

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

January 29, 2009

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

Re: BioDrain Medical, Inc.

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

Filed January 12, 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.

#### Fee Table

1. Please tell us, with a view toward disclosure, how you concluded to register the resale of 7,101,267 shares of common stock and 4,689,290 shares underlying warrants and that you have 8,180,831 shares outstanding. It appears that adding the numbers in the bullet points in your response to prior comment 1 does not result in the totals expressed prior to those bullet points, in your fee table and throughout your document.

#### Prospectus Cover Page

2. We will continue to evaluate your response to prior comment 4 after the warrants underlying the convertible notes have been issued.

3. We note that you put in a price range. Prior to effectiveness, please state the specific fixed price at which the securities will be sold until they are trading on the OTC Bulletin Board.

# Prospectus Summary, page 1

4. If you have already received a United States patent for your product, as indicated by your responses to prior comments 10 and 11, then please revise your second paragraph here accordingly.

# Risk Factors, page 3

#### We face intense competition . . ., page 5

5. We note your response to prior comment 12. Because it appears you have not provided us with the supplemental materials we requested, we reissue the first sentence of prior comment 12. Also, please reconcile your disclosure here and on pages 38 and 46 regarding the market share currently held by Cardinal Health and Stryker.

# If we do not succeed . . ., page 6

- 6. We note your responses to prior comments 6 and 15.
  - Please clarify how the risks disclosed in the last paragraph relate to the restructuring agreement and how it may impact potential investors. For example, you refer here to the loss of management that could delay the implementation of your business plan. It is unclear how this poses a risk to potential investors, given your disclosure in the preceding paragraph, pages 53-54 and exhibit 10.42 that your operations will cease and your assets will be transferred to Privco. Please revise; and
  - Explain clearly, if true, that potential investors may own shares in a public shell company if the FDA does not approve your product by the end of August 2009.

Please also refer to comment 38 below.

# We do not have a class of securities registered . . .,page 10

7. Regarding your response to prior comment 7:

- Revise your disclosure in the first paragraph, which misstates the registrant's reporting obligations in the event that it registers a class of securities pursuant to Section 12 of the Exchange Act;
- Clarify your reference in the caption and first paragraph of this risk factor to registering your securities on a "national securities exchange." Do you mean registering a class of your securities under the Exchange Act?;
- We reissue the second bullet in part because that bullet requested an explanation of the effects of the inapplicability of Section 16 of the Exchange Act, not Section 26; and
- We note that you do not intend to register a class of your securities before this registration statement is effective; however, your disclosure on page 68 indicates that you will register a class of your securities at a later date. Please clarify when and whether you intend on registering a class of your securities under the Exchange Act. If you do not intend to so register, revise your disclosure here and page 68 to remove any implication to the contrary.

# If our common stock is accepted for quotation . . ., page 11

8. We note your response to prior comment 17. Rather than disclosing all listing criteria applicable to the Nasdaq and NYSE markets, please revise to disclose the listing criteria that you do not currently meet, including the criteria noted in the last sentence of this risk factor.

## Use of Proceeds, page 15

9. Expand to disclose the warrant exercise prices for the warrants being registered.

## Market Price of and Dividends on the Registrant's Common Equity..., page 17

10. Reconcile the disclosure here with that on page 29 regarding outstanding warrants.

#### Critical Accounting Policies and Estimates, page 21

- 11. Please clarify your reference on page 22 to TUV SUD being a regulatory body. Is their approval required before you can market and sell your products? Or are they a private company that performs no regulatory oversight?
- 12. We re-issue prior comment 21. Please revise to provide a discussion of your critical accounting policies and estimates. This discussion should present your analysis of the uncertainties involved in applying an accounting principle at a given time or the variability that is reasonably likely to result from its application over time. You should address specifically why your accounting estimates or

assumptions bear the risk of change. For example, it appears that there is significant judgment in valuing stock options and warrants. Refer to FR-72. While we see the changes in response to the comment, the revisions do not provide meaningful disclosure. Please further revise.

## Results of Operations, page 22

# Nine Months ended September 30, 2008 and 2007

13. Please reconcile your reference here to "paying" full annual salary rates with the disclosure throughout your document that you have accrued a salary expense, which will be paid only when sufficient funds are available.

