December 10, 2008

Mail Stop 3030

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

Re: BioDrain Medical, Inc. Registration Statement on Form S-1 Filed November 12, 2008 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.

Please understand that the purpose of our review process is to assist you in your compliance with the applicable disclosure requirements and to enhance the overall disclosure in your filing. We look forward to working with you in these respects. 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 reconcile your disclosures here and on pages 27 and 58 regarding the number of warrants issued by you in your August 2008 financing.
- 2. Given that there does not appear to be an existing market for your securities, your reference to Rule 457(c) appears to be inapplicable. Please revise.

Prospectus Cover Page

3. Because there is no current market for the registrant's securities, please revise to clarify that the selling shareholders will sell at a specified fixed price per share until the registrant's shares are quoted on the OTC Bulletin Board (or other

specified market) and thereafter at prevailing market prices or privately negotiated prices.

4. We note that you are registering the resale of 620,096 common shares underlying warrants that are issuable upon conversion of notes. Because the warrants have not yet been issued, it is premature to register the underlying common shares for resale. Please remove them from this registration statement.

Prospectus Summary, page 1

Our Company, page 1

5. Please disclose that you have not yet requested or received FDA regulatory clearance to market and sell your products.

Risk Factors, page 3

- 6. Include a risk factor to discuss the anticipated restructuring in the event you do not obtain FDA approval by August 2009, and discuss the risks this presents to potential investors.
- 7. We note the disclosure on page 49 regarding registration of a class of your equity securities under the Exchange Act. Please tell us when you plan to register a class of your securities. If you do not intend to register a class of securities before this registration statement is effective, please:
 - disclose the risks related to termination of periodic disclosure due to the automatic reporting suspension under Section 15(d) of the Exchange Act; and
 - explain the effect of the inapplicability of the proxy rules and Section 16 of the Exchange Act.
- 8. It appears from your disclosure on pages 3, 25 and 58 that you recently approved a reverse stock split that reduced the number of shares you are authorized to issue to 11,970,994. We also note that you will be submitting a proposal to your shareholders for approval to increase the number of authorized and unissued shares. Please ensure that shareholder approval is obtained prior to requesting acceleration of this registration statement so that the shares being registered for issuance are actually authorized.

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

9. Please reconcile your disclosure here and on page 13 regarding whether you will receive proceeds from this offering. If the proceeds you will receive from this

offering depend solely on whether the holders of outstanding warrants exercise those securities, then please revise to clarify that fact here.

Our business would be materially and adversely affected . . ., page 4

- 10. Please clarify the nature of your interest in the intellectual property you claim. For example, you indicate in the first sentence on page 5 that the intellectual property developed by Mr. Ryan was "licensed" to you. However, the last sentence of this risk factor states that you are the "exclusive owner of the patent." Additionally, you indicate on pages 1 and 4 that you own patent and patentpending rights and disclose on page 32 that you are the assignee of "the patentpending product."
- 11. We note the disclosure that Mr. Ryan was added as a named inventor to the pending patent application. We also note the disclosure that you removed from the U.S. patent application Messrs. Nord and Drogue as inventors. However, it is our understanding that Messrs. Nord and Drogue continue to be listed as inventors on the pending application and that Mr. Ryan is not listed as an inventor. Please revise or advise.

We face intense competition . . ., page 5

- 12. Please provide us with supplemental support for the data referenced in your prospectus, marking the relevant sections to support the disclosure. For example, you cite to Frost & Sullivan here and page 28. You also cite to numerous other publications throughout your "Description of Business" section. Also, please tell us whether the studies and articles you cite were financed by you or performed at your direction and whether the authors have consented to use of their name in this document.
- 13. It is generally inappropriate for a risk factor to contain language that mitigates the risk discussed. We note specifically the discussion at the end of the first paragraph regarding the "distinct advantages" of your product. Also, it appears that Stryker and other competitors have designed systems that also eliminate handling and exposure to infectious fluids, so the disclosure, if retained, should be more balanced.

Our products require FDA approval . . ., page 6

14. Given the variety of uncertainties discussed in this risk factor, please revise the first paragraph to remove your belief that "the likelihood of regulatory approval for our products is very high."

15. Expand to discuss your obligation to obtain FDA approval by the end of August, 2009, and the related risks if you have not done so, as described on pages 39 and 40.

There is currently no public trading market . . ., page 8

16. Please clarify when you anticipate submitting an application for quotation to the OTC Bulletin Board. Also disclose any obstacles that exist before such an application will be submitted and accepted. For example, it is our understanding that an application for quotation must be submitted by a market maker. Has a market maker already committed to submitting such an application?

If our common stock is accepted for quotation . . ., page 9

17. We note the reference here and your prospectus cover page to applying for trading on the Nasdaq or NYSE markets. Please disclose here and on your cover page whether you currently meet the objective listing criteria for those markets. Also disclose here what hurdles remain before you will satisfy those criteria.

