

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**AMENDMENT NO. 11 TO FORM S-1/A**

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

**BIODRAIN MEDICAL, INC.**

(Exact name of registrant as specified in its charter)

Minnesota

3842

33-1007393

(State or other jurisdiction  
of incorporation or  
organization)

(Primary Standard Industrial  
Classification Code  
Number)

(I.R.S. Employer  
Identification No.)

**2060 Centre Pointe Boulevard, Suite 7  
Mendota Heights, Minnesota 55120  
(651) 389-4800**

(Address, Including Zip Code and Telephone Number,  
Including Area Code, of Registrant's Principal Executive Offices)

**Kevin R. Davidson**

**Chief Executive Officer**

**2060 Centre Pointe Boulevard, Suite 7  
Mendota Heights, Minnesota 55120  
(651) 389-4800**

(Name, Address, Including Zip Code and Telephone Number,  
Including Area Code, of Agent for Service)

*Copy to:*

**Ryan Hong, Esq.**

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Approximate date of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box.  x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b2 of the Exchange Act.

Large accelerated filer  o

Accelerated filer  o

Non-accelerated filer (Do not check if a smaller reporting company)  o

Smaller reporting company  x

**CALCULATION OF REGISTRATION FEE**

Title of each class of securities to be registered	Amount to be Registered	Proposed maximum offering price per share	Proposed maximum aggregate offering price	Amount of registration fee
Common stock, \$0.01 par value (1)	7,101,266	.46	\$ 3,266,583	\$ 182.27
Common stock underlying warrants to purchase common stock (2)	4,689,291	\$ .46	\$ 2,157,074	\$ 120.36
Common stock underlying convertible debentures (1)	620,095	.46	\$ 285,244	\$ 15.92

Common stock underlying warrants (3)	620,095	\$	.46	\$	285,244	\$	15.92
<b>TOTAL</b>	<b>13,030,747</b>		<b>N/A</b>	<b>\$</b>	<b>5,994,145</b>	<b>\$</b>	<b>334.47</b>

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. As a result, only the title of class of securities to be registered, the proposed maximum aggregate offering price and the amount of registration fee need to appear in this Calculation of Registration Fee table.
- (2) Calculated in accordance with Rule 457 (g) under the Securities Act on the basis of an exercise price of \$.46 per share.
- (3) Calculated in accordance with Rule 457 (g) under the Securities Act on the basis of an exercise price of \$.35 per share.

**THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SECTION 8(A), MAY DETERMINE.**

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**Subject to Completion, dated October 8, 2009**

**PRELIMINARY PROSPECTUS**

**BioDrain Medical, Inc.**

13,030,747 Shares of Common Stock

\$0.01 par value

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This prospectus covers the resale by selling shareholders named on page 69 of up to 13,030,747 shares of common stock which include:

- 7,101,266 shares of common stock;
- 5,309,386 shares of common stock underlying common stock purchase warrants, which includes 4,689,291 and 620,095 shares of common stock underlying warrants issued in conjunction with an October 2008 financing and bridge loans we undertook in July 2007, respectively; and
- 620,095 shares of common stock underlying the convertible notes.

There is no current trading market for our securities and this offering is not being underwritten. These securities will be offered for sale by the selling shareholders identified in this prospectus in accordance with the methods and terms described in the section of this prospectus titled "Plan of Distribution." The selling shareholders will sell the securities at \$0.46 per share, until our shares are quoted on the OTC Bulletin Board ("OTCBB") and thereafter at prevailing market prices or privately negotiated prices. We intend to seek and obtain quotation of our common stock for trading on the OTC Bulletin Board. We intend to cause a market maker to submit an application for quotation to the OTC Bulletin Board before September 30, 2009. Newbridge Securities Corporation has agreed to submit an application to the OTC Bulletin Board on our behalf.

AN INVESTMENT IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING AT PAGE 3. NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

You should rely only on the information contained in this prospectus to make your investment decision. We have not authorized anyone to provide you with different information. This prospectus may be used only where it is legal to sell these securities. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus.

The following table of contents has been designed to help you find important information contained in this prospectus. We encourage you to read the entire prospectus carefully.

The date of this prospectus is October 8, 2009

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Neither we nor the selling shareholders have authorized anyone to provide you with information different from that contained in this prospectus. These securities may be sold only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the effective date of this offering, regardless of the time of delivery of this prospectus or of any sale of the securities. You must not consider that the delivery of this prospectus or any sale of the securities covered by this prospectus implies that there has been no change in our affairs since the effective date of this offering or that the information contained in this prospectus is current or complete as of any time after the effective date of this offering.

Neither we nor the selling shareholders are making an offer to sell the securities in any jurisdiction where the offer or sale is not permitted. No action is being taken in any jurisdiction outside the United States to permit a public offering of our securities or the possession or distribution of this prospectus in any such jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside of the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable in that jurisdiction.

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## Prospectus Summary

*This summary highlights material information contained elsewhere in this prospectus. It is not complete and does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, including the section titled "Risk Factors" and our financial statements and the related notes. In this prospectus, we refer to BioDrain Medical, Inc. as "BioDrain," "our company," "we," "us" and "our."*

### Our Company

BioDrain is an early-stage company developing a patented medical device designed to provide medical facilities with effective, efficient and affordable means to safely dispose of potentially contaminated fluids generated in the operating room and other similar medical locations in a manner that protects hospital workers from exposure to such fluids, reduces costs to the hospital, and is environmentally conscientious. We recently filed a 510(k) submission with the U.S. Food and Drug Administration (the "FDA") with respect to our products, the fluid management system ("FMS") and related products and received written confirmation of our clearance on April 1, 2009.

BioDrain was incorporated in Minnesota on April 23, 2002. We are the registered owner of a U.S. and European patent for our current FMS. We plan to distribute our products to medical facilities where bodily and irrigation fluids produced during surgical procedures must be contained, measured, documented and disposed of with minimal exposure potential to the healthcare workers who handle them. Our goal is to create products that dramatically decrease staff exposure without significant changes to established operative procedures, historically a major stumbling block to innovation and product introduction. In addition to simplifying the handling of these fluids, our technologies will provide cost savings to facilities over the aggregate costs incurred today using their current methods of collection, neutralization and disposal. Initially, our products will be sold through independent distributors and manufacturers representatives in the United States and Europe.

### Risks Related to Our Business

Our business is subject to a number of risks, which you should be aware of before making an investment decision. These risks are discussed more fully in the section of this prospectus titled "Risk Factors."

### The Offering

The shares issued and outstanding as of August 31, 2009 consist of 10,103,651 shares of common stock and do not include:

- 6,937,813 shares of common stock issuable upon the exercise of warrants having a range of exercise prices from \$.02 to \$1.67 per share (consisting of 5,309,386 shares of common stock underlying the warrants we are registering pursuant to this registration statement, 1,050,000 shares underlying warrants issued in a private placement in April, May, June and August 2009 and 578,427 shares of common stock reserved for issuance upon the exercise of outstanding warrants granted to certain other investors and consultants.
- outstanding options to purchase 1,466,174 shares of our common stock;
- 77,595 shares of common stock remaining reserved for issuance under our 2008 Equity Incentive Plan;
- 620,095 shares of common stock issuable in conjunction with a bridge loan we undertook in July 2007; and
- 297,142 shares subject to issuance upon conversion of certain notes.

We are registering 13,030,747 shares for sale by the selling shareholders identified in the section of this prospectus titled "Selling Security Holders." The shares included in the table identifying the selling shareholders consist of:

- 7,101,266 shares of common stock;
- 5,309,386 shares of common stock underlying common stock purchase warrants, which includes 620,095 shares of common stock underlying warrants issued in conjunction with a bridge loan we undertook in July 2007; and
- 620,095 shares of common stock underlying the 2007 convertible notes.

After this offering, assuming the exercise of all warrants and options and conversion of convertible debt, including underlying shares which are covered by this prospectus, we would have 19,424,875 shares of common stock outstanding as of August 31, 2009, which does not include the 77,595 shares of common stock remaining reserved for issuance under our 2008 Equity Incentive Plan.

BioDrain Medical, Inc. will not receive any of the proceeds from the sale of these shares. However, we may receive up to \$2,374,107 upon the exercise of warrants. If some or all of the warrants are exercised, the money we receive will be used for general corporate purposes, including working capital requirements. We will pay all expenses incurred in connection with the offering described in this prospectus, with the exception of the brokerage expenses, fees, discounts and commissions which will all be paid by the selling shareholders. Information regarding our common stock, warrants and convertible notes is included in the section of this prospectus entitled "Description of Securities."

### **Corporate Information**

Our corporate offices are located at 2060 Centre Pointe Boulevard, Suite 7, Mendota Heights, Minnesota 55120. Our telephone number is (651) 389-4800 and our website address is [www.biodrainmedical.com](http://www.biodrainmedical.com). Information contained on our website shall not be deemed to be part of this prospectus.

### **Reverse Stock Split**

On June 6, 2008, our board of directors approved a 1-for-1.2545 reverse stock split of our common stock, which resulted in the authorized number of our common stock of 20,000,000 to be proportionately divided by 1.2545 to 15,942,607. Pursuant to Section 302A.402 of the Minnesota Business Corporations Act, since the reverse stock split did not adversely affect the rights or preferences of the holders of our outstanding common stock and did not result in the percentage of authorized shares of any class or series of our stock that remains unissued after the reverse stock split exceeding the percentage of authorized shares of that class or series that were unissued before the reverse stock split, no shareholder approval was required.

On October 20, 2008, our board of directors approved a subsequent 1-for-1.33176963 reverse stock split. As a result, the authorized number of our common stock of 15,942,607 was proportionately divided by 1.33177 to 11,970,994. On October 20, 2008, our board of directors also approved a resolution to increase the number of authorized shares of our common stock from 11,970,994 to 40,000,000 and such action was approved by the Company's shareholders holding a majority of the shares entitled to vote thereon at a special meeting of shareholders held on December 3, 2008.

Unless otherwise indicated, all discussions included in this prospectus relating to the outstanding shares of our common stock, including common stock to be issued upon exercise of outstanding warrants, refer to post-second reverse stock split shares.

## **Risk Factors**

*You should carefully consider the risks described below before making an investment decision. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this prospectus, including our financial statements and related notes.*

### **Risks Related to Our Business**

***Our limited operating history makes evaluation of our business difficult.***

We were formed on April 23, 2002 and to date have generated only minimal revenue. Our ability to implement a successful business plan remains unproven and no assurance can be given that we will ever generate sufficient revenues to sustain our business. We have a limited operating history which makes it difficult to evaluate our performance. You must consider our prospects in light of these risks, expenses, technical obstacles, difficulties, market penetration rate and delays frequently encountered in connection with the development of new businesses. These factors include uncertainty whether we will be able to:

- Raise capital;
- Develop and implement our business plan in a timely and effective manner;
- Be successful in uncertain markets;
- Respond effectively to competitive pressures;
- Successfully address intellectual property issues of others;
- Protect and expand our intellectual property rights; and
- Continue to develop and upgrade our products.

***Because we are a development stage company, not profitable and expect to incur additional losses, we will require additional financing to sustain our operation. Our Independent Public Accounting firm has indicated in their audit opinion, contained in our Financial Statements, that they have serious doubt about our ability to remain a going concern.***

We incurred a net loss of approximately \$1,763,000 and \$752,000, respectively, for the fiscal years ended December 31, 2008 and 2007, respectively and a net loss of approximately \$1,742,000 for the six months ended June 30, 2009. We have never earned a profit and we anticipate that we will continue to incur losses for at least the next 12 months. We continue to operate on a negative cash flow basis. We have generated only minimal revenues and are still developing our planned principal operations. We believe that we will need to raise at least an aggregate of \$3 million from future offerings in order to have sufficient financial resources to fund our operations for the next 12 months because we are running a cash flow deficit.

Although we will not receive any proceeds from the sale of the shares offered in this offering, we may receive up to \$2,374,107 upon exercise of warrants, the underlying shares of which are included in the registration statement of which this prospectus is a part. If received, such funds will be used for general corporate purposes, including working capital requirements. However, shareholders are not obligated, and we are not currently depending on any exercising of the warrants. Accordingly, we will rely on pursuing alternative sources to obtain the entire amount of funding needed to fund our operations for the next 12 months. We may need additional funds to continue our operations, and such additional funds may not be available when required at attractive prices or at all. If we are unable to obtain additional funds at reasonable rates or at all we will be required to substantially curtail our operations and could cease to exist in our current form. Our Independent Public Accounting firm has indicated in their audit opinion, contained in our Financial Statements, that they have serious doubt about our ability to remain a going concern.

To date, we have financed our operations through the sale of stock and certain borrowings. From 2002 to 2006 we received approximately \$110,000 in debt financing of which approximately \$38,000 remains outstanding as of the date of this prospectus and approximately \$1,692,200 in equity financing. In March 2007 we obtained a \$100,000 convertible note from two private investors. In July 2007 we arranged a convertible bridge loan of \$170,000 from seven private investors. By October 30, 2008, we closed a private placement financing of our common stock and warrants, through which we raised approximately \$1.594 million to date with net proceeds of approximately \$1.238 million. We raised an additional \$525,000 in a private placement of stock at \$.50 per share and warrants to purchase stock at \$.65 per share during April, May, June and August 2009. Approximately \$331,000 will be allocated to outstanding legal fees (\$75,000), finder fees (\$86,000), and investor relations fees (\$170,000 over the next two years).

We expect to continue to depend upon outside financing to sustain our operations for at least the next 12 months. Our ability to arrange financing from third parties will depend upon our performance and market conditions. Our inability to raise additional working capital at all or to raise it in a timely manner would negatively impact our ability to fund our operations, to generate revenues, and to otherwise execute our business plan, leading to the reduction or suspension of our operations and ultimately forcing us to go out of business. Should this occur, the value of any investment in our securities could be adversely affected, and an investor could lose a portion of or even lose their entire investment.

Although we have been able to fund our current working capital requirements, principally through debt and equity financing, there is no assurance that we will be able to do so in the future.

***We are an early-stage company with a limited operating history with minimal revenues.***

Since our formation in 2002, we have engaged in the formulation of a business strategy and the design and development of technologically advanced products. We have generated only minimal revenues to date. Our ability to implement a successful business plan remains unproven and no assurance can be given that we will ever generate sufficient revenues to sustain our business.

***Our business is dependent upon proprietary intellectual property rights, which if we were unable to protect, could have a material adverse effect on our business.***

We currently own and may in the future own or license additional patent rights or trade secrets in the U.S., Europe, Asia, Canada and elsewhere in the world that cover certain of our products. We rely on patent laws, and other intellectual property laws, nondisclosure and other contractual provisions and technical measures to protect our products and intangible assets. These intellectual property rights are important to our ongoing operations and no assurance can be given that any measure we implement will be sufficient to protect our intellectual property rights. We may lose the protection afforded by these rights through patent expirations, legal challenges or governmental action. If we cannot protect our rights, we may lose our competitive advantage or our competitive advantage could be lost if these patents were found to be invalid in the jurisdictions in which we sell or plan to sell our products. The loss of our intellectual property rights could have a material adverse effect on our business.



***If we become subject to intellectual property actions, this could hinder our ability to deliver our products and services and our business could be negatively impacted.***

We may be subject to legal or regulatory actions alleging intellectual property infringement or similar claims against us. Companies may apply for or be awarded patents or have other intellectual property rights covering aspects of our technologies or businesses. Moreover, if it is determined that our products infringe on the intellectual property rights of third parties, we may be prevented from marketing our products. While we are currently not subject to any material intellectual property litigation, any future litigation alleging intellectual property infringement could be costly, particularly in light of our limited resources. Similarly, if we determine that third parties are infringing on our patents or other intellectual property rights, our limited resources may prevent us from litigating or otherwise taking actions to enforce our rights. Any such litigation or inability to enforce our rights could require us to change our business practices, could potentially hinder or prevent our ability to deliver our products and services, and could result in a negative impact to our business. Expansion of our business via product line enhancements or new product lines to drive increased growth in current or new markets may be inhibited by the intellectual property rights of our competitors and/or suppliers. Our inability to successfully mitigate those factors may significantly reduce our market opportunity and subsequent growth.

***Our business would be materially and adversely affected if we were obligated to pay royalties under a competing patent purchase agreement.***

Our revenues would be adversely affected if our intellectual property were found to infringe the intellectual property rights of others. Two individuals, Jay D. Nord and Jeffrey K. Drogue, filed a provisional patent application disclosing a particular embodiment for a medical waste fluid collection system (the “Nord/Drogue Embodiment”). We engaged the services of Marshall C. Ryan to further develop the medical waste fluid collection system for commercialization. Mr. Ryan conceived of an alternative embodiment for the medical waste fluid collection system (the “Ryan Embodiment”). An international (PCT) patent application was subsequently filed claiming priority to the earlier filed provisional application of Nord and Drogue and disclosing and claiming both the Nord/Drogue Embodiment and the Ryan Embodiment. The national stage applications were filed in the U.S., Europe and Canada based on the PCT application. During the national stage prosecutions, the European and U.S. patent offices each rejected the patent claims covering the Nord/Drogue Embodiment as being un-patentable over the prior art. The Canadian patent office has not yet examined the Canadian national stage application. The claims were amended in both the U.S. and European applications to claim only the subject matter of the Ryan Embodiment and Mr. Ryan was added as a named inventor. As required under U.S. law, we removed Nord and Drogue as named inventors from the U.S. application because they were no longer inventors to the subject matter of the remaining patent claims. A U.S. patent was granted to us on December 30, 2008 (U.S. Patent No. 7,469,727). A European patent was granted to us on April 4, 2007 (Patent No. EP1539580) (collectively, “the Patents”).

We entered into a patent purchase agreement in September 2002 with Nord and Drogue prior to engaging Mr. Ryan. Under the patent purchase agreement, certain royalties were to be paid to Nord and Drogue upon issuance of a U.S. patent. However, upon learning that the Nord/Drogue Embodiment was un-patentable, we notified Mr. Nord that the patent purchase agreement we had entered into with Nord and Drogue was no longer valid. Nord and Drogue could pursue legal action against us purportedly for breach of contract and may sue for damages and ownership interest in the patents. Although our management believes that we would prevail in such lawsuit, there is no assurance that we would. We believe that Nord and Drogue have no valid claims of inventorship or ownership of the Patents. Even if Mr. Nord or Mr. Drogue were to assert such a claim, we believe that, independent of our dealings with them, we obtained rights to the Patents from Mr. Ryan, who even if found not to be the sole inventor of the subject matter of the claims of the Patents, is at least a joint inventor. As a joint inventor, Mr. Ryan would have co-ownership of the Patents and would have the power to transfer to us his undivided co-ownership interest in the Patents.

***We face significant competition, including competition from companies with considerably greater resources than ours, and if we are unable to compete effectively with these companies, our market share may decline and our business could be harmed.***

Our industry is highly competitive with numerous competitors ranging from well-established manufacturers to innovative start-ups. A number of our competitors have significantly greater financial, technological, engineering, manufacturing, marketing and distribution resources than we do. Their greater capabilities in these areas may enable them to compete more effectively on the basis of price and production and more quickly develop new products and technologies.

We estimate that the total market for surgical suction canisters is approximately \$100 million and has a compound annual growth rate of 5%. We estimate the total cost of using surgical canisters is a multiple of \$100 million because this amount does not include the labor to handle the canisters, disposal costs and solidifying compounds commonly used to minimize exposure to health care workers. Cardinal Health, Inc., a \$90 billion plus medical manufacturer and distributor, is a leading competitor. Another one of our competitors is Stryker Instruments, a wholly-owned subsidiary of Stryker Corporation, which is a publicly-traded company with revenues of approximately \$5 billion, and has a leading position in this market. Cardinal Health, Inc. has recently begun advertising a powered device similar to that which Stryker currently markets. Both of these competitors are better capitalized than we are.

Although the BioDrain Streamway™ FMS is directly connected to the sanitary sewer, helping to reduce potential exposure to infectious fluids, it is possible that installation of the system will cause inconvenience and lost productivity as the operating rooms in which they are installed will need to be temporarily shut down. In addition, remodel work may be necessary in preparation for, or as a result of, an installation. In some cases, the costs to rework plumbing lines to accommodate for our system may outweigh the expected savings and/or lengthen the expected return on investment time.

Companies with significantly greater resources than ours may be able to reverse engineer our products and/or circumvent our intellectual property position. Such action, should it prove successful, would greatly reduce our competitive advantage in the marketplace.

We believe that our ability to compete successfully depends on a number of factors, including our innovative and advanced research and development capabilities, strength of our intellectual property rights, sales and distribution channels and advanced manufacturing capabilities. We plan to employ these and other elements as we develop our products and technologies, but there are many other factors beyond our control. We may not be able to compete successfully in the future, and increased competition may result in price reductions, reduced profit margins, loss of market share and an inability to generate cash flows that are sufficient to maintain or expand our development and marketing of new products, which could adversely impact the trading price of our common shares.

***Our products require FDA clearance and our business will be subject to intense governmental regulation and scrutiny, both in the U.S. and abroad.***

In March 2009 we filed a 510(k) submission with the U.S. Food and Drug Administration (the “FDA”) with respect to a product classification as a Class II non-exempt device. We cannot generate revenues from our product to be used in the surgical operating room without FDA clearance. We received written confirmation of final FDA clearance on April 1, 2009.

The potential production and marketing of some of our products and our ongoing research and development, any pre-clinical testing and clinical trial activities are subject to extensive regulation and review by FDA and other governmental authorities both in the United States and abroad. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record keeping. If we do not comply with applicable regulatory requirements, violations could result in warning letters, non-approvals, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

Periodically, legislative or regulatory proposals are introduced that could alter the review and approval process relating to medical products. It is possible that the FDA will issue additional regulations further restricting the sale of our present or proposed products. Any change in legislation or regulations that govern the review and approval process relating to our current and future products could make it more difficult and costly to obtain approval for new products, or to produce, market, and distribute existing products.

***Our product may never be commercially viable or producible to satisfy demand.***

The BioDrain FMS is currently a fourth-generation prototype. We have engaged a contract manufacturing entity and we have finalized the product design. These improvements are expected to make the product attractive to the target market; however, other unknown or unforeseen market requirements may appear. There is no assurance that such a product can be produced in sufficient volume to satisfy projected sales volumes.

***If our product is not accepted by our potential customers, it is unlikely that we will ever become profitable.***

The medical industry has historically used a variety of technologies for fluid waste management. Compared to these conventional technologies, our technology is relatively new, and the number of companies using our technology is limited. The commercial success of our product will depend upon the widespread adoption of our technology as a preferred method by hospitals and surgical centers. In order to be successful, our product must meet the technical and cost requirements for these facilities. Market acceptance will depend on many factors, including:

- the willingness and ability of customers to adopt new technologies;
- our ability to convince prospective strategic partners and customers that our technology is an attractive alternative to conventional methods used by the medical industry;
- our ability to select and execute agreements with effective distributors and manufacturers representatives to market and sell our product; and
- our ability to assure customer use of the BioDrain proprietary cleaning fluid.

Because of these and other factors, our product may not gain market acceptance or become the industry standard for the health care industry. The failure of such companies to purchase our products would have a material adverse effect on our business, results of operations and financial condition.

***We are dependent for our success on a few key executive officers. Our inability to retain those officers would impede our business plan and growth strategies, which would have a negative impact on our business and the value of an investment.***

Our success depends on the skills, experience and performance of key members of our management team. We are heavily dependent on the continued services of Lawrence Gadbaw; our Chairman, Kevin Davidson; our Chief Executive Officer and Chief Financial Officer, Kirsten Doerfert; our Vice President of Sales and Marketing and Chad Ruwe; our Chief Operating Officer. We have entered into employment or consulting agreements with all members of our senior management team and we plan to expand the relatively small number of executives. Were we to lose one or more of these key individuals, we would be forced to expend significant time and money in the pursuit of a replacement, which could result in both a delay in the implementation of our business plan and the diversion of limited working capital. We can give you no assurance that we can find satisfactory replacements for these key individuals at all, or on terms that are not unduly expensive or burdensome to our company. Although we intend to issue stock options or other equity-based compensation to attract and retain employees, such incentives may not be sufficient to attract and retain key personnel.

***We are dependent for our success on our ability to attract and retain technical personnel, sales and marketing personnel and other skilled management.***

Our success depends to a significant degree upon our ability to attract, retain and motivate highly skilled and qualified personnel. Failure to attract and retain necessary technical, sales and marketing personnel and skilled management could adversely affect our business. If we fail to attract, train and retain sufficient numbers of these highly qualified people, our prospects, business, financial condition and results of operations will be materially and adversely affected.

***The relative lack of public company experience of our management team may put us at a competitive disadvantage.***

Our management team has limited public company experience, which could impair our ability to comply with legal and regulatory requirements such as those imposed by the Sarbanes-Oxley Act of 2002. The individuals who now constitute our senior management have had limited responsibility for managing a publicly traded company. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. Our senior management may not be able to implement and effect programs and policies in an effective and timely manner that adequately respond to such increased legal, regulatory compliance and reporting requirements. Our failure to do so could lead to the imposition of fines and penalties and result in the deterioration of our business.

***New rules, including those contained in and issued under the Sarbanes-Oxley Act of 2002, may make it difficult for us to retain or attract qualified officers and directors, which could adversely affect the management of our business and our ability to obtain or retain listing of our common stock.***

We may be unable to attract and retain qualified officers, directors and members of board committees required to provide for our effective management as a result of the recent and currently proposed changes in the rules and regulations which govern publicly held companies, including, but not limited to, certifications from executive officers and requirements for financial experts on the board of directors. The perceived increased personal risk associated with these recent changes may deter qualified individuals from accepting these roles. The enactment of the Sarbanes-Oxley Act of 2002 has resulted in the issuance of a series of new rules and regulations and the strengthening of existing rules and regulations by the Securities and Exchange Commission (the "SEC"). Further, certain of these recent and proposed changes heighten the requirements for board or committee membership, particularly with respect to an individual's independence from the Company and level of experience in finance and accounting matters. We may have difficulty attracting and retaining directors with the requisite qualifications. If we are unable to attract and retain qualified officers and directors, the management of our business could be adversely affected.

***Our internal controls over financial reporting may not be effective, and our independent auditors may not be able to certify as to their effectiveness, which could have a significant and adverse effect on our business.***

If we become a publicly traded company, as intended, we will be subject to various regulatory requirements, including the Sarbanes-Oxley Act of 2002. We, like other public companies, would then incur additional expenses and, to a lesser extent, diversion of our management's time, in our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 regarding internal controls over financial reporting.

Since we are a small developing company with a small management team, we have not yet evaluated our internal controls over financial reporting in order to allow management to report on, and our independent auditors to attest to, our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002 and the rules and regulations of the SEC, which we collectively refer to as "Section 404". We will be required to include our Section 404 management's assessment of internal control over financial reporting beginning with our second annual report filed after we become publicly registered, and we will be required to include our independent auditor's attestation on management's report on internal control over financial reporting beginning with our annual report for the fiscal year ending December 31, 2010.

We intend to comply with the Section 404, *Management Assessment of Internal Control over Financial Reporting*, beginning with our second annual report filed after we become publicly registered. However, our lack of familiarity with Section 404 may unduly divert management's time and resources in executing our business plan. If, in the future, management identifies one or more material weaknesses, or our external auditors are unable to attest that our management's report is fairly stated or to express an opinion on the effectiveness of our internal controls, this could result in a loss of investor confidence in our financial reports, have an adverse effect on our stock price and/or subject us to sanctions or investigation by regulatory authorities.

## **Risks Related to Our Securities**

***There is currently no public trading market for our common stock and we cannot assure you that an active public trading market for our common stock will develop or be sustained. Even if a market develops, you may be unable to sell at or near ask prices or at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares.***

There is currently no public trading market for our common stock and no such market may ever develop. While we intend to seek and obtain quotation of our common stock for trading on the OTC Bulletin Board ("OTCBB") during the third quarter of 2009, there is no assurance that our application will be approved. An application for quotation on the OTC Bulletin Board must be submitted by one or more market makers who agree to sponsor the security and who demonstrate compliance with SEC Rule 15(c)2-11 before initiating a quote in a security on the OTC Bulletin Board. In order for a security to be eligible for quotation by a market maker on the OTC Bulletin Board, the security must be registered with the SEC and the company must be current in its required filings with the SEC. There are no listing requirements for the OTC Bulletin Board and accordingly no financial or minimum bid price requirements. We intend to cause a market maker to submit an application for quotation to the OTC Bulletin Board before September 30, 2009. Newbridge Securities Corporation, or an associate firm, has agreed to submit an application to the OTC Bulletin Board on our behalf.

Even if our application for quotation is approved, the number of institutions or persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or nonexistent. This situation may be attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk averse and may be reluctant to follow a relatively unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, assuming that our common stock is accepted for quotation, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot assure you that an active public trading market for our common stock will develop or be sustained.

***Limitations on director and officer liability and indemnification of our officers and directors by us may discourage shareholders from bringing suit against a director.***

Our articles of incorporation and bylaws provide, with certain exceptions as permitted by governing state law, that a director or officer shall not be personally liable to us or our shareholders for breach of fiduciary duty as a director, except for acts or omissions which involve intentional misconduct, fraud or knowing violation of law, or unlawful payments of dividends. These provisions may discourage shareholders from bringing suit against a director for breach of fiduciary duty and may reduce the likelihood of derivative litigation brought by shareholders on our behalf against a director. In addition, our articles of incorporation and bylaws may provide for mandatory indemnification of directors and officers to the fullest extent permitted by governing state law.

***We do not expect to pay dividends for the foreseeable future, and we may never pay dividends.***

We currently intend to retain any future earnings to support the development and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our board of directors after taking into account various factors, including but not limited to, our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. In addition, our ability to pay dividends on our common stock may be limited by state law. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize their investment.

***If our common stock is accepted for quotation on the OTC Bulletin Board it may be thinly traded, so you may be unable to sell at or near ask prices or at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares.***

If our common stock is accepted for quotation on the OTC Bulletin Board, it may be thinly traded on the OTC Bulletin Board, meaning there has been a low volume of buyers and sellers of the shares. Through this registration statement, we are going public without the typical initial public offering procedures which usually include a large selling group of broker-dealers who may provide market support after going public. Thus, we will be required to undertake efforts to develop market recognition for us and support for our shares of common stock in the public market. The price and volume for our common stock that will develop cannot be assured. The number of institutions or persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. This situation may be attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days, weeks or months when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price.

We cannot give you any assurance that a broader or more active public trading market for our common stock will develop or be sustained. In addition to trading on the OTC Bulletin Board, our ultimate intention is to apply for trading on either the Nasdaq Capital Market or the NYSE Alternext U.S. LLC (formerly American Stock Exchange) at such time that we meet the requirements for listing on those exchanges. We currently do not meet the objective listing criteria for listing on those exchanges and there can be no assurance as to when we will qualify for either of these exchanges or that we will ever qualify for these exchanges.

In order for us to be eligible to trade on the Nasdaq Capital Market, we would need, among other things, a bid price of \$4, \$5 million in stockholders' equity, and \$15 million market value of publicly held shares. In order for us to be eligible to trade on the NYSE Alternext U.S. LLC, which is a market for small and mid-sized companies, we would need, among other things, at least \$3 million market value of public float, a minimum price of \$3 and \$4 million in shareholders' equity.

Currently, our market capitalization, revenues and stockholders' equity are insufficient to qualify for these exchanges. We also do not have a sufficient number of shareholders. We would also need to meet the corporate governance and independent director and audit committee standards of Nasdaq and/or the NYSE Alternext U.S. LLC. We do not satisfy such standards at this time.

If our common stock is accepted for quotation and begins trading on the OTC Bulletin Board, the trading volume we develop may be limited by the fact that many major institutional investment funds, including mutual funds, as well as individual investors follow a policy of not investing in OTC Bulletin Board stocks and certain major brokerage firms restrict their brokers from recommending OTC Bulletin Board stocks because they are considered speculative, volatile and thinly traded.

***The application of the “penny stock” rules to our common stock could limit the trading and liquidity of the common stock, adversely affect the market price of our common stock and increase your transaction costs to sell those shares.***

If our common stock is accepted for quotation on the OTC Bulletin Board, as long as the trading price of our common stock is below \$5 per share, the open-market trading of our common stock will be subject to the “penny stock” rules, unless we otherwise qualify for an exemption from the “penny stock” definition. The “penny stock” rules impose additional sales practice requirements on certain broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with net assets in excess of \$1,000,000 or annual income exceeding \$200,000 or \$300,000 together with their spouse). These regulations, if they apply, require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the associated risks. Under these regulations, certain brokers who recommend such securities to persons other than established customers or certain accredited investors must make a special written suitability determination regarding such a purchaser and receive such purchaser’s written agreement to a transaction prior to sale. These regulations may have the effect of limiting the trading activity of our common stock, reducing the liquidity of an investment in our common stock and increasing the transaction costs for sales and purchases of our common stock as compared to other securities.

***The OTC Bulletin Board is a quotation system, not an issuer listing service, market or exchange. Therefore, buying and selling stock on the OTC Bulletin Board is not as efficient as buying and selling stock through an exchange.***

The OTC Bulletin Board is a regulated quotation service that displays real-time quotes, last sale prices and volume limitations in over-the-counter securities. Because trades and quotations on the OTC Bulletin Board involve a manual process, the market information for such securities cannot be guaranteed. In addition, quote information, or even firm quotes, may not be available. The manual execution process may delay order processing and intervening price fluctuations may result in the failure of a limit order to execute or the execution of a market order at a significantly different price. Execution of trades, execution reporting and the delivery of legal trade confirmation may be delayed significantly. Consequently, one may not be able to sell shares of our common stock at the optimum trading prices.

When fewer shares of a security are being traded on the OTC Bulletin Board, volatility of prices may increase and price movement may outpace the ability to deliver accurate quote information. Lower trading volumes in a security may result in a lower likelihood of an individual’s orders being executed, and current prices may differ significantly from the price one was quoted by the OTC Bulletin Board at the time of the order entry.

Orders for OTC Bulletin Board securities may be canceled or edited like orders for other securities. All requests to change or cancel an order must be submitted to, received and processed by the OTC Bulletin Board. Due to the manual order processing involved in handling OTC Bulletin Board trades, order processing and reporting may be delayed, and an individual may not be able to cancel or edit his order. Consequently, one may not be able to sell shares of common stock at the optimum trading prices.

The dealer’s spread (the difference between the bid and ask prices) may be large and may result in substantial losses to the seller of securities on the OTC Bulletin Board if the common stock or other security must be sold immediately. Further, purchasers of securities may incur an immediate “paper” loss due to the price spread. Moreover, dealers trading on the OTC Bulletin Board may not have a bid price for securities bought and sold through the OTC Bulletin Board. Due to the foregoing, demand for securities that are traded through the OTC Bulletin Board may be decreased or eliminated.

***Shares eligible for future sale may adversely affect the market.***

From time to time, certain of our shareholders may be eligible to sell all or some of their shares of common stock pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, subject to certain limitations. In general, pursuant to Rule 144 as in effect as of the date of this prospectus, a shareholder (or shareholders whose shares are aggregated) who has satisfied the applicable holding period and is not deemed to have been one of our affiliates at the time of sale, or at any time during the three months preceding a sale, may sell their shares of common stock. Any substantial sale, or cumulative sales, of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our securities.

***We expect volatility in the price of our common stock, which may subject us to securities litigation.***

If established, the market for our common stock may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will be more volatile than a seasoned issuer for the indefinite future. In the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources.

**Special Note Regarding Forward-Looking Statements**

This prospectus, including the sections titled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Description of Business," contains forward-looking statements.

Forward-looking statements include, but are not limited to, statements about:

- our ability to raise capital when we need it;
- our ability to market and distribute or sell our Fluid Management System (FMS) and related products; and
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others.

These statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks and other factors include those listed under "Risk Factors" and elsewhere in this prospectus. In some cases, you can identify forward-looking statements by terminology such as "may," "could" "expects," "intends," "plans," "anticipates," "believes," "potential," "continue" or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We do not intend to update any of the forward-looking statements after the date of this prospectus or to conform these statements to actual results. Neither the Private Securities Litigation Reform Act of 1995 nor Section 27A of the Securities Act of 1933, as amended, provides any protection for statements made in this prospectus.



### **Use of Proceeds**

We will not receive any proceeds from the sale of the shares by the selling shareholders. All proceeds from the sale of the shares offered hereby will be for the account of the selling shareholders, as described below in the sections entitled "Selling Security Holders" and "Plan of Distribution." However, we may receive up to \$2,374,107 upon exercise of warrants with exercise prices ranging from \$.35 to \$.46 per share, the underlying shares of which are included in the registration statement of which this prospectus is a part. If received, such funds will be used for general corporate purposes, including working capital requirements. With the exception of any brokerage fees and commissions which are the obligation of the selling shareholders, we are responsible for the fees, costs and expenses of this offering which are estimated to be approximately \$225,000, inclusive of our legal and accounting fees, printing costs and filing and other miscellaneous fees and expenses.

### **Determination of Offering Price**

There has been no public market for our common stock prior to this offering and there will be no public market until our common stock is approved for quotation on the OTC Bulletin Board. The offering price has been arbitrarily determined and does not bear any relationship to our assets, results of operations, or book value, or to any other generally accepted criteria of valuation.

We cannot assure you that an active or orderly trading market will develop for our common stock or that our common stock will trade in the public markets subsequent to this offering at or above the offering price.

## Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters

At this time, our common shares are not traded on any public markets. We have 10,103,651 shares of common stock issued and outstanding as of August 31, 2009. We have 106 shareholders of record of our common stock.

We also have outstanding warrants as of August 31, 2009, to purchase 6,937,813 shares of our common stock, which include (i) 5,309,386 shares of common stock underlying the warrants we are registering pursuant to this registration statement; and (ii) 1,628,427 shares of common stock reserved for issuance upon the exercise of outstanding warrants granted to certain consultants and investors. We also have outstanding options to purchase 1,466,174 shares of our common stock, which include 943,292 shares of common stock reserved for issuance upon the exercise of outstanding options granted pursuant to employment agreements with three officers and an employee of the Company.

After this offering, assuming exercise of all the warrants and options and conversion of convertible debt, we will have 19,424,875 shares of common stock outstanding, which does not include 77,595 shares of common stock remaining reserved for issuance under our 2008 Equity Incentive Plan, but which does include outstanding notes that may be converted into 620,095 shares of our common stock which were issued in conjunction with a bridge loan we undertook in July 2007. Of the amount outstanding, 950,995 shares could be sold pursuant to Rule 144 under the Securities Act of 1933, as amended (assuming compliance with the requirements of Rule 144).