# Research and Development, page 22

- 14. We reference prior comment 24. We see that you were notified in 2007 that you would be billed \$100,000 for product development work performed by a contractor in 2003 2007. Please respond to the following:
  - Tell us and disclose when you recorded the \$100,000 accrual.
  - Reconcile the disclosures in the "research and development" discussions on pages 22 and 23 of MD&A. From those disclosures it is not clear whether the \$100,000 was accrued in 2006 or 2008.
  - If the discussions on pages 22 and 23 are addressing different accruals, please clarify the disclosure. Please ensure that you have provided a clear and complete discussion of research and development costs and the accruals for those costs.
  - Tell us why you did not make accruals for the work as that work was performed. In that regard, tell us why you believe there is no error in the financial statements as it appears that product development work performed in prior years is expensed in a later year.

#### Years ended December 31, 2007 and 2006

#### General and Administrative, page 22

15. We refer to your response to prior comment 27. Please provide us and disclose a clear basis in GAAP for the accounting applied in the reduction of the accrued salaries. While we see the revisions to the disclosure, those revisions do not provide a clear and transparent discussion of the basis in GAAP for the accounting.

## Liquidity and Capital Resources, page 23

- 16. We note your response to prior comment 29. Please:
  - Reconcile your disclosures on pages 23, 26 and 27 regarding the amount of outstanding debt payments you are obligated to make;
  - Expand the third paragraph on page 25 to clearly disclose the nature of the "risks to investors" from your early stage position. Also disclose the "risk in this process" mentioned in the penultimate paragraph on page 25. For example, do you anticipate providing an inducement similar to the restructuring agreement you provided the "Investors" in order to obtain funds through your October 2008 financing?;
  - Expand the sixth paragraph on page 25 to disclose the amount of funds from your secondary financing that will be used to satisfy the obligations noted in that paragraph;.
  - Disclose the rights the holders of your debts have in the event they demanded payment and you were unable to fulfill your obligations. We note the disclosure on page 25 that this would "create a liquidity issue," which does not appear to sufficiently describe the results of a formal payment demand;
  - Reconcile your disclosure in the first paragraph under this caption that you expect research and development expenses to increase with your disclosure in the second paragraph on page 26 that there will be "nominal, if any, additional expenses incurred for the development of our product";
  - Expand to discuss in more detail "the progress we have made and the opportunities ahead of us" in raising additional funds. Include in such discussion the types of additional financing you are pursuing;
  - Explain why you are "confident" that you will have the ability to raise \$3 million during the first half of 2009, particularly in light of your stage of development, lack of revenues, and "current economic turmoil.";
  - Clarify the nature of the "other operating expenses" mentioned on page 23; and
  - Please tell us how you have communicated and will communicate with potential investors consistent with Section 5 of the Securities Act, in light of this pending registration statement.

Nine Months Ended September 30, 2008 and 2007, page 24

- 17. You indicate that cash used in operations in 2008 was impacted by an "increase in escrow cash." Please tell us what you mean by "escrow cash" and explain to us why that item is appropriately reported as an operating activity under SFAS 95.
- 18. Tell us the terms of the "escrow cash" and explain where the "escrow cash" is presented in the balance sheet. If included in cash, tell us why that classification is appropriate in GAAP.
- 19. You also indicate that cash used in operating activities in 2008 was increased by an "increase in vested options." Please revise to clarify what you mean by an "increase in vested options" and how that increase impacted cash flows from operations.

## Commitments and Contingencies, page 26

20. Please reconcile the amount of debt on the contractual obligation table to the balance sheet as of September 30, 2008 on page F-3. Explain how \$11,800 of "long-term debt" can be due in less than one year. Please also revise to present the \$10,000 notes payable and the current portion of long-term debt on the table.

# Stock Options and Warrants, page 28

21. For each issuance in the transactions beginning on page 31, state the warrant or option exercise price.

# Description of Business, page 35

# Overview, page 35

- 22. Please reconcile your response to prior comment 38 with exhibit 3.1, which was included as an exhibit to your original filing.
- 23. We note your response to prior comment 39; however, we also note that you continue to make claims regarding the safety and efficacy of your product. For example, you state on page 39 that the FMS "greatly reduces" safety issues and is "uniquely positioned to dominate its market segment." You also state on page 40 that your product is "unique" and disclose on page 44 that FMS will "redefine the manner in which [infectious fluid] is collected, measured and disposed." Please reconcile these statements with your response to prior comment 60 and the fact other companies have already developed and sold fluid collection and disposal systems in your target market without exposure to healthcare workers.