Other Securities For Issuance Upon Certain Contingencies, page 18

- 18. Please disclose the identities of the persons with whom you entered into the agreements mentioned here. Also describe the nature of the services to be provided by the regulatory consultant and file that agreement as an exhibit. Include a description of the purpose of the provision requiring the attainment of performance goals and disclosure of those performance goals.
- 19. Please expand the notes to financial statements to describe the equity arrangements disclosed under this heading. Your disclosure should fully describe the accounting applied or that will be applied, as appropriate, and the basis in GAAP for that accounting. The disclosure should also describe the specific performance goals and any other conditions of the grants that impact vesting or exercisability. Refer to SFAS 123(R) for further guidance. Please ensure that the notes to financial statements include disclosure about all obligations to issue equity securities, including contingent obligations.

Management's Discussion and Analysis . . ., page 20

20. We note your disclosure that your capital requirements for the next 12 months are expected to be "rather moderate." Please reconcile this statement with your disclosure on page 3 that you will need to raise at least \$3 million in order to have sufficient financial resources to fund our operations for the next 12 months and

your disclosure on page 22 that you anticipate needing a secondary financing during 2009.

Critical Accounting Policies and Estimates, page 20

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.

Results of Operations, page 21

- 22. We see that general and administrative expense increased in the six months ended June 30, 2008 in part due to \$91,400 of "product development" costs. In addition, you disclose that research and development costs increased to \$91,400 for the six months ended June 30, 2008. Please explain whether these disclosures are referring to the same expenses and, if so, how they can be included in two different expense classifications. Please revise as appropriate.
- 23. Please revise to discuss the reasons for the increase in legal fees of \$78,500 and salaries of \$68,100 for 2008 compared to 2007.
- 24. We reference the disclosure that research and development expense increased in 2008 due to "an accumulation of unbilled work from 2003 to 2007" and the discussion of the increase in research and development expense in 2006 due to "unbilled development fees since inception." Please revise to discuss the nature of the unbilled work, the timing of the billings for work performed and the circumstances that resulted in the aforementioned increased expenses.
- 25. As a related matter, it would appear unusual for a third party to incur billable work since 2003 without billing and payment. If you have incurred costs or entered into other transactions with related parties, such as non-employee shareholders, please ensure that the notes to financial statements provide all of the disclosures required by SFAS 57.
- 26. With a view toward disclosure, tell us to whom the \$91,400 was paid.
- 27. You disclose that accrued payroll totaling \$336,600 was "eliminated" in 2007. Please expand the notes to financial statements to describe this significant transaction and the accounting applied. If these individuals were also shareholders, it is not clear why the "elimination" of these salaries is not a capital

contribution. Accordingly, please explain to us the basis in GAAP for your accounting. We refer you to APB 26.

28. Further, please clarify in MD&A why general and administrative expenses for six months ended June 30, 2007 are 153,900 but general and administrative expenses for the year ended 12/31/07 are \$125,300. If this is related to the "elimination" of payroll, please elaborate by providing additional disclosure in your MD&A.

Liquidity and Capital Resources, page 21

- 29. We note your disclosure on page 22 regarding sufficiency of funds through the first half of 2009 and anticipated need for a secondary financing. We also note your disclosure on page 3 regarding the need to raise \$3 million to fund your operations for the next 12 months. Please provide investors with a better understanding of your currently known capital requirements and amounts needed to satisfy your outstanding obligations. For example, discuss and quantify, among other things:
 - the accrued payroll expenses as of June 30, 2008 noted on page 3;
 - the amounts necessary to seek and obtain approval from the FDA and Underwriters Laboratories mentioned on page 39;
 - the expenses you will incur in connection with this offering, as noted on page II-4;
 - the fees you owe in connection with your August 2008 financing, as noted on page 4;
 - any ongoing payments required by you to satisfy outstanding debt, such as the instruments mentioned on page 23, including if the holders of those instruments decide not to receive shares in lieu of cash; and
 - the amount you will need to satisfy your reporting obligations under the Exchange Act.

Please also provide your assessment of the accessibility of and risks to accessing needed capital. For example, will your doubts about your ability to continue as a going concern make your access to needed capital more difficult or expensive? How does your statement regarding sufficiency of funds account for the uncertainty regarding whether holders of your outstanding warrants will exercise those securities?

30. We see that you have experienced recurring operating losses and negative cash flows. We also note that you will need significant additional capital to fund the development of your business. Please expand the disclosure in this section to discuss the following:

- Your plan of operation for the next twelve months, including a how you expect to obtain additional financing and plans for the "secondary financing" that is anticipated in 2009;
- The effect of the current economic conditions on your operating plans;
- A summary of any product research and development that you will perform for the term of the plan;
- An indication of the amount of cash that will be required to bring your products under development to market;
- Any expected purchase or sale of plant and significant equipment; and
- Any expected significant changes in the number of employees.

Refer to Item 303 of Regulation S-K.

Six Months Ended June 30, 2008 and 2007, page 22

31. Please clarify how net cash provided by financing activities increased during the six months ended June 30, 2008 due to the receipt of investment capital from a private offering that occurred subsequent to that period.