### Dividends

We have never paid dividends and do not currently intend to pay dividends on our common stock in the foreseeable future. Instead, we anticipate that any future earnings will be retained for the development of our business. Any future determination relating to dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including, but not limited to, our financial condition, operating results, cash needs, growth plans, the terms of any credit agreements that we may be a party to at the time and the Minnesota Business Corporations Act, which provides that dividends are only payable out of surplus or current net profits.

### Securities Authorized for Issuance under Equity Compensation Plans

On October 20, 2008, our board of directors approved the BioDrain Medical, Inc. 2008 Equity Incentive Plan (the "Plan") to promote the success of the Company by providing incentives to our directors, officers, employees and contractors by linking their personal interests to the long-term financial success of the Company, and to promote growth in shareholder value. The Plan was subject to the approval of our shareholders, and if it is not so approved on or before 12 months after the date of adoption of the Plan by our board of directors, it would not come into effect and any options granted pursuant to the Plan would be deemed cancelled. Shareholder approval was obtained in a special meeting of shareholders held on December 3, 2008. Awards may be granted only to a person who on the date of the grant is a director, officer, employee or contractor of the Company (or a parent or subsidiary of the Company), subject to certain restrictions set forth in the Plan. Awards granted under the Plan shall be evidenced by an award agreement and shall consist of:

- (i) incentive stock options, as defined in Section 422 of the Internal Revenue Code of 1986 (the "Code");
- (ii) nonqualified stock options, defined as any option granted under the Plan other than an incentive stock option;

- (iii) stock appreciation rights (“SARs”), defined as an award granted under the Plan that is exercisable either in lieu of options, in addition to options, independent of options or in any combination thereof, which, upon exercise, entitles the holder to receive payment of an amount determined by multiplying (a) the difference between the fair market value of a share on the date of exercise and the exercise price established by the administrator of the Plan on the date of grant by (b) the number of shares with respect to which the SAR is exercised, the payment of which will be made in cash or stock; or
- (iv) restricted stock, defined as stock granted under the Plan that is subject to restrictions on sale, transfer, pledge, or assignment.

The Plan is administered by a committee whose members are appointed by our board of directors (the Plan is administered by our board of directors during such times as no committee is appointed or during such times as the board of directors is acting in lieu of the committee). At any time that our securities are listed on a national securities exchange or quoted on Nasdaq Global Markets (“Nasdaq GM”), or Nasdaq Global Select Markets (“Nasdaq GS”), the committee shall consist of not less than three independent directors, as determined by applicable securities and tax laws. The committee has the authority to (i) construe and interpret the Plan; (ii) to establish, amend or waive rules for its administration; (iii) to accelerate the vesting of any options or SARs; (iv) to amend the terms and conditions of any outstanding option, SAR or restricted stock award (provided that the committee shall not replace or re-grant options or SARs with an exercise price that is less than the original exercise price or change the exercise price to a lower price than the original exercise price without prior shareholder approval); (v) to choose grantees of Plan awards; (vi) to impose conditions on the exercisability terms of the awards granted under the Plan; (vii) to determine the number of shares subject to options granted; and (viii) to make all other determinations necessary or advisable for the administration of the Plan.

Subject to adjustment, the aggregate number of shares that may be delivered under the Plan will not exceed 975,405 shares. As of August 31, 2009 897,810 shares have been issued under the Plan. If any award granted under the Plan terminates, expires or lapses, any stock subject to such award shall be available for future grant under the Plan, provided, however, that if any outstanding shares are changed into or exchanged for a different number or kind of shares or other security in another company by reason of reorganization, merger, consolidation, recapitalization, stock split, reverse stock split, combination of shares or stock dividends, an appropriate adjustment will be made in the number and kind of shares as to which awards may be granted and as to which outstanding options and SARs then unexercised shall be exercisable, such that the proportionate interest of the grantee will be maintained. Such adjustment will be made without change in the total price applicable to the unexercised portion of such awards and with a corresponding adjustment in the exercise price per share.

In the event of a change of control of the Company (as defined in the Plan), any award granted under the Plan, to the extent not already terminated, shall become vested and immediately exercisable, and any period of restriction on restricted stock shall terminate, provided, however, that the period during which any option or SAR is exercisable shall not be limited or shortened. If an option or SAR provides for exercisability during a period of time after a triggering event and the initial exercisability is accelerated by means of a change in control, the expiration of the option or SAR shall be delayed until after the period provided for has ended and the option or SAR shall remain exercisable for the balance of the period initially contemplated by the grant. In addition, if the Company is then subject to the provisions of Section 280G of the Code and if the acceleration or vesting or payment pursuant to a change in control could be deemed a parachute payment, as defined in the Code, then the payments to the grantee shall be reduced to an amount as will result in no portion of such payments being subject to the excise tax imposed by Section 4999 of the Code.

Fair market value, for the purposes of the Plan, means the price per share of the Company’s common stock determined as follows: (i) if the security is listed on one or more national securities exchanges or quoted on the Nasdaq GS or Nasdaq GM, the reported last sales price on such exchange on the date in question (or if not traded on such date, the reported last sales price on the first day prior thereto on which the security was traded); or (ii) if the security is not listed on a national securities exchange and not quoted on Nasdaq GS or Nasdaq GM but is quoted on the Nasdaq Capital Market System or otherwise traded in the over-the-counter market, the mean of the highest and lowest bid prices for such security on the date in question (or if there are no such bid prices on such date, the mean of the highest and lowest bid prices on the most recent day prior thereto on which such prices existed, not to exceed 10 days prior to the date in question); or (iii) if neither (i) or (ii) is applicable, by any means determined fair and reasonable by the committee.

## Options

Only employees are eligible to receive incentive stock options. Directors who are not also employees and consultants are not eligible to receive incentive stock options and instead are entitled to receive nonqualified stock options. Subject to this restriction and other terms and conditions of the Plan, options may be granted by the committee with such number of underlying shares, such vesting terms and such exercise times and prices with such restrictions as the committee shall determine. The aggregate fair market value (determined at the time the option is granted) of the stock with respect to which incentive stock options are exercisable for the first time by a grantee during any calendar year shall not exceed \$100,000. To the extent that the aggregate fair market value of the stock with respect to which such incentive stock options are exercisable for the first time exceeds \$100,000, the excess options will be treated as nonqualified stock options.

If a vesting schedule is not specified by the committee at the time an option is granted, such option shall vest, with respect to 25% of the options on the first anniversary date of the grant, and, with respect to 2.083% of the options, beginning on 30 days immediately following the first anniversary of the date of grant and continuing on the same day of each month for the next 35 months thereafter (in each case, rounding up to the nearest whole share). The price at which an option may be exercised shall be determined by the committee but may not be less than the fair market value of the stock on the date the option is granted, provided, however, that the exercise price of an incentive stock option granted to an employee who, on the date of execution of the option agreement owns more than 10% of the total combined voting power of all series of stock then outstanding ("10% Shareholder"), shall be at least 110% of the fair market value of a share on the date the option agreement is signed. No option may be exercised after 10 years from the date on which the option was granted (or on the date preceding the 10<sup>th</sup> anniversary in the case of an incentive stock option) and unless specified by the committee at the time of grant, each option shall expire at the close of business on the 10<sup>th</sup> anniversary of the date of grant, provided, however, that in the case of an incentive stock option held by a 10% Shareholder, such option shall expire at the close of business on the date preceding the 5<sup>th</sup> anniversary of the date of grant.

An option may be exercised at such times and with such rights as provided in the applicable option agreement. An option shall be deemed exercised immediately prior to the close of business on the date the Company is in receipt of the original option agreement, written notice of intent to exercise the option, and payment for the number of shares being acquired upon exercise. There shall be no exercise at any one time for fewer than 100 shares or all of the remaining shares then purchasable by the person exercising the option.

In the case of death or disability of a director, officer, employee or contractor, any of such individual's outstanding options, which were not vested and exercisable on the date of death or the date the committee determines that the individual incurred a disability, shall immediately become 100% vested, and all outstanding options shall be exercisable at any time prior to the sooner of the expiration date of the options or 12 months following the date of death or disability. In the case of termination for "cause" (defined as (i) willful breach of any agreement entered into with the Company; (ii) misappropriation of the Company's property, fraud, embezzlement, breach of fiduciary duty, or other acts of dishonesty against the Company; or (iii) conviction of any felony or crime involving moral turpitude), all of the grantee's outstanding options, whether or not then vested, shall be immediately forfeited back to the Company. In the case of termination for any reason other than death, disability or cause, (i) with respect to outstanding nonqualified options which were then vested and exercisable, such options shall be exercisable at any time prior to the sooner of the expiration date of such options or 12 months following the date of termination and (ii) with respect to outstanding incentive stock options which were then vested and exercisable shall be exercisable at any time prior to the sooner of the expiration date of such options or 3 months following the date of termination, provided, however, that in the event of the individual's death during such 3-month period and prior to the expiration date of the options, such options then vested and unexercised may be exercised within 12 months following the date of termination by the individual's beneficiary or in accordance with the laws of descent and distribution. Any options not then vested and exercisable shall be forfeited back to the Company.

Incentive stock options are transferable only by will or pursuant to the laws of descent and distribution. Nonqualified stock options are transferable to a grantee's family member or family trust by a bona fide gift or pursuant to a domestic relations order, by will or pursuant to the laws of descent and distribution, or as otherwise permitted pursuant to the rules and regulations of the SEC. No other transfers, assignments, pledges, or dispositions of any options, or the rights or privileges conferred thereby, are permitted by the Plan and options are only exercisable, during the grantee's lifetime, by the grantee or his guardian or legal representative.

### ***Stock Appreciation Rights***

The committee shall have the sole discretion, subject to the requirements of the Plan, to determine the actual number of shares subject to SARs granted, to specify the period of time over which vesting shall occur and to provide for the acceleration of vesting upon the attainment of certain goals, provided, however that the exercise of a SAR shall not be less than the fair market value of a share of the Company's stock on the date of grant. Unless specified by the committee at the time the SAR is granted, SARs shall have the same vesting schedule as options. The term of a SAR granted under the Plan shall be determined by the committee, but shall not exceed 10 years and if not specified by the committee at the time of grant, each SAR shall expire at the close of business on the date preceding the 10<sup>th</sup> anniversary of the date of grant.

SARs granted in lieu of options may be exercised for all or part of the shares subject to the related option upon the surrender of the related options representing the right to purchase an equivalent number of shares. The SAR may be exercised only with respect to the shares for which its related option is then exercisable. SARs granted in addition to options shall be deemed to be exercised upon the exercise of the related options. SARs granted independently of options may be exercised upon whatever terms and conditions the committee imposes.

SARs have the same termination consequences as nonqualified stock options, no SAR granted under the Plan may be sold, transferred, pledged, assigned or otherwise alienated or hypothecated, and all SARs granted shall be exercisable during a grantee's lifetime only by such grantee.

### ***Restricted Stock***

The committee may grant shares of restricted stock under the Plan to such grantees, in such amounts, with such purchase price and under such other conditions or restrictions as the committee may determine. Each restricted stock grant shall be evidenced by a restricted stock agreement that must specify the period of time over which the shares of restricted stock shall vest (the period of restriction) and the number of shares of restricted stock granted. The committee may also provide for the acceleration of the lapse of a period of restriction upon the attainment of certain goals. Restricted stock shall at all times be valued at its fair market value without regard to restrictions. If not specified by the committee, the period of restriction shall elapse in accordance with the same vesting schedule as options and SARs.

The committee may legend the restricted stock certificates with such restrictions as it determines, provided that each certificate must bear a legend stating that the sale or other transfer of the shares of restricted stock is subject to the BioDrain Medical, Inc. 2008 Equity Incentive Plan and the related restricted stock agreement. Shares of restricted stock shall become freely transferable by the grantee after the last day of the period of restriction and once released from restrictions, the grantee shall be entitled to have the legend removed. Under no other conditions may the restricted stock granted be sold, transferred, pledged, assigned or otherwise alienated or hypothecated until the termination of the period of restriction.

During the period of restriction, grantees holding shares of restricted stock may exercise full voting rights with respect to those shares and shall be entitled to receive all dividends and distributions paid with respect to those shares. In the case of termination of a grantee due to death or disability during a period of restriction, any remaining period of the period of restriction applicable to the restricted stock shall automatically terminate and unless the committee imposed additional restrictions on the shares, the shares shall thereafter be free of restrictions and be fully transferable. In the case of termination of a grantee other than by death or disability during a period of restriction, all shares of restricted stock still subject to restrictions as of the date of the termination shall automatically be forfeited and returned to the Company and any amounts paid by the grantee to the Company for the purchase of such shares shall be returned to the grantee, subject to any modifications or waivers as the committee deems appropriate.

#### **Other Securities For Issuance Upon Certain Contingencies**

Please refer to the Management's Discussion and Analysis of Financial Condition and Result of Operations Section on page 32 for a discussion of other securities for issuance upon certain contingencies.

### **Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes to those statements included elsewhere in this prospectus. In addition to the historical financial information, the following discussion and analysis contains forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under "Risk Factors" and elsewhere in this prospectus.*

#### **Overview**

Our Company was incorporated in Minnesota in April 2002. We are an early-stage development company developing an environmentally conscientious system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. We achieved our first sale in June 2009. Since our inception in 2002, we have invested significant resources into product development and in preparing for approval from the FDA. We believe that our success depends upon converting the traditional process of collecting and disposing of infectious fluids from the operating rooms of medical facilities to our wall-hung Fluid Management System ("FMS") and use of our proprietary cleaning fluid.

Since inception, we have been unprofitable. We incurred net losses of approximately \$1,763,000 for the fiscal year ended 2008, approximately \$752,000 for the fiscal year ended 2007 and a net loss of approximately \$1,742,000 for the six months ended June 30, 2009. As of June 30, 2009, we had an accumulated deficit of approximately \$4,880,000. As a company in the early stage of development, our limited history of operations makes prediction of future operating results difficult. We believe that period to period comparisons of our operating results should not be relied on as predictive of our future results.

We are an early-stage development stage company and we have been focused on finalizing our production and obtaining final FDA clearance to sell our product to the medical facilities market. FDA final clearance was obtained on April 1, 2009. Our innovative FMS will be sold through experienced, independent medical distributors and manufacturers representatives that are intended to enhance acceptability in the marketplace. We are currently in the process of signing agreements with independent sales representative and product installation organizations and conducting training sessions. We achieved our first billable shipment in June 2009 and are hopeful to receive several orders during the second half of 2009. Since our FDA clearance to sell our FMS product was only received on April 1, 2009 it is too early to know with a high degree of confidence how quickly, and in what amounts, new orders will develop.

Since we do not expect to generate sufficient revenues in 2009 to fund our capital requirements, our capital needs for the next 12 months are expected to be approximately \$3 million even though we plan to use outside third party contract manufacturers to produce the FMS and independent sales representatives to sell the FMS. Our future cash requirements and the adequacy of available funds will depend on our ability to sell our FMS and related products now that FDA final clearance has been obtained. We expect that we will require additional funding to finance operating expenses and to enter the international marketplace.

As of December 31, 2008, we have funded our operations through a bank loan of \$41,400, an equity investment of \$68,000 from the Wisconsin Rural Enterprise Fund (“WREF”) and \$30,000 in early equity investment from several individuals. WREF had also previously held debt in the form of three loans of \$18,000, \$12,500 and \$25,000. In December 2006, WREF converted two of the loans totaling \$37,500 into 43,000 shares of common stock. In August 2006, we secured a \$10,000 convertible loan from one of our vendors. In February 2007, we obtained \$4,000 in officer and director loans and in March 2007, we arranged a \$100,000 convertible note from two private investors. In July 2007, we obtained a convertible bridge loan of \$170,000. In June 2008, we paid off the remaining \$18,000 loan from WREF and have raised approximately \$1.6 million through our October 2008 financing. During April, May, June and August 2009 we raised an additional \$525,000 in a private placement of 1,050,000 stock units at \$.50 per unit, including one share of stock and a warrant to purchase one share of stock at \$.65 per share.

## **Critical Accounting Policies and Estimates and Recent Accounting Developments**

### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations are based upon our audited Financial Statements, which have been prepared in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”). The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of our financial statements, the reported amounts of revenues and expenses during the reporting periods presented, as well as our disclosures of contingent assets and liabilities. On an on-going basis, we evaluate our estimates and assumptions, including, but not limited to, fair value of stock-based compensation, fair value of acquired intangible assets and goodwill, useful lives of intangible assets and property and equipment, income taxes, and contingencies and litigation.

We base our estimates and assumptions on our historical experience and on various other information available to us at the time that these estimates and assumptions are made. We believe that these estimates and assumptions are reasonable under the circumstances and form the basis for our making judgments about the carrying values of our assets and liabilities that are not readily apparent from other sources. Actual results and outcomes could differ from our estimates.

Our significant accounting policies are described in Note 1 *Summary of Significant Accounting Policies*, in Notes to Financial Statements of this Form S-1. We believe that the following discussion addresses our critical accounting policies and reflect those areas that require more significant judgments, and use of estimates and assumptions in the preparation of our Financial Statements.

**Revenue Recognition** We recognize revenue in accordance with the SEC’s Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by Staff Accounting Bulletin No. 104 (together, SAB 101), and Statement of Financial Accounting Standards No. 48, *Revenue Recognition When Right of Return Exists* (SFAS 48).

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable and collectibility is probable. Delivery is considered to have occurred upon either shipment of the product or arrival at its destination based on the shipping terms of the transaction. Our standard terms specify that shipment is FOB BioDrain and we will, therefore recognize revenue upon shipment in most cases. This revenue recognition policy applies to shipments of our FMS units as well as shipments of cleaning solution kits. When these conditions are satisfied, we recognize gross product revenue, which is the price we charge generally to our customers for a particular product. Under our standard terms and conditions there is no provision for installation or acceptance of the product to take place prior to the obligation of the customer. The Customer’s right of return is limited only to our standard one year warranty whereby we replace or repair, at our option, and it would be very rare that the unit or significant quantities of cleaning solution kits may be returned. Additionally, since we buy both the FMS units and cleaning solution kits from “turnkey” suppliers we would have the right to replacements from the suppliers if this situation should occur.

**Stock-Based Compensation.** Effective January 1, 2006, we adopted SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)) which replaced SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123) and superseded Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25). Under SFAS 123(R), stock-based employee compensation cost is recognized using the fair value based method for all new awards granted after January 1, 2006 and unvested awards outstanding at January 1, 2006. Compensation costs for unvested stock options and non-vested awards that were outstanding at January 1, 2006, are being recognized over the requisite service period based on the grant-date fair value of those options and awards as previously calculated under SFAS 123 for pro forma disclosures, using a straight-line method. We elected the modified-prospective method in adopting SFAS 123(R), under which prior periods are not retroactively restated.

SFAS 123(R) requires companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. We use the Black-Scholes-Merton option-pricing model which requires the input of significant assumptions including an estimate of the average period of time employees and directors will retain vested stock options before exercising them, the estimated volatility of our common stock price over the expected term, the number of options that will ultimately be forfeited before completing vesting requirements and the risk-free interest rate.

Because we do not have historical trading data on our stock we relied upon trading data from a composite of 10 medical companies traded on major exchanges and 15 medical companies traded on the OTCBB to help us arrive at expectations as to volatility of our own stock when public trading commences. Likewise, we have no history of option and warrant exercises because there is no liquidity in our stock as a private company and we were required to make a significant judgment as to expected option and warrant exercise patterns in the future regarding employee and director options and warrants. In the case of options and warrants issued to consultants and investors we used the legal term of the option/warrant as the estimated term unless there was a compelling reason to use a shorter term. The measurement date for employee and non-employee options and warrants is the grant date of the option or warrant. The vesting period for options that contain service conditions is based upon management's best estimate as to when the applicable service condition will be achieved. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognized. The assumptions we use in calculating the fair value of stock-based payment awards represent our best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our equity-based compensation expense could be materially different in the future. See Note 3, *Stock-Based Compensation*, in Notes to Financial Statements of this Form S-1 for additional information.

When an option or warrant is granted in place of cash compensation for services we deem the value of the service rendered to be the value of the option or warrant. In most cases, however, an option or warrant is granted in addition to other forms of compensation and its separate value is difficult to determine without utilizing an option pricing model. For that reason we also use the Black-Scholes-Merton option-pricing model to value options and warrants granted to non-employees, which requires the input of significant assumptions including an estimate of the average period that investors or consultants will retain vested stock options and warrants before exercising them, the estimated volatility of our common stock price over the expected term, the number of options and warrants that will ultimately be forfeited before completing vesting requirements and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognized that. Since we have no trading history in our stock and no first-hand experience with how these investors and consultants have acted in similar circumstances, the assumptions we use in calculating the fair value of stock-based payment awards represent our best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our equity-based consulting and interest expense could be materially different in the future.



Since our company stock has no public trading history we were required to take an alternative approach to estimating future volatility and the future results could vary significantly from our estimates. We compiled historical volatilities over a period of 2-7 years of 15 small-cap medical companies traded on major exchanges and 10 medical companies in the middle of the market cap size range on the OTC Bulletin Board and combined the results using a weighted average approach. In the case of standard options to employees we determined the expected life to be the midpoint between the vesting term and the legal term. In the case of options or warrants granted to non-employees we estimated the life to be the legal term unless there was a compelling reason to make it shorter.

**Valuation of Intangible Assets** We review identifiable intangible assets for impairment in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144), whenever events or changes in circumstances indicate the carrying amount may not be recoverable. Our intangible assets are currently solely the costs of obtaining trademarks and patents. Events or changes in circumstances that indicate the carrying amount may not be recoverable include, but are not limited to, a significant change in the medical device marketplace and a significant adverse change in the business climate in which we operate. If such events or changes in circumstances are present, the undiscounted cash flows method is used to determine whether the intangible asset is impaired. Cash flows would include the estimated terminal value of the asset and exclude any interest charges. If the carrying value of the asset exceeds the undiscounted cash flows over the estimated remaining life of the asset, the asset is considered impaired, and the impairment is measured by reducing the carrying value of the asset to its fair value using the discounted cash flows method. The discount rate utilized is based on management's best estimate of the related risks and return at the time the impairment assessment is made

Our accounting estimates and assumptions bear various risks of change, including the length of the current recession facing the United States, the expansion of the slowdown in consumer spending in the U.S. medical markets despite the early expressed opinions of financial experts that the medical market would not be as affected as other markets and failure to gain acceptance in the medical market.

### Recent Accounting Developments

In June 2008, the Financial Accounting Standards Board ("FASB") ratified Emerging Issues Task Force (EITF) Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* (EITF 07-5). EITF-07-5 mandates a two-step process for evaluating whether an equity-linked financial instrument or embedded feature is indexed to the entity's own stock. It is effective for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years, which is our first quarter of 2009. Most of the warrants issued by the Company contain a strike price adjustment feature which upon adoption of EITF-07-5 changed the classification (from equity to liability) and the related accounting for many warrants with an estimated fair value of \$479,910 as of December 31, 2008. As of January 1, 2009 the Company removed \$486,564 from paid-in-capital (representing the combined fair values of the warrants on their date of grant), recorded a positive adjustment to accumulated deficit representing the gain on the valuation of the warrants from the grant dates to January 1, 2009, and established a liability for equity-linked instruments in the net amount of \$479,910. The Company also re-computed the value of the warrants as of March 31, 2009 and June 30, 2009 and recorded a loss of \$496,502 in the first quarter and a loss of \$436,423 in the six-month period ended June 30, 2009 as a result of the increase in the valuation of the liability. See Note 12 to the Financial Statements.

In May 2008, the FASB issued FSB APB No. 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ("FSB APB No. 14-1"), to clarify that convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) are not addressed by paragraph 12 of APB Opinion No. 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants*. The FSP requires the issuer of certain convertible securities that may be settled in cash on conversion to separately account for the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. The Company's convertible debt instruments do not provide that the instruments may be settled in cash and this FSP does not apply.

## Results of Operations

### Twelve Months Ended December 31, 2008 and 2007

*Revenue.* None.

*General and Administrative expense.* General and administrative expense consists of, management salaries, professional fees, consulting fees, travel expense, administrative fees and general office expenses.

General and administrative expense increased to \$1,316,000 for the year ended December 31, 2008 from \$637,000 for the year ended December 31, 2007. General and administrative expense increased primarily due to an increase of \$120,000 in stock based compensation expense, a \$234,000 increase in legal fees and a \$336,000 increase in consulting fees including stock based consulting. The increase in stock based compensation expense resulted from a significant increase the number of stock options that were granted in 2008 and expensed in accordance with SFAS 123 R. Legal fees increased primarily due to expenses related to the preparation and filing of our Form S-1 and amendments as well as general corporate legal expense in connection with issuance of stock certificates and warrants, creation of the 2008 Equity Incentive Plan and other general corporate legal work. Consulting fees, including stock based consulting expense, increased primarily in connection with our preparation for making application for FDA clearance to sell our FMS unit. We anticipate that general and administrative expense will increase in absolute dollars in 2009 as we incur increased costs associated with a growing company, of adding personnel, paying market rate salaries, proceeding from the development phase to the operating phase, and operating as a public company.

*Operations expense.* Operations expense primarily consists of expenses related to product development and prototyping and testing in the company's current stage.

Operations expense, including product development expense, increased to \$321,000 in the year ended December 31, 2008 compared to \$1,400 in the year ended December 31, 2007 as the Company aggressively worked on developing the FMS for FDA clearance and commercial sale in 2009. Salaries and stock based compensation grew to \$131,000 in 2008 compared to no expense in 2007 and product development expense grew to \$183,000 in 2008 compared to \$1,400 in 2007.

*Sales and Marketing expense.* Sales and marketing expense consists of expenses required to sell products through independent reps, attendance at trades shows, product literature and other sales and marketing activities.

Sales and marketing expenses grew to \$36,000 in the year ended December 31, 2008 compared to \$13,000 in the year ended December 31, 2007 as a result of an increase of \$25,000 in salaries and stock based compensation offset, in part, by a reduction of \$4,500 in business meeting expense. On February 1, 2009 the Company also hired a Vice President of Sales and Marketing and began purchasing marketing literature and attending trade shows in anticipation of receiving clearance from the FDA, which the Company received on April 1, 2009, to begin commercial sale of the Streamway™ Fluid Management System. Consequently, the Company expects sales and marketing expenses in 2009 to exceed, by a significant amount, the expenses incurred in 2008.

*Interest expense.* Interest expense decreased to \$89,000 in the year ended December 31, 2008 from \$101,000 in the year ended December 31, 2007 primarily due to a reduction in the amortization of debt discount as additional interest, using the interest method of amortization related to the value assigned to the warrants issued in connection with debt incurred in 2007.

### Six months ended June 30, 2009 and 2008

*Revenue.* The Company recorded revenue of \$15,737 during the six-month period ended June 30, 2009 compared to \$0 in the six-month period ended June 30, 2008 as the Company received its first order for 4 FMS units and a case of cleaning solution kits from a hospital in Texas and shipped the first FMS unit and the cleaning solution kits in June 2009. The revenue was approximately \$14,000 for the FMS unit, approximately \$1,000 for the cleaning solution kits and \$750 for installation. The remaining 3 FMS units and additional cleaning solution kits are expected to be shipped during the third and fourth quarters of 2009.

*Cost of sales.* Cost of sales was \$7,450 for the six months ended June 30, 2009 and \$0 for the six months ended June 30, 2008 as there were no sales in the 2008 period. The gross profit margin was approximately 53% for both the hardware and the cleaning solution kits in the six months ended June 30, 2009 but should increase over time as volume purchasing discounts on both the equipment and the cleaning solution begin to take effect.

*General and Administrative expense* . General and administrative expense primarily consists of, management salaries, professional fees, consulting fees, travel expense, administrative fees and general office expenses.

General and Administrative (G&A) expenses increased to \$872,000 in the six months ended June 30, 2009 from \$409,000 in the six months ended June 30, 2008 primarily due to an accrual of \$318,700 for a registration payment arrangement, a \$60,000 increase in legal and audit fees, a \$12,000 increase in board of director fees, an \$18,000 increase in rent and utilities and a \$221,000 increase in consulting fees. This was offset, in part, by a \$90,000 decrease in salaries and a \$221,000 decrease in stock based compensation expense. The increase in legal and audit fees was primarily related to accounting and legal work in connection with amendments to the Form S-1. The increase in consulting fees was primarily related to finalization of the application for FDA clearance and consulting work related to the Form S-1 amendments and general corporate work. Salaries declined as a result of the departure of our former Chief Financial Officer and former Chief Executive Officer. The decrease in stock-based compensation expense was due to significant stock option grants in 2008 compared to relatively few in the 2009 period. Total G&A expenses are expected to increase due to increased insurance premiums and audit fees, resulting from becoming a public company, but otherwise remain relatively constant, except for the registration payment expense incurred in June 2009, over the next several quarters.

*Operations expense*. *Operations expense primarily consists of expenses related to product development and prototyping and testing in the company's current stage.*

Operations expense increased to \$195,000 in the six months ended June 30, 2009 from \$91,000 in the six months ended June 30, 2008 due to a \$69,000 increase in salaries, a \$32,000 increase in consulting expense and a \$40,000 increase in testing expense offset, in part, by a reduction of \$64,000 in product development expense. The increase in salaries is the result of hiring an Executive Vice President of Operations (promoted to Chief Operating Officer in 2009) in June, 2008. The increases in consulting expense and testing expense were directly related to finalizing the product design and preparing for the application to the FDA for 510k clearance. Consulting and testing expenses are expected to decline in the next several quarters but other expenses related to ramping up production, establishing a shipping and receiving function and other expenses necessary to support sales growth will likely more than offset the decreases in consulting and testing.

*Sales and Marketing expense*. *Sales and marketing expense consists of expenses required to sell products through independent reps, attendance at trades shows, product literature and other sales and marketing activities.*

Sales and marketing expenses increased to \$209,000 in the six months ended June 30, 2009 compared to \$0 in the six months ended June 30, 2008 primarily due to a \$93,000 increase in salaries and benefits, an \$16,000 increase in stock based compensation, a \$58,000 increase in trade show expense and marketing supplies, a \$14,000 increase in travel expenses and a \$17,000 increase in web development, promotion and consulting. Sales and marketing expense is expected to grow significantly in the next several quarters as we ramp up our sales and marketing activities to establish our products in the marketplace and we commence the payment of commissions to independent sales reps.

*Interest expense* .

Interest expense, including loss on revaluation of warrants, increased to \$476,000 in the six months ended June 30, 2009 from \$7,000 in the six months ended June 30, 2008. The increase in expense was primarily due to the \$436,000 loss on valuation of equity-linked instruments (increase in the liability) resulting from adoption of EITF 07-5 in January 2009. The valuation of the warrants liability is likely to continue to increase over the next several quarters as EITF 07-5 requires a revaluation of the liability on every balance sheet date and, provided the market value of the underlying stock continues to increase, the Black-Scholes valuation formula will produce a higher valuation until such time that the warrants are either exercised or expire.

## **Liquidity and Capital Resources**

We had a cash balance of \$463,838 as of December 31, 2008 and \$235,227 as of June 30, 2009. Since our inception, we have incurred significant losses. As of December 31, 2008 we had an accumulated deficit of \$3,144,000, and as of June 30, 2009 our accumulated deficit was \$4,880,000. We have not achieved profitability and anticipate that we will continue to incur net losses for the foreseeable future. We expect that our operations expense, including product development expense, sales and marketing and general and administrative expenses will increase, and as a result we will need to generate significant revenue to achieve profitability.

The table below summarizes our currently known capital requirements and amounts needed to satisfy our outstanding obligations. The following amounts do not include the outstanding balances on our long term debt, long term convertible debt, current portions of long term debt and current portions of convertible debt and convertible debenture. Those amounts are shown on page 27 and may not be payable in cash because it is the intention of the parties, except for the bank, to convert their debt into common stock upon commencement of trading on the OTCBB.

### Capital Requirements

Expense Item	Amount	Total
Expected expenses in connection with our current offering		225,200
SEC registration fee	200	
Printing fees	30,000	
Legal fees and expenses	80,000	
Accounting fees and expenses	60,000	
Miscellaneous	55,000	
Financing fees owed in connection with our current offering (1)		0
Accounts payable:		640,000
Marshall C. Ryan	100,000	
Richardson & Patel LLP	200,000	
Complete Automation	25,000	
TriVirix	22,000	
Evergreen Medical	20,000	
Olsen Thielen, CPAs	35,000	
Larkin Hoffman	87,000	
Various accounts payable	121,000	
Andcor Companies, Inc.	50,000	
Sales, marketing, administrative, operations and other operating expenses		1,200,000
Market expansion to Europe and Pacific Rim		500,000
Personnel additions		200,000
Miscellaneous		100,000
<b>Total</b>		<b>\$ 2,885,200</b>

(1) All fees were withheld by the broker of our current offering.

There is no certainty that access to needed capital will be successful. We have not depended on the future exercise of outstanding warrants to provide additional funding.

To date, our operations have been funded through a bank loan in the original amount of \$41,400, private party loans totaling \$10,000, convertible debt in the amounts of \$170,000 and \$100,000 and equity investments totaling approximately \$2,177,000. As of December 31, 2008, we had accounts payable of \$497,029 and accrued liabilities of \$93,339, and as of June 30, 2009 we had accounts payable of \$649,445 and accrued liabilities of \$593,343.

### **Years Ended December 31, 2008 and 2007**

Net cash used in operating activities was \$901,000 for 2008 as compared with net cash used of \$225,000 for 2007. The increased use of cash was due primarily to an increase in net loss to \$1,763,000 offset, in part, by an increase of \$290,000 in accounts payable and the net loss including \$394,000 in stock based compensation and consulting fees and amortization of debt discount that did not consume cash.

Cash flows used in investing activities was \$42,000 for 2008 as compared to cash used in investing activities of \$46,000 for 2007. The amount in both years primarily represented investments in intellectual property and also included \$12,258 in purchases of furniture in 2008.

Net cash provided by financing activities was \$1,402,000 for 2008 as compared to net cash provided by financing activities of \$273,000 for 2007. The increase in 2008 was primarily the result of selling approximately \$1.6 million in stock in 2008, offset by a \$28,125 reduction in debt.

### **Six months ended June 30, 2009 and 2008**

Net cash used in operating activities was \$707,000 in the six months ended June 30, 2009 compared to \$410,000 net cash used in operating activities in the six months ended June, 2008. The additional cash used in the 2009 period was primarily due to the \$1,742,000 loss compared to a loss of \$508,000 in the 2008 period offset, in part, by the \$497,000 in loss on valuation of equity-linked instruments and \$82,000 in stock based compensation and consulting fees that did not consume cash. Additionally, accounts payable increased by \$152,000 in the 2009 period compared to \$44,000 in the 2008 period and accrued expenses increased by \$288,000 in the 2009 period compared to \$64,000 in 2008.

Net cash used in investing activities was \$0 in the 2009 period compared to \$6,000 used in the 2008 period. The company will likely increase its cash used in investing activities in the next several quarters as we prepare to support the expected growth in sales.

Net cash provided by financing activities was \$478,000 in the 2009 period compared to \$761,000 in the 2008 period. The Company expects to show cash provided by financing activities in the next few quarters as we raised \$525,000 in April, May, June and August 2009 and plan to raise up to \$3 million by December 31, 2009.

Based on our current operating plan we believe that we have sufficient cash, cash equivalents and short-term investment balances to last approximately through the third quarter of 2009, during which time an additional financing of \$3 million is anticipated. The Company expects the transaction, if successful, to close by December 31, 2009 with an early closing of up to \$500,000 by September 30, 2009. While holders of our warrants could exercise and provide cash to us during that time frame, we are not depending on that in our fund raising efforts.

Management hired Newbridge Securities Corporation, an investment banker, in February 2009, to raise an additional \$3-\$5 million in new equity by December 31, 2009 with an interim closing of up to \$500,000 expected by September 30, 2009. Although our ability to raise this new capital is in substantial doubt we have received \$525,000 as of August 31, 2009 and our April 1, 2009 510(k) clearance from the FDA to authorize us to market and sell our FMS products is being received very positively. If the Company is successful in raising at least \$3 million in new equity we will have sufficient capital to operate our business and execute our business plan for at least the next 12 months. If the Company raises the additional capital by issuing additional equity securities its shareholders could experience substantial dilution.

The funds remaining from our October 2008 offering have allowed us to complete the testing and certification of our FMS unit and have now submitted our application and received, on April 1, 2009, final FDA clearance. We are confident that our existing funds will also be sufficient to pay for normal operating expenses as we await additional funding. We have doubts about raising capital because of our early stage position and history of losses. We also note the recent economic downturn which has made the overall market nervous about investing.

Items such as delinquent convertible debt, totaling \$170,000, would be difficult to fully satisfy with the remaining proceeds of the past financings. We have been in contact with the holders of these convertible notes. These holders, while legally able to demand payments, have been willing to work with us regarding the satisfaction of their convertible debts, which could be either from conversion to our common stock or through repayment of the debt from funds raised in future financings. This note will automatically convert to 620,095 common shares upon the effective date of this registration statement. Any formal payment demand by these convertible note holders prior to our securing additional financing would create a severe liquidity issue for the Company. Such note holders could bring a cause of action against the Company to compel repayment of the debt obligations which could deplete the Company's cash position. Because these note holders hold a secured interest in all our assets, they could seize our assets in such cause of action.

Certain amounts of payroll for three current and former officers were unpaid as of June 2008 and the individuals agreed to accept a reduction in the cash to ultimately be paid in exchange for future cash payments and new stock options. The individuals have agreed to be paid at such time as the Company obtains at least another \$3 million of additional equity financing, with the exception of Lawrence Gadbaw, our Chairman, who began receiving \$2,000 per month in October 2008 in repayment of his \$46,000 accrued salary liability in addition to a future cash payment of \$25,000 contingent on raising \$3 million. After another \$3 million of additional financing has been obtained, the amount of accrued expense items due to management and a board member that will be paid from the proceeds of such financing including the balance remaining, if any, under Mr. Gadbaw's payment arrangement.

We believe that we have sufficient funds to satisfy our obligations through the third quarter of 2009. We will need additional funds to continue to satisfy such obligations beyond that time period.

Our operating plan assumes that we will achieve certain levels of operating costs and expenses, as to which there can be no assurance that we will be able to achieve. This plan is completely dependent on our ability to raise additional capital through future financings. In addition, if events or circumstances occur such that we are unable to meet our operating plan as expected, we will be required to seek additional capital, pursue other strategic opportunities, or we will be forced to reduce the level of expenditures, which could have a material adverse effect on our ability to achieve our intended business objectives and to continue as a going concern. Even if we achieve our operating plan, we will be required to seek additional financing or strategic investments.