#### Private Placement Financing, page 35

24. Disclose the date or dates when the warrants become exercisable.

## Current Techniques of Collecting Infectious Fluids, page 37

25. We note your response to prior comment 49. Clarify how your product will "significantly reduce the risk of healthcare worker exposure" to infectious fluids, as stated in the second paragraph on page 38, given your disclosure in the following paragraph regarding products already developed and marketed by your competitors that "address the deficiencies described above." Also expand the last bullet point on page 40 to compare how the competitors' products mentioned in the second paragraph on page 38 are different from your own.

# The Fluid Management System (FMS), page 38

- 26. Regarding your responses to prior comments 42 and 55:
  - Clarify how the estimated installation cost disclosed on page 50 accounts for the uncertainty regarding the accessibility of sewer lines and suction systems noted on page 39. Also clarify the basis for your estimates regarding the cost and time of installation, given that it appears you have not yet installed your product in any facility; and
  - Revise the last sentence of the penultimate paragraph on page 39 to clarify whether the information in that sentence reflects your opinion. Your current disclosure appears to attribute such information to third parties; and
- 27. We note your response to prior comment 43. While your disclosure on pages 40 and 52 refers to "established timeframes and plans" for the regulatory process, it appears that the work you have done in preparation of your submission to the FDA solely involves the hiring of regulatory consultants. Please revise to clarify what work, if any, you have done in preparation of that submission. For example, have you or your regulatory consultant begun compiling any of the documents or preparing the "Submittal Document" referenced on page 52?

# Patents and Intellectual Properties, page 41

- 28. We note from your response to prior comment 45 that you "do not expect to acquire ownership of any patent rights or claims pertaining to such fluid." Expand to state whether you currently have any intellectual property rights with respect to your disposable cleaning kit. Also disclose whether you have any agreements with any party regarding the disposable cleaning kit.
- 29. Please clarify how the continuous operation feature mentioned in the last paragraph on page 41 provides you with a significant competitive advantage, given your disclosure on page 37 that current techniques and products are also capable of continuous operation.

## The Disposable Cleaning Kit, page 43

- 30. Please expand your response to prior comment 47 to disclose all material obstacles to achieving the "razor blade business model" referenced in your disclosure. For example, given your response to prior comment 45 regarding your lack of intellectual property rights to the cleaning kit, including the "special adapter," it appears that medical providers could use kits made by others rather than those made by you. Please revise.
- 31. Please tell us how the "forecast" mentioned in the second paragraph under this caption satisfies the requirements of Item 10 of Regulation S-K.

#### Drainage Systems, page 46

32. Please reconcile your disclosures here and the second and third paragraphs on page 38 regarding whether competitive systems that utilize canisters have or need FDA approval.

# Current Competition, Technology and Costs, page 46

33. Please expand your responses to prior comments 42 and 50 to include a complete discussion of the disadvantages of your product that may result in difficulty penetrating your target market. For example, we note the numerous statements regarding the limited floor space and handling needed for your product; however, it is unclear where you have discussed the disadvantages resulting from the immobility of your system, as indicated in your response to prior comment 42. Please revise to include such a discussion. For example, would the mobility of your competitors' products enable them to be used in multiple rooms in a hospital whereas use of your product would be confined to the room in which it was installed?

#### Pricing, page 49

34. Please explain the basis underlying the first sentence under this caption, given that you have not yet finalized any agreement related to the manufacture and distribution of your product and have not yet sold your product commercially. Also clarify the meaning of the second sentence; it is unclear to what strategy and sales objectives you are referring. The purpose of the clause following the hyphen is also unclear. Please revise.

# Engineering and Manufacturing, page 50

35. We note your response to prior comment 57. Ensure that your disclosure distinguishes between aspirations and accomplishments. If you know the material terms of the supply agreement, disclose those terms, including the information requested by prior comment 57. If you do not know the material terms, revise your disclosure to state that fact. Also file that agreement as an exhibit when it is finalized and reconcile your statement in the first paragraph that your relationship is finalized with your subsequent disclosure that it is still being negotiated.