Commitments and Contingencies, page 22

- 32. From your disclosure on page 23, it appears that notes payable previously issued by you are now overdue. Please disclose the potential consequences of failing to make required payments on these instruments, such as quantification of the monetary payments mentioned on page 59. Please also refer to our first comment under the heading "Liquidity and Capital Resources."
- 33. Please disclose the number of shares into which the \$100,000 note payable may be converted. Given the dates on which exhibits 10.20 and 10.21 were executed and the disclosure in your document regarding the August 2008 private placement, it appears that the "next completed financing" has already occurred.

Stock Options and Warrants, page 24

- 34. Please tell us why your tables here and page 25 do not include
 - the stock option issuance to Mr. Ruwe on June 16, 2008 that is mentioned on page 46;
 - the stock option grant to Mr. Davidson on June 5, 2008 that is mentioned on page 44; and

- the stock option grants mentioned in the last paragraph of page 50.
- 35. Please ensure that your disclosure regarding the reverse stock splits consistently and completely describes the nature and amount of those transactions. For example, we note:
 - your disclosures here and on pages 2, F-5, F-9, F-10 and F-20 refer to inconsistent reverse stock split ratios;
 - your disclosure does not describe the impact of those transactions on the number of shares that were outstanding before and after each transaction;
 - that the purpose for the multiple reverse stock splits within a short period of time is unclear; and
 - that your disclosure regarding the reverse stock split approved on October 20, 2008 appears to be inconsistent with your disclosure on page F-3, in that the disclosure on page F-3 indicates that the transaction occurred prior to June 30, 2008.
- 36. We note that the reverse stock splits mentioned here changed the number of shares that you were authorized to issue. It also appears from your disclosure on page 2 that no shareholder approval was obtained for these transactions. Please tell us how not obtaining shareholder approval is consistent with your governing documents and the laws of the state in which you are incorporated. Cite all authority on which you rely.
- 37. It is not clear whether the impact of the stock splits have been fully reflected in the table on page 25 since the numbers of options and warrants and related exercise prices as of December 31, 2007 do not appear to agree to the corresponding information presented on page 24. Please appropriately revise.

Overview, page 27

- 38. Please disclose the identities of the "three other individuals" who founded the company.
- 39. We note that you make numerous claims regarding the safety and efficacy of your product, including that it "minimizes the exposure potential to the healthcare workers who handles such fluids," "greatly reduces the safety issues facing operating room nurses" and has "distinct advantages" over existing products. You also state on page 33 that it represents the "first true innovation" and "will redefine the manner in which such material is collected . . ." Reconcile these statements with the fact that other companies have also developed systems that dispose infectious fluids into sanitary sewer systems without exposure of healthcare workers to infectious fluids.

Private Placement Financing, page 27

40. Please ensure that the description of your transactions is accurate and complete. For example, you describe the private offering here as having been completed in August 2008, but disclose on page F-10 that it closed on November 1, 2008. Please revise. Also reconcile your disclosures on pages 4, 27, F-10 and F-20 regarding the amount of funds you have received in the private financing and when you received those funds.

Products, page 30

The Fluid Management System ("FMS"), page 30

- 41. Please clarify how your product significantly reduces the risk of healthcare worker exposure to infectious fluids and requires minimal human interaction. We note, for example, your disclosure here that your proprietary cleaning fluid needs to be attached near the end of each procedure. We also note your disclosure on page 37 regarding the disposal of suction tubing and empty cleaning solution containers.
- 42. Please fully describe the potential steps and costs involved in the installation of your system, including those relating to labor and professional fees, such as architects. For example, might a hospital need to redirect sewer lines and wall suction systems to join with your system? Would the room also be unavailable for use during this period of installation? Where would the "large fluid reservoir" be located? Also explain how the system could be installed "on or in the wall" of the operating room. It appears that other systems on the market that dispose infectious fluids directly into sanitary sewers are portable. Discuss any disadvantages that may result from an immovable system in an operating room.
- 43. Clarify the nature of the "substantial" regulatory work you have done to date in preparation of your submission to the FDA as mentioned on page 31.

Patents and Intellectual Properties, page 32

44. We note the disclosure on page 5. Please expand the disclosure here to describe in more detail the issues related to the Nord/Drogue patent application. For example, describe the Nord/Drogue embodiment, and the Ryan embodiment. Describe your current relationship with Nord and Drogue, including whether you are aware of any intention by them to challenge your use of their technology and/or pursue legal action against you for breach of contract and/or infringement.

- 45. We note your disclosure on page 33 that the disposable cleaning kit is an "integral, critical component of the FMS" and consists of a proprietary cleaning solution. Please disclose whether you have any intellectual property rights to the cleaning kit and the cleaning solution.
- 46. Please disclose the material terms of Mr. Ryan's consulting agreement with you, including the amount of cash and warrants you provided to Mr. Ryan in exchange for the assignment of intellectual property rights, the amounts you are obligated to compensate him for consulting services and any payments required upon a change in control. Also clarify when you anticipate completing the expected filing of the "CIP" mentioned here, including any steps that you need to complete before making that submission.