The current economic turmoil has a significant impact on the overall funding environment, and we cannot assure you that our opportunity will be positively received by potential investors. We are not planning on any significant capital or equipment investments and we will only have a few human resource additions over the next 12 months. A significant amount of funds will be utilized to launch our product into the market. With the expenses associated with FDA clearance having already been incurred, and with the product development primarily complete, future funds, if any, will be used primarily to launch our product into the market.

There can be no assurance that any additional financing will be available on acceptable terms, or at all. Furthermore, any equity financing likely will result in dilution to existing shareholders and any debt financing likely will include restrictive covenants.

We expect to continue to depend upon outside financing to sustain our operations for at least the next 12 months. Our ability to arrange financing from third parties will depend upon our operating performance and market conditions. Our inability to raise additional working capital at all or to raise it in a timely manner would negatively impact our ability to fund our operations, to generate revenues, and to otherwise execute our business plan, leading to the reduction or suspension of our operations and ultimately forcing us to go out of business. Should this occur, the value of any investment in our securities could be adversely affected, and an investor could lose a portion of or even lose their entire investment.

## Commitments and Contingencies

Effective December 31, 2008, we had notes payable, loans and debentures to several individuals and entities, including a bank loan of \$38,180; \$10,000 due to Andcor in connection with a convertible loan; \$4,000 of officer and director loans; \$100,000 due to two private investors in connection with a convertible note; and \$170,000 of a convertible bridge loan with seven individuals.

The Company has a convertible debenture with Andcor Companies, Inc. ("Andcor") of \$10,000 with interest at 10.25% that matured in 2007. The debenture is convertible to shares of the Company's common stock at the lower of \$0.90 per share or the price per share at any equity financing is completed (currently re-set to \$.35 per share). The convertible debenture has not yet been paid, and it is currently in default. While Andcor could demand payment on this note at any time, they have verbally expressed an interest in working with us to wait until additional funds are secured by the Company. Further, Andcor has left open the possibility of converting the note into shares of the Company's common stock, which would require no cash outlay.

Our contractual obligations consisted of the following as of December 31, 2008.

	<b>Payment Due by Period as of December 31</b>				
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>After 5 Years</b>
Long Term Debt	\$ 322,183	\$ 197,620	\$ 24,563	\$ 100,000	—
Operating Leases	150,000	35,000	59,000	56,000	—
Capital Leases	—	—	—	—	—
Total Contractual Cash Obligations	\$ 472,183	\$ 232,620	\$ 83,563	\$ 156,000	—

Long-term debt is as follows:

	<b>December 31,</b>		<b>June 30,</b>
	<b>2008</b>	<b>2007</b>	<b>2009 (Unaudited)</b>
Notes payable to seven individuals due April 2008 including 8% fixed interest and are now delinquent. The 2007 balance is shown net of a \$30,899 debt discount based upon the Black-Scholes valuation assigned to the warrants issued in connection with the debt. The notes are convertible into 620,095 shares of the Company's common stock and automatically convert at the effective date of this registration statement.	\$ 170,000	\$ 139,101	\$ 170,000
Note payable to bank in monthly installments of \$1,275/including variable interest at 2% above the prevailing prime rate (3.25% at December 31, 2008) to August 2011 when the remaining balance is payable. The note is personally guaranteed by former executives of the Company.	38,183	48,308	31,486
Note payable to NWBDC with interest only payments at 8% to December 2008 when the remaining balance is payable. The note was personally guaranteed by former executives of the Company. The note was paid in full on June 24, 2008.	—	18,000	—
Notes payable to two individuals, net of discounts of \$26,157, \$34,205 and \$21,631 with interest only payments at 12% to March 2012 when the remaining balance is payable. The notes are convertible into 285,715 shares of stock in the Company at \$.35 per share.	73,843	65,794	78,369
Notes payable to four shareholders of the Company that are overdue. The notes are convertible into 11,429 shares of stock in the Company at \$.35 per share.	4,000	4,000	4,000
Total	286,026	275,203	283,855
Less amount due within one year	187,620	172,901	187,620
Long-Term Debt	<u>\$ 98,406</u>	<u>\$ 102,302</u>	<u>\$ 96,235</u>

Cash payments for interest were \$5,175 for the year ended December 31, 2008 and \$5,071 for 2007 and \$950 for the six months ended June 30, 2009. The notes payable of \$10,000 (discussed in Note 6 to the financial statements), \$170,000 and \$4,000 (shown in the table above) are delinquent and could be called by the holders, putting additional strains on our liquidity. The note for \$170,000 contains provisions for a one-time penalty of \$25,000 if this registration statement is not filed within 120 days of August 31, 2008 and \$5,000 per 30 day period, after February 27, 2009, until the registration statement is declared effective by the SEC. The total amount accrued as additional interest expense at June 30, 2009 is \$20,500. There is no maximum penalty. In addition, beginning March 2009 the Company is obligated to issue additional shares to the investors who purchased units in October 2008 financing equal to 2% of the units sold for each month until the registration is declared effective. This represents 91,057 shares per month to a maximum of 728,458 shares, or 16% of the total units sold. At June 30, 2009 the Company estimates that its ultimate obligation will be to issue 637,401 shares with a value of \$318,701 at \$.50 per share. Payment of the accrued interest and penalties will occur upon receipt of a significant portion of the \$3 million funding subsequent to our listing on the OTC Bulletin Board and issuance of the additional shares will occur within 30 days of the earlier of the effective registration of our shares or October 31, 2009 when the maximum is reached.

In July 2007, we entered into a restructuring agreement, in connection with our October 2008 financing, whereby in the event that we failed to obtain FDA clearance by the end of August 2009, the majority-in-interest of investors (“the Investors”) through our October 2008 offering would have the right to cause the Company to make significant restructuring changes. The Company received final FDA clearance on April 1, 2009 and such restructuring will be avoided.

In 2007, Mr. Davidson, Mr. Gadbaw and Mr. Rice each received less in base salary than they were entitled to under their employment agreements due to lack of funds. In December 2007, the Company reduced accrued payroll liabilities by a total of \$346,714. This total included waived compensation from Mr. Davidson in the amount of \$90,000, waived compensation from Mr. Rice in the amount of \$125,000 and waived compensation from Mr. Gadbaw in the amount of \$138,500. In addition, Mr. Davidson waived \$58,350, Mr. Rice waived \$40,725 and Mr. Gadbaw waived \$30,610 in underpaid compensation from 2008. In exchange, per an agreement in June 2008, Mr. Davidson will be granted a one-time cash payment of \$23,000 as well as an option to purchase 80,000 shares of common stock at \$.35 per share and Mr. Rice will be granted a one-time cash payment of \$46,000 as well as an option to purchase 160,000 shares of common stock at \$.35 per share when the Company raises an additional \$3 million of funding subsequent to the financing completed in October 2008. Mr. Gadbaw will be granted a one-time cash payment of \$25,000 and an option to purchase 160,000 shares of common stock at \$.35 per share upon the Company raising an additional \$3 million and is currently receiving \$2,000 per month until a total of \$46,000 of accrued salary liability is paid. The balance remaining, if any, of the amount due Mr. Gadbaw will also be paid upon the Company raising an additional \$3 million. The Company’s agreement to pay the cash payments and grant the stock options is solely dependent on raising the \$3 million and does not require the participation of the three individuals in the fund raising activity.

Waived salaries in the amount of \$90,000 for Mr. Davidson, \$125,000 for Mr. Rice and \$138,500 for Mr. Gadbaw were treated as a capital contribution in 2007 in accordance with Staff Accounting Bulletin (SAB) 79. The years to which the waived salaries originated were \$102,700 for 2007 and \$244,000 for 2006 and prior years. In addition, the company recorded a capital contribution in the amount of \$129,685 in 2008 representing \$58,350, \$40,375 and \$30,610 in waived 2008 salaries for Mr. Davidson, Mr. Rice and Mr. Gadbaw, respectively.

The obligation to grant stock options is being valued under FAS123(R) using the Black-Scholes valuation model, 55-59% expected volatility, a zero percent dividend rate and an expected life of 3.5 years for two options and 5 years for the other option, taking into account the likely period of time the individuals will exercise their options. The legal term of the options will be 5 years from the date of the grant and 6 years, therefore, from the date of the obligation because the obligation to grant the options contingent on a \$3 million funding occurred in June 2008 and we estimated the \$3 million funding will occur by July 2009.

As of December 31, 2007, \$115,000 remained in accrued expenses for the above expenses and as of December 31, 2008 \$40,000 remained in accounts payable for the obligation to Mr. Gadbaw’s and \$94,000 remained in accrued expenses for the obligations to Mr. Rice, Mr. Gadbaw and Mr. Davidson.



## Amortization of Intangible Assets

Intangible assets currently consist solely of patent costs. These assets are not subject to amortization until the property patented is in production. The assets are reviewed for impairment annually, and impairment losses, if any, are charged to operations when identified. No impairment losses have been identified by management to date.

## Income Tax Expense

The Company provides for deferred taxes using the asset and liability approach. Under this method, deferred tax assets and liabilities are recognized for future tax consequences attributable to operating loss and tax credit carry-forwards, as well as differences between the carrying amounts of existing assets and liabilities and their respective tax bases. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The major temporary differences are net operating losses. Due to historical losses on the accrual basis, the related tax assets are not recorded in our financial statements.

## Stock Options and Warrants

Our 2008 Equity Incentive Plan allows for the issuance of incentive and non-qualified stock options and other forms of stock-based compensation to our employees, directors and consultants, subject to the restrictions provided in the plan. The exercise price for each stock option is determined by our board of directors, or a committee designated by our board of directors, as are the vesting requirements, which currently range from immediate to three years. Options granted have terms varying from three to ten years.

Effective January 1, 2006, the Company adopted the requirements of SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)). As specified in SFAS 123R, we value stock option awards using the "grant date fair value" method and expense them on a straight-line basis over the service period, generally the vesting period. We opted for early adoption of the provisions of SFAS 123R. The provisions of SFAS 123R are applicable to stock options awarded beginning in 2005 and we are recognizing compensation expense for options granted in 2005 and thereafter. Options and warrants granted to consultants for services rendered are similarly valued and expensed under SFAS 123 and other guidance.

We have elected to value the options and warrants using the Black-Scholes-Merton option valuation model. The fair value of these options was calculated using a risk-free interest rate of 1.2% to 4.00%, an expected life of 2 to 7.5 years, an expected volatility ranging from 53-66% and a dividend rate of 0%. Stock based compensation and consulting expenses recognized in our financial statements was \$355,000 and \$74,000 for the years ended 2008 and 2007, respectively.

A summary of stock option and warrant activity for the years ended December 31, 2008 and 2007 is presented below:

	Stock Options (1)		Warrants (1)	
	Number of Shares	Average Exercise Price	Number of Shares	Average Exercise Price
Outstanding at December 31, 2005	17,956	\$ 1.67	20,950	\$ 2.62
Issued	23,942	1.67	71,826	0.85
Outstanding at December 31, 2006	41,898	\$ 1.67	92,776	\$ 1.25
Issued	5,985	1.67	28,502	0.35
Outstanding at December 31, 2007	47,882	\$ 1.67	121,278	\$ 1.04
Issued	1,243,293	0.20	5,075,204	0.45
Expired			(11,971)	3.76
Outstanding at December 31, 2008	1,291,174	\$ 0.26	5,184,511	0.45

(1) Adjusted for the reverse stock splits in total at June 6, 2008 and October 20, 2008, of 1-for-1.670705.

At December, 2008, 651,174 stock options were fully vested and exercisable and 5,606,606 warrants were fully vested and exercisable. At December 31, 2007, 23,942 stock options were fully vested and exercisable and 121,278 warrants were fully vested and exercisable. At June 30, 2009 881,174 options and 6,639,606 warrants were fully vested and exercisable.

A summary of the status of options and warrants outstanding at December 31, 2007, December 31, 2008 and June 30, 2009 is presented below:

Range of Exercise Prices	Shares	Weighted Average Remaining Life
<b>At December 31, 2007:</b>		
Options:		
\$0.35	11,970	4.37
\$1.67	41,898	3.31
Warrants:		
\$0.02	35,913	5.45
\$0.35	28,502	4.17
\$1.67	44,892	3.69
\$3.34	11,971	0.79
<b>At December 31, 2008:</b>		
Options:		
\$0.01	543,292	9.43
\$0.35	700,000	4.29
\$1.67	47,882	2.50
Warrants:		
\$0.02	71,826	5.45
\$0.35	178,502	4.29
\$0.46	4,889,291	2.57
\$1.67	44,892	2.01
<b>At June 30, 2009:</b>		
Options:		
\$0.01	543,292	8.94
\$0.35	875,000	4.12
\$1.67	47,882	2.26
Warrants:		
\$0.02	71,826	4.95
\$0.35	798,597	3.29
\$0.45	4,954,291	2.05
\$0.65	970,000	2.83
\$1.67	44,892	2.19

Stock options and warrants expire on various dates from August 2010 to June 2018.

Based upon an agreement with investors in the October 2008 financing we agreed to limit our post-financing ownership percentage and that we would cause our common stock to be reverse split such that 1,920,000 shares of our common stock on a fully-diluted basis would be outstanding among holder, existing prior to the new investment (such shareholders also referred to as the "original shareholders" or the "Founders") and July 2007 bridge loans. Since the total of our fully-diluted shares of common stock was greater than 1,920,000, our board of directors approved a reverse stock split of 1-for-1.2545. After this split was approved, additional options and warrants were identified, requiring a second reverse stock split in order to reach the 1,920,000. The second reverse stock split on the reduced 1-for-1.2545 balance was determined to be 1-for-1.33176963. Taken together, if only one reverse stock were performed, the number would have been a reverse stock split of 1-for 1.670705.

On June 6, 2008, our board of directors approved the first reverse stock split. The authorized number of common stock of 20,000,000 was proportionately divided by 1.2545 to 15,942,607.

On October 20, 2008, our board of directors approved a second reverse stock split. The authorized number of common stock of 15,942,607 was proportionately divided by 1.33177 to arrive at 11,970,994.

On October 20, 2008, our board of directors also approved a resolution to increase the number of authorized shares of our common stock from 11,970,994 to 40,000,000, which was approved by the Company's shareholders holding a majority of the shares entitled to vote thereon at a special meeting of shareholders held on December 3, 2008.

The table below reflects the effect of the reverse stock splits on our shares outstanding.

#### Reverse Stock Split Table

	Number of Shares Outstanding		Reverse Split Ratio
	Before	After	
<b>As of June 30, 2008:</b>			
- original shareholders	1,376,105 <sup>(1)</sup>	1,096,935	1.2545
- new investors, other	3,720,293	3,720,293	
<b>Total</b>	<b>5,096,398</b>	<b>4,817,228</b>	
<b>As of September 30, 2008:</b>			
- original shareholders	1,096,935	1,096,935	
- new investors, other	6,997,842	6,997,842	
<b>Total</b>	<b>8,094,237</b>	<b>8,094,237</b>	
<b>As of October 20, 2008:</b>			
- original shareholders	1,096,935	823,676	1.33177
- new investors, other	7,307,165	7,307,165	
<b>Total</b>	<b>8,403,560</b>	<b>8,130,841</b>	
<b>As of October 30, 2008 (closing date):</b>			
- original shareholders	823,676		
- new investors, other	7,307,165		
<b>Total</b>	<b>8,130,841</b>		

(1) 1,376,105 divided by 1.670705 equals 823,676.

#### *Valuation and accounting for options and warrants*

The Company determines the grant date fair value of options and warrants using a Black-Scholes-Merton option valuation model based upon assumptions regarding risk-free interest rate, expected dividend rate, volatility and estimated term. For grants during 2008 we used a 2.0 to 4.5% risk-free interest rate, 0% dividend rate, 53-66% volatility and estimated term of 2.5 to 7.5 years. Values computed using these assumptions ranged from \$.102 per share to \$.336 per share. Warrants or options awarded for services rendered are expensed over the period of service (normally the vesting period) as compensation expense for employees or an appropriate consulting expense category for awards to consultants and directors. Warrants granted in connection with a common equity financing are included in stockholders' equity and warrants granted in connections with a debt financing are treated as a debt discount and amortized using the interest method as interest expense over the term of the debt. Please refer to Note 3 to the Financial Statements for greater details of stock options and warrants granted.

In 2007, Mr. Davidson, Mr. Gadbow and Mr. Rice each received less in base salary than they were entitled to under their employment agreements due to lack of funds. In December 2007, the Company reduced accrued payroll liabilities by a total of \$346,714 and treated it as a contribution to capital. This total included waived compensation from Mr. Davidson in the amount of \$90,000, waived compensation from Mr. Rice in the amount of \$125,000 and waived compensation from Mr. Gadbow in the amount of \$138,500. In addition Mr. Davidson waived \$58,350 in underpaid compensation, Mr. Rice waived \$40,725 and Mr. Gadbow waived \$30,610 in underpaid compensation from 2008 which was treated as a contribution to capital in 2008. In exchange, per an agreement in June 2008, Mr. Davidson will be granted a one-time cash payment of \$23,000 as well as an option to purchase 80,000 shares of common stock at \$.35 per share and Mr. Rice will be granted a one-time cash payment of \$46,000 as well as an option to purchase 160,000 shares of common stock at \$.35 per share when the Company raises an additional \$3 million of funding subsequent to the financing completed in October 2008. Mr. Gadbow will be granted a one-time cash payment of \$25,000 and an option to purchase 160,000 shares of common stock at \$.35 per share upon the Company raising an additional \$3 million and is currently receiving \$2,000 per month until a total of \$46,000 of accrued salary liability is paid. The balance remaining, if any, of the amount due Mr. Gadbow will also be paid upon the Company raising an additional \$3 million. The Company's agreement to pay the cash payments and grant the stock options is solely dependent on raising the \$3 million and does not require the participation of the three individuals in the fund raising activity.

Waived salaries in the amount of \$90,000 for Mr. Davidson, \$125,000 for Mr. Rice and \$138,500 for Mr. Gadbow were treated as a capital contribution in 2007 in accordance with Staff Accounting Bulletin (SAB) 79. The years to which the waived salaries originated were \$102,700 for 2007 and \$244,000 for 2006 and prior years. In addition, the company recorded a capital contribution in the amount of \$129,685 in 2008 representing \$58,350, \$40,375 and \$30,610 in waived 2008 salaries for Mr. Davidson, Mr. Rice and Mr. Gadbow, respectively.

In September 2002, an oral agreement was made with director Peter Morawetz whereby he would provide sales, marketing and general administrative consulting to the Company for a fee of \$1,770 per month. The Company's expectation at the time was that the Company would have received equity financing to fund these payments but the Company did not receive that funding. Pursuant to an oral agreement with Mr. Morawetz the Company could defer payment of these amounts until such date that they had cash to pay him. The Company accrued these fees through August 2006 when Mr. Morawetz's consulting services ended. On May 15, 2009 Mr. Morawetz and the Company reached agreement whereby he would waive payment of his consulting fees, in the amount of \$84,600, and accept a cash payment of \$30,000 and an option to buy 75,000 shares of common stock at \$.35 per share upon the Company raising \$3 million. Mr. Morawetz has no obligation to participate in raising the funds. The debt forgiveness was treated as a capital contribution, in accordance with SAB 79, because Mr. Morawetz is both a director and a significant shareholder, and the \$30,000 obligation and the Black-Scholes value of the option were expensed in the second quarter of 2009.

On June 16, 2008, we entered into an employment agreement with Chad Ruwe, Executive Vice President of Operations, pursuant to which we granted an option to purchase 250,000 shares of common stock at an exercise price of \$.35 per share with 50,000 shares vested immediately and increments of 50,000 shares vesting upon achievement of certain milestones related to obtaining FDA clearance and achieving commercial sales of our Streamway™ Fluid Management System. On April 1, 2009 Mr. Ruwe earned 100,000 shares, as a result of FDA application and final clearance, and on June 15, 2009 he earned an additional 50,000 shares based upon achieving our first revenue producing FMS unit.

On August 11, 2008, we entered into an employment agreement with David Dauwalter, Director of Sales, pursuant to which we granted him an option to purchase 50,000 shares of common stock at an exercise price of \$.35 per share with 10,000 shares vested immediately and increments of 10,000 shares vesting upon reaching certain performance milestones. On April 1, 2009 Mr. Dauwalter earned 10,000 shares, as a result of FDA application and final clearance, and on June 15, 2009 he earned an additional 10,000 shares based upon achieving our first revenue producing FMS unit.

In August and September 2008 we issued a warrant to purchase 75,000 shares of common stock at \$.35 per share to each of two human resource consulting firms, Andcor Companies, Inc. and Taylor & Associates, Inc., as payment for their search for candidates to fill the position of Vice President of Sales and Marketing for our Company. Andcor and Taylor will not earn the warrants until the candidate is hired and remains an employee for a period of at least 1 year. Ms. Kirsten Doerfert was hired as VP of Sales and Marketing on February 1, 2009 and the warrants will, therefore, vest on February 1, 2010 provided Ms. Doerfert continues as an employee on that date.

On October 20, 2008, we entered into an agreement with Gregory Sachs, a regulatory consultant, pursuant to which the Company agreed to grant a warrant to purchase up to 50,000 shares of our common stock contingent upon reaching certain performance goals from April 1, 2009 to June 30, 2009. Mr. Sachs assisted the Company in obtaining FDA 510(k) clearance. The purpose of the performance goal provision was to help to ensure a timely clearance of the 510(k). Upon reaching FDA clearance by April 1, 2009, Mr. Sachs received a warrant to purchase 50,000 shares of our common stock at \$.46 per share.

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet transactions.

#### **Dividend Policy**

We follow a policy of retaining earnings, if any, to finance the expansion of our business. We have not paid, and do not expect to declare or pay, cash dividends in the foreseeable future.

## Description of Business

### Overview

We are an early-stage medical device company and our mission is to provide medical facilities with an effective, efficient and affordable means to safely dispose of contaminated fluids generated in the operating room and other similar medical locations in a manner that protects hospital workers from exposure and is environmentally friendly. We have obtained patent rights in the United States and Europe to our Streamway™ Fluid Management System (“FMS”) and will distribute our products to medical facilities where bodily and irrigation fluids produced during surgical procedures must be contained, measured, documented and disposed. Our products minimize the exposure potential to the healthcare workers who handle such fluids. Our goal is to create products that dramatically reduce staff exposure without significant changes to established operative procedures, historically a major stumbling block to innovation and product introduction. In addition to simplifying the handling of these fluids, our technologies will provide cost savings to facilities over the aggregate costs incurred today using the traditional canister method of collection, neutralization and disposal. Our products will be sold through independent distributors and manufacturers representatives in the United States and Europe, initially, and eventually to other areas of the world.

We were founded as a Minnesota corporation in 2002 by Lawrence Gadbow, who has over 40 years of experience in the medical devices field, Peter L. Morawetz, who has extensive experience consulting with development-stage companies in the medical and high technology field, Jay Nord, Jeffery K. Drogue and Gerald Rice. Our address is 2060 Centre Pointe Boulevard, Suite 7, Mendota Heights, Minnesota 55120. Our telephone number is (651) 389-4800 and our website address is [www.biodrainmedical.com](http://www.biodrainmedical.com) .. The website is not a part of this registration statement.

We do not currently file reports with the Securities and Exchange Commission (the “SEC”). Upon the effectiveness of the registration statement of which this prospectus forms a part, we will be subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended, and we intend to file periodic reports, proxy statements and other information with the SEC. We will also register our common stock under the Exchange Act at that time.

### Private Placement Financing

From July 2007 through October 2008, we completed a private placement financing with certain accredited and institutional investors (the “Investors”). We received gross proceeds of approximately \$1.6 million from this financing. Pursuant to securities purchase agreements entered into with these Investors, we sold an aggregate total of 4,552,862 units at a price per unit of \$0.35, with each unit consisting of one share of our common stock, par value \$0.01 per share, and one warrant to purchase one share of our common stock at \$0.46 per share. We also issued 547,285 shares valued at \$.35 per share and warrants to purchase 136,429 shares at an exercise price of \$.46 per share to “Finders” who provided services in connection with the private placement. The warrants issued to Investors and Finders are immediately exercisable (other than a provision that prohibits exercise of warrants if it would cause the holder to hold more than 4.99% of the outstanding shares of common stock).

The issuance of our common stock and warrants in connection with the private placement financing, including, upon exercise, the shares of our common stock underlying the warrants, is intended to be exempt from registration under the Securities Act of 1933, as amended, (the “Securities Act”) pursuant to Section 4(2) and such other available exemptions. As such, these issued securities may not be offered or sold in the United States unless they are registered under the Securities Act, or an exemption from the registration requirements of the Securities Act is available. No registration statement covering these securities has been filed with the SEC or with any state securities commission in respect of the private placement financing.

In connection with the private placement financing, we entered into a registration rights agreement (the “Registration Rights Agreement”) with the Investors. Pursuant to this agreement, we are required to register all the common stock and shares underlying the warrants issued beneficially owned by the Investors to permit the offer and re-sale from time to time of such securities. Additional information regarding the Registration Rights Agreement is set forth below under the section titled “Description of Securities”.

## Industry and Market Analysis

### *Infectious and Biohazardous Waste Management*

There has long been recognition of the collective potential for ill effects to healthcare workers from exposure to infectious/biohazardous materials. Federal and state regulatory agencies have issued mandatory guidelines for the control of such materials, in particular bloodborne pathogens. The medical device industry has responded to this need by developing various products and technologies to limit exposure or to alert workers to potential exposure.

The presence of infectious materials is most prevalent in the surgical suite and post-operative care units where often, large amounts of bodily fluids, including blood, bodily and irrigation fluids are continuously removed from the patient during the surgical procedure. Surgical teams and post-operative care personnel may be exposed to these potentially serious hazards during the procedure via direct contact of blood materials or more indirectly via splash and spray.

According to the Occupational Safety and Health Administration (“OSHA”), workers in many different occupations are at risk of exposure to bloodborne pathogens, including Hepatitis B and C, and HIV/AIDS. First aid team members, housekeeping personnel in some settings, nurses and other healthcare providers are examples of workers who may be at risk of exposure.

In 1991, OSHA issued the Bloodborne Pathogens Standard to protect workers from this risk. In 2001, in response to the Needlestick Safety and Prevention Act, OSHA revised the Bloodborne Pathogens Standard. The revised standard clarifies (and emphasizes) the need for employers to select safer needle devices and to involve employees in identifying and choosing these devices. The revised standard also calls for the use of “automated controls” as it pertains to the minimization of healthcare exposure to bloodborne pathogens. Additionally, employers are required to have an exposure control plan that includes universal precautions to be observed to prevent contact with blood or other potentially infectious materials, such as implementing work practice controls, requiring personal protective equipment and regulating waste and waste containment. The exposure control plan is required to be reviewed and updated annually to reflect new or modified tasks and procedures which affect occupational exposure and to reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens.

According to the American Hospital Association’s (AHA) Beyond Health Care January 2009 update, America’s hospitals performed 27 million surgeries. In a January 2009 report, The National Center for Health Statistics (NCHS) of the Center for Disease Control (CDC) cites that nearly 43% of the 35 million ambulatory surgeries, or a total of 15 million surgeries, are performed in freestanding ambulatory surgery centers. Therefore, the total US surgeries are estimated at approximately 42 million per year.

The majority of these procedures produce potentially infectious materials that must be disposed of with the lowest possible risk of cross-contamination to healthcare workers. Current standards of care allow for these fluids to be retained in canisters, which are located in the operating room where they can be monitored throughout the surgical procedure. Once the procedure is complete these canisters and their contents are disposed of using a variety of methods all of which include manual handling and result in a heightened risk to healthcare workers for exposure to their contents. A Frost & Sullivan research report released in 2003 estimates that the U.S. market for suction canisters is \$94 million and, driven by the aging population, is expected to grow at .4% per year.

With an average cost of \$2.00 per canister, \$2.00 per container of solidification powder and an average disposal cost of \$0.40/lb of infectious waste at approximately 8 lbs per canister as reported by Stanley Shelver in an Infection Control Today article. Therefore, the estimated disposal cost to the hospitals who use solidifiers is \$7.20 per canister. This number increases significantly for disposal of high capacity containers.

According to an October 2005 article from Healthcare Purchasing entitled "Safe and Cost-Effective Disposal of Infectious Fluid Waste," infectious fluid waste accounts for more than 75% of U.S. hospitals biohazard disposal costs. The article also includes findings from a bulletin published by the University of Minnesota's Technical Assistance Program, "A vacuum system that uses reusable canisters or empties directly into the sanitary sewer can help a facility cut its infectious waste volume, and save money on labor, disposal and canister purchase costs." The Minnesota's Technical Assistance Program bulletin also estimated that, in a typical hospital, "...\$75,000 would be saved annually in suction canister purchase, management and disposal cost if a canister-free vacuum system was installed."

We expect the hospital surgery market to continue to increase due to population growth, the aging of the population, expansion of surgical procedures to new areas, (for example, use of the endoscope, which requires more fluid management) and new medical technology. According to the most recent American Institute of Architects Consensus Construction Forecast, Health care is expected to be one of the strongest performers in 2009 with projected growth of 3.6 percent.

There are an estimated 40,000 operating rooms in the U.S. The hospital market has typically been somewhat independent of the U.S. economy; therefore we believe that our targeted market is not cyclical, and the demand for our products will not be dependent on the state of the economy. We benefit by having our products address the surgical procedure market of nearly 42 million procedures performed in the country's 40,000 operating rooms. .

### ***Current Techniques of Collecting Infectious Fluids***

Typically, during the course of a surgical procedure, fluids are continuously removed from the site via wall suction and tubing and collected in large canisters (1,500 - 3,000 milliliters (ml) capacity or 1.5 – 3.0 liters) adjacent to the surgical table.

These canisters, made of glass or high impact plastic, have graduated markers on them allowing the surgical team to make estimates of fluid loss in the patient both intra-operatively as well as for post operative documentation. Fluid contents are retained in the canisters until the procedure is completed, or until the canister is full and needs to be removed. During the procedure the surgical team routinely monitors fluid loss using the measurement calibrations on the canister and by comparing these fluid volumes to quantities of saline fluid introduced to provide irrigation of tissue for enhanced visualization and to prevent drying of exposed tissues. After the procedure is completed the fluids contained in the canisters are measured and a calculation of total blood loss is determined. This is done to ensure no excess fluids of any type remain within the body cavity or that excessive blood loss has occurred, both circumstances that may place the patient at an increased risk post-operatively.

Once total blood loss has been calculated, the healthcare personnel must dispose of the fluids. This can be done by manually transporting the fluids from the operating room to a waste station and directly pouring the material into a sink that drains to the sanitary sewer where it is subsequently treated by the local waste management facility, a process that exposes the healthcare worker to the most risk for direct contact or splash exposure. Once emptied these canisters are placed in large, red pigmented, trash bags and disposed of as infectious waste - a process commonly referred to as "red-bagging."

Alternatively, the canisters may be opened in the operating room and a gel-forming chemical powder is poured into the canister, rendering the material gelatinous. These gelled canisters are then red-bagged in their entirety and removed to a biohazardous/infectious holding area for disposal. In larger facilities the canisters, whether pre-treated with gel or not, are often removed to large carts and transported to a separate special handling area where they are processed and prepared for disposal. Material that has been red-bagged is disposed of separately, and more expensively, from other medical and non-medical waste by companies specializing in that method of disposal.



Although all of these protection and disposal techniques are helpful, they represent a partial solution to the problem and fall short of providing adequate protection for the surgical team and other workers exposed to infectious waste. A major spill of fluid from a canister, whether by direct contact as a result of leakage or breakage, splash associated with the opening of the canister lid to add gel, while pouring liquid contents into a hopper, or during the disposal process, is cause for concern of acute exposure to human blood components—one of the most serious risks any worker faces in the performance of their job. Once a spill occurs, the entire area must be cleaned and disinfected and the exposed worker faces a potential of infection from bloodborne pathogens. These pathogens include, but are not limited to, HIV, HPV, and other infectious agents. Given the current legal liability environment the hospital, unable to identify at-risk patients due to concerns over patient rights and confidentiality, must treat every exposure incident as a potentially infectious incident and treat the exposed employee according to a specific protocol that is both costly to the facility and stressful to the affected employee and their co-workers. In cases of possible exposure to communicable disease the employee could be placed on paid administrative leave, frequently involving worker's compensation, and additional workers must be assigned to cover the affected employee's responsibilities. The facility bears the cost of both the loss of the affected worker and the replacement healthcare worker in addition to any ongoing health screening and testing of the affected worker to confirm if any disease has been contracted from the exposure incident. Employee morale issues also weigh heavily on staff and administration when a healthcare worker suffers a potentially serious exposure to bloodborne pathogens.

Canisters are the most prevalent means of collecting and disposing of infectious fluids in hospitals today. Traditional, non-powered canisters and related suction and fluid disposable products are exempt and do not require FDA clearance. Our management believes that our virtually hands free technology will (a) significantly reduce the risk of healthcare worker exposure to these infectious fluids by replacing canisters, (b) further reduce the risk of worker exposure when compared to powered canister technology that requires transport to and from the operating room, (c) reduce the cost per procedure for handling these fluids, and (c) enhance the surgical team's ability to collect data to accurately assess the patient's status during and after procedures.

In addition to the traditional canister method of waste fluid disposal, several new powered medical devices have been developed which address some of the deficiencies described above. MD Technologies, Inc., DeRoyal (formerly Waterstone), Dornoch Medical Systems, Inc. and Stryker Instruments have all developed systems that provide for disposal into the sanitary sewer without pouring the infectious fluids directly through a hopper disposal or using expensive gel powders and most are sold with 510(K) concurrence from the FDA. Cardinal Health, Inc. has received 510(K) concurrence to market a similar device that they have recently begun advertising. Most of them continue to utilize some variant on the existing canister technology, and while not directly addressing the canister, most have been successful in eliminating the need for expensive gel and its associated handling and disposal costs.

Our existing competitors that already have products on the market have a clear competitive advantage in terms of brand recognition and market exposure. In addition, the aforementioned companies have extensive marketing and development budgets that could overpower an early-stage company like ours. Information obtained by the Company from surgical clinicians during interviews indicates that Stryker Instruments has the dominant market share position. Cardinal Health, Inc., though having FDA concurrence, has not yet made significant sales into the market place. These clinicians have also indicated that the competitive devices are used in select procedures and often in some, but not all, surgical rooms.

## Products

### *The Fluid Management System (“FMS”)*

The BioDrain Streamway™ FMS, a fluid collection and measurement system, addresses the need for a simple, safe, virtually hands-free, touch-screen computer-controlled, method of removing, retaining, calculating fluid loss and disposing of fluid waste during operative procedures. The FMS would replace the manual process of collecting fluids in canisters and transporting and dumping in sinks outside of the operating room that is still being used by many hospitals and surgical centers. The manual process involving canisters requires that the operating room personnel open the canisters that contain waste fluid, often several liters, at the end of the surgical procedure and either add a solidifying agent or empty the canisters in the hospital drain system. Some facilities require that used canisters be cleaned by staff and reused. It is during these processes that there is increased potential for contact with the waste fluid through splashing or spills. The FMS eliminates the use of canisters and these cleaning and disposal steps by collecting the waste fluid in the internal collection chamber and automatically disposing of the fluid with no handling by personnel. Near the end of each procedure, a proprietary cleaning fluid, that is provided under an exclusive licensing agreement with Oculus Innovative Sciences, for surgical fluid management applications, is attached to the FMS and an automatic cleaning cycle ensues, making the FMS ready for the next procedure. The cleaning fluid bottle is attached to the port on the FMS device. The cleaning fluid bottle and its contents are not contaminated and are used to clean the internal fluid pathway in the FMS device to which personnel have no exposure. During the cleaning cycle, the cleaning fluid is pulled from the bottle into the FMS, and then disposed in the same manner as the waste fluid from the surgical case. At the end of the cleaning cycle, the bottle is discarded. Any suction tubing used during the procedure must be disposed of in the same manner as suction tubing used with the canister system. Handling of this tubing does present the potential for personnel exposure but that potential is minimal.

It is in the facilities that still use manual processes that our product may provide substantial cost savings and improvements in safety. In cases where healthcare organizations re-use canisters, the FMS cleaning process eliminates the need for cleaning of canisters for re-use. The FMS reduces the safety issues facing operating room nurses, the cost of the handling process, and the amount of infectious waste generated when the traditional method of disposing of canisters is used. The FMS is fully automated, does not require transport to and from the operating room and eliminates any canister that requires emptying. It is positioned to penetrate its market segment due to its virtually hands free operation, simple design, ease of use and efficiency in removal of infectious waste with minimal exposure of operating room personnel to potentially infectious material.

In contrast to competitive products, the wall-mounted FMS does not take up operating room floor space and it does not require the use of external canisters or handling by operating room personnel. It does require a dedicated system in each operating room where it is to be used. With the exception of MD Technologies, Inc., to our knowledge the BioDrain FMS will be the only system that is wall mounted and designed to collect, measure and dispose of, surgical waste. The product from DeRoyal does not collect surgical waste fluid and is used in conjunction with traditional canisters to assist in emptying the canisters. Other systems on the market are portable, meaning that they are rolled to the bedside for the surgical case and then rolled to a cleaning, are after the case, and use canisters, which still require processing or require a secondary device (such as a docking station) used to dispose of the fluid in the sanitary sewer after it has been collected. They are essentially powered canisters. A comparison of the key features of the devices currently marketed and the FMS is presented in the table below.

**Key Feature Comparison**

<b>Feature</b>	<b>BioDrain Medical</b>	<b>Stryker</b>	<b>Cardinal Health</b>	<b>DeRoyal</b>	<b>Dornoch</b>	<b>MD Technologies</b>
<b>Portable to Bedside vs. Fixed Installation</b>	Fixed	Portable	Portable	Fixed	Portable	Fixed
<b>Uses Canisters</b>	No	Yes	Yes	Yes	Yes	No
<b>Secondary Installed Device Required for Fluid Disposal</b>	No	Yes	Yes	Yes	Yes	No
<b>Numeric Fluid Volume Measurement</b>	Yes	Yes	No	No	Yes	Optional
<b>Unlimited Fluid Capacity</b>	Yes	No	No	No	No	Yes
<b>Installation Requirements</b>						
• <b>Water</b>	No	Yes	Yes	Yes	Yes	No
• <b>Sewer</b>	Yes	Yes	Yes	Yes	Yes	Yes
• <b>Vacuum</b>	Yes	No	No	No	No	Yes

The FMS system may be installed in or on the wall, during new construction or renovation, or installed in a current operating room by connecting the device to the hospital's existing sanitary sewer drain and wall suction systems. With new construction or renovation, the system will be placed in the wall and the incremental costs are minimal, limited to connectors to the hospital drain and suction systems (which systems are already required in an operating room), the construction of a wooden frame to hold the FMS in position, and minimal labor. The fluid collection chamber is internal to the FMS unit and requires no separate installation. Based upon management's consultation with several architects we believe that there is no appreciable incremental expense in planning for the FMS system during construction.