# Government Regulation, page 51

- 36. We reissue prior comment 61.
  - While you may encourage investors to investigate aspects related to regulation by the FDA, simply inserting a hyperlink and reference to the chapter of the Code of Federal Regulations does not provide investors with sufficient information regarding the material requirements that such regulation will have on you; and
  - Although you refer on page 23 to market expansion to Europe and the Pacific Rim, it is unclear where you provided disclosure regarding regulations in foreign jurisdictions in which you will seek to do business.
- 37. Please reconcile your disclosure on pages 6, 53 and exhibit 10.42 regarding the date on which the "restructuring agreement" was entered into.
- 38. Regarding your responses to prior comments 64 and 65:
  - It appears that investors who may acquire the shares offered pursuant to this registration statement will not receive the rights referenced in your disclosure. It also appears that those potential investors will not receive shares of "Privco" and will, instead, only hold the shares of a public shell company. If that is correct, please expand to state so directly. Also revise your disclosure on page 1 and throughout your document to disclose this consequence to potential investors;
  - Expand the first paragraph to clarify how the "Investors" will maintain their shares of your common stock, given that such shares are registered for resale here:
  - Reconcile your disclosures in paragraphs 1, 3 and 6 and third paragraph on page 54 regarding who will receive shares of Privco. Paragraph 1 and page 54 currently suggest that the "Investors" will receive Privco shares immediately after the transfer of your assets to Privco; however, paragraphs 3 and 6 indicate that the "Company" will retain the Privco equity remaining after distributing Privco shares to the "Founders";

- Expand paragraph 6 to clarify whether the "Company shareholders" who will receive either Privco shares or the net proceeds from the sale of those shares include only the "Investors" or whether subsequent purchasers of your securities will also receive those shares or proceeds;
- Disclose whether investors who may acquire your shares offered pursuant to this registration statement will be entitled to vote on the transfer of your assets to Privco. If it is your belief that such investors will not be entitled to vote on the asset transfer, then tell us how your conclusion is consistent with your governing documents and the laws of the jurisdiction in which you are incorporated. Cite all authority on which you rely;
- Expand the third paragraph on page 54 to disclose whether a reverse merger or similar transaction involving you, as opposed to Privco, is currently being negotiated or considered; and
- Clarify the meaning of the last sentences in the second and third paragraphs on page 54. Given your disclosure that your assets will be transferred to Privco and that you will retain the "rest of Privco equity," it is unclear what assets the "Investors" will be able to liquidate and distribute the proceeds in connection with a shareholder vote or reverse merger or similar transaction.

Please also revise your disclosure on pages 6, 7 and 27 in accordance with this comment.

- 39. Please reconcile your response to prior comment 66 and disclosure on page 53 with paragraphs 2 and 4 of exhibit 10.42, which indicate that all company stock, options and warrants will be cancelled, not just the securities held by the founders. Also reconcile your disclosure in paragraph 3 on page 53 with paragraph 3 of exhibit 10.42, which indicates that all equity holders, not only the "Founders," will receive Privco shares and options.
- 40. If your private placement memorandum has already been modified, as noted in your response to prior comment 67, then please disclose the date on which it was modified and tell us why exhibit 10.42 was filed separately rather than as part of exhibit 10.31.
- 41. As a related matter, please confirm our understanding of your response to prior comment 67 that you and the "Investors" entered into the restructuring agreement and agreed to modify the private placement memorandum prior to the date on which this registration statement was filed. Generally, it is inconsistent with Section 5 of the Securities Act to renegotiate the terms of a private placement while the related shares are registered for resale.

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

42. We note your response to prior comment 18. Please disclose the information required by Item 401(c) of Regulation S-K with respect to Mr. Sachs as well as the "two independent FDA consultants" and the "third party firm" mentioned on page 40. Please also tell us why you have not disclose the information required by Item 401 with respect to Mr. Dauwalter and Ms. Doerfert.

#### Medical Advisory Board, page 60

- 43. Regarding your response to prior comment 68:
  - We note the numerous claims you make regarding the business experience of your medical advisory board. For example, you state that Dr. Leonard is an "outstanding . . .world-wide medical pioneer" and that he has "distinguished himself in a great number of areas too numerous to detail." You also indicate that Mr. Feroe and and Ms. Gorman were "instrumental" in gaining acceptance of new technologies and changing existing guidelines. Please revise to present a more balanced picture of the qualifications of the members of your medical advisory board;
  - We note your disclosure regarding the awards previously granted to Dr. Leonard. Please tell us, with a view toward disclosure, how recipients of those awards are chosen and whether others received the awards in addition to Dr. Leonard; and
  - Please expand the first paragraph under this heading to clarify how this board assists you in "understanding the needs of [y]our market and ways to better serve that market," in light of the fact that you have not yet begun marketing or selling your product.

# Executive Compensation, page 62

44. Please update your disclosures required by Item 402 of Regulation S-K to include compensation information for your last completed fiscal year.

## Summary Compensation Table, page 62

45. Please tell us how your responses to prior comments 70 and 72 considers the 75% salary rates you paid in 2007, as noted on page 22.

#### Corporate Governance, page 68

46. We note your response to prior comment 75. Since it is unclear from your response how your conclusion as to Mr. Morawetz's independence considers the

nature of your relationship with him disclosed on page 69, we reissue the last sentence of prior comment 75.

