these comments. You may wish to provide us with marked copies of the amendment to expedite our review. Please furnish a cover letter with your amendment that keys your responses to our comments and provides any requested information. Detailed cover letters greatly facilitate our review. Please understand that we may have additional comments after reviewing your amendment and responses to our comments.

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 all information required under the Securities Act of 1933 and that they have provided all information investors require for an informed investment decision. 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.

In addition, please be advised that the Division of Enforcement has access to all information you provide to the staff of the Division of Corporation Finance in connection with our review of your filing or in response to our comments on your filing.

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. We will act on the request and, pursuant to delegated authority, grant acceleration of the effective date.

We direct your attention to Rules 460 and 461 regarding requesting acceleration of a registration statement. Please allow adequate time after the filing of any amendment for further review before submitting a request for acceleration. Please provide this request at least two business days in advance of the requested effective date.

You may contact Kristin Lochhead at (202) 551-3664 or Gary Todd, Reviewing Accountant, at (202) 551-3605 if you have questions regarding comments on the financial statements and related matters. Please contact Geoffrey Kruczek at (202) 551-3641 or me at (202) 551-3800 with any other questions.

Sincerely,

Peggy Fisher Assistant Director

cc (via fax): Ryan Hong, Esq.—Richardson & Patel LLP