For on-the-wall installation in a current operating room, the location of the FMS may be chosen based on proximity to the existing hospital drain and suction systems. Installation will require access to those systems through the wall and connection to the systems in a manner similar to that for within-the-wall installation. The FMS system is mounted on the wall using a mounting bracket supplied with the system and standard stud or drywall attachments. Labor is estimated based on conclusions made on information gathered from third parties at an estimated average of 6 hours but will vary depending on the actual drain and suction systems already resident in the hospital.

By contrast, the majority of competing products are mobile, allowing movement from room to room. The mobility adds time and labor to the process and increases the chance of worker exposure to waste fluids but also allows the hospital to purchase less than one mobile unit for each operating room. With the FMS, a unit must be purchased and installed in each room where it is intended to be used.

Once installed, the FMS has one inflow port positioned on the front of the device that effectively replaces the current wall suction ports most commonly used to remove fluids during surgery. Additionally, a disposable external manifold, which will be provided as part of our disposable cleaning kit, allows for expansion to up to three inflow suction ports.

Although the BioDrain FMS is directly connected to the sanitary sewer, helping to reduce potential exposure to infectious fluids, it is possible that installation of the system will cause inconvenience and lost productivity as the operating rooms will need to be temporarily shut down. In addition, remodel work may be necessary in preparation for, or as a result of, an installation. In some cases, the costs to rework plumbing lines to accommodate for the system may outweigh the expected savings and/or lengthen the expected return on investment time.

One of the current techniques typically utilize two to eight canisters positioned on the floor or on elaborate rolling containers with tubing connected to the hospital suction system and to the operative field. Once the waste fluids are collected, they must be transported out of the operating room and disposed of using various methods. These systems take up floor space in and around the operating room and require additional handling by hospital personnel, thereby increasing the risk of exposure of these people to infectious waste fluids generated by the operating room procedure. Handling infectious waste in this manner is also more costly.

Using the BioDrain FMS during a procedure, potentially infectious fluid suctioned from the patient is drawn through standard surgical tubing into the FMS. There, the fluid is separated from the air stream and deposited into a large fluid reservoir where it is retained until a measurement cycle is initiated. Once a certain fluid level is reached in the chamber, a solenoid switch is opened and the fluid is pumped from the fluid reservoir using a pump. The action of the pump removes the fluid and measures the quantity of the fluid as it is removed. This volume measurement is then continuously transmitted to a computer display, which allows the surgical team to immediately assess the total amount of fluid removed from the patient to that point in the procedure. The fluid removed from the fluid reservoir is passed through the pump and transported directly to the hospital sanitary sewer.

The FMS has completed four prototype iterations. The product has undergone significant testing, including being utilized in veterinary cases and limited human surgical cases. We have finalized the production specifications for the production unit and anticipate gearing up the production capabilities for the mass production needed to meet the projected market demand. We will utilize an ISO 13485-certified outsource manufacturing service organization as our manufacturer, at least until such time as it may make sense to vertically integrate this process.

We received written confirmation from the FDA on April 1, 2009 that our FMS products have received final 510(k) clearance. This clearance allows us to commence our sales and marketing efforts and to get the Company ready for significant production capability.

*A summary of the features of the wall unit include:*

- Minimal Human Interaction . The wall-mounted FMS provides for a small internal reservoir that keeps surgical waste isolated from medical personnel and disposes the medical waste directly into the hospital sanitary sewer with minimal medical personnel interaction. This minimal interaction is facilitated by the automated electronic controls and computerized LCD touch-screen allowing for simple and safe single touch operation of the FMS.
- Minimizes Exposure . The FMS minimizes surgical team and cleaning crew exposure to bloodborne pathogens, as the system is hands-free and fully automated with electronic controls with regards to handling any waste fluid. The FMS provides advanced fluid management technology in that it eliminates the use of canisters, traditional or powered, for fluid collection, is directly connected to the hospital sanitary sewer, provides continuous flow of waste fluids from the operative field, allows visualization of those fluids prior to disposal and provides measurement of disposed fluids. It does not require any transport to and from the operating room or any secondary procedure such as attachment to a companion device for disposal of the waste fluids
- Fluid Measurement . The FMS volume measurement allows for in-process, accurate measurement of blood/saline suctioned during the operative procedure, and eliminates much of the estimation of fluid loss currently practiced in the operating room. This will be particularly important in minimally invasive surgical procedures, where accounting for all fluids, including saline added for the procedure, is vital to the operation. The surgical team can view in real time the color of the extracted or evacuated fluid through the viewing window on the FMS.
- Disposable Cleaning Kit . A single-use, disposable cleaning kit that is used for the automated cleaning cycle at the conclusion of each procedure prepares the FMS for the next use, reducing operating room turnover time. The cleaning kit includes a BioDrain proprietary cleaning fluid for cleaning the internal tubing, pathways and chamber within the FMS unit and a disposable external manifold required for each surgical procedure. The cleaning solution bottle is attached to the FMS with a cleaning fluid adapter which is designed to mate with the special connector on the FMS. One manifold will be supplied with each bottle of cleaning fluid, attached to the bottle for user convenience in securing all consumables needed for each use of the FMS. The disposable cleaning fluid bottle collapses at the end of the cleaning cycle rendering it unusable; therefore it cannot be refilled with any other solution. The instructions for use clearly state that the FMS cleaning fluid, and only the FMS cleaning fluid, must be used with the FMS following each surgical case. The cleaning fluid should be a substantial revenue generator for the life of the FMS.
- Ease of Use . The FMS simply connects to the existing suction tubing from the operative field (causing no change to the current operative methods). Pressing the *START* button on the FMS touch screen causes the suction tip to operate similarly to preexisting systems, thereby minimizing the learning curve for operation at the surgical site.

- **Installation** . BioDrain will arrange installation of the FMS through a partnership or group of partnerships. Such partnerships will include but not be limited to being executed with distribution partners, manufacturer's representatives, hospital supply companies and the like. We will train our partners and standardize the procedure to ensure the seamless installation of our products. The FMS is designed for minimal interruption of operating room and surgical room utilization. Plug-and-play features of the design allow for almost immediate connection and hook up to hospital utilities for wall-hung units allowing for quick start-up post installation.
- **Sales Channel Partners** . The FMS will be sold to end-users through a combination of independent stocking distributors, manufacturers' representatives and, possibly later, direct sales personnel. All personnel involved in direct contact with the end-user will have extensive training and will be approved by BioDrain. Exclusive agreements will be in place between BioDrain and the sales channel partners outlining stocking expectations, sales objectives, target accounts, and the like. Contractual agreements with the sales channel partners will be reviewed on an annual basis and could possibly be terminated at any time by BioDrain based on certain specified conditions.
- **Competitive Pricing** . Estimated end-user pricing is expected to be in the range of \$12,000 - \$15,000 list per system (one per operating room - installation extra) and \$15 - \$20 per unit retail for the proprietary cleaning kit to the U.S. hospital market. The distributor or channel partner then sets the final retail price based on quantity discounts for multiple installations.

## Patents and Intellectual Properties

We were granted a European patent on April 4, 2007 (Patent No. EP1539580) and a U.S. patent on December 30, 2008 (U.S. Patent No. 7,469,727) (collectively, the "Patents"). We also have a divisional application pending before the U.S. Patent Office. A feature claimed in the Patents is the ability to continue suctioning waste fluids into a collection chamber, to measure the fluid collected, and to pump that collected fluid from the collection chamber all while negative pressure is being maintained. This provides for continuous operation of the FMS unit in suctioning waste fluids, which means that the unit never has to be shut off or paused during a surgical operation, for example, to empty a fluid collection container or otherwise dispose of the collected fluid. We believe that this continuous operation feature provides us with a significant competitive advantage, particularly on large fluid generating procedures. With the exception of one model from MD Technologies, all competing products have a limited fluid collection capacity necessitating that the device be emptied when capacity is reached during the surgical procedure.

We also have an exclusive licensing agreement for surgical room fluid management applications with Oculus Innovative Sciences (Petaluma, CA) for the supply of a cleaning fluid manufactured according to a proprietary recipe exclusive to BioDrain Medical. The proprietary fluid for BioDrain Medical is derived from a fluid on which Oculus has 10 patents issued and over 80 patents pending.

In June 2008 we executed an agreement with Marshall C. Ryan, the named inventor of the Patents, to secure exclusive ownership of the Patents. In exchange for the transfer of his ownership interests in the Patents, we paid Mr. Ryan a combination of cash and warrants, agreed to pay him 4% royalty on FMS sales for the life of the Patents and agreed to make additional payments if there is a change in control of the Company (defined in the agreement as either 50% or more of the Company's outstanding stock or substantially all of its assets being transferred to one independent person or entity). At the signing of the agreement, we paid Mr. Ryan \$75,000 and agreed to pay a corporation wholly owned by Mr. Ryan, Mid-State Stainless, Inc., an additional \$100,000 payment on June 30, 2009 for past research and development activities. We also granted Mr. Ryan a warrant to purchase 150,000 shares of our common stock at a price of \$.35 per share. The warrant has a term of five years, ending on June 30, 2013. Should there be a change in control of the Company, we will pay Mr. Ryan a total of \$2 million to be paid out over the life of the U.S. patent if the change in control occurs within 12 months of the first sale of any products, or \$1 million to be paid out over the life of the U.S. patent if the change in control occurs between 12 and 24 months of the first sale of any products, or \$500,000 to be paid out over the life of the U.S. patent if the change in control occurs between 24 and 36 months of the first sale of any product.

Our competitive advantage, if any, based upon the Patents, would be lost if these Patents were found to be invalid in the jurisdictions in which we sell or plan to sell our products. No assurance can be given that any measure we implement will be sufficient to protect our intellectual property rights or that we could afford to take such measures. If we cannot protect our rights, we may lose our competitive advantage. There is no assurance that any of these protections can be maintained or that they will afford us a meaningful competitive advantage. Moreover, if it is determined that our products infringe on the intellectual property rights of third parties, we may be prevented from marketing our products.

In 2002, two individuals, Jay D. Nord and Jeffrey K. Drogue, who are no longer affiliated with the Company, filed a provisional patent application disclosing a particular embodiment for a medical waste fluid collection system (the “Nord/Drogue Embodiment”). The Nord/Drogue Embodiment included a separation chamber and a collection chamber. A negative pressure source in communication with the separation chamber would cause liquid surgical waste to be drawn into the separation chamber. When the amount of collected liquid reached a high level sensor, a valve would open in the bottom of the separation chamber to allowing the collected liquid to flow by gravity into the collection chamber below. When the liquid flowing into the collection chamber reached a high level sensor, the valve would close. A second valve would then open allowing the known volume within the collection chamber to flow by gravity into a drain. Each time the collection chamber was emptied, the known volume of the collection chamber was added to the total collected volume.

We engaged the services of Marshall C. Ryan to further develop the medical waste fluid collection system for commercialization. Mr. Ryan conceived of an alternative embodiment for the medical waste fluid collection system (the “Ryan Embodiment”). In the Ryan Embodiment, a pump was utilized to measure and discharge the collected fluid while negative pressure was maintained in the separation and collection chambers. An international (PCT) application was timely filed disclosing both the Nord/Drogue Embodiment and the Ryan Embodiment. National stage applications were subsequently timely filed in the U.S., Europe and Canada based on the PCT application. During prosecution of the U.S. and European national stage applications, the claims directed to the Nord/Drogue Embodiment were rejected as being an un-patentable form of prior art. Accordingly, the claims directed to the Nord/Drogue Embodiment were canceled and the remaining claims were amended to specifically claim only the Ryan Embodiment. It was learned during prosecution of the U.S. and European applications that Mr. Ryan was inadvertently omitted as a named inventor. Appropriate documents were then filed with the European and U.S. patent offices to add Mr. Ryan as a named inventor. Additionally, pursuant to U.S. patent law, because the claims directed to the Nord/Drogue Embodiment were canceled, leaving only the Ryan Embodiment claimed, appropriate documents were filed to remove Nord and Drogue as named inventors. The U.S. patent and the European patent were allowed after the claims were amended to relate solely to the Ryan Embodiment. The Canadian patent office has not yet examined the Canadian national stage application (which will be amended consistent with the U.S. and European patents to claim only the Ryan Embodiment).

We filed a divisional application with the U.S. Patent Office with claims directed to the method of use of the Ryan Embodiment. We also filed, in March 2009 a Continuation-In-Part (CIP) application to cover additional features and functionalities of our FMS.

We have not communicated with Mr. Nord or Mr. Drogue since notifying them that they have been removed as inventors of the then-pending patent applications. We are not aware of any current intention by Mr. Nord or Mr. Drogue to challenge ownership or inventorship of the Patents. We believe that Nord and Drogue have no valid claims of inventorship or ownership of the Patents. Even if Mr. Nord or Mr. Drogue were to assert such a claim, we believe that, independent of our dealings with them, we obtained rights to the Patents from Mr. Ryan, who even if found not to be the sole inventor of the subject matter of the claims of the Patents, is at least a joint inventor. As a joint inventor, he would have co-ownership interest in the Patents and would have the power to transfer to us his undivided co-ownership interest in the Patents.

The Company's patented system includes a cleaning kit that contains a pre-measured amount of a cleaning solution for cleaning the suction unit before each use. We signed, in March 2009, an exclusive distribution agreement with Oculus Innovative Science, the manufacturer of the fluid we will use in the cleaning kit to be utilized with our FMS. Our exclusive licensing agreement applies to all surgical fluid management applications.

From time to time, we may encounter disputes over rights and obligations concerning intellectual property. Also, the efforts we have taken to protect our proprietary rights may not be sufficient or effective. Any significant impairment of our intellectual property rights could harm our business, our reputation, or our ability to compete. Also, protecting our intellectual property rights could be costly and time consuming.

### **The Disposable Cleaning Kit**

The disposable cleaning kit is an integral, critical component of the FMS and our total value proposition to the customer. It consists of a proprietary, pre-measured amount of cleaning solution in a plastic pouch, bottle or similar container with a connection mechanism to attach to the FMS. The disposal cleaning kit also includes an external manifold allowing for up to three suction ports. The proprietary cleaning solution placed in the specially designed holder is attached and recommended to be used following each surgical procedure. Due to the nature of the fluids and particles removed during surgical procedures, the FMS is recommended to be cleaned following each use. Utilizing the available vacuum of the wall system, the proprietary cleaning fluid is drawn into the FMS to provide a highly effective cleaning process that breaks up bio-film at the cellular level. Proper cleaning is required for steady, dependable and repeated FMS performance and for maintenance of the warranty of the FMS.

The BioDrain proprietary cleaning fluid is a critical component of our business model. The cleaning fluid has the "razor blade business model" characteristic with an ongoing stream of revenue for every FMS unit installed, and revenues from the sale of fluids are expected to be significantly higher over time than the revenues from the unit. We will have exclusive distribution rights to the fluid and facilitate the use of our fluid for cleaning following procedures by incorporating a special adapter to connect the fluid to the special connector on the FMS system. We will also tie the fluid usage, which we will keep track of with the FMS software, to the product warranty. While it could be possible for other manufacturers to provide fluids for utilization in this process, it would require that they manufacture an adapter compatible with our connector on the FMS, obtain a container that fits in the specially designed container holder on the FMS and perform testing to demonstrate that any other fluid would not damage the FMS. We believe that these barriers and the warranty control will allow us to achieve substantial revenue from our cleaning fluid. The instructions for use which accompany the product will clearly state how the fluid is to be hooked up to the FMS machine. Further, a diagram on the FMS will also assist the user in attaching the fluid bottle to the machine. This will be a very simple task, and we do not anticipate that any training of operating room staff will be necessary.

All installations of our FMS product will be completed by a service and maintenance organization that is familiar with completing such installations in health care settings. We have had conversations with more than one of this type of company and we are now in the process of selecting the best company(s) to partner with regarding this function. The general availability of these types of service and maintenance personnel in the health care sector should not hinder us from forming a beneficial relationship in this area.

### **Corporate Strategy**

BioDrain intends to become successful by deploying a strategy of focused expansion within its core product and market segments, while utilizing a progressive approach to manufacturing and marketing to ensure maximum flexibility and profitability.

Our strategy will be to:

- n *Develop a complete line of wall-installed fluid evacuation systems (“FMS”) for use in hospitals and free standing surgery centers as well as clinics and physicians’ offices.* Initially, we have developed the FMS to work in hospital operating rooms and surgical centers. This device was developed for use with the wall vacuum suction currently installed in hospitals. Opportunities for future products include an FMS developed for post-operation and recovery rooms with multiple inlet ports and multiple volume measurements.
- n *Provide products that greatly reduce worker and patient exposure to harmful materials present in infectious fluids and that contribute to an adverse working environment.* As one of the few stand-alone surgical fluid disposal systems directly connected to the sanitary sewer, the FMS could advance the manner in which such material is collected, measured and disposed of in operating rooms, post-operating recovery, emergency rooms and intensive care settings by eliminating the need to transport a device to the patient bedside and remove it for emptying and cleaning at the end of the procedure. The cost of such exposures, measured in terms of human suffering, disease management costs, lost productivity, liability or litigation, will be, when properly leveraged, the strongest motivating factor for facilities looking at investing in the FMS line of products..
- n *Utilize experienced independent distributors and manufacturers representatives of medical products to achieve the desired market penetration.* Contacts have been established with several existing medical products distributors and manufacturers’ representatives and interest has been generated regarding the sales of the BioDrain FMS and cleaning kits. In addition to their normal sales practices, the distributors will carry a significant inventory of cleaning kits for their current customers and could purchase an FMS for demonstration to new potential customers.
- n *Continue to utilize operating room consultants, builders and architects as referrals to hospitals and day surgery centers.* To date, referrals have been received from this group resulting in several potential sales and a potential beta site. These referrals have shortened the time frame for contacting and demonstrating the FMS to potential customers as well as providing us with valuable responses to the FMS from the customer base, the vast majority of which have been extremely positive to date.
- n *Utilize a Medical Advisory Board to assist in market penetration.* We have a Medical Advisory Board consisting of a respected surgeon, two operating room consultants and a nurse anesthetist to assist us in understanding the needs of our market and ways to better serve that market. From time to time executive management may elect to change the composition of the Medical Advisory Board, including but not limited to, expanding the size of the Medical Advisory Board.

Other strategies may include:

- n Employing a lean operating structure, while utilizing the latest trends and technologies in manufacturing and marketing, to achieve both market share growth and projected profitability.
- n Providing a leasing program and/or “pay per use” program as purchasing alternatives.
- n Providing service contracts to establish an additional revenue stream.
- n Utilizing the international manufacturing experience of our management team to develop international sources of supply and manufacturing to take advantage of the lower cost of labor and materials while still obtaining excellent quality. While cost is not a major consideration in the roll-out of leading edge products we believe that being a low cost provider will be important over time.
- n Offering an innovative warranty program that is contingent on the exclusive use of our disposable cleaning kit to insure the success of our after-market disposable products.



## Technology and Competition

### *Fluid Management for Surgical Procedures*

The management of infectious fluids produced during and after surgery is a complex mix of materials and labor that consists of primary collection of fluid from the patient, transportation of the waste fluid within the hospital to a disposal or processing site and finally to the disposal of that waste either via incineration or in segregated landfills.

Once the surgical procedure has ended, the canisters and their contents must be removed from the operating room and disposed. There are several methods used for disposal, all of which present certain risks to the operating room team, the crews who clean the rooms following the procedure, and the other personnel involved in their final disposal. These methods include:

- *Direct Disposal Through the Sanitary Sewer.* In virtually all municipalities, the disposal of liquid blood may be done directly to the sanitary sewer where it is treated by the local waste management facility. This practice is approved and recommended by the EPA. In most cases these municipalities specifically request that disposed bio-materials not be treated with any known anti-bacterial agents such as glutaldehyde, as these agents not only neutralize potentially infectious agents but also work to defeat the bacterial agents employed by the waste treatment facilities themselves. Disposal through this method is fraught with potential exposure to the service workers, putting them at risk for direct contact with these potentially infectious agents through spillage of the contents or via splash when the liquid is poured into a hopper - a specially designated sink for the disposal of infectious fluids. Once the infectious fluids are disposed of into the hopper, the empty canister is sent to central processing for re-sterilization (glass and certain plastics) or for disposal in the biohazardous/infectious waste generated by the hospital (red-bagged).
- *Conversion to Gel for Red-Bag Disposal.* In many hospital systems the handling of this liquid waste has become a liability issue due to worker exposure incidents and in some cases has even been a point of contention during nurse contract negotiations. Industry has responded to concerns of nurses over splash and spillage contamination by developing a powder that, when added to the fluid in the canisters, produces a viscous, gel-like substance that can be handled more safely. After the case is completed and final blood loss is calculated, a port on the top of each canister is opened and the powder is poured into it. It takes several minutes for the gel to form, after which the canisters are placed on a service cart and removed to the red-bag disposal area for disposal with the other infectious waste. There are four major drawbacks to this system:
  - o It does not ensure protection for healthcare workers, as there remains the potential for splash when the top of the canister is opened.
  - o Based on industry pricing data, the total cost per canister increases by approximately \$2.00.
  - o Disposal costs to the hospital increase dramatically as shipping, handling and landfill costs are based upon weight rather than volume in most municipalities. The weight of an empty 2,500 ml canister is approximately one pound. A canister and its gelled contents weigh approximately 7.5 pounds.
  - o The canister filled with gelled fluid must be disposed; it cannot be cleaned and re-sterilized for future use.

Despite the increased cost of using gel and the marginal improvement in health care worker protection it provides, several hospitals have adopted gel as their standard procedure.

## *Drainage Systems*

Several new medical devices have been developed which address some of the deficiencies described above. MD Technologies, Inc., DeRoyal (formerly Waterstone), Dornoch Medical Systems, Inc. and Stryker Instruments have all developed systems that provide disposal into the sanitary sewer without pouring the infectious fluids directly through a hopper disposal or using expensive gel powders and all of these newer products are currently sold with 510(K) concurrence from the FDA. Cardinal Health, Inc. has received 510(K) concurrence to market a similar device that they have begun advertising. Most of them incorporate an internal collection canister with finite capacity, and while not directly eliminating the need to transport a device to and from the surgical room, most have been successful in eliminating the need for expensive gel and its associated handling and disposal costs.

Our existing competitors that already have products on the market have a clear competitive advantage over us in terms of brand recognition and market exposure. In addition, the aforementioned companies have extensive marketing and development budgets that could overpower an early-stage company like ours. Information the Company obtained from surgical clinicians during interviews indicate that Stryker Instruments has the dominant market share position. Cardinal Health, Inc., though having FDA concurrence, is only now beginning to advertise their product. These clinicians have also indicated that the competitive devices are used in select procedures and often in some, but not all, surgical rooms.

### ***Current Competition, Technology, and Costs***

#### *Single Use Canisters*

In the U.S., glass reusable containers are infrequently used as their high initial cost, frequent breakage and costs of reprocessing are typically more costly than single use high impact plastic canisters, even when disposal is factored in. Each single use canister costs roughly \$2.00 each and it is estimated that a range of two to eight canisters are used in each procedure, depending on the operation.

Our FMS would replace the use of canisters and render them unnecessary, as storage and disposal would be performed automatically by the FMS. It should be noted that these canisters are manufactured by companies with substantially more resources than BioDrain. Cardinal Health, a very significant competitor, manufactures both single use canisters as well as a more automated fluid handling system that will compete with us. Accordingly, faced with this significant competition, we may have difficulty penetrating this market.

#### *Solidifying Gel Powder*

The market potential for solidifying gel was estimated at over \$100 million in 2002. This market is not yet fully realized, but many hospitals, responding to increased concerns over inadvertent worker exposure to liquid waste, are converting to this technology. There have been many reports (Allina and Fairview to name two Minneapolis-based health systems) of nursing contracts containing language that requires the facilities to use gels after every procedure. Our management is aware that at a large healthcare facility in Minneapolis, Minnesota, routine usage of gel increased annual operating room expenditures by \$63,000, based on 14,000 procedures done in 2006. It is clear that solidifying gels, while not providing complete freedom from exposure to workers does present a level of safety and peace of mind to the healthcare workers who handle gel-treated canisters. While several gel manufacturers proclaim that sterility of the contents is achieved with the use of their product, protocols continue to recommend that red-bag procedure is followed when using these products. One drawback of the solidifying gels is that they increase the weight of the materials being sent to the landfill by a factor of five to seven times, resulting in a significant cost increase to the hospitals that elect to use the products.

BioDrain's Streamway™ FMS would eliminate the need for solidifying gel, providing savings in both gel powder usage and associated landfill costs.

## *Sterilization and Landfill Disposal*

Current disposal methods include the removal of the contaminated canisters (with or without the solidifying gel) to designated biohazardous/infectious waste sites. Previously many hospitals used incineration as the primary means of disposal, but environmental concerns at the international, domestic and local level have resulted in a systematic decrease in incineration worldwide as a viable method for disposing of blood, organs or materials saturated with bodily fluids. When landfill disposal is used, canisters are included in the general red-bag disposal and, when gel is used, comprise a significant weight factor. Where hopper disposal is still in use, most of the contents of the red-bag consist only of outer packaging of supplies used in surgery and small amounts of absorbent materials impregnated with blood and other waste fluid. These, incidentally, are retained and measured at the end of the procedure to provide a more accurate assessment of fluid loss or retention. Once at the landfill site, the red-bagged material is often steam-sterilized with the remaining waste being ground up and interred into a specially segregated waste dumpsite.

On a related note, many countries are struggling with landfills within their own borders, and a thriving and growing biohazardous/infectious waste disposal business is emerging. The inevitable disputes connected with such a highly charged and potentially politically sensitive topic have developed, particularly in Europe and the former Soviet Republics, over the disposition and disposal of these infectious wastes. Such disputes have also arisen in the U.S. as states lacking landfill capacity (New Jersey, for example) seek to offload their medical waste on less populous states or those which lack stringent enforcement.

Moreover, as incineration increasingly loses its appeal, and as individual countries and states reject importation of infectious materials, the disposal of these fluids may take on more important political and environmental overtones. For example, there are several recent rulings within the European Union that resulted in medical waste being categorized as a tradable commodity meaning that no member country can reject medical waste from another European Union partner. Germany, which used to dump its medical waste in the former East Germany, is now exporting its waste to Belgium and France. France in particular is fighting this waste and wants Germany to deal with its own waste within its own borders. In other parts of the world, landfills are often occupied by otherwise homeless or poverty level people, who scavenge the sites for food and clothing, and often come into contact with blood soaked medical waste. Disposal of fluid down the sanitary sewer and elimination of large numbers of canisters from the volume of red-bag material, while not addressing all of the concerns regarding landfills, would certainly reduce the amount of disposed and blood impregnated waste.

By eliminating large numbers of canisters and the gel powder, our FMS products would reduce costs and the amount of canisters sent to landfills dramatically.

## *Handling Costs*

Once the surgical team has finished with the procedures and a blood loss estimate is calculated, the liquid waste (with or without solidifying gels) is removed from the operating room, and either disposed of down the sanitary sewer or transported to an infectious waste area of the hospital for later removal.

Our FMS would significantly reduce the labor costs associated with the disposal of fluid or handling of contaminated canisters, as the liquid waste is automatically emptied into the sanitary sewer after measurements are obtained. We will utilize the same suction tubing currently being used in the operating room, so no additional cost is incurred with our process. While each hospital handles fluid disposal differently, we believe that the cost of our cleaning fluid after each procedure will be less than the current procedural cost that could include the cost of canisters, labor to transport the canisters, solidifying powder, gloves, gowns, mops, goggles, shipping and transportation, as well as any costs associated with any spills that may occur due to manual handling.

## *Nursing Labor*

Often overlooked as a direct cost, nursing personnel spend significant time in the operating room readying canisters for use, calculating blood loss and removing or supervising the removal of the contaminated canisters after each procedure. Various estimates have been made, but an internal study at a large healthcare facility in Minneapolis, Minnesota, revealed that the average nursing team spends twenty minutes pre-operatively and intra-operatively setting up, monitoring fluid levels and changing canisters as needed and twenty minutes post-operatively readying blood loss estimates or disposing of canisters. Estimates for the other new technologies reviewed have noted few cost savings to nursing labor.

Our FMS products would save nursing time as compared to the manual process of collecting and disposing of surgical waste. Set-up is as easy as attaching the suction tube to the inflow port of the FMS. Post-operative clean-up requires approximately five minutes, the time required to dispose of the suction tubing to the red-bag, calculate the patient's blood loss, attach the bottle of cleaning solution to the inlet port of the unit, initiate the cleaning cycle, and dispose of the emptied cleaning solution. The steps that our product avoids, which are typically involved with the manual disposal process include, canister setup, interpretation of an analog read out for calculating fluid, canister management during the case (i.e. swapping out full canisters) and then temporarily storing, transferring, dumping and properly disposing of the canisters.

## *Competitive Products*

Disposable canister system technology for fluid management within the operating room has gone virtually unchanged for decades. As concern for the risk of exposure of healthcare workers to bloodborne pathogens, and the costs associated with canister systems has increased, market attention has increasingly turned toward fluid management. The first quarter of 2001 saw the introduction of three new product entries within the infectious material control field. Stryker Instruments introduced the "Neptune" system, offering a combination of bio-aerosol and fluid management in a portable two piece system; Waterstone Medical (now DeRoyal) introduced the "Aqua Box" stationary system for fluid disposal; and Dornoch Medical Systems, Inc. introduced the "Red Away" stationary system for fluid collection and disposal. All companies, regardless of size, have their own accessory kits. For purposes of comparison, based on information obtained from a surgical center in Minnesota, the Stryker Neptune system's estimated cost per procedure is more than \$15.00 (including single-use-manifold plus cleaning solution).

We differentiate from these competitors since we have the most automatic, hands-free process of any of the systems currently on the market. Each of our competitors, with the exception of MD Technologies, Inc., has some significant manual handling involved in the process. It may require the need to transport the mobile unit to a docking port and then empty the fluid or it may be that the canister is still manually transported to a more efficient dumping station. Regardless, most of our competitors require more human interaction with the fluid than BioDrain. Please refer to the chart on page 39 for a comparison of the key features of the devices currently marketed vs. the FMS.

Although the mobility associated with most of the competing products adds time and labor to the process and increases the chance of worker exposure to waste fluids, it also allows the hospital to purchase only as many mobile units needed for simultaneous procedures in multiple operating rooms. With the FMS, a unit much be purchased and installed in each room where it is intended to be used.

## **Marketing and Sales**

### ***Distribution***

Our FMS products will be sold through independent distributors and manufacturers' representatives covering the vast majority of major U.S. markets. The targeted customer base will include nursing administration, operating room managers, CFOs, risk management, and infection control. Other professionals with an interest in the product include physicians, nursing, biomedical engineering, anesthesiologists, human resources, legal, administration, and housekeeping.

The major focus of the marketing effort will be to introduce our product as a standalone device capable of effectively removing infectious waste and disposing of it automatically while providing accurate measurement of fluids removed, and also limiting exposure of the surgical team and healthcare support staff.

Governmental and professional organizations have become increasingly aggressive in attempting to minimize the risk of exposure by medical personnel to bloodborne pathogens. It is believed that our technology provides a convenient and cost effective way to collect and dispose of this highly contaminated material.

Distributors will either have installation and service expertise, or we will contract those functions to an independent service/maintenance company. We have been in contact with both distributors and service companies regarding these installation requirements. The Company will establish extensive training and standards for the service and installation of the FMS to ensure consistency and dependability in the field. Users of the system will require a minimal amount of training to operate the FMS. The instructions for use and the installation guide will be included with every system along with a quick start guide and a trouble shooting manual.

We will structure our pricing and relationships with distributors and/or service companies to ensure that these entities receive at least a typical industry level compensation for their activities. The cost and price estimates currently in place with the Company conservatively allow for reasonable profit margins for all entities in the FMS and the cleaning fluid supply chain. Although the customer may arrange their own installation of the FMS unit we have contracted with Bellimed to our preferred installation company and we are in the early stages of training their personnel.

### ***Promotion***

The dangers of exposure to infectious fluid waste are well recognized in the medical community. It is our promotional strategy to effectively educate medical staff regarding the risks of contamination using current waste collection procedures and the advantages of the FMS in protecting medical personnel from inadvertent exposure. We intend to leverage this medical awareness and concern with education of regulatory agencies at the local, state and federal level about the advantages of the FMS.

We intend to supplement our sales efforts with a promotional mix that will include a number of printed materials, video support and a web site. Our management team believes its greatest challenge lies in reaching and educating the 1.6 million medical personnel who are exposed daily to fluid waste in the operating room or in other healthcare settings (OSHA, CPL 2-2.44C). These efforts will require utilizing single page selling pieces, video educational pieces for technical education, liberal use of scientific journal articles and a web page featuring product information, educational materials, and training sites.

We will support our sales organization by attending major scientific meetings where large numbers of potential users are in attendance. The theme of the trade show booth will focus on education, the awareness of the hazards of infectious waste fluids and the Company's innovative solution to the problem. We will focus our efforts in initially on the Association of Operating Room Nurses ("AORN") trade show, where the largest concentration of potential buyers and influencers are in attendance. We will obtain an Internet mailbox and will feature information on protection of the healthcare worker as well as links to other relevant sites. We intend to invest in limited journal advertising until targeted audiences have been fully identified. The initial thrust will focus on features of the product and ways of contacting the Company via the web page or directly through postage paid cards or direct contact. Additionally, we will create a press release mailing to clinician oriented periodicals for inclusion in New Product News columns. These periodicals will provide the reader with an overview of the product and will direct readers to pursue more information by direct contact with us by accessing our web page.

## **Pricing**

Prices for the FMS and its disposable cleaning kit will reflect a cost saving to the hospital compared to its current procedure costs over time. This pricing strategy should ensure that the customer will realize actual cost savings when using the FMS and replacing traditional canisters, considering the actual costs of the canisters and associated costs such as biohazard processing labor and added costs of biohazard waste disposal. Suction tubing that is currently used in the operating room will continue to be used with our system and should not be considered in the return on investment equation. An argument could be made that our system produces waste through the disposable cleaning solution bottle. However, our cleaning solution's bottle is completely recyclable, and the anticipated selling price of the fluid is built into our cost analysis. In comparison, an operation using traditional disposal methods will often produce multiple canisters destined for biohazard processing. Biohazard disposal costs are estimated by Outpatient Surgery Magazine to be 5 times more per pound to dispose of than regular waste (Outpatient Surgery Magazine, April 2007, p.44). Once the canister has touched blood, it is considered "red bag" biohazard waste, whereas the cleaning fluid bottle used in our system can be recycled with the rest of the facility's plastics or, less desirably, they can be thrown in the regular trash.

The FMS will list for approximately \$17,000 per system (one per operating room - installation extra) and \$15.00 - \$20.00 per unit retail for the proprietary cleaning kit to the U.S. hospital market. By comparison, the disposal system of Stryker Instruments, one of our competitors, retails for \$10,000 plus a \$9,000 docking station and requires a disposable component with an approximate cost of \$15.00 and a proprietary cleaning fluid (cost unknown per procedure). Per procedure cost of the traditional disposal process includes approximate costs of \$2.00 per liter canister, plus solidifier at \$2.00 per liter canister, plus the biohazard premium disposal cost approximated at \$1.80 per liter canister. In addition, the labor, gloves, gowns, goggles, and other related material handling costs are also included in the current disposal expenses.

Installation will be done by distributors, independent contractors, or in the case of larger facilities by in-house engineering at an estimated price of \$2,000, depending on the operating room. Installation of the FMS requires access only to the hospital's sanitary sewer, vacuum suction, and electricity. To help facilities maintain their utilization rates, we will recommend installation during off peak hours. In smaller facilities an outside contractor may be called in, larger institutions have their own installation and maintenance workforce. Installation time should not seriously impact the use of the operating room. Each FMS will have an industry standard warranty period that can be extended through documented use of the Company's sterilization kit.

Actual selling price of the hardware will be at a standard rate to the distributor, permitting them to have price flexibility when selling multiple units to hospitals and clinics. The current plan is for the disposable cleaning kit to be priced at \$15.00 - \$20.00, and a commission to be paid to the distributor or independent representative upon each sale.

## **Engineering and Manufacturing**

We have are currently in negotiations to finalize our relationship with TriVirix, Inc. for the engineering and manufacturing of our product, FMS, cleaning fluid packaging, external manifold or any other accessories. TriVirix, Inc. is ISO 13485:2003 and GMP-certified and has the necessary expertise and experience to build our product in a cost-effective manner. We are in negotiations, but have not yet executed a Manufacturing Supply Agreement with TriVirix.

Upon execution, we believe that the Manufacturing Supply Agreement will specify the quantities for production of our product, which we anticipate will be based on a 6-month rolling forecast, the allocation of production and the price and price increase terms. Under the terms of the expected Manufacturing Supply Agreement, TriVirix, Inc. would manufacture only our FMS device. Upon execution of the Manufacturing Supply Agreement, Trivirix, Inc. would be considered a primary supplier of the FMS device. Our management, as part of a broader manufacturing sourcing strategy plans to identify at most two second sources of production for the FMS device.

We have entered into an exclusive licensing agreement for surgical room fluid management applications with Oculus Innovative Sciences (Petaluma, CA) for the supply of a cleaning fluid manufactured according to a proprietary recipe exclusive to BioDrain Medical. The proprietary fluid for BioDrain Medical is derived from a fluid on which Oculus has 10 patents issued and over 80 patents pending. The agreement has an initial term of 5 years and contains minimum quantity purchase requirements to maintain preferential pricing but does not contain an absolute obligation to purchase the minimum quantities.

The disposable cleaning kit consists of a proprietary cleaning solution, a cleaning solution package (high density polyethylene bottle), a cleaning solution adapter assembly (barbed bottle cap, attached surgical tubing, and attached valved quick coupling), and a multi-port external, non-sterile manifold. Oculus has multiple production facilities located in North America and Europe. The proprietary cleaning solution can be obtained from any of these locations. Other single use disposable accessories, such as a fluid sampling system, will be sourced separately, as individual components. We have not yet entered into agreements with any suppliers for these products.

To further our manufacturing sourcing strategy we hired, in June 2008, an Executive Vice President of Operations, Chad Ruwe, who has 20 years of fluid management systems experience and a demonstrated history of driving lean manufacturing global sourcing and joint venture leadership.

### **Government Regulation**

To date, no regulatory agency has established exclusive jurisdiction over the area of biohazardous and infectious waste in healthcare facilities. Several prominent organizations maintain oversight function concerning various aspects of pertinent technologies and methods of protection.