## Certain Relationships and Related Transactions, page 69

- 47. We note from your response to prior comment 35 and disclosure on page 30 that 1,920,000 shares were to be allocated to your "existing shareholders." Please tell us the identities of these individuals and the number of shares they received. If your affiliates and principal stockholders received shares, disclose the information required by Item 404 of Regulation S-K with respect to that transaction, including the purpose of the share allocation.
- 48. Regarding your response to prior comment 77:
  - Please reconcile your disclosures in the second and third paragraphs regarding whether Mr. Morawetz agreed to waive or reduce the outstanding fees you owe:
  - Disclose the amount you agreed to pay Mr. Morawetz pursuant to the "oral understanding";
  - Clarify whether Mr. Morawetz's efforts at contacting distributors and investors were successful. Also clarify the nature of the "general counsel services" he provided; and
  - Please include as an exhibit the summary of the oral agreement when it is approved by the parties.
- 49. We reissue prior comment 78, given the continued reference to Mr. Morawetz in the third paragraph of this section.
- 50. We note your responses to prior comments 79 and 80:
  - It appears from your disclosure that your affiliates will receive cash bonuses and have their option vesting accelerate upon receipt of \$3 million in funding. Please revise to disclose on an individual and aggregate basis the dollar amounts and number of shares to be received, including whether the unpaid, accrued salaries will be paid from such funds;
  - Revise your table on page 76 to disclose the number of unexercisable stock options currently held by your officers, directors and principal stockholders;
  - Update your disclosure to discuss whether salaries were paid or accrued from June 2008 to present.
- 51. Regarding your response to prior comment 82, please:

- Tell us why you did not include Erick Richardson in your disclosure on page 69, given your disclosure on page 76 regarding the number of shares he beneficially owns;
- Reconcile your disclosure here that James Taylor IV acquired more than 5% of your shares with your disclosure on page 76 that James Taylor III holds more than 5% of your shares; and
- tell us, with a view toward disclosure, why David Dauwalter is not listed as a 5% shareholder here and on page 76, given the amount of his investment in you at the time he commenced his employment that is mentioned in exhibit 10.37.
- 52. We note your response to prior comment 83. We reissue the first bullet point of that comment because it is unclear where you provided the disclosure requested by that comment.

#### Selling Security Holders, page 70

- 53. It is unclear from your response to prior comment 85 how you considered the referral services provided by Mr. Roll, as noted on page II-6. Therefore, we reissue the comment. Also tell us how your response to prior comment 85 accounts for the consulting relationship mentioned in the fourth bullet on page 70 and on page II-5.
- 54. We note your response to prior comment 86. In addition to disclosing the general terms of the transactions in which the selling security holders acquired the shares, please indicate by footnote which selling security holders participated in each of the transactions noted in the bullet points on page 70.
- 55. We note your response to prior comment 88. Please identify the natural persons that exercise voting and/or dispositive powers with respect to the shares to be offered and sold by Schwartz Holding.
- 56. We note your response to prior comment 89. However, your disclosure continues to appear inconsistent regarding the number of shares underlying warrants that are held by Mr. Roll. For example, you disclose on page 70 that Mr. Roll holds warrants to purchase 40,001 shares but your disclosure on pages 31, F-10 and II-6 indicates that Mr. Roll holds warrants to purchase only 11,429 shares. Therefore, we reissue prior comment 89.
- 57. Please reconcile your disclosures in the first bullet and in notes 11-17 regarding the aggregate number of shares underlying the convertible note.

# Plan of Distribution, page 74

58. Please revise your disclosure here consistent with your response to prior comment 3.

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

- 59. Please update your disclosure here to be of the most recent practicable date.
- 60. We note your response to prior comment 90; however, your disclosure on pages 71 and 77 continues to disclose different numbers of shares underlying warrants held by James Taylor. Additionally, the number of common shares held by RP Capital, as disclosed in notes 12 and 13, differs from the number of common shares it holds as disclosed on page 71. Specifically, subtracting your third column from your second column does not equal 142,857. Therefore, we reissue prior comment 90.

#### Warrants and Convertible Notes, page 78

61. We note your response to prior comment 92. However, it continues to be unclear how your July 2007 convertible note financing relates to your October 2008 financing, given your disclosure that the October 2008 financing only involved common stock and warrants. For example, it is unclear why the monetary penalties noted on page 79 will be paid *pro rata* to investors in your October 2008 financing and how the registration rights relate to the October 2008 financing. Please revise. Also identify the "seven holders" who acquired and hold the convertible notes.