The Disposable Cleaning Kit, page 33

- 47. Please clarify how you will "ensure that only our fluid will be utilized following procedures." For example, will the system only operate with a kit and fluid made by you or could medical providers use kits and fluids made by others?
- 48. We note the disclosure on page 37 regarding the establishment of extensive training and services standards for the persons who will service and install your FMS. Please clarify whether users of this system will also require training, including with respect to the installation and use of the disposable cleaning kit.

Drainage Systems, page 35

49. We note the disclosure under this caption. Explain the current status of these technologies, including whether they have received FDA approval and the extent to which they are currently in use in hospitals. Please also disclose this information under the caption "Current Techniques of Collecting Infectious Fluids" beginning on page 29. Under the caption "Products," compare your system with those already developed that dispose of infectious fluids directly into the sanitary sewer.

Current Competition, Technology and Costs, page 35

50. Please disclose your competitive disadvantages with equal prominence as you disclose your perceived competitive advantages. For example, we note your disclosure that the current standard of care involves the collection, retention and disposal of fluids using canisters and that the large and growing market for suction canisters that is currently served by entities with significantly greater financial resources. Therefore, it appears you may have difficulty penetrating the existing market for canisters and having your product adopted as a standard of care.

Handling Costs, page 36

51. Please clarify how your products would reduce disposal and sterilization costs entirely, as noted here, given your disclosure on page 37 regarding the need to dispose of suction tubing and the cleaning solution.

Competitive Products, page 37

52. Compare and contrast your proposed products with systems that dispose of fluids directly into sanitary sewers and are apparently already on the market and in use in hospitals.

Distribution, page 37

- 53. Explain the basis for the focus of your marketing effort described in the second paragraph. It appears that there are other products already being marketed that are capable of disposing of infectious fluids without direct handling by healthcare workers. It is also not clear why you believe your technology "represents a breakthrough" and will be "widely acclaimed" and "quickly adopted." Please expand to discuss.
- 54. It appears from your disclosure on pages 31, 33 and here that you have not entered into any agreements related to the distribution or installation of your products, begun marketing efforts or demonstrated your product to potential customers. It also appears that no distributors or independent contractors are currently capable of, or have been trained in, the service and installation of your products. If that is correct, please revise your disclosures to state so directly.

Pricing, page 38

- 55. Please clarify how prices "for the FMS and its disposable cleaning kit will reflect a cost saving to the hospital over its current procedure costs." For example, explain how the undetermined installation and labor costs and disposal required for suction tubing and empty cleaning solution factor into that statement. Also explain how your costs compare with automated disposal systems marketed by Waterstone Medical, Dornach Medical Systems, and Stryker.
- 56. Please provide investors with a comparison of the anticipated per-procedure costs to end users of your disposable cleaning kit as opposed to your competitors' canisters.

Engineering and Manufacturing, page 39

- 57. Please disclose the material terms of your relationship for the engineering and manufacturing of your product. For example, do you have a long-term production contract that guarantees the production of a minimum number of units or could the manufacturer choose to prioritize its capacity for other customers, reduce or eliminate deliveries to you on short notice or increase the prices charged to you. If you have entered into a written agreement, please file it as an exhibit.
- 58. As a related matter, please clarify to which of your products the manufacturing relationship noted here relates. Will this third party make your wall mount unit, disposable cleaning kit or both? Your revised disclosure should clearly state who will perform the manufacturing of each of your principal products.

Government Regulation, page 39

- 59. We see the contingency regarding the FDA submission described at the bottom of page 39. Please add footnote disclosure about this contingency and the potential impact on your business and financial statements. It appears that MD&A should present appropriate disclosure about this contingency. Please revise.
- 60. Briefly describe the 510(k) process and the findings the FDA makes when it clears a device under section 510(k).
- 61. Include in your disclosure a description of the following FDA statutory and regulatory requirements:
 - device classification information;
 - registration and labeling requirements;
 - advertising and promotion;
 - quality system regulation and manufacturing of the device; and
 - post-market reporting and record-keeping requirements, including medical device reporting and reports of corrections or removals;

Provide similar disclosure regarding regulations in foreign jurisdictions in which you will seek to do business.

- 62. We note your disclosure here regarding seeking approval from the Underwriters Laboratories. Please:
 - clarify whether you have submitted your application yet and when you expect to seek approval from the Underwriters Laboratories;

- disclose what steps you have taken and must take in the future to secure that approval, including any hurdles you will need to overcome; and
- describe the consequences and risks from failing to secure such approval.
- 63. Please clarify when you anticipate submitting your application to the FDA. Also clarify the products covered by this application. For example, will it include your wall mount unit, disposable cleaning kit and proprietary cleaning solution?
- 64. Please explain the business purpose for and file this restructuring agreement as an exhibit. We may have further comments.
- 65. Regarding the disclosure of the transaction to be effected if you do not obtain FDA approval by the end of August 2009, please:
 - identify the "majority-in-interest of investors" and "Founders";
 - disclose the number and percentage of outstanding stock held by each;
 - clarify who will comprise the "majority-in-interest of investors" after the transaction registered here is completed;
 - tell us, with a view toward disclosure, whether your shareholders will be entitled to vote on the asset sale mentioned on page 39 and reverse merger or similar transaction mentioned on page 40;
 - disclose whether a "reverse merger or other similar transaction" is currently being negotiated or considered by you;
 - disclose the purpose and effect of each of the transactions mentioned here; and
 - explain the purpose of this agreement.
- 66. Clarify in bullet two whether "all Company stock" will be cancelled, or only that company stock held by the "Founders."
- 67. The last paragraph regarding modification of your private placement memorandum is not clear since the offering has already taken place. Please explain your intent.