These agencies include:

- OSHA (Occupational Safety and Health Administration)
- EPA (Environmental Protection Agency)
- DOT (Department of Transportation)
- JCAHO (Joint Commission of Accreditation of Hospitals)
- NFPA (National Fire Protection Association)
- AIA (American Institute of Architects)
- AORN (Association of Operating Room Nurses)
- Specific state, county, hospital or institution guidelines

## *Application for Electrical Safety Testing and Certification*

We sought testing and certification to the IEC 60606-1 and IEC 60606-1-2, two internationally recognized standards. In the United States there are three Nationally Recognized Testing Laboratories (“NRTLs”), Underwriters Laboratories (“UL”), TUV SUD America, Inc. and Intertek-Semko (ETL), that can perform such tests for electrical safety of our FMS device. We issued request for quotes to two of three of these NRTLs in addition to issuing initial inquiries to certified third party testing entities conducting testing on behalf of the NRTLs. Based on responses to our request for quotes noting pricing and timing of conducting the testing, we have contracted with TUV SUD America, Inc. located in New Brighton, MN for this electrical safety testing. On March 11, 2009, we received completed test documentation from TUV SUD America, Inc. confirming the FMS device successfully completed and passed all testing showing compliance to IEC 60606-1 and IEC 60606-1-2.

A previous generation BioDrain FMS device (110/240VAC) successfully passed electrical safety testing conducted by UL in November 2005 (reference UL File E256928).

We filed the 510(k) submission for FDA clearance of the FMS device on March 14, 2009 and received written confirmation on April 1, 2009 that our 510(k) has been cleared by the FDA. The FDA required, pursuant to a final regulation for Establishment Registration and Device Listing for Manufacturers of Devices, that a 510(k) premarket notification be submitted at least ninety days before marketing a device that: (1) is being introduced into distribution for the first time by that person or entity, or (2) is in distribution but is being significantly modified in design or use. A 510(k) submission must contain, among other things (i) proposed labeling sufficient to describe the device’s intended use; (ii) a description of how the device is similar to or different from other devices of comparable type, or information about what consequences a proposed device modification may have on the device's safety and effectiveness; and (iii) any other information necessary to determine whether the device is substantially equivalent (as defined below). The FMS is a Class II device, which is less stringently reviewed as that of a Class III device. We teamed with regulatory consultants with significant experience in the FDA clearance process.

### *FDA Process for Clearing a Device Under Section 510(k)*

The FDA Center for Devices and Radiological Health requires 510(k) submitters to provide information that compares its new device to a marketed device of a similar type, in order to determine whether the device is substantially equivalent (“SE”). This means that a manufacturer can submit a 510(k) comparing a new device to a device that has been found to be SE and the FDA can use this as evidence to determine whether the new device is substantially equivalent to an already legally marketed device (or a “predicate device”). The ultimate burden of demonstrating the substantial equivalence of a new device to a predicate device remains with the 510(k) submitter, and in those occasions when the Center for Devices and Radiological Health is unfamiliar with certain aspects of the predicate device, the submitter will be required to provide information that substantiates a claim of substantial equivalence.

As a matter of practice, the Center for Devices and Radiological Health generally considers a device to be SE to a predicate device if, in comparison to the predicate device, (i) the new device has the same intended use; (ii) the new device has the same technological characteristics (i.e. same materials, design, energy source, etc.); (iii) the new device has new technological characteristics that could not affect safety or effectiveness or (iv) the new device has new technological characteristics that could affect safety or effectiveness but there are accepted scientific methods for evaluating whether safety or effectiveness has been adversely affected and there is data to demonstrate that the new technological features have not diminished safety or effectiveness. Premarket notification submissions are designed to facilitate these determinations.

Following FDA clearance to market our product, which we received on April 1, 2009, we will be subject to the normal ongoing audits and reviews by the FDA and other governing agencies. These audits and reviews are standard and typical in the medical device industry, and we do not anticipate being affected by any extraordinary guidelines or regulations.



### *Foreign Jurisdictions*

Each country in Europe and the Pacific Rim has unique laws, regulations, and directives regarding the manufacture and or marketing of medical devices within their borders that are comparable to the laws and regulations described above. While we have not fully researched each country and the respective laws, regulations, and directives we will completely do so in advance and we recognize product design changes will most likely be necessary based on practices and procedures in the operative environment in the Pacific Rim as well as product design changes necessitated by laws, regulations, and directives.

In June 2007, we entered into a restructuring agreement, in connection with our October 2008 Financing, whereby in the event that we failed to obtain FDA clearance by the end of August 2009, the majority-in-interest of investors (“the Investors”) would have the right to cause the Company to make significant restructuring changes. Since the Company received written notice of a 510(k) clearance from the FDA on April 1, 2009 this restructuring will be avoided.

The following tables identify each of the Investors and the Founders and the number and percentage of the Company's common stock held by each:

### Investors

Name	Number of Shares	Percentage of Common Stock Outstanding
<b>Investors:</b>		
Caron Partners LP	246,500	2.4%
Marc I. Abrams	28,571	0.3%
Douglas Gold	203,571	2.0%
Stuart A. Liner	71,429	0.7%
Steven M & Sheila A. Gold	71,429	0.7%
Tangiers Investors, L.P.	142,857	1.4%
MLPF&S: Jerome Cowan	71,429	0.7%
Jeremy Roll	28,572	0.3%
Bernard & Twyla Vosika	71,429	0.7%
Sally & Naomi Maslon JTWROS	28,571	0.3%
Michael Sobeck	14,286	0.1%
Cavalier Consulting Corp.	71,429	0.7%
RP Capital	183,991	1.8%
Brian Weitman	42,599	0.4%
Bellajule Partners LP	102,429	1.0%
Morris Esquenazi	100,000	1.0%
Schwartz Holding	500,000	4.9%
Jack & Thelma Farbman	100,000	1.0%
Morrie R. Rubin	50,000	0.5%
Lee M. Terpstra & Orlando Stephenson	100,000	1.0%
Bernard Puder Revocable Trust	430,000	4.3%
Thomas J. Klas	71,429	0.7%
Chad Ruwe	571,429	5.7%
Peter Abramowicz	57,143	0.6%
Scott R. Storick	100,000	1.0%
James Dauwalter Living Trust	571,429	5.7%
CGMI as IRA Custodian FBO John D. Villas	71,429	0.7%
Stan Geyer Living Trust	71,429	0.7%
James Taylor, IV	571,429	5.7%
Gregory B. Graves	42,857	0.4%
Fenton Fitzpatrick	8,571	0.1%
Peter Persad	71,429	0.7%
Thomas M. Pronesti	55,964	0.6%
Craig Kulman	38,821	0.4%

## Investors

Name	Number of Shares	Percentage of Common Stock Outstanding
Kulman IR LLC	125,000	1.2%
Cross Street Partners, Inc.	125,000	1.2%
Namaste Financial, Inc.	125,000	1.2%
Ryan Hong	57,404	0.6%
Richardson & Patel LLP	60,714	0.6%
Sean Fitzpatrick	150,000	1.5%
David Baker	225,000	2.2%
Si Phillips	50,000	0.5%
Cameron Broumand	35,000	0.3%
Sylvia Karayan	11,646	0.1%
Jason Cavalier	15,000	0.1%
Greg Suess	104,114	1.0%
Ben Padnos	100,000	1.0%
Nimish Patel	412,411	4.1%
Erick Richardson	399,543	4.0%
Mark Abdou	32,907	0.3%
Addison Adams	8,227	0.1%
Michael Cavalier	8,227	0.1%
Mick Cavalier	8,227	0.1%
Francis Chen	2,334	0.0%
Doug Croxall	6,170	0.1%
Jennifer & Michael Donahue	28,009	0.3%
EGATNIV, LLC	13,710	0.1%
Dan Estrin	823	0.0%
Kevin Friedmann	1,440	0.0%
Abdul Ladha	4,114	0.0%
Jody Samuels	8,227	0.1%
Yossi Stern	10,284	0.1%
Steve Yakubov	10,284	0.1%
<b>Total</b>	<b>7,101,266</b>	<b>70.3%</b>

## Founders

Name	Number of Shares	Percentage of Common Stock Outstanding
Lawrence W. Gadbaw	139,163	1.4%
Peter L. Morawetz	107,739	1.1%
Gerald D. Rice	85,294	0.8%
Jay D. Nord	102,336	1.0%
Sophia M. Nord, Trust	29,928	0.3%
Emily A. Nord, Trust	29,928	0.3%
Jeffrey K. Drogue	53,870	0.5%
Jonathon N. Drogue, Trust	29,928	0.3%
Samantha N. Drogue, Trust	29,928	0.3%
Staci M. Lauer (Spade)	35,913	0.4%
Wisconsin Rural Enterprise	180,000	1.8%
Richard E. & Carol A. Thurk	5,986	0.1%
Thomas W. Gadbaw	599	0.0%
Gail C. & Ginger L. Smith	2,993	0.0%
Charles W. Gadbaw	300	0.0%
Judith A. Bright	1,497	0.0%
Marshall C. Ryan	71,906	0.7%
Alice I. North	399	0.0%
Arliss A. Gadbaw	400	0.0%
Gaynelle A. Templin	399	0.0%
Kevin R. Davidson	29,928	0.2%
Mark K. Lawlis	9,577	0.1%
Wisconsin Business Innovation Corporation	2,993	0.0%
Andcor Companies, Inc.	78,571	0.8%
<b>Total</b>	<b>1,029,575</b>	<b>10.2%</b>

### **Employees**

We currently have 4 full-time employees; a Chief Executive Officer, a Vice President of Sales and Marketing, a Chief Operating Officer and a Director of Product Management. In addition, we use contractors and consultants to supplement our functional needs. We will seek to add additional employees in sales and marketing, operations, product development and other areas as we grow and penetrate the market. No employee is represented by a labor union, and we have never suffered an interruption of business caused by labor disputes. Management believes that our relations with our employees are good.

### **Legal Proceedings**

In April 2009 a former officer of the Company made a formal demand for payment of past wages and threatened to sue the company for in excess of \$100,000 if we did not meet his demand. The company believes that the claim is without merit but we continue to negotiate the issue with his attorney and expect to reach a settlement for less than the demand. We are not a party to any other pending legal proceedings that, if decided adversely to us, would have a material adverse effect upon our business, results of operations or financial condition and are not aware of any threatened or contemplated proceeding by any governmental authority against our company. To our knowledge, we are not a party to any pending civil or criminal action or investigation.

### **Description of Property**

Our corporate offices are located at 2060 Centre Pointe Boulevard, Suite 7, Mendota Heights, Minnesota 55120. We currently lease approximately 3,600 square feet with possible expansion to 4,700 square feet of office space at this location. The monthly base rent for the 3,600 square feet is \$3,000 per month for months 1 through 12; \$2,395 per month for months 13 through 24; \$2,467 per month for months 25 through 36; \$2,541 per month for months 37 through 48; and \$2,617 per month for months 49 through 60. In addition to the base rent, we also pay our share of common area maintenance expenses, real estate tax expenses/assessments and utilities, which are determined by the square footage of the premises we lease in months 13 through 60. The common area maintenance expense is not payable in months 1 through 12. The lease term began on November 1, 2008 and will extend for a period of 5 years, ending on October 31, 2013. We expect that the premises in which our principal executive office is located will be adequate for our office needs for the term of the lease.

## Directors, Executive Officers, Promoters and Control Persons

The following table identifies our current executive officers and directors.

Name	Age	Position Held
Lawrence W. Gadbow	71	Chairman of the Board of Directors
Kevin R. Davidson	49	President, Chief Executive Officer, Chief Financial Officer and Director
Chad A. Ruwe	45	Chief Operating Officer and Director
Kirsten Doerfert	52	Vice President of Sales and Marketing
James E. Dauwalter	58	Director
Peter L. Morawetz	81	Director
Thomas J. McGoldrick	67	Director
Andrew P. Reding	38	Director

We have not set a term of office for any of our directors and each director will serve until their successors are elected and have duly qualified.

There are no family relationships between any of our directors or executive officers. Our executive officers are appointed by our board of directors and serve at the board's discretion. There is no arrangement or understanding between any of our directors or executive officers and any other person pursuant to which any director or officer was or is to be selected as a director or officer.

None of our directors or executive officers has, during the past five years,

- had any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer, either at the time of the bankruptcy or within two years prior to that time,
- been convicted in a criminal proceeding and none of our directors or executive officers is subject to a pending criminal proceeding,
- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities, futures, commodities or banking activities, or
- been found by a court of competent jurisdiction (in a civil action), the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated.

### Business Experience

**Lawrence W. Gadbow, Chairman of the Board of Directors.** Mr. Gadbow has served as a director since our inception in 2002. He served as our President and Chief Executive Officer from 2002 to 2006 and Executive Vice President Business Development from 2006 to 2008. Mr. Gadbow has also been Chairman of Health Care Marketing, Inc., a manufacturer and marketer of health care products, since 1992. From 1990 to 1992, he was President, Chief Operating Officer and Director of Augustine Medical, Inc., a manufacturer of hypothermia treatment products. Mr. Gadbow was President, Chief Executive Officer, Treasurer and Director of Bio-Vascular, Inc., a manufacturer of tissue and biosynthetic-based medical devices and grafts for cardiovascular surgery, from 1985 to 1989. From 1979 to 1981, he was Director of Sales and Marketing for Medical Incorporated, a manufacturer of cardiovascular products. Mr. Gadbow was General Manager of Sween Corporation, a manufacturer of health care products, from 1977 to 1979. He held numerous positions in marketing and sales with Medtronic, Inc., a manufacturer and distributor of cardiovascular products from 1967 to 1977, including the position of Director of U.S. Sales.

**Kevin R. Davidson, President, Chief Executive Officer and Chief Financial Officer.** Mr. Davidson has served as our President and Chief Executive Officer since 2006 and Chief Financial Officer since January 2009, and has several years of experience in the medical technology sector. He has been the Chief Financial Officer of three medical technology companies including his most recent position beginning in 2003 as Chief Financial Officer, Vice President of Business Development at OrthoRehab, Inc., where he led the successful sale of the organization to Otto Bock GmbH. In addition to his Chief Financial Officer experience, Mr. Davidson was an investment banker in the medical technology sector as a Managing Director with the Arthur Andersen Global Corporate Finance Group from 1998 to 2002, where he led and closed several transactions in this sector. Mr. Davidson also has experience in the corporate development function in the medical area, including holding positions at St. Jude Medical, Inc. from 1989 to 1992. In addition, he has extensive domestic and international experience as a management consultant in this area. Mr. Davidson received a BA in Economics from Gustavus Adolphus College in 1982 and an MBA from The Colgate Darden Graduate School of Business Administration at the University of Virginia in 1986.

**Chad A. Ruwe, Chief Operating Officer.** Mr. Ruwe became our Executive Vice President of Operations in 2008 and Chief Operating Officer in 2009. He has over 20 years experience in global business leadership in critical fluid management industries focused on containment, management, and delivery of highly toxic and corrosive fluids. From 2002 to 2007 he held several senior management positions with Entegris, Inc., including General Manager of NT International, a wholly owned subsidiary of Entegris, Vice President of the Fluid Handling Systems business, Vice President of the Semiconductor business and Vice President & General Manager of the Liquid MicroContamination business. From 1996 to 2002, Mr. Ruwe was with Tescom Corporation (now part of Emerson's Climate Technologies Group) serving as Vice President & General Manager of the High Purity Controls Division and Hankuk Tescom, Ltd., an assembly and test facility in South Korea. Mr. Ruwe held several management level positions at Parker Hannifin Corporation from 1987 to 1996. Mr. Ruwe has previously served on the board of directors for two early stage venture start-ups. He holds a Master of Science degree in Management, specializing in Operations Research, from the University of Alabama and he received his Bachelor of Science degree in Mechanical Engineering, specializing in Fluid Dynamics, from The Ohio State University in Columbus, Ohio.

**Kirsten Doerfert, Vice President of Sales and Marketing.** Ms. Doerfert joined BioDrain Medical as our Vice President of Sales and Marketing in 2009. She has over 25 years experience in worldwide medical device sales and marketing leadership, primarily focused in major surgical markets. From 2007 to 2008 and from 1999 to 2004, Ms. Doerfert served as a senior executive at Urologix, Inc., a public company serving the urology market, in the positions of Senior Vice President and General Manager, Vice President Business Development and Strategic Planning, and Vice President Global Marketing. From 2005 to 2007, Ms. Doerfert served as the Vice President Marketing for Gyrus ACMI Surgical Division of Gyrus Group PLC (now wholly owned by Olympus), a medical device company manufacturing and marketing visualization and tissue management systems, instruments and services for the minimally invasive surgery market. From 1991 to 1999, Ms. Doerfert held sales and marketing positions of increasing responsibility at Circon Corporation (now wholly owned by Olympus) also serving the minimally invasive surgery markets. She was employed by Corometrics Medical Systems (now a division of GE Medical) from 1983 to 1999 in sales, marketing and clinical positions. Ms. Doerfert has a strong clinical background with 8 years in clinical practice as a registered nurse. She received a nursing degree from Clemson University, Clemson, SC and a Bachelor of Science degree in nursing from Georgia State University, Atlanta, GA.

**James E. Dauwalter, Director.** Mr. Dauwalter has served as a director of the Company since July 31, 2009. Mr. Dauwalter served as a director of VeraSun Energy Corporation from April 2008 to May 2009. He served as a director of US BioEnergy from July 2006 until April 2008, and served as chairman of the board from November 2007 until April 2008. Mr. Dauwalter also served, from August 2005 until May 2008, as the chairman of the board of directors of Entegris, Inc., a materials integrity management company. Prior to his appointment as chairman of Entegris in August 2005, he served as the chief executive officer of Entegris since January 2001. Mr. Dauwalter joined Entegris in 1972 and held a variety of positions prior to his first executive appointment in March 2000 as chief operating officer. Mr. Dauwalter was also instrumental in founding Metron Technology, B.V., a supplier of semiconductor products in Europe, and served on their board of directors from their date of formation until May 2008, and served on the boards of several subsidiaries and affiliates of Fluoroware, Inc., a predecessor company to Entegris, Inc. Mr. Dauwalter holds a bachelors degree in business management from Bemidji State University.

**Peter L. Morawetz, PhD, Director.** Dr. Morawetz is a consultant to development-stage companies in the medical and high technology field. He has served as a director of the Company since its inception in 2002. From 1985 to 2002, he provided consulting services in the fields of technology and product positioning for a large number of U.S. and foreign corporations. Notable clients included Medtronic, EMPI, Hutchinson Technologies, Minntech, Bauer Biopsy Needles, American Medical, Lectec and Walker Reading Technologies. In the course of a thirty-year career, he covered progressively important positions in engineering and R&D management. His contributions include development of neurological devices at Medtronic, Inc. from 1971 to 1981 and EMPI, Inc. from 1981 to 1985, as well as magnetic-storage devices at Univac from 1958 to 1961 and again from 1965 to 1967 and Fabri-Tek from 1961 to 1965. He has seven patents and has been active in market planning and corporate development.

**Thomas J. McGoldrick, Director.** Mr. McGoldrick has served as a director of the Company since 2005. Prior to that, he served as Chief Executive Officer of Monteris Medical Inc. from November 2002 to November 2005. He has been in the medical device industry for over thirty years and most recently was cofounder and Chief Executive Officer of Fastitch Surgical in 2000. Fastitch is a startup medical device company with unique technology in surgical wound closure. Prior to Fastitch, Mr. McGoldrick was President and Chief Executive Officer of Minntech from 1997 to 2000. Minntech is a \$75 million per year publicly traded (Nasdaq-MNTX) medical device company offering services for the dialysis, filtration, and separation markets. Prior to employment at Minntech from 1970 to 1997, he held senior marketing, business development and international positions at Medtronic, Cardiac Pacemakers, Inc. and Johnson & Johnson. Mr. McGoldrick is on the board of directors of two other startup medical device companies

**Andrew P. Reding, Director.** Mr. Reding is an executive with extensive experience in sales and marketing of capital equipment for the acute care markets. He has served as a director of the Company since 2006 and he is currently the President and Chief Executive Officer of TRUMPF Medical Systems, Inc., a position he has held since April 2007. Prior to that, he was Director of Sales at Smith & Nephew Endoscopy and prior to that, he served as Vice President of Sales and Director of Marketing with Berchtold Corporation from 1994 to 2006. His experience is in the marketing and sales of architecturally significant products for the operating room, emergency department and the intensive care unit. Mr. Reding has successfully developed high quality indirect and direct sales channels, implemented programs to interface with facility planners and architects and developed GPO and IDN portfolios. Mr. Reding holds a bachelors degree from Marquette University and an MBA from The University of South Carolina.

#### **Medical Advisory Board**

We have a Medical Advisory Board to assist us in understanding the needs of our market and ways to better serve that market. From time to time our executive management may elect to change the composition of the Medical Advisory Board, including but not limited to, expanding the size of the Medical Advisory Board.

**Dr. Arnold S. Leonard, MD, PhD.** Dr. Leonard is a surgeon who specialized in orthopedic anterior spine approaches and pediatric surgery from 1956 to 2006. Dr. Leonard served at the University of Minnesota (U of M) 1956-2004 where he was a Professor of Surgery and Chair in Pediatric Surgery, maintains membership in 13 medical societies, is a recipient of many special honors and awards including The Wangenstein Distinguished Professor Award for Excellence in Teaching, is a member of several hospital and national medical committees, and a lecturer and author of over 250 abstracts, publications and presentations. He has also performed several research projects in the treatment of cancer using genetic engineering to boost the immune system. The Arnold S. Leonard, M.D., Ph.D. Chair in Pediatric Surgery was awarded to Dr. Leonard by the University of Minnesota as an endowed scholar alongside two other distinguished Minnesota physicians

**David Feroe.** Mr. Feroe is a practicing nurse anesthetist at Fairview University Hospital and also has a private consulting practice. He previously served as a clinical research executive with Augustine Medical, Inc. while in practice at Fairview University Hospital. He was instrumental in gaining medical facility acceptance of Augustine Medical Inc.'s innovative patient warming devices.



**Debbie Heitzman, RN.** Ms. Heitzman, a healthcare planning consultant with Strategic Hospital Resources, has more than 25 years of international experience as a consultant in clinical architecture and design, medical equipment planning, clinical consulting and nursing. Ms. Heitzman is a member of the educational faculty of Harvard Graduate School of Design Professional Development Program. She formed Strategic Hospital Resources in 2003 and is a principal in that firm. In the course of her Practice, she is called upon to assist medical facilities in designing and planning equipment for operating rooms.

**Mary Wells Gorman, RN, CID.** Ms. Gorman, a healthcare planning consultant with Gorman Resources Ltd., has 14 years of nursing practice and 15 years of healthcare architectural projects experience with her own consulting firm. Like Ms. Heitzman, Ms. Gorman works with healthcare clients in facility programming and planning. She is an advocate for healthcare administrative policy change and was instrumental in changing the Minnesota Health Department's guidelines for inpatient care so that healing environments are more firmly integrated into inpatient practice.

There are no family relationships between any of the members of the Medical Advisory Board and any of our directors or executive officers nor any arrangement or understanding with any of our directors or executive officers pursuant to which any of the Medical Advisory Board members was selected.

None of the members of the Medical Advisory Board has, during the past five years, (i) had any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer, either at the time of the bankruptcy or within two years prior to that time; (ii) been convicted in a criminal proceeding and none of our directors or executive officers is subject to a pending criminal proceeding; (iii) been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities, futures, commodities or banking activities; or (iv) been found by a court of competent jurisdiction (in a civil action), the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated.

Other than the warrant agreements described below, there are no agreements between the Company and any of the members of the Medical Advisory Board.

In 2005, we issued warrants to purchase 2,993 shares of our common stock at \$1.67 per share to each of Debbie Heitzman, Mary Wells Gorman and David Feroe for their services on the Medical Advisory Board.

In 2006, we issued a warrant to purchase 35,913 shares of our common stock at \$.02 per share to Dr. Arnold Leonard for his services on the Medical Advisory Board. The warrant contains an anti-dilution provision that provides that such shares would double upon the Company's total outstanding shares reaching 2 million. The second 35,913 shares of our common stock were granted to Mr. Leonard in June 2008 when we reached the 2 million in outstanding shares of common stock through the October 2008 financing.

In addition, three individuals, Karen Ventura, Nancy Kolb and Kim Shelquist, provided the Company with sales and marketing advisory services in 2006. In consideration for their services, we granted each of them a warrant to purchase 2,993 shares of our common stock at \$1.67 per share.

## Executive Compensation

### Summary of Compensation

The following table summarizes all compensation for the fiscal years ended December 31, 2007 and 2008 paid to our President and Chief Executive Officer and our Former Chief Financial Officer and Secretary. No other executive officer earned total compensation exceeding \$100,000 during the fiscal years ended 2008 or 2007.

## Summary Compensation Table

Name and principal position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$) (4)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Kevin R. Davidson, President and Chief Executive Officer	2008	160,000	25,000		186,307				371,307
	2007	150,000	23,000		14,966				187,966(1)
Gerald D. Rice, Former Chief Financial Officer and Secretary (3)	2008	114,250							114,250
	2007	110,000	46,000		23,990				179,990(2)

- (1) In 2008 Mr. Davidson was entitled to \$160,000 in base salary under his employment agreement and a \$25,000 board approved bonus, but was paid only \$126,650, due to a shortage of cash. The bonus was established by the board as an incentive for Mr. Davidson to complete a financing of not less than \$1 million and was paid after the successful completion of the October 2008 financing. Of the \$126,650 paid Mr. Davidson in 2008 \$25,000 was a bonus and \$101,650 was salary. In 2007, although Mr. Davidson was entitled to \$150,000 in base salary under his employment agreement, he received \$59,375 in base salary due to lack of funds. In June 2008 we reached agreement with three current and former officers to reduce accrued payroll liabilities relating to 2007 and prior years, by a total of \$346,700 (of which Mr. Davidson waived compensation in the aggregate amount of \$90,000 for 2007 and prior years). In addition, Mr. Davidson waived \$58,350 in underpaid compensation related to 2008. In exchange therefore, Mr. Davidson will be granted a one-time cash payment of \$23,000 as well as an option to purchase 80,000 shares of common stock at \$.35 per share when the Company raises an additional \$3 million of funding subsequent to the financing completed in October 2008.
- (2) In 2008 Mr. Rice was entitled to \$114,250 in base salary under his employment agreement and board approved salary increase, but was paid only \$73,525 due to a shortage of cash. In 2007, although Mr. Rice was entitled to \$110,000 in base salary under his employment agreement, he received \$43,542 in base salary due to lack of cash. In June 2008 we reached agreement with three current and former officers to reduce accrued payroll liabilities relating to 2007 and prior years, by a total of \$346,700 (of which Mr. Rice waived compensation in the aggregate amount of \$125,000 relating to 2007 and prior years). In addition, Mr. Rice waived \$40,725 in underpaid compensation related to 2008. In exchange therefore, Mr. Rice will be granted a one-time cash payment of \$46,000 as well as an option to purchase 160,000 shares of common stock at \$.35 per share when we raise an additional \$3 million of funding subsequent to the financing completed in October 2008.
- (3) Mr. Rice terminated his employment as our Chief Financial Officer and Secretary on January 15, 2009.
- (4) Values expressed represent the actual compensation cost recognized by our Company during 2008 for equity awards granted in 2008 and previous years as determined pursuant to Statement of Financial Accounting Standards No. 123, *Share-Based Payment* ("SFAS 123R") utilizing the assumptions discussed in Note 3, "Stock Options and Warrants," in the notes to financial statements included as page F-7 to this filing on Form S-1.

## Outstanding Equity Awards at Fiscal Year-End

The table below provides information concerning unexercised options for our President and Chief Executive Officer and our Former Chief Financial Officer and Secretary outstanding as of December 31, 2008. To date, there have been no stock issuances from these option grants.

### Outstanding Equity Awards at Fiscal Year-End Table

Name	Option awards					Stock awards				
	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price (\$)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares of units of stock that have not vested (\$)	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)	Market value of unearned shares, units or other rights that have not vested (\$)	
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	
Kevin R. Davidson, President and Chief Executive Officer	-	80,000(1)	-	\$ .35	12/31/13	-	-	-	-	
	543,292(2)			.01	06/05/18					
Gerald D. Rice, Former Chief Financial Officer and Secretary	-	160,000(1)	-	\$ .35	12/31/13	-	-	-	-	

- (1) Issuance of these stock options is contingent upon the Company achieving \$3 million in total investment funding.
- (2) Mr. Davidson was entitled to receive 543,292 shares of company stock under terms of his employment agreement, but agreed to accept a stock option to purchase 543,292 shares at \$.01 per share. The option vested immediately and has a 10 year term.

## Discussion of Compensation

Our board of directors currently evaluates and sets the compensation policies and procedures for our executive officers but as soon as established, this function will be performed by a compensation committee composed solely of independent directors. Except as provided for in the employment agreements described below, annual reviews generally determine future salary and bonus amounts for our executive officers, as a part of the Company's compensation procedures.

The amounts reflected in the descriptions of the employment agreements for Mr. Davidson and Mr. Rice below differ from the amounts disclosed in the Summary Compensation Table because the Company did not pay them their full salaries due to lack of funds.

## Employment Agreements, Termination of Employment and Change-in-Control Arrangements

The following discussions provide a description of the material terms and conditions of the employment agreements described below. The discussions are qualified in their entirety by the full text of the agreements.

We entered into an employment agreement with Kevin R. Davidson, President and Chief Executive Officer, on October 4, 2006. The term of the agreement is four years and is automatically renewable except by action of our board of directors. The agreement provides for an annual base salary of \$150,000 (payable beginning when cumulative new funding for the Company reaches \$250,000), with an increase to \$170,000 upon reaching funding of \$1million and \$200,000 upon reaching cumulative net sales of \$5 million. Mr. Davidson's base salary was increased to \$170,000 on July 1, 2008 as a result of reaching the \$1 million in new funding. Mr. Davidson is eligible to participate in the Company's bonus plan when it is completed and approved by our board of directors or compensation committee when established. In addition, pursuant to his employment agreement, Mr. Davidson is entitled to an initial grant of 50,000 shares of BioDrain common stock with an anti-dilution protection amounting to 3.81% of the fully-diluted outstanding common stock of the Company up to the completion of the first \$1million of new funding raised, which pursuant to an option agreement dated June 5, 2008 amending his employment agreement, Mr. Davidson chose to receive in options to purchase 543,292 shares of common stock, exercisable at \$.01, in lieu of obtaining the shares to which he was entitled. The options vest immediately, and the term of the options is 10 years from the date of issuance. In 2008, Mr. Davidson achieved the \$1 million funding target provided for in his employment agreement and therefore his annual salary was increased to \$170,000. In addition, on September 12, 2008, our board of directors ratified the issuance of the 543,292 options to Mr. Davidson as a result of the milestones achieved pursuant to his employment agreement.

In 2007, Mr. Davidson was paid \$59,375 in base salary, which is less than he was entitled to under his employment agreement, due to lack of funds. In June 2008 we reached agreement with three current and former officers to reduce accrued payroll liabilities relating to 2007 and prior years, by a total of \$346,700 (of which Mr. Davidson had waived compensation in the aggregate amount of \$90,000). In addition, Mr. Davidson waived \$58,350 in underpaid compensation for 2008. In exchange therefore, Mr. Davidson will be granted a one-time cash payment of \$23,000 as well as an option to purchase 80,000 shares of common stock at \$.35 per share when we raise an additional \$3 million of funding subsequent to the financing completed in October 2008. Mr. Davidson is also eligible for stock, stock options, deferred compensation, and life insurance, as approved by our board of directors or compensation committee when established, and reimbursements for all reasonable, deductible and substantiated expenses, including, but not limited to, automobile mileage, telephone, cell phone, and expenses related to home office and business meetings. Mr. Davidson is entitled to a minimum of three weeks' vacation per year. In connection with the agreement, Mr. Davidson was granted a position on our board of directors with the option of submitting for board approval one nominee for Board membership.

We entered into an employment agreement with Gerald D. Rice, our former Chief Financial Officer and Secretary, on October 18, 2006. The term of the agreement was four years and automatically renewable except by action of our board of directors. The agreement provided for an annual base salary of \$118,500 (payable beginning when cumulative new funding for the Company reaches \$250,000). Mr. Rice was eligible to participate in the Company's bonus plan when completed and approved by our board of directors. Mr. Rice terminated his employment on January 15, 2009.

In 2007, Mr. Rice was paid \$43,542 in base salary, which is less than he was entitled to under his employment agreement, due to a lack of funds. In June 2008 we reached agreement with three current and former officers to reduce accrued payroll liabilities relating to 2007 and prior years, for a total of \$346,700 (of which Mr. Rice had waived compensation in the aggregate amount of \$125,000). In addition Mr. Rice waived \$40,725 in underpaid compensation for 2008. In exchange therefore, Mr. Rice will be granted a one-time cash payment of \$46,000 as well as an option to purchase 160,000 shares of common stock at \$.35 per share when we raise an additional \$3 million of funding subsequent to the financing completed in October 2008.

On February 1, 2009, we entered into an employment agreement with Kirsten Doerfert, Vice President of Sales and Marketing, pursuant to which we granted her an option to purchase 100,000 shares of common stock at \$.35 per share with 20,000 shares vested immediately and increments of 20,000 shares vesting upon reaching certain performance milestones. In addition, we granted Ms. Doerfert a warrant to purchase 15,000 shares at \$.46 per share as compensation for her consulting services prior to becoming an employee. As of June 30, 2009 the warrant is fully vested and a total of 60,000 shares underlying stock options are vested. The employment agreement specifies an annual salary of \$135,000 until three months after the company receives FDA clearance to sell the FMS product and the product is commercially ready for sale, at which time the annual salary will be reduced to \$125,000 per year but she will be entitled to commissions on sales of all products under a commission plan to be recommended by management and approved by the board of directors.

The following termination, change of ownership and cessation of business clauses apply to the employment agreements for Mr. Davidson, Mr. Rice and Ms. Doerfert, collectively referred to as "Employee":

We are entitled to terminate Employee's employment for "cause" at any time during the term of the Employee's employment and Employee may voluntarily resign from his employment with us at any time. For purposes of the agreements, termination for "cause" means termination for any of the following reasons:

- a. the continued noncompliance by the Employee with our directors' written instructions, directives or regulations, after fifteen (15) days' written notice of such noncompliance from us; a breach by the Employee of any material term of the employment agreement, which breach is not cured within seven (7) days of written notice thereof from us; unsatisfactory performance of employment duties, obligations and work and production standards that is not corrected within thirty (30) days after written notice of such unsatisfactory performance from us, or such longer period as specified in such notice;
- b. malfeasance, misfeasance, or nonfeasance by the Employee in the course of his employment;
- c. fraud or a criminal act committed by Employee, provided such criminal act adversely affects our business;
- d. any breach by Employee of his fiduciary duties and obligations to us or any act or omission of Employee constituting a breach of his obligations contained in the confidentiality and non-competition agreements entered into by and between the Company and the Employee; and
- e. the Employee's voluntary resignation at any time.

In the event of termination for cause, Employee is only entitled to receive payment of base salary, adjusted pro-rata to the date of termination, subject to offset, and to the extent permitted, for any amounts then owed to us by the Employee.

In the event the Employee is terminated by us without cause, Employee will be entitled to receive an amount equal to twelve (12) months of Employee's annual base salary for the year of termination, conditioned upon (i) the return to us in good condition any property owned by or belonging to us; (ii) Employee's disclosure of any passwords or procedures necessary for access to any computer software or program; and (iii) Employee's continued adherence to the confidentiality and non-competition agreements entered into by and between the Company and Employee for two (2) years from the date of termination.

In the case of any termination, the Employee's rights and obligations regarding stock options and shares of the Company's common stock owned by the Employee will be determined in accordance with and be governed by any shareholder agreement entered into by and between the Company and the Employee and the 2008 Stock Option Plan.

Employee may terminate this agreement for good reason and may also terminate without good reason by giving a notice of termination during the year immediately following a change in control of more than 40% of our outstanding common stock, with the exception of stock issued by us, provided that, with the exception of dilution, Employee is adversely affected by such change in control. In the case of termination for good reason or without good reason, Employee will be entitled to the same payments and benefits as if Employee was terminated by us without cause.

Upon the death or disability of the Employee, bonuses and other related benefits will be paid pro-rata for the year in which such event occurred. The employment agreements will remain in force in the event the Company is sold or if majority ownership passes from the existing majority shareholders. The employment agreements (and the confidentiality and non-competition agreements entered into by the Company and the Employee) will become null and void in the event the Company becomes insolvent or ceases business due to lack of funds.

We entered into an employment agreement with Chad A. Ruwe, Executive Vice President Operations, on June 16, 2008. Pursuant to the agreement, upon execution of an investment in the Company of \$200,000, we agreed to employ Mr. Ruwe for two years, with such term to be automatically renewable annually except by action of our President or board of directors. The agreement provides for an annual base salary of \$135,000. Pursuant to the agreement, Mr. Ruwe received a one-time signing bonus of \$15,000 and will be eligible to participate in the Company's bonus plan when it is completed and approved by our board of directors or compensation committee when established. Mr. Ruwe is eligible to receive stock options to purchase 250,000 shares of BioDrain common stock at \$.35 per share, which is governed by the 2008 Stock Option Plan. The options vest as follows: (i) 50,000 shares upon execution of the employment agreement; (ii) an additional 50,000 shares upon submission of the 510(k) to the FDA for clearance of the FMS unit; (iii) an additional 50,000 shares upon clearance of the 510(k) by the FDA; (iv) an additional 50,000 shares upon the sale of the first commercial-ready FMS unit; and (v) an additional 50,000 shares upon sale of the fiftieth commercial-ready FMS unit. As a result of the FDA application and April 1, 2009 clearance Mr. Ruwe earned the vesting of 100,000 shares and earned an additional 50,000 shares in June 2009 as a result of the first sale of our FMS unit.

Mr. Ruwe is also eligible for stock, stock options, deferred compensation, and life insurance, as approved by our board of directors or compensation committee when established, and reimbursements for all reasonable, deductible and substantiated expenses, including, but not limited to, automobile mileage, telephone, cell phone, and expenses related to home office and business meetings. In addition, beginning as of the date of his employment agreement, Mr. Ruwe receives a monthly benefit amount of \$1,000 until a Company-sponsored medical benefits program is established. Mr. Ruwe is entitled to a minimum of three weeks' vacation per year. In connection with the agreement, Mr. Ruwe was granted a position on our board of directors.