#### Legal Matters and Interests of Named Experts, page 86

- 62. We note your response to prior comment 93. Please:
  - disclose the aggregate number of shares beneficially owned by all affiliates of Richardson & Patel and registered for resale, as requested by that comment;
  - reconcile the number of shares held by the law firm and its affiliates that are
    disclosed here with the numbers disclosed in the selling security holders'
    table. We note, for example, that your disclosure here regarding the number
    of shares held and offered by Erick Richardson, Nimish Patel and RP Capital
    differs from the number of shares disclosed in that table;
  - ensure that your disclosure here includes all interests of the law firm and its affiliates. For example, we note the debt you owe to the law firm that is mentioned on page 23; and
  - provide us your assessment of the materiality of any risks resulting from the interests of the law firm and its affiliates.

#### **Financial Statements**

- 63. Please update the financial statements when required by Rule 8-08 of Regulation S-X.
- 64. We re-issue prior comment 94. Please have your auditor tell us why they have asked that their consent appear in the body of the filing on page F-2. The consent should appear as an appropriately numbered exhibit.

# Interim Financial Statements for the Nine Months Ended September 30, 2008

65. We re-issue prior comment 96. Please revise to remove the label "audited" from the top of the balance sheet, statement of operations and cash flows as of and for the year ended December 31, 2007. Since full audited financial statements, including an audit opinion, are not included in the interim presentation, amounts derived from the audited financial statements should not be labeled "audited."

# Statement of Stockholders' Equity (Deficit), page F-5

- 66. Various line items on the statement indicate that shares were issued at \$1.67 per share. However, the shares do not appear to be recorded based on that assigned value. For instance, we see an issuance in 2006 of 86,869 shares for "vendor contractual consideration" where the disclosure indicates that the shares were valued at \$1.67 per share, but the amount recorded totals only \$1,451, which does not appear to reflect the \$1.67 per share value. Please tell us and clearly disclose how share issuances were accounted for and valued. Demonstrate to us that your accounting is appropriate in GAAP.
- 67. Please remove the captions "un-audited" from the sub-totals for all annuals periods.

#### Statements of Cash Flows, page F-6

- 68. Please provide a cash flow statement for the nine months ended September 30, 2007. Please refer to Article 8 of Regulation S-X.
- 69. We reference prior comment 100 and see the footnote disclosure added to the bottom of the statement of cash flows regarding the stock issuances during 2008. Please expand the notes to the financial statements to present a full discussion of the private placements and related stock and warrant issuances consummated in 2008. This discussion should (1) describe all significant terms and provisions of the private placements and equity instruments issued and (2) provide a clear and complete discussion of the accounting applied. As a related matter, if you entered into registration rights agreements in connection with the 2008 private

- placements, the notes to financial statements should include the disclosure required by FSP EITF 00-19-2.
- 70. Please tell us why cash as of December 31, 2007 on the statement of cash flows does not agree with cash at December 31, 2007 on the face of the balance sheet. In this regard, it appears that the summation of the total net cash provided by financing activities for this period is not mathematically correct. Please revise as necessary.

# Note 1. Patent and Intellectual Property, page F-7

- 71. We refer to the disclosure added in response to prior comment 102. We see that you paid Mr. Ryan \$75,000 and 150,000 warrants in exchange for the exclusive assignment of the patent. Disclose when this transaction took place and clarify whether the transaction is reflected in the accompanying financial statements. Please also disclose how you are accounting for the value of the cash and warrants.
- As a related matter, you state that you assigned a fair value of \$52,500 to the warrants based on the per share price of the October 2008 financing. It does not appear that you have used an option pricing model, such as the Black-Scholes Merton model, to determine the fair value of the warrants. Please tell us why your valuation method is appropriate in GAAP, including how your valuation method considers the guidance from SFAS 123(R). Also tell us how the disclosure is consistent with the response to prior comment 118. In that response you informed us that warrants are valued based on the Black-Scholes Merton model.

#### Note 3. Stock Options and Warrants, page F-8

73. We refer to the first sentence under the table appearing at the top of page F-9. Based on the weighted average remaining lives disclosed in the referenced table, your statement that options expire through 2013 does not appear accurate. Please revise or advise.