Directors, Executive Officers, Promoters and Control Persons, page 41

- 68. Please identify and discuss the business experience of the members of the medical advisory board mentioned on page 34. Also disclose the principal functions performed by that board and the material terms of agreements you have with its members.
- 69. Please disclose the term of office for each of your directors.

Summary Compensation Table, page 44

70. It appears from your disclosure on page 50 that during 2007, Messrs. Davidson and Rice agreed to waive accrued and unpaid salaries in exchange for stock options. Please tell us how your summary compensation table accounts for that agreement. Refer to Instruction 2 to Item 402(n)(2)(iii) and (iv).

Outstanding Equity Awards at Fiscal Year-End, page 44

71. We note the disclosure that you have made no equity awards during the fiscalyear ended December 31, 2007. Please note that Item 402(p) of Regulation S-K requires disclosure of equity awards <u>outstanding</u> at fiscal-year end, not simply those that were made during that fiscal year. Please revise, as appropriate. Also reconcile your current disclosure with your disclosure on page 50 regarding the options granted to your named executives during 2007.

Employment Agreements . . ., page 44

- 72. Reconcile the amounts in employment agreements with the amounts in the summary compensation table, and explain the differences. Also disclose whether the funding targets have been achieved and what salary each of your named executives earned during your 2007 fiscal year. In this regard, please note that Item 402 of Regulation S-K requires clear disclosure of all compensation earned by your named executives.
- 73. Please ensure that the disclosure regarding your compensation arrangements is complete. We note that you have not disclosed the bonus shares to be issued to Mr. Davidson that are discussed in section 4.b. of exhibit 10.1. We also note that you have not discussed the waiver of accrued salary and stock option grants mentioned on page 50.
- 74. Please disclose the number of shares acquired by Mr. Ruwe in connection with his investment of \$200,000.

Corporate Governance, page 49

75. We note that you believe Mr. Gadbaw is considered "independent" under Nasdaq Marketplace Rule 4200. Please tell us how you reached this conclusion, given your disclosure on page 41 and in exhibit 10.13 that Mr. Gadbaw was employed by you until August 2008. Please refer to Nasdaq Marketplace Rule 4200(a)(15)(A). Also tell us how your conclusion regarding Mr. Morawetz's independence considers the nature of your relationship with him, as noted on page 50.

Certain Relationships and Related Transactions, page 50

- 76. Please provide financial statement disclosure about the transactions described in the third paragraph. In that regard: (1) provide a description of the arrangements with your directors/officers, (2) disclose how you accounted for the arrangements, (3) disclose the basis in GAAP for the accounting and (4) disclose the fair value assigned to the equity instruments granted. If this disclosure is related to the "elimination" of accrued salaries described in MD&A, please revise the filing to reconcile the amounts on page 50 to the \$336,600 disclosed in MD&A.
- 77. Please file as an exhibit a written summary of the oral agreement with Mr. Morawetz. Also describe the services rendered in view of the fact that you have no product available to market or sell.
- 78. Please clarify your disclosure regarding Mr. Morawetz by discussing the registrant's relationship with him separately.
- 79. We note the disclosure in the last paragraph on page 50 regarding the waiver of accrued and unpaid salaries. This disclosure indicates that the amounts owed by you were waived by December 2007 with the exception of fees owed to Mr. Morawetz. However, your disclosure on page 3 indicates that these unpaid salaries and fees continued to accrue through June 30, 2008. Please revise or advise.
- 80. Please revise the last paragraph to discuss each related party individually, including the amount of unpaid salary waived and the number of shares and options received. Reconcile the options disclosure here with the disclosure in the beneficial ownership table for these individuals.
- 81. Also include in your revised disclosure a description of the material terms of the severance agreement between you and Mr. Gadbaw, filed as exhibit 10.4. For example, we note that your current disclosure does not identify the yearly stock option grant mentioned in paragraph 4 or the acceleration of payments mentioned in paragraph 2.b. Please also file copies of the agreements governing the waivers as exhibits.
- 82. Please note that the information set forth in Item 404 of Regulation S-K is required to be disclosed if a transaction resulted in the person becoming a 5% shareholder or continues after that date, such as through the ongoing receipt of payments. It appears from your disclosure on pages 27, 51 and 52 that several of your selling shareholders beneficially own more than 5% of your common shares. Therefore, please expand your disclosure here to provide the information required

by Item 404 with respect to the transaction that resulted in their becoming a related party.