Mr. Ruwe's employment agreement also provides that throughout his employment and for one (1) year thereafter, he shall not, for any reason, directly or indirectly, plan, organize, advise, own, manage, operate, control, be employed by, participate or be connected in any manner with the ownership, management or control of any business engaged in the development, marketing and sales of medical devices dedicated or designed to safely manage and dispose of contaminated fluids generated in the operating room and other similar locations. For the purposes of the agreement, indirect competition includes any activity in aid of a competing business such as being a partner, shareholder, officer, director, member, owner, manager, governor, agent, employee, advisor, consultant or independent contractor of any competing business. Furthermore, Mr. Ruwe's employment agreement provides that all rights, titles and interests of every kind and nature, whether currently known or unknown, in any "Intellectual Property" defined to include patent rights, trademarks, copyrights, ideas, creations and properties invented, created, written, developed, furnished, produced or disclosed by Mr. Ruwe in the course of his service to the Company, shall be and remain the sole and exclusive property of the Company and Mr. Ruwe shall have no right, title or interest therein or thereto or in and to any results and proceeds therefrom. Also under the agreement, subject to applicable Minnesota Statutes, Mr. Ruwe agreed to irrevocably assign to us, all worldwide rights, title and interest, in perpetuity, in respect of any and all rights he may have or acquired in the Intellectual Property, to waive any moral rights he may have or many obtain in the Intellectual Property, and to assist us in every proper way to apply for, obtain, perfect and enforce rights in the Intellectual Property and to execute all documents for use in applying for, obtaining and perfecting such rights and enforcing the same as the Company may desire.

In addition, the following terms apply to the employment agreement for Mr. Ruwe, also referred to as "Employee":

We are entitled to terminate Employee's employment for "cause" at any time during the term of the Employee's employment. For purposes of Mr. Ruwe's employment agreement, for "cause" shall mean termination for any of the following reasons:

- a. the material noncompliance by Employee with written instructions, directions or regulations of our board of directors applicable to him, the breach of any material term of the agreement, or the unsatisfactory performance of his duties, obligations, work and production standards and the failure of Employee to correct such non-compliance, breach or performance within thirty (30) days after receipt by him of written notice of the same by us;
- b. any willful or grossly negligent act by Employee having the effect of materially injuring the Company, as determined by a majority vote of our board of directors (excluding Employee);
- c. the commission by Employee of fraud or a criminal act that adversely affects our business; or
- d. the determination by an affirmative vote of the majority of our board of directors (excluding Employee), after reasonable and good faith investigation by the Company following a written allegation by another Company employee that he engaged in some form of harassment or other improper conduct prohibited by law, unless such actions were specifically directed by our board.

In the event of termination for cause, Employee is only entitled to receive payment of base salary, adjusted pro-rata to the date of termination, subject to offset, and to the extent permitted, for any amounts then owed to us by the Employee. The Employee's rights and obligations regarding stock options and shares of the Company's common stock owned by the Employee will be determined in accordance with and be governed by any shareholder agreement entered into by and between the Company and the Employee and the 2008 Stock Option Plan, as well as taking into account the completion (or non-completion) of Mr. Ruwe's aforementioned milestones. Only stock options that have vested as a result of completed milestones are eligible for ownership by the Employee in the event of termination for cause.

In the event the Employee is terminated by us without cause, Employee will be entitled to receive an amount equal to twelve (12) months of Employee's annual base salary for the year of termination as well as bonus payments on a pro-rata basis for the portion of the year at termination, conditioned upon (i) the return to us in good condition any property owned by or belonging to us; and (ii) Employee's disclosure of any passwords or procedures necessary for access to any computer software or program. In lieu of a shareholders' agreement, all non-vested stock options held by Mr. Ruwe shall immediately vest upon termination by us without cause and we will provide outplacement services, upon mutual agreement between the Employee and our President and Chief Executive Officer, for an amount of \$15,000 for one (1) year.

Employee may terminate his employment at any time for good reason. For the purposes of the agreement, "good reason" means (i) any material breach by us of the agreement that is not cured by us within thirty (30) days after receipt of written notice from Employee of such breach; (ii) any material diminution or adverse change to Employee of his duties, responsibilities, rights, or reporting relationships available to him before at the time of such diminution or change, without his consent, except as a result of termination by us for cause; (iii) any requirement from our board of directors that Employee must relocate his office outside the Twin Cities metropolitan area; or (iv) by Employee giving a notice of termination during the year immediately following a change in control of more than 40% of our outstanding common stock, except stock issued by us, provided that, with the exception of dilution, Employee is adversely affected by the change in control.

Employee may also terminate employment at any time for any reason with one (1) month notice and in such case, agrees to aid in transition and exit from the Company causing no harm or hardship during such transition. Employee is not eligible for salary continuation or bonus if he voluntarily resigns for reasons other than good reason.

Upon the death or disability of the Employee, bonuses and other related benefits will be paid pro-rata for the year in which such event occurred. The employment agreement will remain in force in the event the Company is sold or if majority ownership passes from the existing majority shareholders and in such case, all of Mr. Ruwe's non-vested stock options, whether the milestone has been achieved or not, shall become vested with the completion of the sale. The employment agreement and all the terms thereof will become null and void in the event the Company becomes insolvent or ceases business due to lack of funds.

In 2008, Mr. Ruwe invested \$200,000 and received 571,429 shares of common stock and a warrant to purchase an additional 571,429 shares of common stock at \$0.46 per share. In April 2009 Mr. Ruwe made an additional investment of \$25,000 and received 50,000 shares of common stock and a warrant to purchase 50,000 shares of common stock at \$.65 per share.

### **Compensation of Directors**

None of our directors received cash compensation during the fiscal year ended December 31, 2007. Lawrence Gadbow, Chairman of our board of directors, began receiving \$2,000 per month starting in October 2008 for his services as Chairman of the board of directors. He also receives \$2,000 per month as payment of deferred compensation, which he accrued while serving as our President and Chief Executive Officer.

### **Corporate Governance**

We currently have five active non-employee members of the board of directors, Lawrence W. Gadbow, James E. Dawalter, Peter L. Morawetz, Thomas J. McGoldrick, and Andrew P. Reding. Messrs. Dawalter, Morawetz, McGoldrick and Reding are each considered independent directors, as defined in Nasdaq Marketplace Rule 4200.

### **Compliance with Section 16(a) of the Exchange Act**

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our executive officers and directors, and persons who beneficially own more than 10.0% of a registered class of our equity securities to file with the Securities and Exchange Commission initial statements of beneficial ownership, reports of changes in ownership and annual reports concerning their ownership of our common shares and other equity securities, on Forms 3, 4 and 5 respectively. Since prior to this offering, we did not have a class of equity securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended, we were not required to file such forms with the Securities and Exchange Commission. We do not intend to register a class of our securities on a national securities exchange before this registration statement is effective. Once we have a class of equity securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended, we intend on filing all such forms in a timely manner and if not, to disclose any untimely filings in accordance with Item 405 Regulation S-K.

### **Code of Ethics**

In November 2008, our board of directors adopted a Code of Ethics which is applicable to all of our officers, directors and employees.



## Certain Relationships and Related Transactions

Described below are certain transactions or series of transactions since inception between us and our executive officers, directors and the beneficial owners of 5.0% or more of our common stock, on an as converted basis, and certain persons affiliated with or related to these persons, including family members, in which they had or will have a direct or indirect material interest in an amount that exceeds the lesser of \$120,000 or 1% of the average of our total assets for the last three years, other than compensation arrangements that are otherwise required to be described under "Executive Compensation."

In June 2008 we reached agreement with an employee and three current and former officers to reduce accrued payroll liabilities relating to 2007 and prior years, by a total of \$346,700. This includes waived compensation from Mr. Davidson in the amount of \$90,000, Mr. Rice in the amount of \$125,000 and Mr. Gadbaw in the amount of \$138,500. In addition Mr. Davidson waived \$58,350, Mr. Rice waived \$40,725 and Mr. Gadbaw waived \$30,610 in underpaid compensation for 2008. In exchange therefore, Mr. Gadbaw and Mr. Rice will be each granted an option to purchase 160,000 shares of common stock and Mr. Davidson will be granted an option to purchase 80,000 shares of common stock, all at \$.35 per share upon the Company raising an additional \$3 million in financing subsequent to the October 2008 financing. In addition, Mr. Rice is entitled to receive a one-time cash payment of \$46,000, Mr. Gadbaw is entitled to receive a one-time cash payment of \$25,000 and Mr. Davidson is entitled to receive a one-time cash payment of \$23,000 when the Company raises an additional \$3 million subsequent to the October 2008 financing. Mr. Gadbaw is currently receiving \$2,000 per month until a total of \$46,000 is paid with the remaining balance, if any, paid upon the Company raising an additional \$3 million.

Pursuant to the terms of the Separation Agreement and Release between Mr. Gadbaw and the Company, if we raise at least \$3 million in additional funding prior to fully paying off Mr. Gadbaw's accrued salary at the rate of \$2,000 per month, we will then pay off any remaining balance on the accrued salary within 30 days of receipt of the new funding. As part of the agreement, for as long as Mr. Gadbaw remains Chairman of our board of directors, he will receive an additional 30,000 stock options annually, so long as he is Chairman as of September 1 of that year. These options will be priced based on the fair market value of the Company's common stock at the time of grant as determined by our board of directors.

In September 2002, an oral agreement was made with director Peter Morawetz whereby he would provide sales, marketing and general administrative consulting to the Company for a fee of \$1,770 per month. The Company's expectation at the time was that the Company would have received equity financing to fund these payments but the Company did not receive that funding. Pursuant to an oral agreement with Mr. Morawetz the Company could defer payment of these amounts until such date that they had cash to pay him. The Company accrued these fees through August 2006 when Mr. Morawetz's consulting services ended. On May 15, 2009 Mr. Morawetz and the Company reached agreement whereby he would waive payment of his consulting fees, in the amount of \$84,600, and accept a cash payment of \$30,000 and an option (outside of the Plan) to buy 75,000 shares of common stock at \$.35 per share upon the Company raising \$3 million. Mr. Morawetz has no obligation to participate in raising the funds. The debt forgiveness was treated as a capital contribution, in accordance with SAB 79, because Mr. Morawetz is both a director and a significant shareholder, and the \$30,000 obligation and the Black-Scholes value of the option were expensed in the second quarter of 2009.

The following selling shareholders beneficially own more than 5.0% of our common stock: Schwartz Holding, Bernard Puder Revocable Trust, Chad A. Ruwe, James E. Dauwalter Living Trust, James R. Taylor IV, Erick Richardson and Nimish Patel. All became a related party through investing in the October 2008 funding.

### Selling Security Holders

The following table sets forth the names of the selling shareholders who may sell their shares under this prospectus from time to time. No selling shareholder has, or within the past three years has had, any position, office or other material relationship with us or any of our predecessors or affiliates other than as a result of the ownership of our securities, except as set forth in the footnotes of certain selling stockholders.

The following table also provides certain information with respect to the selling shareholders' ownership of our securities as of June 30, 2009, the total number of securities they may sell under this prospectus from time to time, and the number of securities they will own thereafter assuming no other acquisitions or dispositions of our securities. The selling shareholders can offer all, some or none of their securities, thus we have no way of determining the number they will hold after this offering. Therefore, we have prepared the table below on the assumption that the selling shareholders will sell all shares covered by this prospectus.

Some of the selling shareholders may distribute their shares, from time to time, to their limited and/or general partners or managers, who may sell shares pursuant to this prospectus. Each selling shareholder may also transfer shares owned by him or her by gift, and upon any such transfer the donee would have the same right of sale as the selling shareholder.

We may amend or supplement this prospectus from time to time to update the disclosure set forth herein. None of the selling shareholders are or were affiliated with any broker-dealers. See our discussion entitled "Plan of Distribution" for further information regarding the selling shareholders' method of distribution of these shares.

The common shares included in this selling security holder table include:

- Shares underlying a convertible bridge loan from seven investors who loaned us \$170,000 in July 2007. Such securities are convertible into 620,095 shares and the lenders also received warrants to purchase 620,095 shares at \$.35 per share;
- 4,552,862 common shares and 4,552,862 common shares underlying warrants (at an exercise price per share of \$0.46) to 33 investors pursuant to an equity private placement from June 2007 to October 2008 for \$0.35 per share for an aggregate of approximately \$1.6 million;
- 547,285 common shares and 136,429 warrants to consultants who provided services in connection with such equity private placement; and
- Shares issued pursuant to a binding term sheet with a consultant pursuant to which the consultant would assist us in obtaining bridge financing and subsequent equity financing and the consultant and its assigns received 2,001,119 shares in satisfaction of such obligation.

<b>Name of Selling Shareholder</b>	<b>Number of Shares Owned Before Offering(1)</b>	<b>Number of Shares Underlying Warrants Owned Before Offering</b>	<b>Number of Shares Offered in this Offering(1)</b>	<b>Number of Shares Owned After Offering(2)</b>	<b>Percentage Owned After Offering(2)</b>
Caron Partners LP(3) (25)(31)	246,500	100,000	246,500	0	0
Alan Topchik (25)(1)	200,000	100,000	200,000	0	0
Marc I. Abrams (25)(31)	57,142	28,571	57,142	0	0
Douglas J. Gold (21) (25) (27)(31)	232,142	28,571	232,142	0	0
Stuart A. Liner (25)(31)	142,858	71,429	142,858	0	0
Steven M. Gold and Sheila A. Gold (25)(31)	142,858	71,429	142,858	0	0
Tangiers Investors, L.P.(4) (25)(31)	285,714	142,857	285,714	0	0
Jerome M. Cowan (25)(31)	142,858	71,429	142,858	0	0
Jeremy Roll (25) (26)(31)	68,573	40,001	68,573	0	0
Bernard Vosika and Twyla Vosika (25)(31)	142,858	71,429	142,858	0	0
Sally Maslon & Naomi Maslon JTWR0S (25)(31)	57,142	28,571	57,142	0	0
Michael Sobeck (25)(31)	28,572	14,286	28,572	0	0
Cavalier Consulting Corp.(5) (25)(31)	142,858	71,429	142,858	0	0
RP Capital(6) (21) (25)(31)	326,848	142,857	326,848	0	0
Brian Weitman (25)(31)	64,028	21,429	64,028	0	0
Bellajule Partners LP(7) (25)(31)	173,858	71,429	173,858	0	0
Morris Esquenazi (25)(31))	200,000	100,000	200,000	0	0
Schwartz Holding (25)(28)(31)	1,000,000	500,000	1,000,000	0	0
Jack Farbman and Thelma Farbman (25)(31)	200,000	100,000	200,000	0	0
Morrie R. Rubin (25)(31)	225,000	50,000	100,000	125,000	1.3%
Lee M. Terpstra and Orlando Stephenson (25)(31)	200,000	100,000	200,000	0	0
Bernard Puder Revocable Trust (25)(31)	860,000	430,000	860,000	0	0
Thomas J. Klas (25)(31)	142,858	71,429	142,858	0	0
Chad A. Ruwe(22) (25) (30)(31)	1,642,858	621,429	1,142,858	500,000(8)	4.6%
Peter Abramowicz (25)(31)	114,286	57,143	114,286	0	0

<b>Name of Selling Shareholder</b>	<b>Number of Shares Owned Before Offering(1)</b>	<b>Number of Shares Underlying Warrants Owned Before Offering</b>	<b>Number of Shares Offered in this Offering(1)</b>	<b>Number of Shares Owned After Offering(2)</b>	<b>Percentage Owned After Offering(2)</b>
Scott R. Storick (25)(31)	200,000	100,000	200,000	0	0
James R. Taylor, IV(25)(31)	1,142,858	571,429	1,142,858	0	0
Citigroup Global Markets Inc. as IRA Custodian FBO John D. Villas (25)(31)	242,858	121,429	142,858	100,000	1.0%
Gregory B. Graves (25)(31)	125,714	62,857	85,714	40,000	*
James E. Dauwalter Living Trust dated 12/11/01(9) (25) (29) (31)	1,622,858	771,429	1,142,858	480,000	4.4%
Stan Geyer Living Trust dated 10/15/2001, as amended, Stan Geyer & Beverly Geyer, Trustees(10) (25)(31)	142,858	71,429	142,858	0	0
Fenton Fitzpatrick (25)(31)	17,142	8,571	17,142	0	0
Peter Persad (25)(31)	142,858	71,429	142,858	0	0
Nimish Patel(11) (21) (24)	503,601	45,595	503,601	0	0
Erick Richardson(12) (21) (24)	490,733	45,595	490,733	0	0
Core Fund Management, LP(13) (24)	364,762	182,381	364,762	0	0
James Jensen(14) (24)	364,762	182,381	364,762	0	0
Steve Andress(15) (24)	72,952	36,476	72,952	0	0
Kendall Morrison(16) (24)	72,952	36,476	72,952	0	0
EGATNIV, LLC(17) (24)	196,092	91,191	196,092	0	0
Thomas Pronesti(23) (26)	55,964		55,964	0	0
Craig Kulman(23) (26)	38,821		38,821	0	0
Kulman IR LLC(18)(23) (26)	125,000		125,000	0	0
Cross Street Partners, Inc.(19)(23) (26)	125,000		125,000	0	0
Bill Glaser(23) (26)	250,000	125,000	250,000	0	0
Ryan Hong(21) (27)	57,404		57,404	0	0
Richardson & Patel, LLP(20) (27)	60,714		60,714	0	0
Sean Fitzpatrick (27)	150,000		150,000	0	0
David Baker (27)	225,000		225,000	0	0
Si Phillips (27)	50,000		50,000	0	0
Cameron Broumand (27)	35,000		35,000	0	0
Sylvia Karayan(21) (27)	10,000		10,000	0	0
Jason Cavalier (27)	15,000		15,000	0	0
Greg Suess (27)	104,114		104,114	0	0
Ben Padnos (27)	100,000		100,000	0	0
Mark Abdou (27)	32,907		32,907	0	0
Addison Adams(21) (27)	8,227		8,227	0	0
Michael Cavalier (27)	8,227		8,227	0	0
Mick Cavalier	8,227		8,227	0	0
Francis Chen (21) (27)	2,334		2,334	0	0
Doug Croxall (27)	6,170		6,170	0	0
Jennifer & Michael Donohue (21) (27)	28,009		28,009	0	0
Dan Estrin (27)	823		823	0	0
Kevin Friedmann(21) (27)	1,440		1,440	0	0
Sylvia Karayan(21) (27)	1,646		1,646	0	0
Abdul Ladha (27)	4,114		4,114	0	0
Jody Samuels(21) (27)	8,227		8,227	0	0
Yossi Stern (27)	10,284		10,284	0	0
Steve Yakubov	10,284		10,284	0	0
<b>TOTAL</b>	<b>14,275,747</b>	<b>5,629,386</b>	<b>13,030,747</b>	<b>1,245,000</b>	<b>10.4%</b>

\* Less than 1.0% based on a total of 9,225,841 shares of common stock outstanding on June 30, 2009

- (1) Includes up to that number of shares of common stock issuable upon the exercise of a warrant listed in the selling security holder table.
- (2) Assumes that all shares will be resold by the selling shareholders after this offering.
- (3) The natural person with voting and dispositive powers for this stockholder is Beth Levine.
- (4) The natural person with voting and dispositive powers for this stockholder is Michael Sobeck.
- (5) The natural person with voting and dispositive powers for this stockholder is Jason Cavalier.
- (6) The natural persons with voting and dispositive powers for this stockholder are Nimish Patel and Erick Richardson.
- (7) The natural person with voting and dispositive powers for this stockholder is Donald Levine.
- (8) Includes 200,000 shares subject to exercise of options to purchase common stock, and includes 200,000 shares of restricted issued August 24, 2009 under the 2008 Equity Incentive Plan. Also includes 50,000 shares purchased on April 14, 2009 and a warrant to purchase 50,000 shares at an exercise price of \$.65 per shares but does not include an option to purchase 50,000 shares at \$.35 per share that have not vested as of June 30, 2009 and does not include 200,000 shares purchased April 20, 2009 and a warrant to purchase 200,000 at an exercise price of \$.65 per share held by Dean M. and Carol L. Ruwe, the parents of Chad A. Ruwe.
- (9) The natural person with voting and dispositive powers for this stockholder is James E. Dauwalter. Mr. Dauwalter became a director of the Company on July 31, 2009.
- (10) The natural persons with voting and dispositive powers for this stockholder are Stan Geyer and Beverly Geyer.
- (11) Includes 45,595 shares of common stock subject to conversion of a convertible bridge loan.
- (12) Includes 45,595 shares of common stock subject to conversion of a convertible bridge loan.
- (13) The natural person with voting and dispositive powers for this stockholder is David Baker. Includes 182,381 shares of common stock subject to conversion of a convertible bridge loan.
- (14) Includes 182,381 shares of common stock subject to conversion of a convertible bridge loan.
- (15) Includes 36,476 shares of common stock subject to conversion of a convertible bridge loan.
- (16) Includes 36,476 shares of common stock subject to conversion of a convertible bridge loan.
- (17) Includes 91,191 shares of common stock subject to conversion of a convertible bridge loan. The natural person with voting and dispositive powers for this stockholder is Shai Stern.
- (18) The natural person with voting and dispositive powers for this stockholder is Craig Kulman.

- (19) The natural person with voting and dispositive powers for this stockholder is Thomas Pronesti.
- (20) The natural person with voting and dispositive powers for this stockholder is Douglas Gold. Richardson & Patel LLP is the outside legal counsel for the Company.
- (21) The shareholder is an employee or partner of Richardson & Patel LLP, outside legal counsel for the Company.
- (22) Mr. Ruwe is an officer and director of the Company. Includes an option to purchase 200,000 common shares at \$.35 per share but does not include an option to purchase 50,000 common shares at \$.35 per share that have not vested as of June 30, 2009.
- (23) The shareholder has assisted the Company in obtaining financing or investor relations services.
- (24) Each person that participated in lending \$170,000 to the Company under a convertible promissory note has a right to convert their note into common shares at \$.27 per share and also received a warrant to purchase an equal number of shares at \$.35 per shares. In the aggregate the note holders have rights to convert their debt into 620,095 shares and also hold warrants to purchase 620,095 shares.
- (25) Participated in the sale of up to 4,552,862 common shares and 4,552,862 common shares underlying warrants (at an exercise price per share of \$0.46) to 33 investors pursuant to an equity private placement from June 2007 to October 2008 for \$0.35 per share for an aggregate of \$1.6 million;
- (26) Participated in the acquisition of 547,285 common shares and 136,429 warrants by certain consultants who provided services in connection with such equity private placement;
- (27) Obtained shares to a binding term sheet with a consultant pursuant to which the consultant would assist us in obtaining bridge financing and subsequent equity financing and the consultant and its assigns received 2,001,119 shares in satisfaction of such obligation.
- (28) The natural person with voting and dispositive powers for this stockholder is Charles I. Schwartz.
- (29) Includes an option to purchase 30,000 shares at \$.35 per share and 50,000 restricted shares, issued August 24, 2009 under the 2008 Equity Incentive Plan, held by David Dauwalter, the son of James Dauwalter. Does not include an option to purchase 20,000 shares at \$.35 per share held by David Dauwalter that are exercisable only upon achievement of certain performance conditions.
- (30) Participated in the sale of 970,000 units at \$.50 per unit, including one share of common stock and one warrant to purchase a share of common stock at \$.65 per share.
- (31) Shareholder is entitled to additional shares at the rate of 2% per month, based upon the shares purchased in the October 2008 financing, commencing March 1, 2009 until the earlier of an effective registration of the Company's shares or October 31, 2009 when the 16% maximum is reached. Such shares will be issued within 30 days of the determination of their final amount.

## Plan of Distribution

Each selling shareholder of the common stock and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on the OTC Bulletin Board or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. Until such shares are traded on the OTC Bulletin Board a selling shareholder will sell shares at a fixed price of \$.46 per shares. A selling shareholder may use any one or more of the following methods when selling shares, subject to applicable federal and state securities laws:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;

broker-dealers may agree with the selling shareholders to sell a specified number of such shares at a stipulated price per share;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

a combination of any such methods of sale; or

any other method permitted pursuant to applicable law.

The selling shareholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling shareholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling shareholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440, and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440. The maximum commission or discount to be received by any Financial Industry Regulatory Authority ("FINRA") member or independent broker-dealer will not be greater than 8% for the sale of any securities included in the registration statement of which this prospectus is a part.

In connection with the sale of the common stock or interests therein, the selling shareholders may enter into hedging transactions with broker-dealers or other financial institutions, which may, subject to applicable federal state securities laws, in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling shareholders may also, in compliance with applicable federal and state securities laws, sell shares of the common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling shareholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities that require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling shareholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be “underwriters” within the meaning of the Securities Act, in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling shareholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute our common stock.

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares. We have agreed to indemnify the selling shareholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because selling shareholders are deemed to be “underwriters” within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act, including Rule 172 thereunder. In addition, any securities covered by this prospectus that qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling shareholders.

We have agreed to use reasonable efforts to keep this registration statement continuously effective (the “Effective Period”) until the first anniversary of the effective date of this registration statement plus whatever period of time as shall equal any period, if any, during the Effective Period in which the Company was not current with our reporting requirements under the Exchange Act of 1934, as amended (the “Exchange Act”). The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling shareholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common stock by the selling shareholders or any other person. We will make copies of this prospectus available to the selling shareholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

#### **Security Ownership of Certain Beneficial Owners and Management**

The following tables set forth certain information regarding beneficial ownership of our securities as of August 31, 2009 by (i) each person who is known by us to own beneficially 5% or more of the Company’s outstanding common stock, (ii) each of our directors, (iii) each of our named executive officers, and (iv) all of our directors and executive officers as a group. We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. Under these rules, beneficial ownership generally includes voting or investment power over securities. A person (or group of persons) is deemed to be the “beneficial owner” of our securities if he or she, directly or indirectly, has or shares the power to vote or to direct the voting of, or to dispose or direct the disposition of such securities. Accordingly, more than one person may be deemed to be the beneficial owner of the same security. Unless otherwise indicated, the persons named in the table below have sole voting and/or investment power with respect to the number of shares of common stock indicated as beneficially owned by them. A person is also deemed to be a beneficial owner of any security, which that person has the right to acquire within 60 days, such as options or warrants to purchase shares of our common stock. Beneficial ownership and percentage ownership are based on 10,103,651 shares of common stock outstanding as of August 31, 2009. Unless otherwise stated, the address of our directors and executive officers is c/o BioDrain Medical, Inc., 2060 Centre Pointe Boulevard, Suite 7, Mendota Heights, Minnesota 55120.

<b>Name of Beneficial Owner</b>	<b>Amount and Nature of Beneficial Ownership</b>	<b>Percent Of Class</b>
Lawrence W. Gadbow (1)	139,563	1.4%
Kevin R. Davidson (2)	873,219	8.0%
Chad A. Ruwe (3)(11)	1,021,429	9.7%
Peter L. Morawetz (4)	207,739	2.0%
Thomas J. McGoldrick (5)	63,942	0.6%
Andrew P. Reding (6)	43,942	0.4%
Kirsten Doerfert (14)	150,000	1.5%
James Dauwalter Living Trust (9)(11)	851,429	8.4%
Carl Schwartz (7)(11)	500,000	4.9%
Bernard Puder Revocable Trust (8)	430,000	4.3%
James R. Taylor IV (10) (11)	571,429	5.7%
Nimish Patel (12)	687,592	6.7%
Erick Richardson (13)	674,724	6.6%
<b>Total</b>	<b>6,215,008</b>	<b>60.2%</b>
<b>All directors and executive officers as a group (8 persons)</b>	<b>3,351,263</b>	<b>28.6%</b>

- (1) Includes 139,563 shares of common stock. Does not include an option to purchase 160,000 shares at \$.35 per shares to be issued upon the Company raising an additional \$3 million in equity. Mr. Gadbow does not currently have any outstanding options to acquire additional shares of common stock of the Company.
- (2) Includes (i) 29,927 shares of common stock, (ii) 300,000 shares of restricted stock issued August 24, 2009 under the 2008 Equity Incentive Plan and (iii) options to acquire up to an additional 543,292 shares of common stock of the Company, all of which are presently exercisable. Does not include an option to purchase 80,000 shares at \$.35 per shares to be issued upon the Company raising an additional \$3 million in equity.
- (3) Includes 621,429 shares of common stock, 200,000 shares of restricted stock issued August 24, 2009 under the 2008 Equity Incentive Plan and options to acquire an additional 200,000 shares of common stock at \$.35 per share that are presently exercisable. Does not include (i) 621,429 shares of common stock underlying warrants that are not exercisable within 60 days and (ii) options to purchase 50,000 shares of common stock at \$.35 per share that are not exercisable until achievement of certain performance targets as provided in Mr. Ruwe's employment agreement.



- (4) Includes 107,739 shares of common stock and 100,000 shares of restricted stock, issued August 24, 2009 under the 2008 Equity Incentive Plan, but does not include an option to purchase 75,000 shares at \$.35 per share to be issued upon the Company raising an additional \$3 million in equity.
- (5) Includes 40,000 restricted shares, issued August 24, 2009 under the 2008 Equity Incentive Plan, and an option to acquire up to 23,942 shares of common stock, which are presently exercisable, granted pursuant to a director stock option agreement by and between Mr. McGoldrick and the Company.
- (6) Includes 20,000 restricted shares, issued August 24, 2009 under the 2008 Equity Incentive Plan, and an option to acquire up to 23,942 shares of common stock, which are presently exercisable, granted pursuant to a director stock option agreement by and between Mr. Reding and the Company.
- (7) Includes 500,000 shares of common stock. Does not include 500,000 shares of common stock underlying warrants that are not exercisable within 60 days.
- (8) Includes 430,000 shares of common stock. Does not include 430,000 shares of common stock underlying warrants that are not exercisable within 60 days.
- (9) Includes 771,429 shares of common stock. Does not include 771,429 shares of common stock underlying warrants that are not exercisable within 60 days. Includes an option to purchase 30,000 shares and 50,000 restricted shares, issued August 24, 2009 under the 2008 Equity Incentive Plan, held by David Dauwalter, the son of James Dauwalter. Does not include an option to purchase 20,000 held by David Dauwalter because they vest only upon achieving certain performance conditions and are, therefore, not exercisable within 60 days.
- (10) Includes 571,429 shares of common stock. Does not include 571,429 shares of common stock underlying warrants that are not exercisable within 60 days.
- (11) These warrants are fully vested. However they include a clause that prohibit the warrants to be exercised if it would cause the holdings of such equity holder to be in excess of 4.99% of our total outstanding shares. The warrant holder may amend this clause to eliminate this requirement. However, such clause will not take effect until the 61 day after notice has been given. Consequently they cannot exercise their warrants within 60 days of the current date, and those warrants are not included in the total outstanding and percentage of outstanding shares.
- (12) Includes 412,411 shares of common stock, 45,595 shares of common stock underlying warrants and, 45,595 shares of common stock underlying convertible notes. Also includes 183,991 shares of common stock held by RP Capital LLC, for which Nimish Patel and Erick Richardson have shared voting and dispositive control. Does not include a warrant for 142,857 shares held by RP Capital LLC because these warrants are not exercisable within 60 days. Does not include 60,714 shares of common stock held by Richardson & Patel LLP. The voting and dispositive control of such shares are held by Mr. Douglas Gold. Mr. Patel does not currently have options to acquire additional shares of common stock of the Company.
- (13) Includes 399,543 shares of common stock, 45,595 shares of common stock underlying warrants and, 45,595 shares of common stock underlying convertible notes. Also includes 183,991 shares of common stock held by RP Capital LLC, for which Nimish Patel and Erick Richardson have shared voting and dispositive control. Does not include a warrant for 142,857 shares held by RP Capital LLC because these warrants are not exercisable within 60 days. Does not include 60,714 shares of common stock held by Richardson & Patel LLP. The voting and dispositive control of such shares are held by Mr. Douglas Gold. Mr. Richardson does not currently have options to acquire additional shares of common stock of the Company.
- (14) Includes a warrant to purchase 15,000 shares at \$.46 per share, an option to purchase 60,000 shares at \$.35 per share and 75,000 restricted shares issued August 24, 2009 under the 2008 Equity Incentive Plan. Does not include an option to purchase 40,000 shares at \$.35 per share that are not exercisable until achievement of certain performance targets as provided in Ms. Doerfert's employment agreement.

## Description of Securities

### General

We are authorized to issue only one class of shares, which is designated as common stock. On October 20, 2008, our board of directors approved a resolution to increase the total number of shares of common stock that we are authorized to issue from 11,970,994 to 40,000,000 with \$0.01 par value per share. Such action was approved by the Company's shareholders holding a majority of the shares entitled to vote thereon at a special meeting of shareholders held on December 3, 2008.

### Common Stock

The securities being offered by the selling shareholders are shares of our common stock. Prior to this offering there has been no public or private trading market for our common stock and there will be no such trading market until our common stock is approved for quotation on the OTC Bulletin Board. As of August 31, 2009, there were issued and outstanding 10,103,651 shares of common stock that were held by 106 shareholders of record.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the shareholders; provided that no proxy shall be voted if executed more than one year prior to the date of the stockholders' meeting except as may otherwise be provided by our board of directors from time to time. Only stockholders of record at the close of business on day twenty prior to the date of the meeting are entitled to vote at the stockholders' meeting. Holders of our common stock do not have cumulative voting rights.

The holders of common stock are entitled to receive ratably any dividends that may be declared from time to time by our board of directors out of funds legally available for that purpose. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities. The common stock has no preemptive or conversion rights or other subscription rights and there are no redemption provisions applicable to our common stock. All outstanding shares of common stock are fully paid and non-assessable, and the shares of common stock offered in this offering will be fully paid and not liable for further call or assessment.

Except for directors, who are elected by receiving the highest number of affirmative votes of the shares entitled to be voted for them, or as otherwise required by Minnesota law, and subject to the rights of the holders of preferred stock then outstanding (if any), all shareholder action is taken by the vote of a majority of the issued and outstanding shares of common stock present at a meeting of shareholders at which a quorum consisting of a majority of the issued and outstanding shares of common stock is present in person or proxy. In the absence of a quorum for the transaction of business, any meeting may be adjourned from time to time. The stockholders present at a duly called or held meeting may continue to do business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum. The Company's President or, in his absence, the Vice-President or any other person designated from time to time by the board of directors, shall preside at all meetings of stockholders.

### Warrants and Convertible Debt

As of August 31, 2009, there were outstanding warrants to purchase 6,937,813 shares of our common stock, including 620,095 warrants exercisable at a price of \$0.35 per share, issued in conjunction with a convertible bridge loan we undertook in July 2007, and 4,689,291 warrants exercisable at a price of \$0.46 per share, issued in conjunction with the private offering we completed in October 2008, including 4,552,862 warrants issued to investors and 136,429 warrants issued to consultants who provided services in connection with the offering. These warrants are immediately exercisable (except for a provision that prohibits exercise of warrants if it would cause the holder to hold more than 4.99% of the outstanding shares of common stock) and have a three year term. If there is no effective registration statement registering the underlying shares by August 31, 2009, these warrants contain cashless exercise provisions that allow the holder to exercise the warrant for a lesser number of shares of common stock in lieu of paying cash. The number of shares that would be issued in this case would be based upon the market price of the common stock at the time of the net exercise, or if there is no market price, the price per share as determined by mutual agreement of the Company and the holder. As of August 31, 2009, there were warrants to purchase 1,050,000 shares at \$.65 issued in connection with a private placement in April, May, June and August 2009, and there are other outstanding warrants to purchase 578,427 shares of our common stock at exercise prices ranging from \$.02 to \$1.67 per share.

There are also bridge loan notes outstanding convertible into shares of our common stock at a conversion price of \$.27 per share, which were issued in conjunction with the bridge loan we undertook in July 2007 but also considered part of the October 2008 financing. The bridge loan was undertaken primarily to give the private placement agents sufficient time to raise additional equity and they were ultimately successful in raising approximately \$1.6 million by October 2008. The convertible notes total \$170,000 and are held by seven holders. The names, individual face amounts of the convertible bridge loan notes and the number of shares upon conversion is as follows:

Name	Amount	Conversion Price 0.274151 Shares of Stock
Core Fund Mgmt LP	\$ 50,000	182,381
C. James Jensen	50,000	182,381
Steve Andress	10,000	36,476
Kendall Morrison	10,000	36,476
EGATNIV, LLC	25,000	91,191
Erick Richardson	12,500	45,595
Nimish Patel	12,500	45,595
Total	\$ 170,000	620,095

The notes are convertible into 620,095 shares of common stock and warrants to purchase 620,095 shares of common stock at \$.35 per share were granted in connection therewith. The notes bear interest at 8% and have passed their original maturity date of April 2008. If there is no effective registration statement registering the underlying shares by within 180 days of the closing of the October 2008 private placement offering, these notes contain certain monetary penalties imposed upon the Company. The Company will incur a penalty of \$5,000 payable pro-rata to note holders for each 30 day period after February 27, 2009 until such registration is declared effective or until the shares are available for sale under Rule 144.

In addition, the Company will be required to issue additional shares to the purchasers of units in the October 2008 financing, equal to 2% of the shares purchased in the financing, for each 30 day period beyond 180 days from the August 31, 2008 closing date until the registration is declared effective with a maximum of 16% or 728,458 shares. This penalty was provided to create an incentive for the Company to complete the registration of the securities tied to this investment in a timely manner. As of June 30, 2009 the Company is obligated to pay \$20,500 in accrued penalties to the note holders, in addition to regular accrued interest of \$43,360. The penalty will continue to accrue at \$5,000 for each 30 day period after February 27, 2009 until there is an effective registration of the Company's shares and there is no maximum. The accrued penalties are included as interest expense in the financial statements contained in the Form S-1. Additionally, the company estimated that it will be obligated to issue an additional 637,401 shares of stock to the purchasers of the 4,552,862 units in the October 2008 financing and has accrued \$318,701 in expense as of June 30, 2009 to reflect this obligation. The accrued interest and penalties will be paid at such time as the Company raises a significant portion of the \$3 million in new capital subsequent to getting our shares listed on the OTC Bulletin Board. The additional shares will be issued within 30 days of the earlier of an effective registration of the Company's shares or October 31, 2009 when the 16% maximum is reached.

The exercise price and the number of shares issuable upon exercise of all the above-referenced warrants will be adjusted upon the occurrence of certain events, including reclassifications, reorganizations or combinations of the common stock. At all times that the warrants are outstanding, we will authorize and reserve at least that number of shares of common stock equal to the number of shares of common stock issuable upon exercise of all outstanding warrants.

## **Stock Options**

As of August 31, 2009, there were employee, consultant and director stock option agreements outstanding with options to purchase 1,466,174 shares of common stock with various vesting periods and amounts. We have 77,595 shares remaining reserved for issuance under the 2008 Equity Incentive Plan.