# Stock, Stock Options and Warrants Granted by the Company, page F-9

- 74. Please revise the disclosure so that the narratives describing the various share, warrant and option issuances can be readily reconciled with the transactions disclosed on the face of the statements of stockholders' equity and statements of cash flows and with the issuances
- 75. Refer to your responses to prior comments 103, 110 and 111. Please revise to disclose how each issuance was valued and accounted for, including the model(s) and all significant assumptions. In that regard, please disclose the fair value

assigned to each issuance and how that amount was recorded in the financial statements. Pursuant to SFAS 7, the disclosure should also describe management's basis for the fair value assigned in non-cash transactions. Refer to SFAS 7 and SFAS 123(R).

## Stock and Stock options, page F-10

76. We refer to the revisions in response to comment 104. You disclose that 543,292 options priced at \$0.01 per share were issued to Mr. Davidson. You also disclose that on September 12, 2008 the Board ratified the issuance and that the options vest immediately; however, the options are recorded by footnote only in the financial statements and *will be* recorded as compensation expense in the operating statement. Please tell us the value assigned to the options and why the amounts have not been recorded as compensation at September 30, 2008. Your response should fully explain how the accounting is appropriate under SFAS 123(R).

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

- 77. We reference prior comment 19 and the additional disclosure included in response to that comment on page F-12 for contingent stock and option issuances. Please revise to disclose your accounting for each of the contingent issuances. In that regard, your disclosure should be sufficiently detailed so that it is clear that you are appropriately accounting for the agreements. Also, disclose whether you have recognized any compensation for these issuances or, if not, when you expect to recognize compensation. Please refer to SFAS 123(R) for issuances to employees and EITF Issue No. 96-18 for issuances to non-employees.
- 78. We see that you entered into an oral agreement with director Peter Morawetz for services. You disclose that fees owed to him total \$84,963, yet no amounts have been expensed or accrued because there is an oral understanding that "the amount to be paid will be less." Please tell us why you should not accrue and expense the amount owed to Mr. Morawetz. We refer to SFAS 140 which states that an liability is not extinguished until (a) the debtor pays the creditor and is relieved of its obligation for the liability or (b) the debtor is legally released from being the primary obligor under the liability, either judicially or by the creditor.
- 79. We reference the paragraph at the top of page F-13. Please tell us what this paragraph is intended to convey and how it makes meaningful accounting disclosure. In that regard, please explain how the statements are consistent with the accounting guidance on the valuation of and accounting for stock-based compensation as set forth in SFAS 123(R) and related literature.

## Note 6. Long-term Debt, page F-14

- 80. We see that certain of your debt are convertible. Please revise to label the debt as convertible on the face of your balance sheet.
- As you disclose that notes totaling \$284,000 are "passed their due dates and could be called by the holders," please tell us why only \$186,000 is classified as current in the balance sheet. Explain the basis in GAAP for your conclusion.
- 82. We note the disclosure that the \$170,000 note contains penalties until the registration statement is declared effective by the SEC. Disclose whether you have accrued any liability under the registration rights agreement and provide an accounting policy disclosure. Refer to FSP EITF 00-19-2.

# Audited Financial Statements for the year ended December 31, 2007

# Report of Independent Registered Public Accounting Firm, page F-16

83. We re-issue prior comment 108. We see that you are a development stage business with recurring losses, operating cash flow deficits and no revenues. Please have your auditors tell us how they evaluated the requirements of AU Section 341 in concluding that the audit report should not include a paragraph regarding going concern with accompanying footnote disclosure as specified in the referenced guidance. While we see your response it fails to address the requirements of the cited guidance. Also have your auditor reconcile their view with the management's disclosure on page 3 that various matters "raise substantial doubt about our ability to continue as a going concern."

#### Balance Sheet, page F-18

- 84. Please revise so that the numbers of outstanding shares as of December 31, 2007 and 2006 agree to the corresponding numbers from the statement of stockholders' equity (deficit).
- We reissue prior comment 109. We do not see where you have labeled your notes payable and long-term debt as "convertible," as applicable. Please advise.

Statement of Stockholders' Equity (Deficit), page F-20

- 86. Please remove the captions "un-audited" from the sub-totals for all applicable periods.
- 87. We re-issue to prior comment 111. Please also revise to include a discussion in the footnotes to the audited financial statements of shares and equity instruments issued during all periods presented. In that regard describe the individual transactions, consideration received by the Company and how the equity instruments issued in those transactions were accounted for and valued. Refer to SFAS 7, SFAS 123(R) and SFAS 129. The expanded disclosure should be readily reconcilable to disclosure in the statement of stockholders' equity (deficit) and statement of cash flows. While we see your response, the footnotes to the audited financial statements should present all relevant required disclosure.