- 83. Please tell us why you have not provided the information required by Item 404 of Regulation S-K with respect to
 - the transactions noted in exhibits 10.15-10.18; and
 - the transaction in which Mr. Ruwe acquired your warrants, as noted on page 51.

Selling Security Holders, page 51

- 84. Given the nature and size of the transaction being registered, advise the staff of the company's basis for determining that the transaction is appropriately characterized as a transaction that is eligible to be made on a shelf basis under Rule 415(a)(1)(i).
- 85. We note your disclosure in the first paragraph regarding the lack of material relationships between you and the selling shareholders. Please tell us how this disclosure considers the referral, consulting, finder and investor relations agreements mentioned on page II-6 and filed as exhibits.
- 86. Please describe in this section the transactions in which the selling shareholders acquired the offered shares. Include the date of the transaction and the amount of consideration received.
- 87. Please tell us whether any of the selling shareholders are broker-dealers. A selling shareholder who is a broker-dealer must be identified in the prospectus as an underwriter. In addition, we note your disclosure that none of the selling shareholders are or were affiliated with registered broker-dealers. Please tell us whether any of the selling shareholders are affiliated with any broker-dealer. A selling shareholder who is an affiliate of a broker-dealer must be identified in the prospectus as an underwriter unless that selling shareholder is able to make the following representations in the prospectus:
 - the selling shareholder purchased the shares being registered for resale in the ordinary course of business, and
 - at the time of the purchase, the selling shareholder had no agreements or understandings, directly or indirectly, with any person to distribute the securities.

Please revise as appropriate.

- 88. Please identify the natural persons with voting and/or dispositive powers with respect to the shares to be offered and sold by Egavnit LLC.
- 89. Please reconcile your disclosures here and on page II-6 regarding the number of shares underlying warrants held by Jeremy Roll.

Security Ownership of Certain Beneficial Owners and Management, page 56

- 90. Please reconcile your disclosures in note 11 and on page 51 regarding the number of shares underlying warrants held by James R. Taylor. Also reconcile your disclosures in notes 12 and 13 and on pages 51 and 66 regarding the number of common shares held by RP Capital LLC. Also tell us why the number of shares underlying warrants held by RP Capital, as noted on page 51, was excluded from your disclosure here.
- 91. Please tell us how you determined that Mr. McGoldrick holds 23,942 shares underlying options. We note that exhibit 10.7 indicates that his option grant was for 10,000 shares.

Warrants and Convertible Notes, page 58

92. Please clarify why the imposition of monetary penalties related to the July 2007 convertible note financing is tied to the registration rights granted in your August 2008 private placement. Also disclose the amount of monetary penalties that you may owe.

Legal Matters and Interests of Named Experts, page 66

93. Expand to state the total number of shares and warrants currently held by all affiliates of the law firm and the number that are being registered in this offering that are beneficially owned by Richardson & Patel, Mr. Richardson, Mr. Patel, RP Capital, and other affiliates. Reconcile the amounts with those listed in the selling shareholder table. We may have further comments.

Financial Statements

Interim Financial Statements for the six months ended June 30, 2008, page F-1

94. We see that you included the consent of your independent registered public accounting firm on page F-2. Note that the consent should be filed as an exhibit to your registration statement, as specified in Item 601 of Regulation S-K. Please revise to remove the consent from this section and to present the consent as an appropriately numbered exhibit.

- 95. Please update the financial statements as required by Rule 8-08 of Regulation S-X.
- 96. Please revise to remove the label "audited" from the top of the balance sheet, statement of operations and statement of 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.

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

- 97. Please revise so that the amount of Total Stockholders' Equity (Deficit) as of June 30, 2008 agrees to the corresponding amount presented on the face of the Balance Sheet as of that date. As a related matter, the column for Accumulated Deficit does not appear to be mathematically accurate. Please verify the mathematical integrity of any updated financial statements.
- 98. Please revise to present a statement of Stockholders' Equity (Deficit), showing from inception:
 - For each issuance, the date and number of shares of stock, warrants, rights, or other equity securities issued for cash and for other consideration.
 - For each issuance, the dollar amounts (per share or other equity unit and in total) assigned to the consideration received for shares of stock, warrants, rights, or other equity securities. Dollar amounts should be assigned to any noncash consideration received.
 - For each issuance involving noncash consideration, disclose the nature of the noncash consideration and the basis for assigning amounts.

This analysis should be presented in the form of a reconciliation of the beginning balance to the ending balance for each period since inception. Please note that issuances should not be combined except for separate issuances of equity securities within the same fiscal year for the same type of consideration and for the same amount per equity unit. Refer to paragraph 11(d) of SFAS 7 and Rule 3-04 of Regulation S-X.

99. In addition, we see that the effect of the reverse stock split instituted on 6/6/08 is reflected as a separate line item in the Statement of Stockholders' Equity (Deficit). Under SAB Topic 4C, changes in capital structure such as a reverse stock split must be given retroactive effect, even if the change occurs after the date of the balance sheet. An appropriately cross-referenced note should disclose the retroactive treatment, explain the change made and state the date the change became effective. Please revise for all applicable stock splits.