## **Dividends**

We have never paid dividends and do not currently intend to pay any dividends on our common stock in the foreseeable future. Instead, we anticipate that any future earnings will be retained for the development of our business. Any future determination relating to dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including, but not limited to, our financial condition, operating results, cash needs, growth plans, the terms of any credit agreements that we may be a party to at the time and the Minnesota Business Corporations Act, which provides that dividends are only payable out of surplus or current net profits.

## **Registration Rights**

Under the Registration Rights Agreement entered into in connection with the October 2008 financing with certain accredited and institutional investors (the "Investors"), we are obligated to register the following securities beneficially owned by the Investors to permit the offer and resale from time to time of such securities: (i) all of the common stock issued or issuable upon the conversion of shares of common stock (including the shares underlying the warrants we issued in conjunction with our private placement financing) acquired from the Company pursuant to a Subscription Agreement entered into between the Investors and the Company; and (ii) any securities issued or issuable directly or indirectly with respect to the securities referred to in (i) by way of stock dividend or stock split or in connection with a combination of shares, recapitalization, merger, consolidation or other reorganization.

## **Anti-Takeover Effects of Certain Provisions of Minnesota Law**

Certain provisions of Minnesota law described below could have an anti-takeover effect. These provisions are intended to provide management flexibility, to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by our board of directors and to discourage an unsolicited takeover if our board of directors determines that such a takeover is not in our best interests or the best interests of our shareholders. However, these provisions could have the effect of discouraging certain attempts to acquire us that could deprive our shareholders of opportunities to sell their shares of our stock at higher values.

Section 302A.671 of the Minnesota Business Corporation Act applies, with certain exceptions, to any acquisitions of our stock (from a person other than us, and other than in connection with certain mergers and exchanges to which we are a party) resulting in the beneficial ownership of 20% or more of the voting stock then outstanding. Section 302A.671 requires approval of any such acquisition by a majority vote of our shareholders prior to its consummation. In general, shares acquired in the absence of such approval are denied voting rights and are redeemable by us at their then-fair market value within 30 days after the acquiring person has failed to give a timely information statement to us or the date the shareholders voted not to grant voting rights to the acquiring person's shares.

Section 302A.673 of the Minnesota Business Corporation Act generally prohibits any business combination by us, or any of our subsidiaries, with an interested shareholder, which means any shareholder that purchases 10% or more of our voting shares within four years following such interested shareholder's share acquisition date, unless the business combination is approved by a committee of all of the disinterested members of our board of directors before the interested shareholder's share acquisition date.

## Disclosure of Commission Position of Indemnification for Securities Act Liabilities

We are a Minnesota corporation and certain provisions of the Minnesota Statutes and our Bylaws provide for indemnification of our officers and directors against liabilities which they may incur in such capacities. A summary of the circumstances in which indemnification is provided is discussed below, but this description is qualified in its entirety by reference to our Bylaws and to the statutory provisions.

Section 302A.521, Subd. 2 of the Minnesota Statutes requires a corporation to indemnify a person made or threatened to be made a party to a proceeding by reason of the former or present official capacity of the person against judgments, penalties, fines, including, without limitation, excise taxes assessed against the person with respect to an employee benefit plan, settlements, and reasonable expenses, including attorneys' fees and disbursements, incurred by the person in connection with the proceeding, if, with respect to the acts or omissions of the person complained of in the proceeding, the person:

- (1) has not been indemnified by another organization or employee benefit plan for the same judgments, penalties, fines, including, without limitation, excise taxes assessed against the person with respect to an employee benefit plan, settlements, and reasonable expenses, including attorneys' fees and disbursements, incurred by the person in connection with the proceeding with respect to the same acts or omissions;
- (2) acted in good faith;
- (3) received no improper personal benefit and Section 302A.255, if applicable, has been satisfied;
- (4) in the case of a criminal proceeding, had no reasonable cause to believe the conduct was unlawful; and
- (5) in the case of acts or omissions occurring in the person's performance in the official capacity of director or, for a person not a director, in the official capacity of officer, board committee member or employee, reasonably believed that the conduct was in the best interests of the corporation or, in the case of performance by a director, officer or employee of the corporation involving service as a director, officer, partner, trustee, employee or agent of another organization or employee benefit plan, reasonably believed that the conduct was not opposed to the best interests of the corporation. If the person's acts or omissions complained of in the proceeding relate to conduct as a director, officer, trustee, employee, or agent of an employee benefit plan, the conduct is not considered to be opposed to the best interests of the corporation if the person reasonably believed that the conduct was in the best interests of the participants or beneficiaries of the employee benefit plan

Section 302A.521 Subd. 2 further provides that the termination of a proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent does not, of itself, establish that the person did not meet the criteria set forth in this subdivision.

In addition, Section 302A.521, Subd. 3, requires that if a person is made or threatened to be made a party to a proceeding, the person is entitled, upon written request to the corporation, to payment or reimbursement by the corporation of reasonable expenses, including attorneys' fees and disbursements, incurred by the person in advance of the final disposition of the proceeding, (a) upon receipt by the corporation of a written affirmation by the person of a good faith belief that the criteria for indemnification set forth in Section 302A.521, Subd. 2 have been satisfied and a written undertaking by the person to repay all amounts so paid or reimbursed by the corporation, if it is ultimately determined that the criteria for indemnification have not been satisfied, and (b) after a determination that the facts then known to those making the determination would not preclude indemnification under this section. The written undertaking required by clause (a) is an unlimited general obligation of the person making it, but need not be secured and shall be accepted without reference to financial ability to make the repayment.

Section 302A.521 Subd. 4 provides that the articles of incorporation or bylaws of a corporation either may prohibit indemnification or advances of expenses otherwise required by Section 302A.521 or may impose conditions on indemnification or advances of expenses in addition to the conditions contained in Subd. 2 and 3 including, without limitation, monetary limits on indemnification or advances of expenses, if the prohibition or conditions apply equally to all persons or to all persons within a given class. A prohibition or limit on indemnification or advances may not apply to or affect the right of a person to indemnification or advances of expenses with respect to any acts or omissions of the person occurring prior to the effective date of a provision in the articles of incorporation or the date of adoption of a provision in the corporation's bylaws establishing the prohibition or limit on indemnification or advances.

Section 302A.521 Subd. 5 provides that Section 302A.521 does not require, or limit the ability of a corporation to reimburse expenses, including attorneys' fees and disbursements, incurred by a person in connection with an appearance as a witness in a proceeding at a time when the person has not been made or threatened to be made a party to a proceeding

Section 302A.521 Subd. 6 further provides that:

(a) all determinations whether indemnification of a person is required because the criteria set forth in Subd. 2 have been satisfied and whether a person is entitled to payment or reimbursement of expenses in advance of the final disposition of a proceeding as provided in Subd. 3 shall be made:

- (1) by the board by a majority of a quorum, if the directors who are at the time parties to the proceeding are not counted for determining either a majority or the presence of a quorum;
- (2) if a quorum under clause (1) cannot be obtained, by a majority of a committee of the board, consisting solely of two or more directors not at the time parties to the proceeding, duly designated to act in the matter by a majority of the full board including directors who are parties;
- (3) if a determination is not made under clause (1) or (2), by special legal counsel, selected either by a majority of the board or a committee by vote pursuant to clause (1) or (2) or, if the requisite quorum of the full board cannot be obtained and the committee cannot be established, by a majority of the full board including directors who are parties;
- (4) if a determination is not made under clauses (1) to (3), by the affirmative vote of the shareholders required by Section 302A.437 of the Minnesota Statutes, but the shares held by parties to the proceeding must not be counted in determining the presence of a quorum and are not considered to be present and entitled to vote on the determination; or
- (5) if an adverse determination is made under clauses (1) to (4) or under paragraph (b), or if no determination is made under clauses (1) to (4) or under paragraph (b) within 60 days after (i) the later to occur of the termination of a proceeding or a written request for indemnification to the corporation or (ii) a written request for an advance of expenses, as the case may be, by a court in this state, which may be the same court in which the proceeding involving the person's liability took place, upon application of the person and any notice the court requires. The person seeking indemnification or payment or reimbursement of expenses pursuant to this clause has the burden of establishing that the person is entitled to indemnification or payment or reimbursement of expenses.

(b) With respect to a person who is not, and was not at the time of the acts or omissions complained of in the proceedings, a director, officer, or person possessing, directly or indirectly, the power to direct or cause the direction of the management or policies of the corporation, the determination whether indemnification of this person is required because the criteria set forth in Subd. 2 have been satisfied and whether this person is entitled to payment or reimbursement of expenses in advance of the final disposition of a proceeding as provided in Subd. 3 may be made by an annually appointed committee of the board, having at least one member who is a director. The committee shall report at least annually to the board concerning its actions.

Section 302A.521 Subd 7 allows a corporation to purchase and maintain insurance on behalf of a person in that person's official capacity against any liability asserted against and incurred by the person in or arising from that capacity, whether or not the corporation would have been required to indemnify the person against the liability under the provisions of section 302A.521 of the Minnesota Statutes.

Section 302A.521 Subd. 8 requires a corporation that indemnifies or advances expenses to a person in accordance with Section 302A.521 in connection with a proceeding by or on behalf of the corporation to report to the shareholders in writing the amount of the indemnification or advance and to whom and on whose behalf it was paid not later than the next meeting of shareholders.

Section 302A.521 Subd. 9 provides that nothing in Section 302A.521 shall be construed to limit the power of the corporation to indemnify persons other than a director, officer, employee, or member of a committee of the board of the corporation by contract or otherwise.

Pursuant to our Bylaws, we may indemnify our directors and executive officers to the fullest extent not prohibited by any applicable law; provided, however, that we may modify the extent of such indemnification by individual contracts with our directors and executive officers; and, provided, further, that we shall not be required to indemnify any director or executive officer in connection with any proceeding (or part thereof) initiated by such person unless: (i) such indemnification is expressly required to be made by law; (ii) the proceeding was authorized by our Board of Directors; or (iii) such indemnification is provided by the Company, in our sole discretion, pursuant to the powers vested in the Company under any applicable law. We shall have the power to indemnify our other officers, employees and other agents as set forth in any other applicable law. Our Board of Directors shall have the power to delegate the determination of whether indemnification shall be given to any such person to such officers or other persons as our board of directors shall determine.

In addition, our Bylaws provide that we will advance to any person who was or is a party to a threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he is or was a director or executive officer, of the Company, prior to the final disposition of the proceeding, promptly following request therefore, all expenses incurred by any director or executive officer in connection with such proceeding; provided, however, that the advancement of expenses shall be made only upon delivery to the Company of an undertaking by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal that such indemnitee is not entitled to be indemnified for such expenses. Notwithstanding the foregoing, unless otherwise determined, no advance shall be made by the Company to an officer of the Company (except by reason of the fact that such officer is or was a director of the Company in which event this paragraph shall not apply) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, if a determination is reasonably and promptly made: (i) by a majority vote of directors who are not parties to the proceeding; (ii) by a committee of such directors designated by a majority vote of such directors; or (iii) if there are no such directors, or such directors so direct, by a written opinion from independent legal counsel, that the facts known to the decision making party at the time such determination is made demonstrate clearly and convincingly that such person acted in bad faith or in a manner that such person did not believe to be in the best interests of the Company.

Our Bylaws also provide that without the necessity of entering into an express contract, all rights to indemnification and advances to our directors and executive officers shall be deemed to be contractual rights and to be effective to the same extent and as if provided for in a contract between the Company and the director or executive officer. Any right to indemnification or advances granted to a director or executive officer shall be enforceable by or on behalf of the person holding such right in any court of competent jurisdiction if: (i) the claim for indemnification or advances is denied, in whole or in part; or (ii) no disposition of such claim is made within ninety (90) days of request therefore. The claimant in such enforcement action, if successful, shall be entitled to be paid also the expense of prosecuting the claim. In connection with any claim for indemnification, the Company shall be entitled to raise as a defense to any such action that the claimant has not met the standards of conduct that make it permissible under applicable law for the Company to indemnify the claimant for the amount claimed. In connection with any claim by an executive officer of the Company (except in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such executive officer is or was a director of the Company) for advances, the Company shall be entitled to raise a defense as to any such action clear and convincing evidence that such person acted in bad faith or in a manner that such person did not believe to be in the best interests of the Company, or with respect to any criminal action or proceeding that such person acted without reasonable cause to believe that his conduct was lawful. A determination by the Company (including the board of directors, independent legal counsel or the stockholders) that indemnification of the claimant is proper because he has met the applicable standard of conduct or that the claimant has not met such applicable standard of conduct shall not be a defense to the action nor shall it create a presumption that claimant has not met the applicable standard of conduct.

## Where You Can Find More Information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the common stock being offered in this offering. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules filed as part of the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, we refer you to the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The reports and other information we file with the SEC can be read and copied at the SEC's Public Reference Room at 100 F Street, N.E., Washington D.C. 20549, on official business days during the hours of 10 a.m. to 3 p.m. Copies of these materials can be obtained at prescribed rates from the Public Reference Section of the SEC at the principal offices of the SEC, 100 F Street, N.E., Washington D.C. 20549. You may obtain information regarding the operation of the public reference room by calling 1(800) SEC-0330. The SEC also maintains a website (<http://www.sec.gov>) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

After this offering, we will be subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended, and we intend to file periodic reports and other information with the Securities and Exchange Commission. We are not required by these requirements to deliver an annual report to our shareholders and, due to the cost involved, it is not likely that we will deliver an annual report with audited financial statements to our shareholders.

## Experts

Olsen Thielen & Co., Ltd., our independent registered public accounting firm, audited our financial statements at December 31, 2008 and December 31, 2007, as set forth in their report. We have included our financial statements and financial information in this prospectus and elsewhere in this registration statement in reliance on the report of Olsen Thielen & Company, Ltd. given on their authority as experts in accounting and auditing.

## Legal Matters and Interests of Named Experts

Richardson & Patel LLP has given us an opinion relating to the due issuance of the common stock being registered. The law firm of Richardson & Patel, LLP ("R & P") owns 60,714 shares of our common stock. Nimish Patel, a principal of R & P, holds 412,411 shares of our common stock, 45,595 shares underlying certain convertible notes, and 45,595 shares underlying certain warrants. Erick Richardson, another principal of R & P, holds 399,543 shares of our common stock, 45,595 shares underlying certain convertible notes, and 45,595 shares underlying certain warrants. RP Capital, a limited liability company owned by Mr. Richardson and Mr. Patel, holds 183,991 shares of our common stock and warrants to purchase 142,857 shares of our common stock. Other R & P employees and principals beneficially own 320,858 shares of our common stock and warrants to purchase 28,571 shares of our common stock. The aggregate number of BioDrain securities held by Richardson & Patel LLP and its affiliates includes 1,336,383 shares of common stock, 91,190 shares of common stock underlying convertible notes, and 353,808 shares of common stock subject to exercise of warrants. This describes all Company securities held by Richardson & Patel LLP and its affiliates. All of these shares are being registered pursuant to this registration statement.

Nimish Patel and Erick Richardson, both principals of Richardson & Patel LLP, hold notes in the amount of \$12,500 each, as participants in the convertible bridge loan dated July 23, 2007, that was due April 23, 2008 and is now in default. As of June 30, 2009 the Company has accrued \$3,188 in interest and \$1,507 in penalties on each of the notes. In addition, the Company owes Richardson & Patel approximately \$200,000 in unpaid legal fees as of June 30, 2009.



## Financial Information

The audited financial statements for the periods ended December 31, 2008 and December 31, 2007 and unaudited financial statements for the periods ended June 30, 2009 and June 30, 2008 are included on the following pages:

### INDEX TO FINANCIAL STATEMENTS

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors  
BioDrain Medical, Inc.  
Mendota Heights, MN

We have audited the accompanying balance sheets of BioDrain Medical, Inc. (a development stage company) as of December 31, 2008 and 2007 and the related statements of operations, stockholders' deficit and cash flows for the years then ended. These financial statements are the responsibility of the company's management. Our responsibility is to express an opinion on these financial statements based on our audits. As shown in Note 11, the Company has restated its 2008 and 2007 financial statements to properly record debt forgiveness, stock option and warrant valuation and debt discounts in conformity with accounting principles generally accepted in the United States of America.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of BioDrain Medical, Inc. (a development stage company) as of December 31, 2008 and 2007, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the company will continue as a going concern. As discussed in Note 1 to the financial statements, the company has incurred losses since inception, has an accumulated deficit and has not received revenue from sales of products and services. These factors raise substantial doubt about its ability to continue as a going concern. Managements' plan in regard to these matters are also described in Note 1. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Olsen Thielen & Co., Ltd.

St. Paul, Minnesota  
May 14, 2009

**BIODRAIN MEDICAL, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**BALANCE SHEET**

	June 30, 2009 <u>(Restated)</u> <u>(Unaudited)</u>	December 31, 2008 <u>(Restated)</u>	2007 <u>(Restated)</u>
<b>ASSETS</b>			
<b>Current Assets:</b>			
Cash	\$ 235,227	\$ 463,838	4,139
Prepaid expense and other assets	6,166	7,974	4,558
Accounts receivable	15,737	-	-
Restricted cash in escrow (See Note 4)	163,333	163,333	-
<b>Total Current Assets</b>	<u>420,463</u>	<u>635,145</u>	<u>8,737</u>
Fixed assets, net	10,475	11,689	-
Intangibles, net	141,532	142,145	112,456
<b>Total Assets</b>	<u>\$ 572,470</u>	<u>\$ 788,979</u>	<u>\$ 121,283</u>
<b>LIABILITIES AND SHAREHOLDERS' DEFICIT</b>			
<b>Current Liabilities:</b>			
Current portion of long term debt (See Note 8)	\$ 17,620	\$ 17,620	\$ 33,800
Current portion of convertible debt, net of discount of \$30,899 in 2007	170,000	170,000	139,101
Accounts payable	649,445	497,150	207,148
Accrued expenses	593,343	305,248	341,429
Convertible debenture	10,000	10,000	10,000
<b>Total Current Liabilities</b>	<u>1,440,407</u>	<u>1,000,018</u>	<u>731,478</u>
Long term debt and convertible debt, net of discounts of \$21,631, \$26,157 and \$34,206 (See Note 8)	96,235	98,406	102,302
Liability for equity-linked financial instruments (See Note 12)	1,086,186	-	-
Commitments and contingencies (See Note 9)	-	-	-
<b>Stockholders Deficit:</b>			
Common stock, 40,000,000 authorized, 9,225,841, 8,130,841, and 823,676 outstanding	92,258	81,308	8,237
Additional paid-in capital	2,736,946	2,753,039	660,430
Deficit accumulated during development stage	(4,879,563)	(3,143,792)	(1,381,164)
<b>Total Shareholder' Deficit</b>	<u>(2,050,358)</u>	<u>(309,445)</u>	<u>(712,497)</u>
<b>Total Liabilities and Shareholders' Deficit</b>	<u>\$ 572,470</u>	<u>\$ 788,979</u>	<u>\$ 121,283</u>

See Accompanying Notes to Financial Statements.

**BIODRAIN MEDICAL, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**STATEMENT OF OPERATIONS**

	<u>Year ended December 31,</u>		<u>Six Months Ended June 30,</u>		<u>Period From</u>
	<u>2008</u>	<u>2007</u>	<u>2009</u>	<u>2008</u>	<u>April 23, 2002</u>
	<u>(Restated)</u>	<u>(Restated)</u>	<u>(Unaudited)</u>	<u>(Unaudited)</u>	<u>(Inception)</u>
					<u>To June 30,</u>
					<u>2009</u>
					<u>(Unaudited)</u>
					<u>(Restated)</u>
Sales	\$ -	\$ -	\$ 15,737	\$ -	\$ 15,737
Cost of goods sold	-	-	7,450	-	7,450
Gross margin	-	-	8,287	-	8,287
General and administrative expense	1,316,398	636,517	871,540	409,159	3,301,680
Operations expense	321,205	1,434	194,926	91,449	648,800
Sales and marketing expense	35,682	13,392	208,503	210	257,578
Interest expense	89,343	101,071	39,320	7,001	250,023
Loss on valuation of equity-linked financial instruments	-	-	436,423	-	429,769
Total expense	<u>1,762,628</u>	<u>752,414</u>	<u>1,750,712</u>	<u>507,819</u>	<u>4,887,850</u>
Net loss available to common shareholders	<u>\$ (1,762,628)</u>	<u>\$ (752,414)</u>	<u>\$ (1,742,425)</u>	<u>\$ (507,819)</u>	<u>\$ (4,879,563)</u>
Loss per common share basic and diluted	<u>\$ (0.41)</u>	<u>\$ (0.91)</u>	<u>\$ (0.20)</u>	<u>\$ (0.38)</u>	<u>\$ (2.72)</u>
Weighted average shares used in computation, basic and diluted	<u>4,335,162</u>	<u>823,676</u>	<u>8,531,200</u>	<u>1,349,506</u>	<u>1,793,898</u>

See Accompanying Notes to Financial Statements.

**BIODRAIN MEDICAL, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**STATEMENT OF STOCKHOLDERS' DEFICIT**  
**PERIOD FROM APRIL 23, 2002 (INCEPTION) TO JUNE 30, 2009**

	Shares	Amount	Paid-in Capital	Accumulated Deficit	Total
Issuance of common stock 9/1/02, \$.0167 (1)	598,549	\$ 5,985	\$ 4,015	\$ -	\$ 10,000
Issuance of common 10/23/02, \$1.67/share	2,993	30	4,970		5,000
Net loss				(51,057)	(51,057)
Balance 12/31/02	601,542	\$ 6,015	\$ 8,985	\$ (51,057)	\$ (36,057)
Issuance of common 2/12/03, \$.0167 (2)	23,942	239	161		400
Issuance of common 6/11&12, \$1.67 (3)	21,548	216	34,784		35,000
Net Loss				(90,461)	(90,461)
Balance 12/31/03	647,032	\$ 6,470	\$ 43,930	\$ (141,518)	\$ (91,118)
Issuance of common 5/25/04, \$.0167 (4)	6,567	66	44		110
Net Loss				(90,353)	(90,353)
Balance 12/31/04	653,599	\$ 6,536	\$ 43,974	\$ (231,871)	\$ (181,361)
Issuance of common 12/14/05, \$.0167 (5)	14,964	150	100		250
Vested stock options and warrants			2,793		2,793
Net Loss				(123,852)	(123,852)
Balance 12/31/05	668,563	\$ 6,686	\$ 46,867	\$ (355,723)	\$ (302,170)
Issuance of common 5/16 & 8/8, \$.0167 (6)	86,869	869	582		1,451
Issuance of common 10/19 & 23, \$.0167 (7)	38,906	389	261		650
Issuance of common 12/01, \$1.67 (8)	28,739	287	44,523		44,810
Vested stock options and warrants			13,644		13,644
Net Loss				(273,026)	(273,026)
Balance 12/31/06	823,077	\$ 8,231	\$ 105,877	\$ (628,749)	\$ (514,641)
Issuance of common 1/30/07 @ 1.67 (9)	599	6	994		1,000
Value of equity instruments issued with debt			132,938		132,938
Capital contributions resulting from waivers of debt			346,714		346,714
Vested stock options and warrants			73,907		73,907
Net loss				(752,415)	(752,415)
Balance 12/31/07 (Restated)	823,676	\$ 8,237	\$ 660,430	\$ (1,381,164)	\$ (712,497)
Issuance of common 6/11 to 9/30, \$.35 (10)	4,552,862	45,528	1,547,974		1,593,502
Shares issued to finders, agents	2,012,690	20,127	(20,127)		-
Shares issued to pay direct legal fees	285,714	2,857	(2,857)		-
Issuance of common due to anti-dilution provisions	205,899	2,059	(2,059)		-
Shares issued to pay investor relations services 6/23/08, \$.35	250,000	2,500	85,000		87,500
Vested stock options and warrants			354,994		354,994
Capital contributions resulting from waivers of debt			129,684		129,684
Net loss				(1,762,628)	(1,762,628)
Balance 12/31/08 (Restated)	8,130,841	\$ 81,308	\$ 2,753,039	\$ (3,143,792)	\$ (309,445)
Cumulative effect of adoption of EITF 07-5			(486,564)	6,654	(479,910)
Vested stock options and warrants			81,676		81,676
Shares issued 3/20/09 to pay for fund raising	125,000	1,250	(1,250)		-
Shares issued under PPM in April 2009, \$.50	700,000	7,000	343,000		350,000
Shares issued under PPM in May 2009, \$.50	220,000	2,200	107,800		110,000
Shares issued under PPM in June 2009, \$.50	50,000	500	24,500		25,000
Capital contributions resulting from waivers of debt			84,600		84,600
Value of equity-linked financial instruments issued in connection with PPM			(169,855)		(169,855)
Net Loss				(1,742,425)	(1,742,425)
Balance 6/30/09 (Restated unaudited)	9,225,841	\$ 92,258	\$ 2,736,946	\$ (4,879,563)	\$ (2,050,358)

- (1) Founders shares, 1,000,000 pre-split
- (2) 23,492 (40,000 pre-split) shares valued at \$.0167 per share as compensation for loan guarantees by management
- (3) Investment including 670 shares issued as a 10% finders fee
- (4) For payment of patent legal fees
- (5) Compensation for loan guarantees by management
- (6) For vendor contractual consideration
- (7) Employment agreements
- (8) Investment
- (9) Conversion of convertible notes by management
- (10) Investment, "October 2008 financing".

See Accompanying Notes to Financial Statements.

**BIODRAIN MEDICAL, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**STATEMENTS OF CASH FLOWS**

	Year Ended December 31,		Six Months Ended June 30,		April 23,
	2008	2007	2009	2008	(Inception)
	(Restated)	(Restated)	(Unaudited) (Restated)	(Unaudited)	To June 30, 2009
<b>Cash flow from operating activities:</b>					
Net loss	\$ (1,762,628)	\$ (752,414)	\$ (1,742,425)	\$ (507,818)	\$ (4,879,563)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization	569	47	1,827	-	2,746
Vested stock options and warrants	354,994	73,907	81,675	6,084	527,004
Stock issued for consulting services	87,500	-	-	-	87,500
Conversion of accrued liabilities to capital	129,684	346,714	84,600	-	560,998
Amortization of debt discount	38,948	67,833	4,526	-	111,307
Loss on valuation of equity-linked instruments	-	-	436,423	-	429,769
Changes in assets and liabilities:					
Accounts receivable	-	-	(15,737)	-	(15,737)
Prepaid expense and other	(3,417)	(4,287)	1,808	(6,792)	(6,166)
Notes payable to shareholders	-	(10,973)	-	(8,500)	(10,964)
Accounts payable	290,003	126,616	152,293	43,801	649,445
Accrued expenses	(36,181)	(72,092)	288,115	63,684	593,343
Net cash used in operating activities:	(900,528)	(224,649)	(706,894)	(409,542)	(1,950,319)
<b>Cash flow from investing activities:</b>					
Purchase of fixed assets	(12,258)	-	-	-	(12,258)
Purchase of intangibles	(29,599)	(45,583)	-	(5,796)	(142,495)
Net cash used in investing activities	(41,857)	(45,583)	-	(5,796)	(154,753)
<b>Cash flow from financing activities:</b>					
Proceeds from long term debt	-	264,000	-	-	421,505
Principal payments on long term debt	(28,125)	(1,592)	(6,697)	(18,065)	(95,046)
Restricted cash in escrow	(163,333)	-	-	(163,333)	(163,333)
Issuance of common stock	1,593,502(1)	11,000	485,000	941,898	2,177,173
Net cash provided by (used in) financing activities	1,402,044	273,408	478,303	760,500	2,340,299
Net increase (decrease) in cash	459,659	3,176	(228,591)	345,162	235,227
Cash at beginning of period	4,179	1,003	463,818	4,179	-
Cash at end of period	\$ 463,838	\$ 4,179	\$ 235,227	\$ 349,341	\$ 235,227
<b>Supplemental disclosure:</b>					
<b>Non-cash financing activities:</b>					
Discount of issuance of debt	\$ -	\$ 132,938	\$ -	\$ -	\$ 132,938

(1) All funds were a part of the October 2008 financing at \$.35 per unit, which included one share of common stock and one warrant to purchase an equal number of shares at \$.46 per share.

See Accompanying Notes to Financial Statements.

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**BIODRAIN MEDICAL, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS**  
**(Amounts presented at and for the six months ended June 30, 2008 and**  
**June 30, 2009 are unaudited)**

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**NOTE 1 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Nature of Operations and Continuance of Operations**

BioDrain Medical, Inc. was incorporated under the laws of the State of Minnesota in 2002. The Company is developing an environmentally safe system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The company has suffered recurring losses from operations and has a stockholders' deficit. These factors raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Management hired Newbridge Securities Corporation, an investment banker, in February 2009, to raise an additional \$3-\$5 million in new equity by December 31, 2009 with an interim closing of up to \$500,000 expected by September 30, 2009. Although our ability to raise this new capital is in substantial doubt we have received \$525,000 in April, May, June and August 2009, and our April 1, 2009 510(k) clearance from the FDA to authorize us to market and sell our FMS products is being received very positively. If the Company is successful in raising at least \$3 million in new equity we will have sufficient capital to operate our business and execute our business plan for at least the next 12 months. If the Company raises the additional capital by issuing additional equity securities its shareholders could experience substantial dilution.

**Recent Accounting Developments**

In June 2008, the Financial Accounting Standards Board ("FASB") ratified Emerging Issues Task Force (EITF) Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* (EITF 07-5). EITF 07-5 mandates a two-step process for evaluating whether an equity-linked financial instrument or embedded feature is indexed to the entity's own stock. It is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, which is our first quarter of 2009. Most of the warrants issued by the Company contain a strike price adjustment feature, which upon adoption of EITF 07-5, will result in the instruments no longer being considered indexed to the Company's own stock. Accordingly, adoption of EITF 07-5 changed the classification (from equity to liability) and the related accounting for many warrants with an estimated fair value of \$479,910 as of January 1, 2009. See Note 12 for explanation of the impact of adoption.

In May 2008, the FASB issued FSP APB No. 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ("FSP APB No. 14-1"), to clarify that convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) are not addressed by paragraph 12 of APB Opinion No. 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants*. The FSP requires the issuer of certain convertible securities that may be settled in cash on conversion to separately account for the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. The Company's convertible debt instruments do not provide that the instruments may be settled in cash and this FSP does not apply.

**Accounting Estimates**

The presentation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**Interim Financial Statements**

The Company has prepared the unaudited interim financial statements and related unaudited financial information in the footnotes in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. These interim financial statements reflect all adjustments consisting of normal recurring accruals, which, in the opinion of management, are necessary to present fairly the Company's financial position, the results of its operations and its cash flows for the interim periods. These interim financial statements should be read in conjunction with the annual financial statements and the notes thereto contained herein. The nature of the Company's business is such that the results of any interim period may not be indicative of the results to be expected for the entire year.

**Revenue Recognition** We recognize revenue in accordance with the SEC's Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by Staff Accounting Bulletin No. 104 (together, SAB 101), and Statement of Financial Accounting Standards No. 48, *Revenue Recognition When Right of Return Exists* (SFAS 48).

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable and collectibility is probable. Delivery is considered to have occurred upon either shipment of the product or arrival at its destination based on the shipping terms of the transaction. Our standard terms specify that shipment is FOB BioDrain and we will, therefore recognize revenue upon shipment in most cases. This revenue recognition policy applies to shipments of our FMS units as well as shipments of cleaning solution kits. When these conditions are satisfied, we recognize gross product revenue, which is the price we charge generally to our customers for a particular product. Under our standard terms and conditions there is no provision for installation or acceptance of the product to take place prior to the obligation of the customer. The Customer's right of return is limited only to our standard one year warranty whereby we replace or repair, at our option, and it would be very rare that the unit or significant quantities of cleaning solution kits may be returned. Additionally, since we buy both the FMS units and cleaning solution kits from "turnkey" suppliers we would have the right to replacements from the suppliers if this situation should occur.

**Property and Equipment**

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the respective assets. Estimated useful asset life by classification is as follows:

	<u>Years</u>
Computers and office equipment	3
Furniture and fixtures	5

Upon retirement or sale, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

### **Intangible Assets**

Intangible assets consist of patent costs. These assets are not subject to amortization until the property patented is in production. The assets are reviewed for impairment annually, and impairment losses, if any, are charged to operations when identified. No impairment losses have been identified by management.

### **Income Taxes**

The Company accounts for income taxes in accordance with SFAS No. 109, Accounting for Income Taxes ("SFAS No. 109"). Under SFAS No. 109, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and net operating loss and credit carry forwards using enacted tax rates in effect for the year in which the differences are expected to impact taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. In June 2006, the FASB issued Interpretation 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"), which became effective for the Company beginning January 1, 2007. FIN 48 addresses how tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under FIN 48, the tax benefit from an uncertain tax position can be recognized only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. The adoption of FIN 48 had no impact on the Company's financial condition, results of operations or cash flows.

### **Product Development**

Product development costs are charged to operations as incurred. Product development costs were \$182,893 and \$1,434 for the year ended December 31, 2008 and 2007, respectively. Product development costs in our financial statements are the same as research and development costs as defined in SFAS 2.

### **Patents and Intellectual Property**

The Company, in June 2008, completed and executed an agreement to secure exclusive ownership of the patent- from an inventor, Marshall Ryan. Mr. Ryan received a combination of cash and warrants, and he will receive a 4% royalty on FMS (the Product) sales for the life of the patent. At the signing of the agreement, Mr. Ryan received \$75,000 in exchange for the exclusive assignment of the patent. In addition, on June 30, 2009, Mr. Ryan, through his Mid-State Stainless, Inc. entity, was entitled to receive \$100,000 as payment (currently recorded as an account payable with the Company) for past research and development activities. Should Mr. Ryan be utilized in the future for additional product development activities, he will be compensated at a rate of ninety five dollars (\$95.00) per hour.

Mr. Ryan also received a warrant, with immediate vesting, to purchase 150,000 shares of our common stock at a price of \$.35 per share. The warrant has a term of five years, ending on June 30, 2013 and is assigned a value of \$28,060 using a Black-Scholes formula and this amount was expensed as consulting expense in 2008 using a 5 year expected life, a 3.73% risk free interest rate, an expected 59% volatility and a zero dividend rate. Should there be a change in control of the Company (defined as greater than 50% of the Company's outstanding stock or substantially all of its assets being transferred to one independent person or entity), Mr. Ryan will be owed a total of \$2 million to be paid out over the life of the patent if the change in control occurs within 12 months of the first sale of the Product; or \$1 million to be paid out over the life of the patent if the change in control occurs between 12 and 24 months of the first sale of the Product; or \$500,000 to be paid out over the life of the patent if the change in control occurs between 24 and 36 months of the first sale of the Product. There will be no additional payment if a change in control occurs more than 36 months after the first sale of the Product.



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**NOTE 2 – DEVELOPMENT STAGE OPERATIONS**

The Company was formed April 23, 2002. Since inception to June 30, 2009, 9,225,841 shares have been issued between par value and \$1.67. Operations since incorporation have been devoted to raising capital, obtaining financing, development of the Company's product, and administrative services.

**NOTE 3 – STOCKHOLDERS' DEFICIT, STOCK OPTIONS AND WARRANTS**

In connection with the financing completed in October 2008, the Company has effected two reverse stock splits, one on June 6, 2008 and another on October 20, 2008. In accordance with SAB Topic 4C, all stock options and warrants and their related exercise prices are stated at their post-reverse stock split values.

The Company has an equity incentive plan, which allows issuance of incentive and non-qualified stock options to employees, directors and consultants of the Company, where permitted under the plan. The exercise price for each stock option is determined by the board of directors. Vesting requirements are determined by the board of directors when granted and currently range from immediate to three years. Options under this plan have terms ranging from three to ten years.

*Accounting for share-based payment*

Effective January 1, 2006, we adopted SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)) which replaced SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123) and superseded Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25). Under SFAS 123(R), stock-based employee compensation cost is recognized using the fair value based method for all new awards granted after January 1, 2006 and unvested awards outstanding at January 1, 2006. Compensation costs for unvested stock options and non-vested awards that were outstanding at January 1, 2006, are being recognized over the requisite service period based on the grant-date fair value of those options and awards as previously calculated under SFAS 123 for pro forma disclosures, using a straight-line method. We elected the modified-prospective method in adopting SFAS 123(R), under which prior periods are not retroactively restated.

SFAS 123(R) requires companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model or other acceptable means. We use the Black-Scholes option valuation model which requires the input of significant assumptions including an estimate of the average period of time employees will retain vested stock options before exercising them, the estimated volatility of our common stock price over the expected term, the number of options that will ultimately be forfeited before completing vesting requirements, the expected dividend rate and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognized. The assumptions we use in calculating the fair value of stock-based payment awards represent our best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our equity-based compensation expense could be materially different in the future.

Since our company stock has no public trading history, and we have experienced no option exercises in our history, we were required to take an alternative approach to estimating future volatility and estimated life and the future results could vary significantly from our estimates. We compiled historical volatilities over a period of 2-7 years of 15 small-cap medical companies traded on major exchanges and 10 medical companies in the middle of the size range on the OTC Bulletin Board and combined the results using a weighted average approach. In the case of ordinary options to employees we determined the expected life to be the midpoint between the vesting term and the legal term. In the case of options or warrants granted to non-employees we estimated the life to be the legal term unless there was a compelling reason to make it shorter.

When an option or warrant is granted in place of cash compensation for services we deem the value of the service rendered to be the value of the option or warrant. In most cases, however, an option or warrant is granted in addition to other forms of compensation and its separate value is difficult to determine without utilizing an option pricing model. For that reason we also use the Black-Scholes-Merton option-pricing model to value options and warrants granted to non-employees, which requires the input of significant assumptions including an estimate of the average period the investors or consultants will retain vested stock options and warrants before exercising them, the estimated volatility of our common stock price over the expected term, the number of options and warrants that will ultimately be forfeited before completing vesting requirements, the expected dividend rate and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based consulting and/or compensation and, consequently, the related expense recognized.

Since we have no trading history in our stock and no first-hand experience with how these investors and consultants have acted in similar circumstances, the assumptions we use in calculating the fair value of stock-based payment awards represent our best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our equity-based consulting and interest expense could be materially different in the future.