## Statement of Cash Flows, page F-21

88. We see that you revised your statement of cash flows in response to prior comment 113 and that this changed the total cash used in operating activities and provided by financing activities for the year ended December 31, 2007 and inception to date. Please the label the statement of cash flows as "restated" and provide appropriate footnote disclosure. Refer to paragraph 26 of SFAS 154.

# Note 1. Summary of Significant Accounting Policies, page F-22

# Intangible Assets, page F-22

89. We do not see where you have included any additional disclosure about your policy for patent costs in response to prior comment 114. Please revise.

# Research and Development, page F-22

- 90. Please reconcile the numerical disclosures of the amounts of research and development expense in 2007 and 2006 as presented in this footnote with the corresponding numerical disclosures of the amounts of research and development expense in 2007 and 2006 as presented in MD&A on page 23.
- 91. We reference the statement that as of December 31, 2007 you have "accrued \$100,000 for unbilled product development work since 2002." However, we see that total research and development expense for the year ended December 31, 2007 is only \$1,434. Please disclose the actual date of the accrual. Please also clarify disclosure in the "research and development" discussions on pages 22 and 23 of MD&A. From those disclosures it is not clear whether the \$100,000 was accrued in 2006 or 2008.

# Note 3. Stock Options and Warrants, page F-23

- 92. Please tell us whether the numerical disclosures of vested options and warrants described in the sentence appearing directly under the stock option/warrant roll-forward were updated for the stock splits.
- 93. We re-issue prior comment 116. You disclose that you use the calculated value method to value stock options. Under SFAS 123(R) that method is defined as a measure of the value of a share option or similar instrument determined by substituting the historical volatility of an appropriate industry sector index for the expected volatility of a nonpublic entity's share price in an option-pricing model. Your disclosure suggests that you did not apply a measure of volatility since that measure is zero. Tell us why your volatility assumption is appropriate under the guidance set forth in paragraphs A43 through A48 of SFAS 123(R). Please also refer to the guidance about volatility set forth in SAB Topic 14. Your response should fully demonstrate that you have appropriately applied SFAS 123(R) in establishing a volatility assumption.
- 94. We re-issue prior comment 17. SFAS 123(R) calls for numerous disclosures as set forth in paragraphs A240 and A241 that are required for both employee and non-employee transactions. Also note that you should comply with all disclosures applicable to a public company as a result of your registration statement. Your disclosures do not appear complete under the cited guidance. Please appropriately revise.
- 95. We re-issue prior comment 118. Please revise to disclose how you value warrants and to provide all relevant valuation disclosures about warrants required by SFAS 123-R. Refer to paragraph 64 and Paragraphs A240 and A241 of the Statement.
- 96. We reissue prior comment 120. Please note that under the definitions in the Glossary to SFAS 123(R) you are no longer a non-public entity as of the filing date of the Form S-1. Accordingly, any share options or similar instruments issued on or after that date should be valued and accounted for under the guidance applicable to public companies under SFAS 123(R). That is, you should not use the calculated value method for instruments issued or modified on or after November 12, 2008. Refer to SAB Topic 14 for further guidance.

# Part II

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

97. We note your response to prior comment 123. We reissue that comment because it appears you have provided the information required by Item 701 of Regulation S-K with respect to your transaction with Mr. Sachs that is noted on page 33 and the options granted to your executive officers, as disclosed on page 32.

98. We reissue prior comment 125, given the continued inconsistencies regarding the number of common shares outstanding disclosed on pages 1 and F-5. Also tell us, with a view toward disclosure, how your balance sheet as of September 30, 2008 on page F-3 states that you have 8,180,832 shares outstanding, given that your disclosure that the recent financing did not close until the end of October 2008.

# Item 27. Exhibits, page II-7

99. We note your response to prior comments 128 and 130. We reissue the first sentence of prior comment 130 because it appears that exhibits 10.43 and 10.44 both omit Schedule A.

# Item 28. Undertakings, page II-8

100. We note your response to prior comment 126. However, your filing still appears to lack the first clause of Item 512(a)(5). It also appears that your filing continues to lack the undertaking required by Item 512(a)(6) of Regulation S-K. Therefore, we reissue prior comment 126.

# Signatures, page II-10

101. We note your response to prior comment 127. Please reconcile your disclosures on pages 58 and 59 and here regarding the identity of your chief executive officer.

#### Exhibit 3.1

102. We note your response to prior comment 131; however, it appears that you have not filed an amended copy of your articles of incorporation with this amendment. Please file a complete copy of your articles, as previously requested.

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

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 Melissa Mallah, Esq.—Richardson & Patel LLP