Statements of Cash Flows, page F-6

100. We see that you issued common stock for cash proceeds of \$824,534 in the six months ended June 30, 2008. Please revise to provide footnote disclosure that fully describes the transaction, including all significant terms of the equity instruments issued.

Note 1. Summary of Significant Accounting Policies, page F-7

- 101. Please revise to provide an affirmative representation that the interim financial statements include all adjustments that, in the opinion of management, are necessary in order to make the financial statements not misleading. Refer to Rule 8-03 of Regulation S-X.
- 102. We note disclosure on page 32 that you recently completed and executed an agreement to secure the assignment of patent-pending product and rights from an inventor in exchange for cash, warrants and future royalties. Please expand the notes to financial statements to describe the transaction, the rights and assets acquired and the accounting applied. Your disclosure should fully describe all significant terms of the warrants, the fair value assigned to those warrants and how that fair value was determined.

Note 3. Stock Options and Warrants, page F-7

- 103. Please add footnote disclosure that describes all significant terms and provisions of the 2.6 million warrants issued in the first six months of 2008. In that regard, (1) describe the transaction(s) leading to the issuances, (2) clarify whether the warrants were sold in financing arrangements or were issued in compensatory arrangements, (3) describe any terms or provisions that may lead to changes exercise prices or the number of warrants outstanding, (4) describe any cashless exercise provisions, (5) describe any registration obligations and (5) describe any liquidated damages or potential penalties that you may incur under the arrangement(s). Also disclose how the warrants were valued and accounted for, including the model(s) and all significant assumptions. The list is not intended to be comprehensive and your disclosure should be based on the terms and provisions of the underlying agreements. The substance of this comment also applies to warrants issued in annual periods and subsequent to June 30, 2008
- 104. We see from page 44 that in June 2008, it was agreed that Mr. Davidson would be issued options to purchase 543,292 shares of common stock exercisable at \$.01 upon completion of the first \$1 million of new funding raised. It appears that this funding may have been received in the third quarter of 2008. Please add footnote disclosure to describe the arrangement, including the performance obligation, and to describe the terms of the options. Disclose how these options have been or will be recorded in your financial statements, as applicable.

Note 6. Long-term Debt, page F-9

105. The tabular information indicates that a \$100,000 note matures in 2012. However, the last sentence of the footnote appears to suggest that the maturity date is 2013. Please reconcile here and on page 23.

Consolidated Financial Statements for the year ended December 31, 2007

Report of Independent Registered Public Accounting Firm, page F-11

- 106. Please have your auditors revise the second paragraph of their audit report to state that the audit was performed in accordance with "the standards of the Public Company Accounting Oversight Board (United States)."
- 107. Please also revise the report to include the signature or name of the independent registered public accounting firm.
- 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.

Balance Sheet, page F-13

109. We see from Note 5 and Note 6 that certain of your notes payable and long-term debt are convertible into shares of your common stock. Please revise to accurately label convertible debt as convertible on the face of your balance sheet, as applicable.

Statement of Stockholders' Equity (Deficit), page F-15

- 110. Please revise to present a Statement of Stockholders' Equity (Deficit), showing from inception:
 - For each issuance, the date and number of shares of stock, warrants, rights, or other equity securities issued for cash and for other consideration;
 - For each issuance, the dollar amounts (per share or other equity unit and in total) assigned to the consideration received for shares of stock, warrants, rights, or other equity securities. Dollar amounts should be assigned to any noncash consideration received;
 - For each issuance involving noncash consideration, disclose the nature of the noncash consideration and the basis for assigning amounts.

This analysis should be presented in the form of a reconciliation of the beginning balance to the ending balance for each period since inception. Please note that

issuances should not be combined except for separate issuances of equity securities within the same fiscal year for the same type of consideration and for the same amount per equity unit. Refer to paragraph 11(d) of SFAS 7 and Rule 3-04 of Regulation S-X.

- 111. As a related matter, we see in Item 26 (Recent Sales of Unregistered Securities) that you have issued shares and other equity instruments in exchange for assets, services and in connection with borrowings and other financing arrangements with both related and unrelated parties. For other than employee stock options, please expand the notes to financial statements to describe the individual transactions, to describe the consideration received by the Company and to disclose how the equity instruments issued in those transactions were accounted for and valued. We may have further comment on your accounting for these transactions after you have provided us the revised disclosure. The expanded disclosure should be readily reconcilable to disclosure in the revised Statement of Stockholders' Equity (Deficit).
- 112. We see that the Board of Directors approved reverse stock splits on June 6, 2008 and October 20, 2008. Please clarify whether the equity information included in the Statement of Stockholders' Equity (Deficit) is on a post-split basis. Under SAB Topic 4C, changes in capital structure such as a reverse stock split must be given retroactive effect, even if the change occurs after the date of the balance sheet. An appropriately cross-referenced note should disclose the retroactive treatment, explain the change made and state the date the change became effective. Please revise as appropriate for all splits. All per share information included in the footnotes (for instance for stock options) should be similarly retroactively restated.

Statement of Cash Flows, page F-16

113. Tell us why the change in notes payable to shareholder is included as an operating cash outflow. Cash flows from notes payable are normally financing activities under SFAS 95. Please revise or advise how the presentation conforms to SFAS 95.

Note 1. Summary of Significant Accounting Policies, page F-17

114. We see that you have capitalized \$113,056 of patent costs. Please revise to disclose the nature of the patent costs capitalized as an intangible asset. Please note that costs of internally developing intangible assets that are not specifically identifiable, that have indeterminate lives, or that are inherent in a continuing business and related to an entity as a whole are expensed as incurred pursuant to the requirements of SFAS142. Generally, only legal fees and similar costs relating to patents, copyrights, and trademarks may be capitalized. Please advise.

115. Tell us why the patent costs should not be expensed as research and development.

Note 3. Stock Options and Warrants, page F-17

- 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.
- 117. As a related matter, 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.
- 118. Your filing indicates that you have applied the Black-Scholes Merton method for stock options, but appears to be silent with respect to warrants. Please make all relevant valuation disclosures about warrants required by SFAS 123(R).
- 119. Tell us the common share fair values used in applying the Black-Scholes model for options and warrants granted in 2007 and 2008 and tell us how you determined those common share fair values. Specifically address the common share fair values applied in valuing the options granted to Mr. Davidson and the 2.6 million warrants both issued in 2008. If those common share fair values are less than the per share prices realized in your recent private placement, please provide us an analysis that explains the basis for the common share fair value used for Black-Scholes purposes.
- 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.
- 121. We see that in October 2007, the exercise price of the \$2.00 warrants increased to \$2.25. Please revise to disclose all of the significant terms and conditions of the

warrants, including a discussion of the provision leading to the change in exercise prices. Also disclose how you accounted for the change. In addition, tell us why the warrants are still included in the table on page F-18 at a \$2.00 exercise price.

Note 5. Note Payable, page F-19

122. We see that your convertible debenture matures in 2007. Since the financial statements are as of December 31, 2007, please revise to update this disclosure and state whether the maturity date has been extended, the amount is past due or otherwise how you plan to settle the outstanding debt.

Part II

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

- 123. Please ensure that your description of unregistered sales of securities during the past three years is complete. We note, for example, that you have not included the information required by Item 701 of Regulation S-K with respect to the August 2008 private placement noted on pages 3, 4 and 27 and the March 2007 convertible loan financing mentioned on page 3 and 23. You have also not disclosed the information required by Item 701 of Regulation S-K with respect to the shares acquired by Mr. Ruwe in exchange for his \$200,000 investment noted on page 46 or the transactions referenced in exhibits 10.15-10.19.
- 124. Please disclose the information required by Item 701 of Regulation S-K with respect to each unregistered sale of your securities. We note that many of the unregistered sales you disclose do not identify the nature and amount of consideration provided. We also note that none of the unregistered sales you disclose identify the exemption relied on and factual basis supporting that exemption.
- 125. As of June 30, 2008, your balance sheet states that there are 3,644,524 shares issued and page 1 of the prospectus states there are 8,163,687 shares outstanding. Please reconcile, and ensure that all issuances are disclosed here.

Item 28. Undertakings, page II-8

126. Please include the full undertaking required by Regulation S-K Item 512(a)(5)(ii). Also, please note that due, in part, to the language of Securities Act Rule 430C(d), the undertaking included in Item 512(a)(6) of Regulation S-K should be included in filings for initial public offerings. Please revise your filing to include that undertaking.

Signatures, page II-10

127. Please indicate below the second paragraph of text which individual signed in the capacity of principal accounting officer or controller.

Exhibits

- 128. Please file as exhibits:
 - the 2008 Stock Option Plan mentioned on page 46. Also revise your document to include disclosure of the material terms of that plan;
 - the employment agreement with Mr. Dauwalter that is noted on page II-6; and
 - the documents governing the \$170,000 convertible bridge loan mentioned on pages 22 and 59;
- 129. Please tell us which exhibit relates to the warrants issued in your August 2008 financing. We note that exhibit 10.34 includes a year 2007 date of issuance.
- 130. Please file complete exhibits to this registration statement. As one example, we note that exhibit 10.32 currently omits Schedule A.

Exhibit 3.1

131. Please ensure that the exhibits you file are correct and current. We note, for example, that exhibit 3.1 lists the number of authorized shares as 10 million and does not appear to include subsequent amendments that changed your authorized share capital, such as those described on pages 2 and 25. Also note that when you amend your charter and bylaws, you should file a complete copy of the document as amended rather than require investors to piece together documents from multiple exhibits. See Regulation S-K Item 601(b)(3).

Exhibit 23.1

132. Please include a currently dated and signed consent from your independent auditors prior to requesting effectiveness.

* * * * * * *

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.

Notwithstanding our comments, in the event the company requests acceleration of the effective date of the pending registration statement, it should furnish a letter, at the time of such request, 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.

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