*Valuation and accounting for options and warrants*

The Company determines the grant date fair value of options and warrants using a Black-Scholes-Merton option valuation model based upon assumptions regarding risk-free interest rate, expected dividend rate, volatility and estimated term. For grants during 2008 we used a 2.0 to 4.5% risk-free interest rate, 0% dividend rate, 53-66% volatility and estimated term of 2.5 to 7.5 years. Values computed using these assumptions ranged from \$.102 per share to \$.336 per share. Warrants or options awarded for services rendered are expensed over the period of service (normally the vesting period) as compensation expense for employees or an appropriate consulting expense category for awards to consultants and directors. Warrants granted in connection with a common equity financing are included in stockholders' equity, provided that there is no re-pricing provision that requires they be treated as a liability (See Note 12) and warrants granted in connections with a debt financing are treated as a debt discount and amortized using the interest method as interest expense over the term of the debt. Warrants issued in connection with the \$100,000 convertible debt, closed March 1, 2007, created a debt discount of \$40,242 that is being amortized as additional interest over its 5 year term. Warrants issued in connection with the \$170,000 in convertible "bridge" debt, closed in July 2007, created a calculated debt discount of \$92,700 that was fully expensed over its loan term that matured April 30, 2008.



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The following summarizes transactions for stock options and warrants for the periods indicated:

	Stock Options (1)		Warrants (1)	
	Number of Shares	Average Exercise Price	Number of Shares	Average Exercise Price
Outstanding at December 31, 2005	17,956	\$ 1.67	20,950	\$ 2.62
Issued	23,942	1.67	71,826	0.85
Outstanding at December 31, 2006	41,898	\$ 1.67	92,776	\$ 1.25
Issued	5,984	1.67	28,502	0.35
Outstanding at December 31, 2007	47,882	\$ 1.67	121,278	\$ 1.04
Issued	1,243,292	0.20	5,075,204	0.45
Expired			(11,971)	3.76
Outstanding at December 31, 2008	1,291,174	\$ 0.26	5,184,511	0.45
Issued	175,000	0.35	635,095	0.35
Outstanding at June 30, 2009	1,466,174	0.27	6,839,606	0.48

(1) Adjusted for the reverse stock splits in total at June 6, 2008 and October 20, 2008. There were no options or warrants exercised in the periods.

The weighted average grant date fair value of stock options granted through June 30, 2009 and the fair value of shares vesting in each year are as follows:

Year	Options	Fair Value
2005	17,956	\$ 0.671
2006	23,942	\$ 0.682
2007	5,984	\$ 0.687
2008	1,243,292	\$ 0.232
2009	175,000	\$ 0.141
Total	1,466,174	\$ 0.236

  

Year	Fair value vested
2005	\$ 1,673
2006	\$ 12,919
2007	\$ 71,038
2008	\$ 220,287
2009	\$ 48,956
Total	\$ 354,873

At December 31, 2008, 651,174 stock options are fully vested and currently exercisable and 4,984,511 warrants are fully vested and exercisable. There are 640,000 unvested stock options at December 31, 2008 with a total unrecognized compensation expense of \$15,698 to be amortized over a weighted average remaining term of 5.5 months. There are 200,000 unvested warrants at December 31, 2008 with a total unrecognized consulting expense of \$13,301 to be amortized over a weighted average remaining term of 18 months.

At June 30, 2009, 881,174 stock options are fully vested and currently exercisable with a weighted average exercise price of \$.29 and a weighted average remaining term of 5.8 years. There are 6,639,606 warrants that are fully vested and exercisable. There are 585,000 unvested stock options at June 30, 2009 with a total unrecognized compensation expense of \$3,316 to be amortized over a weighted average remaining term of 3.8 months. Stock based compensation recognized in the years ended December 31, 2008 and 2007 were \$220,287 and \$71,038, respectively, and stock based compensation recognized in the six months ended June 30, 2009 and 2008 were \$28,958 and \$6,084, respectively.

The following summarizes the status of options and warrants outstanding at December 31, 2008 and June 30, 2009

December 31, 2008		Shares	Weighted Average Remaining Life
Options	Range of Exercise Prices		
	\$0.01	\$ 543,292	\$ 9.43

\$0.35	700,000	4.46
\$1.67	47,882	2.50
Total	<u>1,291,174</u>	
Warrants		
\$0.02	71,826	5.45
\$0.35	178,502	4.29
\$0.46	4,889,291	2.57
\$1.67	44,892	2.69
Total	<u>5,184,511</u>	

June 30, 2009

Range of Exercise Prices	Shares	Weighted Average Remaining Life
<b>Options</b>		
\$0.01	\$ 543,292	\$ 8.94
\$0.35	875,000	4.12
\$1.67	47,882	2.26
<b>Total</b>	<b>1,466,174</b>	
<b>Warrants</b>		
\$0.02	71,826	4.95
\$0.35	798,597	3.29
\$0.46	4,954,291	2.05
\$0.65	970,000	2.83
\$1.67	44,892	2.19
<b>Total</b>	<b>6,839,606</b>	

Stock options and warrants expire on various dates from August 2010 to June 2018.

Under terms of our agreement with investors in the October 2008 financing 1,920,000 shares of common stock were the maximum number of shares allocated to our existing shareholders at the time of the offering (also referred to as the original shareholders or the Founders). Since the total of our fully-diluted shares of common stock was greater than 1,920,000, in order for us to proceed with the offering, our board of directors approved a reverse stock split of 1-for-1.2545. After this split was approved, additional options and warrants were identified, requiring a second reverse stock split in order to reach the 1,920,000. The second reverse stock split on the reduced 1-for-1.2545 balance was determined to be 1-for-1.33176963. Taken together, if only one reverse stock were performed, the number would have been a reverse stock split of 1-for 1.670705.

On June 6, 2008, the Board of Directors approved the first reverse stock split. The authorized number of common stock of 20,000,000 was proportionately divided by 1.2545 to 15,942,607.

On October 20, 2008, the Board of Directors (i) approved the second reverse stock split pursuant to which the authorized number of shares of common stock of 15,942,607 was proportionately divided by 1.33177 to 11,970,994 and (ii) approved a resolution to increase the number of authorized shares of our common stock from 11,970,994 to 40,000,000, which was approved by the Company's shareholders holding a majority of the shares entitled to vote thereon at a special meeting of shareholders held on December 3, 2008.

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## **Stock, Stock Options and Warrants Granted by the Company**

### *Warrants*

In 2005 and 2006, the Company granted warrants to purchase an aggregate of 17,958 shares (options to purchase 2,993 shares each) of common stock at \$1.67 per share to Debbie Heitzman, Mary Wells Gorman and David Feroe for their services on the Medical Advisory Board and to Karen Ventura, Nancy Kolb and Kim Shelquist for their sales and marketing advisory services.

In 2006, the Company granted a warrant to purchase 35,913 shares of common stock at \$.02 per share to Dr. Arnold Leonard for his services on the Medical Advisory Board. The warrant contains an anti-dilution provision that provides that such shares would double upon the Company's total outstanding shares reaching 2 million. The second warrant to purchase 35,913 shares of the Company's common stock at \$.02 were granted in June 2008 upon reaching 2 million outstanding shares of common stock through the October 2008 financing. The 2008 warrant was valued at \$12,060 using the Black-Scholes valuation model with a 3.57% risk free interest rate, a zero dividend rate, a 66% expected volatility and a 7 year expected life. The full amount was expensed as consulting expense in 2008 as the warrant was immediately vested.

On December 1, 2006, the Company fully repaid two of our three loans, in the combine amount of \$37,500, due to Wisconsin Rural Enterprise Fund ("WREF"). To pay the outstanding loan to WREF, the Company issued a warrant to purchase 20,949 shares of common stock at \$1.67 per share to WREF. The warrant expired October 31, 2008.

In 2006, the Company issued a warrant to purchase 5,985 shares of common stock at \$1.67 per share to Andcor Companies, Inc. as part of a convertible loan agreement. The warrant was valued at \$3,130 using the Black-Scholes valuation model with a 3.00% risk free interest rate, a zero dividend rate, a 45% expected volatility and a 3 year expected life.

In 2007, the Company granted a warrant to purchase up to 28,502 shares of common stock at \$.46 per share to Roy Moore and Carl Moore as part of a convertible loan agreement with them. The warrants contained a provision enabling the two individuals to pay a per share price equal to that of the October 2008 financing when exercising their warrants. The warrants were valued at \$40,240 using the Black-Scholes valuation model with a 3.06% risk free interest rate, a zero dividend rate, a 62% expected volatility and a 5 year expected life. The \$40,250 value is accounted for as a debt discount and is being amortized using the interest method as additional interest expense over the five year term of the convertible loan.

In 2007, the Company agreed to issue warrants to purchase 620,095 shares of common stock at \$.35 per share to seven individuals who provided \$170,000 in a convertible bridge loan. The warrants were issued February 24, 2009 and valued at \$92,700 using the Black-Scholes valuation model with a 1.37% risk free interest rate, a zero dividend rate, an 63% expected volatility and a 3 year expected life. The \$92,700 value was accounted for as a debt discount and was amortized using the interest method as additional interest expense over the one year term of the convertible loan that matured in April 2008.

In June 2008 we executed an agreement with Marshall C. Ryan, the named inventor of the Patents, to secure exclusive ownership of the Patents. In addition to a cash down payment and an agreement to provide future cash payments we also granted Mr. Ryan a warrant to purchase 150,000 shares of our common stock at a price of \$.35 per share. The warrant has a term of five years, ending on June 30, 2013. The warrant has a term of five years, ending on June 30, 2013 and is assigned a value of \$28,060 using a Black-Scholes formula and this amount was expensed as consulting expense in 2008 using a 5 year expected life, a 3.73% risk free interest rate, an expected 59% volatility and a zero dividend rate.

In August 2008, the Company issued a warrant to purchase 50,000 shares of common stock at \$.46 per share to Thomas Bachinski, a regulatory consultant, for his past services. The warrant was valued at \$7,875 using the Black-Scholes valuation model with a 3.06% risk free interest rate, a zero dividend rate, a 58% expected volatility and a 5 year expected life. The warrant has a three year vesting schedule and \$1,092 was amortized in 2008.

In August and September 2008 we issued warrants to purchase 75,000 shares of common stock to each of two human resource consulting firms, Andcor Companies, Inc. and Taylor & Associates, Inc., as payment for their search for candidates to fill the position of Vice President of Sales and Marketing for our Company. Andcor and Taylor will not earn the warrants until the candidate is hired and remains an employee for a period of at least 1 year. The Vice President of Sales and Marketing was hired on February 1, 2009 and the warrants will vest, therefore, on February 1, 2010 provided she is still employed with the Company on that date. Andcor and Taylor are valued at a total of \$60,000 under guidance from EITF 96-18 because that was the value of the cash consideration that was agreed to prior to them accepting warrants in lieu of cash.

The Company issued warrants to purchase an aggregate of 4,552,862 units to investors in connection with the October 2008 financing, which included one share of common stock for \$.35 per share and one warrant to purchase one share of common stock for \$.46 per share. The warrants were valued at \$465,950 using the Black-Scholes valuation model with a 2.75% risk free interest rate, a zero dividend rate, a 53% expected volatility and a 3 year expected life. The value of the warrants is accounted for in the equity section of the balance sheet. In addition, the Company granted warrants to purchase 136,429 shares to finders who helped in raising the \$1.6 million in new equity. The warrants were valued at \$13,965 using the Black-Scholes valuation model with a 2.75% risk free interest rate, a zero dividend rate, a 53% expected volatility and a 3 year expected life. The full value of the warrants was treated as an incremental cost of raising capital and netted against the gross proceeds under the guidance from SAB Topic 5-A.

On February 1, 2009 we issued a warrant to Kirsten Doerfert, in return for consulting work prior to becoming an employee, to purchase 15,000 shares at \$.35 per share. The warrant vested immediately and was valued at \$2,502 using the Black-Scholes valuation model using a 5 year expected term, a 63% expected volatility, a 1.75% risk free interest rate, and a zero dividend rate. The warrant was expensed in February 2009 because it was immediately vested. We used the Black-Scholes model to establish the valuation because the value of the services performed was difficult to measure.

On October 20, 2008, we entered into an agreement with Gregory Sachs, a regulatory consultant, pursuant to which the Company granted an agreement to purchase up to 50,000 shares of our common stock contingent upon reaching certain performance goals from April 1, 2009 to June 30, 2009. Mr. Sachs assisted the Company in obtaining FDA 510(k) clearance. The purpose of the performance goal provision was to help to ensure a timely clearance of the 510(k). Upon reaching FDA clearance on April 1, 2009, Mr. Sachs received a warrant to purchase 50,000 shares of our common stock. The warrant has a 5 year term and an exercise price of \$.46 per share. We determined the value of the warrant to be \$8,318 using the Black-Scholes valuation model using a 5 year expected term, 63% expected volatility, 1.65% risk free interest rate and a zero expected dividend rate. The full amount was expensed in April 2009 because the warrant vested immediately.

Changes in exercise prices or number of warrants would occur if the Company issues any shares of its common stock (other than excluded securities, as defined in the warrant) for a consideration per share less than the exercise price in effect at the time of exercise of the warrant. The warrant contains a cashless exercise provision which provides that after one year following the closing date of the offering, if a registration statement covering the warrants is not available for resale for the warrants, the warrant holder may exercise the warrant in whole or in part in lieu of making a cash payment by electing to receive the net number of common stock determined by the following formula:  $\text{net number} = ((A \times B) - (A \times C)) / B$ . A equals the total number of shares with respect to which the warrant is then being exercised. B equals the closing sale price of the shares of common stock (as reported by Bloomberg) on the date immediately preceding the date of notice of an exercise. C equals the exercise price then in effect for the applicable warrant shares at the time of such exercise. There are no registration obligations on the Company nor are there any liquidated damages or potential penalties to which the Company is subject.

#### *Stock and Stock Options*

On August 22, 2005, we issued an option agreement to purchase 17,957 shares (30,000 shares at \$1 pre-split) of our common stock at \$1.67 per share to Thomas McGoldrick, for his services as a director. In addition to the initial grant the option agreement specifies that he will be granted an option for 5,985 shares per year, on his anniversary date of joining the board, at the market price on the grant date. On August 22, 2006, we issued an option to purchase 5,985 shares of common stock at \$1.67 per share to Mr. McGoldrick.

On November 11, 2006 we issued an option agreement to purchase 17,957 shares (30,000 at \$1 pre-split) of common stock at \$1.67 per share to Andrew Reding, for his services as a director. In addition to the initial grant the option agreement specifies that he will be granted an option for 5,985 shares per year, on his anniversary date of joining the board, at the market price on the grant date. On November 11, 2007, we issued an option to purchase 5,985 shares of common stock at \$1.67 per share to Mr. Reding.

On December 14, 2005, we issued 7,482 shares of common stock to officers Lawrence Gadbow and Gerald Rice as compensation for personal guarantees on Company loans.

On May 16, 2006, the Company issued 71,906 shares of common stock to the inventor of our intellectual property, Marshall C. Ryan, for the development work he performed with respect to our product.

On August 8, 2006, we issued 14,964 shares of common stock to Andcor Companies, Inc. in partial payment of an invoice.

In 2006, Kevin Davidson was granted 29,927 (as split adjusted from the original 50,000 share grant) shares of the Company's common stock in connection with his entering into an employment agreement with the Company. The grant contained an anti-dilution protection amounting to 3.81% of the fully-diluted outstanding common stock of the Company up to the completion of the first \$1,000,000 of new funding raised, which pursuant to an option agreement dated June 5, 2008 amending his employment agreement, Mr. Davidson chose to receive an option to purchase 543,292 shares of common stock, exercisable at \$.01, in lieu of obtaining the additional shares to which he was entitled. The options vest immediately and the term of the options is 10 years from the date of issuance. In 2008, Mr. Davidson achieved the \$1 million funding target provided for in his employment agreement and on September 12, 2008 the Board of Directors ratified the issuance of the 543,292 options to Mr. Davidson as a result of the milestones achieved. The option grant was valued at \$186,826 using the Black-Scholes model. Inputs to the model include a zero dividend rate, a 7.5 year expected life, 66% expected volatility and a 3.94% risk free interest rate.

On October 23, 2006, we issued 8,979 shares of common stock to a former employee as a part of his compensation package in his employment agreement.

On December 1, 2006, we issued 2,983 shares of common stock to pay a consulting fee to Wisconsin Business Innovation Corporation, a related firm of WREF.

On January 30, 2007 we fully repaid a Company loan of \$1,000 due one of its former employees by issuing 599 shares of common stock.

On March 10, 2008, we entered into a finder agreement for referral services for the Company's October 2008 Financing. This agreement covered the following finders: Thomas Pronesti, Craig Kulman, Caron Partners, LP and Bellajule Partners, LP. Under the agreement, in addition to a cash referral fee, the finders were entitled to receive 10% of their gross proceeds raised for us with a fair market value of the Company's common stock, or \$.35 per share. As a result, on June 23, 2008, the group of finders received an aggregate of 155,142 shares of common stock. The fair value of these shares, were determined to be \$54,300 at \$.35 per share and this amount is accounted for as a cost of raising capital and, therefore, is netted against paid in capital under the guidance of SAB Topic 5-A.

On April 15, 2008, we entered into an investor relations agreement with Kulman IR, LLC. Under the agreement, in addition to cash fees, Kulman was entitled to receive 250,000 shares of our common stock. On June 23, 2008 Kulman and Cross Street Partners, Inc., a party related to Kulman, each received 125,000 shares of common stock. The total value of these shares was determined to be \$87,500 using a fair value of \$.35 per share. This amount is shown as a separate line as \$87,500 in common stock and paid in capital in the Statement of Shareholders' Deficit in the Financial Statements, page F-6.

On June 16, 2008, we entered into an employment agreement with Chad Ruwe, Executive Vice President of Operations, pursuant to which we granted him an option to purchase 250,000 shares of common stock with 50,000 shares vested immediately and increments of 50,000 shares vesting upon achievement of certain milestones related to obtaining FDA clearance and achieving commercial sales of our Streamway™ Fluid Management System.

On June 30, 2008, we entered into a consulting agreement with Namaste Financial, Inc. for a one-year period of general business, strategic and growth advisory services. Under the agreement, Namaste received 125,000 shares of common stock and a warrant to purchase 125,000 shares of common stock at \$.46 per share. This firm was engaged to arrange new equity financing and the warrants and shares. The shares were valued at \$43,750 and the warrants were

valued at \$12,800 using a Black-Scholes valuation model. The total value of \$56,550 is shown as a net reduction of paid in capital as they were treated as an incremental cost of raising capital under the guidance of SAB Topic 5-A.

On August 11, 2008, we entered into an employment agreement with David Dauwalter, Director of Sales, pursuant to which we granted him an option to purchase 50,000 shares of common stock with 10,000 shares vested immediately and increments of 10,000 shares vesting upon reaching certain performance milestones.

In connection with the October 2008 financing we issued 250,000 to Kulman Investor Relations/Cross Street Partners for investor relations services. These services were valued at \$87,500 based upon \$.35 per share and were expensed as consulting expenses in 2008. In addition, the company issued 285,714 shares to Richardson & Patel in partial payment of legal fees in connection with the October 2008 financing. The value was determined to be \$100,000 based upon \$.35 per share and was determined to be a direct incremental cost of raising capital and netting in the gross proceeds in accordance with SAB Topic 5-A. We also issued 2,102,690 shares valued at \$704,442, based upon \$.35 per share, to finders and placement agents. This cost was also deemed an incremental direct cost of raising capital and netted against the gross proceeds in accordance with SAB Topic 5-A.

On February 1, 2009 the Company granted an option to purchase 100,000 shares at \$.35 per share, the market value of the stock on that date, to Kirsten Doerfert under terms of her employment agreement. The vesting schedule called for 20,000 shares to vest immediately with increments of 20,000 shares vesting upon achievement of certain performance criteria in her agreement. The value of the option was computed to be \$14,006 using an expected term ranging from 2.5 to 2.8 years, an expected volatility of 63%, a risk free interest rate ranging from 1.085% to 1.191% and a zero dividend rate.

The following table is the listing of stock options and warrants as of December 31, 2008 and June 30, 2009 by year of grant:

Stock Options: Year	December 31, 2008	
	Shares	Price
2005	17,956	\$ 1.67
2006	23,942	1.67
2007	5,984	.35-1.67
2008	1,243,292	.01-.35
<b>Total</b>	<b>1,291,174</b>	<b>\$ .01-\$1.67</b>

Warrants: Year	December 31, 2008	
	Shares	Price
2005	8,979	\$ 1.67
2006	71,826	.02-1.67
2007	28,502	.35
2008	5,075,204	.02-.46
<b>Total</b>	<b>5,184,511</b>	<b>\$ .02-\$1.67</b>



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Stock Options: Year	June 30, 2009	
	Shares	Price
2005	17,956	\$ 1.67
2006	23,942	1.67
2007	5,984	.35-1.67
2008	1,243,292	.01-.35
2009	175,000	.35
Total	1,466,174	\$ .01-\$1.67

Warrants: Year	June 30, 2009	
	Shares	Price
2005	8,979	\$ 1.67
2006	71,826	.02-1.67
2007	28,502	.35
2008	5,075,204	.02-.46
2009	1,655,095	.35-.65
Total	6,839,606	\$ .02-\$1.67

**Other Securities For Issuance Upon Certain Contingencies**

In June 2008, three of our current and former directors/executive officers, Lawrence Gadbow, Gerald Rice and Kevin Davidson agreed to waive an aggregate of approximately \$346,700 in accrued, unpaid salaries relating to 2007 and 2006. This total included waived compensation from Mr. Davidson in the amount of \$90,000, waived compensation from Mr. Rice in the amount of \$125,000 and waived compensation from Mr. Gadbow in the amount of \$138,500. In addition, Mr. Davidson waived \$58,350, Mr. Rice waived \$40,725 and Mr. Gadbow waived \$30,610 in underpaid compensation from 2008. In exchange, therefore, Mr. Gadbow and Mr. Rice will each be granted options to purchase 160,000 shares of common stock and Mr. Davidson will be granted an option to purchase 80,000 shares of common stock, all at \$.35 per share upon the Company raising an additional \$3 million in financing subsequent to the October 2008 financing. In addition, Mr. Rice will be entitled to receive a one-time cash payment of \$46,000, Mr. Davidson will be entitled to receive a one-time cash payment of \$23,000 and Mr. Gadbow will be entitled to receive a one-time cash payment of \$25,000 when the Company raises an additional \$3 million subsequent to the October 2008 financing. Mr. Gadbow is currently receiving \$2,000 per month until a total of \$46,000 of accrued salary liability is paid. The remaining balance due Mr. Gadbow, if any, will be paid upon raising an additional \$3 million. The Company's agreement to pay the cash payments and grant the stock options is solely dependent on raising the \$3 million and does not require the participation of the three individuals in the fund raising activity.

Waived salaries in the amount of \$90,000 for Mr. Davidson, \$125,000 for Mr. Rice and \$138,500 for Mr. Gadbow were treated as a capital contribution in 2007 in accordance with Staff Accounting Bulletin (SAB) 79. The years to which the waived salaries originated were \$102,700 for 2007 and \$244,000 for 2006 and prior years. In addition, the company recorded a capital contribution in the amount of \$129,685 in 2008 representing \$58,350, \$40,375 and \$30,610 in waived 2008 salaries for Mr. Davidson, Mr. Rice and Mr. Gadbow, respectively.

The obligation to grant stock options is being valued under FAS123(R) using the Black-Scholes valuation model, a 55-59% expected volatility, a zero percent dividend rate and an expected life of 5 years for one option and 3.5 years for the other 2 options, taking into account the likely period of time the individuals will exercise their options. The legal term of the options will be 5 years from the date of the grant and 6.2 years, therefore, from the date of the obligation because the obligation to grant the options contingent on a \$3 million funding occurred in June 2008 we expect the \$3 million funding will occur by August 2009.

As of December 31, 2007, \$115,000 remained in accrued expenses for the above expenses and as of December 31, 2008 \$40,000 remained in accounts payable for the obligation to Mr. Gadbow's and \$94,000 remained in accrued expenses for the obligations to Mr. Rice, Mr. Gadbow and Mr. Davidson.

On June 16, 2008, we entered into an employment agreement with Chad Ruwe, Executive Vice President of Operations, pursuant to which we granted him an option to purchase 250,000 shares of common stock with 50,000 shares vested immediately and increments of 50,000 shares vesting upon achievement of certain milestones related to obtaining FDA clearance and achieving commercial sales of our Streamway™ Fluid Management System. As of April 1, 2009 a total of 150,000 shares were vested and an additional 10,000 shares vested on June 15, 2009 as a result of the Company shipping its first revenue producing FMS unit. The Company valued the option at \$33,310 using a Black-Scholes valuation model. The option has a 5 year legal term with 5 separate vesting schedules, an estimated life of 2.5 to 3.2 years, a volatility of 54%, a dividend rate of zero and a risk free interest rate of 3.18-3.4%. The vesting periods for each of the performance tranches range from immediate to 15 months based upon management's assessment of when each of the performance steps will be achieved.

On June 30, 2008, we entered into a consulting agreement with Namaste Financial, Inc. for a one-year period of general business, strategic and growth advisory services. Under the agreement, Namaste received 125,000 shares of common stock and a warrant to purchase 125,000 shares of common stock at \$.46 per share. This firm was engaged to arrange new equity financing and the warrants and shares. The shares were valued at \$43,750 and the warrants were valued at \$12,800 using a Black-Scholes valuation model. The total value of \$56,550 is shown as a net reduction of paid in capital as they were treated as an incremental cost of raising capital under the guidance of SAB Topic 5-A.

On August 11, 2008, we entered into an employment agreement with David Dauwalter, Director of Sales, pursuant to which we granted him an option to purchase 50,000 shares of common stock with 10,000 shares vested immediately and increments of 10,000 shares vesting upon reaching certain performance milestones. On April 1, 2009 10,000 shares were vested, as a result of obtaining FDA clearance, and an additional 10,000 shares vested on June 15, 2009 as a result of the Company shipping its first revenue producing FMS unit. The Company valued the option at \$6,463, an estimated life of 2.5 to 3 years, a

volatility of 53%, a dividend rate of zero and a risk free interest rate of 2.7-2.9%. The vesting periods for each of the performance tranches range from immediate to 13 months based upon management's assessment of when each of the performance steps will be achieved.

On October 20, 2008, we entered into an agreement with Gregory Sachs, a regulatory consultant, pursuant to which the Company granted an agreement to purchase up to 50,000 shares of our common stock contingent upon reaching certain performance goals from April 1, 2009 to June 30, 2009. Mr. Sachs assisted the Company in obtaining FDA 510(k) clearance. The purpose of the performance goal provision was to help to ensure a timely clearance of the 510(k). Upon reaching FDA clearance on April 1, 2009, Mr. Sachs received a warrant to purchase 50,000 shares of our common stock. The warrant has a 5 year term and an exercise price of \$.46 per share. The warrant issued to Sachs and associates was valued at \$8,318 using the Black-Scholes valuation model because it was an extra incentive to finish the FDA work early and its value was not otherwise determinable. The inputs to Black-Scholes were an expected life of 5 years based upon the 5 year legal term, a volatility of 63%, a dividend rate of zero and a risk free interest rate of 1.65%.

In September 2002, an oral agreement was made with director Peter Morawetz whereby he would provide sales, marketing and general administrative consulting to the Company for a fee of \$1,770 per month. The Company's expectation at the time was that the Company would have received equity financing to fund these payments but the Company did not receive that funding. Pursuant to an oral agreement with Mr. Morawetz the Company could defer payment of these amounts until such date that they had cash to pay him. The Company accrued these fees through August 2006 when Mr. Morawetz's consulting services ended. On May 15, 2009 Mr. Morawetz and the Company reached agreement whereby he would waive payment of his consulting fees, in the amount of \$84,600, and accept a cash payment of \$30,000 and an option to buy 75,000 shares of common stock at \$.35 per share upon the Company raising \$3 million. Mr. Morawetz has no obligation to participate in raising the funds. The debt forgiveness was treated as a capital contribution, in accordance with SAB 79, because Mr. Morawetz is both a director and a significant shareholder, and the \$30,000 obligation and the Black-Scholes value of the option were expensed in the second quarter of 2009. The \$84,600 capital contribution is shown on a separate line in the Statement of Shareholders' Deficit. The value of the option was determined to be \$22,658 based upon the Black-Scholes valuation model using a 5 year expected term, a 59% expected volatility and a 2.03% risk free interest rate.

On February 1, 2009, we entered into an employment agreement with Kirsten 1, Vice President of Sales and Marketing, pursuant to which we granted her an option to purchase 100,000 shares of common stock at \$.35 per share with 20,000 shares vested immediately and increments of 20,000 shares vesting upon reaching certain performance milestones. In addition, we granted Ms. Doerfert a warrant to purchase 15,000 shares at \$.46 per share as compensation for her consulting services prior to becoming an employee. As of June 30, 2009 the 15,000 shares underlying the warrant are fully vested and a total of 60,000 shares underlying stock options are vested. The value of the option was computed to be \$14,006 using an expected term ranging from 2.5 to 2.8 years, an expected volatility of 63%, a risk free interest rate ranging from 1.085% to 1.191% and a zero dividend rate. The warrant was valued at \$2,502 using the Black-Scholes valuation model using a 5 year expected term, a 63% expected volatility, a 1.75% risk free interest rate, and a zero dividend rate. The warrant was expensed in February 2009 because it was immediately vested. We used the Black-Scholes model to establish the valuation because the value of the services performed was difficult to measure.

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**NOTE 4- RESTRICTED CASH IN ESCROW**

Under terms of the escrow agreement established in connection with the October 2008 financing certain amounts were to be withheld to pay legal, accounting and placement agent fees as well as to pay for investor relations activities that will commence upon receiving an effective registration of the Company's stock and an initial listing with the OTC Bulletin Board. All amounts related to legal, accounting and placement agent fees have been disbursed and the current balance is solely being held to fund investor relations activities.

The balance in this escrow account will be released to the Company if we should withdraw our registration statement to become a public company or otherwise by mutual agreement of the investors who established the escrow as a condition of the October 2008 financing.

**NOTE 5 - LOSS PER SHARE**

The following table presents a reconciliation of the numerators and denominators used in the basic and diluted loss per common share computations:

	Year Ended December 31,		Six Months Ended		From April
	2008	2007	June 30,	June 30,	23,
	(Restated)	(Restated)	2009	2008	2002 To
			(Unaudited)	(Unaudited)	June 30,
			(Restated)		2009
					(Unaudited)
					(Restated)
<b>Numerator:</b>					
Net Loss available in basic and diluted calculation	\$ 1,762,628	\$ 752,414	\$ 1,724,425	\$ 507,819	\$ 4,879,563
<b>Denominator:</b>					
Weighted average common shares outstanding-basic	4,335,162	823,627	8,531,200	1,349,506	1,793,898
Effect of dilutive stock options and warrants (1)	-	-	-	-	-
Weighted average common shares outstanding-diluted	4,335,162	823,627	8,531,200	1,349,506	1,793,898
Loss per common share-basic and diluted	\$ (0.41)	\$ (0.91)	\$ (0.20)	\$ (0.38)	\$ (2.72)

(1) The number of options and warrants outstanding as of June 30, 2009, June 30, 2008, December 31, 2008 and December 31, 2007 are 8,305,780, 4,100,511, 6,475,685 and 169,160 respectively. The effect of the shares that would be issued upon exercise has been excluded from the calculation of diluted loss per share because those shares are anti-dilutive.

**NOTE 6 – INCOME TAXES**

The provision for income taxes consists of an amount for taxes currently payable and a provision for tax consequences deferred to future periods. Deferred income taxes are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

There is no income tax provision in the accompanying statement of operations due to the cumulative operating losses that indicate a 100% valuation allowance for the deferred tax assets and state income taxes is appropriate.

Federal and state income tax return operating loss carryovers as of December 31, 2008, were approximately \$3,145,000 and will begin to expire in 2017.

The valuation allowance has been recorded due to the uncertainty of realization of the benefits associated with the net operating losses. Future events and changes in circumstances could cause this valuation allowance to change.

The components of deferred income taxes at December 31 and June 30, 2009 are as follows:

	December 31,		June 30,
	2008	2007	2009
			(Unaudited)
<b>Deferred Tax Asset:</b>			
Net Operating Loss	\$ 747,000	\$ 321,000	\$ 1,148,000
Total Deferred Tax Asset	747,000	321,000	1,148,000
Less Valuation Allowance	747,000	321,000	1,148,000
Net Deferred Income Taxes	\$ —	\$ —	\$ —

**NOTE 7 –NOTES PAYABLE**

The Company has a convertible debenture with Andcor Companies, Inc. (“Andcor”) of \$10,000 at 10.25% that matured in 2007. The debenture is convertible to the Company’s common stock at the lower of \$0.90 per share or the price per share at which the next equity financing agreement is completed, and is now re-set to \$.35 per share. The convertible debenture has not yet been paid, and it is currently in default. While Andcor could demand payment on this note at any time, they have verbally expressed an interest in working with us to wait until additional funds are secured by the Company. Further, Andcor has left open the possibility of converting the note into shares of the Company’s common stock, which would require no cash outlay by the Company.

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**NOTE 8 – LONG-TERM DEBT**

Long-term debt is as follows:

	<u>December 31,</u> <u>2008</u>	<u>2007</u>	<u>June 30,</u> <u>2009</u> <u>(Unaudited)</u>
Notes payable to seven individuals due April 2008 including 8% fixed interest and are now delinquent. The 2007 balance is shown net of a \$30,899 debt discount based upon the Black-Scholes valuation assigned to the warrants issued in connection with the debt. The notes are convertible into 620,095 shares of the Company's common stock and automatically convert at the effective date of this registration statement.	\$ 170,000	\$ 139,101	\$ 170,000
Note payable to bank in monthly installments of \$1,275/including variable interest at 2% above the prevailing prime rate (3.25% at December 31, 2008) to August 2011 when the remaining balance is payable. The note is personally guaranteed by former executives of the Company.	38,183	48,308	31,486
Note payable to NWBDC with interest only payments at 8% to December 2008 when the remaining balance is payable. The note was personally guaranteed by former executives of the Company. The note was paid in full on June 24, 2008.	—	18,000	—
Notes payable to two individuals, net of discounts of \$26,157, \$34,205 and \$23,643 with interest only payments at 12% to March 2012 when the remaining balance is payable. The notes are convertible into 285,715 shares of stock in the Company at \$.35 per share.	73,843	65,794	78,369
Notes payable to four shareholders of the Company that are overdue. The notes are convertible into 11,429 shares of stock in the Company at \$.35 per share.	4,000	4,000	4,000
Total	<u>286,026</u>	<u>275,203</u>	<u>283,855</u>
Less amount due within one year	<u>187,620</u>	<u>172,901</u>	<u>187,620</u>
Long-Term Debt	<u>\$ 98,406</u>	<u>\$ 102,302</u>	<u>\$ 96,235</u>

Cash payments for interest were \$5,175 for the year ended December 31, 2008, \$5,071 for the year ended December 31, 2007 and \$953 for the six months ended June 30, 2009. The notes payable of \$10,000 (discussed in Note 6), \$170,000 and \$4,000 (shown in the table above) are delinquent and could be called by the holders, putting additional strains on our liquidity. The note for \$170,000 contains provisions for a one-time penalty of \$25,000 if this registration statement is not filed within 120 days of August 31, 2008 and \$5,000 per 30 day period, after February 27, 2009, until the registration statement is declared effective by the SEC. The total amount accrued as additional interest expense is \$20,500 at June 30, 2009. There is no maximum penalty. In addition, beginning March 2009 the Company is obligated to issue additional shares to the investors who purchased units in October 2008 financing equal to 2% of the units sold for each month until the registration is declared effective. This represents 91,057 shares per month to a maximum of 728,458 shares, or 16% of the total units sold. At June 30, 2009 the Company estimates it will be obligated to issue 637,401 shares with a value of \$318,701 at \$.50 per share. Payment of the accrued interest and penalties will occur upon receipt of a significant portion of the \$3 million funding subsequent to our listing on the OTC Bulletin Board and issuance of the additional shares will occur within 30 days of the earlier of the effective registration of our shares or October 31, 2009 when the maximum is reached.

Principal payments required during the next five years as of December 31, 2008 are:

2009 -	\$ 197,620
2010 -	\$ 14,353
2011 -	\$ 10,210
2012 -	\$ 100,000
2013 -	\$ 0

**NOTE 9 – COMMITMENTS AND CONTINGENCIES**

In July 2007, we entered into a restructuring agreement whereby in the event that we fail to obtain FDA clearance by the end of August 2009, the majority-interest of investors ("the Investors") through our October 2008 offering would have the right to cause the Company to make significant restructuring changes. As a result of receiving written approval from the FDA on April 1, 2009 this restructuring will be avoided.

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**NOTE 10 – RENT OBLIGATION**

The Company leases its principal office under a non-cancelable lease that extends 5 years. In addition to rent the Company also pays real estate taxes, repairs and maintenance on the leased property. Rent expense charged to operations amounted to approximately \$13,000 and \$0 in 2008 and 2007, respectively.

The Company's obligation for rent as of December 31, 2008 over the next 5 years is as follows:

2009	\$	35,000
2010		29,000
2011		30,000
2012		30,000
2013		26,000

**NOTE 11– RESTATEMENT OF 2007, 2008 and 2009**

The Company's previously reported financial statements for 2007, 2008 and 2009 have been restated herein to reflect the adoption of Staff Accounting Bulletin (SAB) 79 as the preferred accounting principle for reflecting forgiveness of debt by certain officers/shareholders. In addition, the Company corrected errors in accounting estimates related to expected volatility and expected term in the Black-Scholes valuation model assumptions, for warrants and options, and applied the applicable expense to the appropriate year. Finally, the Company recorded a liability under a registration payment arrangement as of June 30, 2009 which required a 2009 restatement.

**2007**

The Company relied upon the guidance of SAB 79 to record expense in 2007 for waived officer/shareholder salaries previously credited to salary expense and re-classified as a capital contribution. The change in accounting for debt forgiveness, applied retrospectively to 2007, consisted of reversing a \$346,700 credit to salary expense with a corresponding increase in paid-in capital and recording \$115,000 in general and administrative expenses with an equal increase in accrued expenses to reflect the future cash payments that the Company is obligated to make upon raising \$3 million. Additionally, the company corrected an error in accounting estimate and expensed \$62,945 in stock-based compensation expense in accordance with SFAS 123(R), and a corresponding increase in paid-in capital related to the total valuation of the Company's obligation to issue stock options to such officers when the Company raises an additional \$3 million.

Finally, the Company recorded a \$40,242 debt discount based upon the Black-Scholes valuation model fair value of the warrants issued in connection with the \$100,000 convertible note dated March 1, 2007 and \$92,696 as a debt discount related to warrants issued in connection with the \$170,000 convertible secured bridge loan dated July 23, 2007. Interest expense, based upon the amortization of the debt discounts, was \$67,833 in 2007 and the remaining debt discounts at December 31, 2007 are \$34,206 and \$30,899 for the March 1, 2007 and July 23, 2007 notes, respectively.

**2008**

As a result of the restatement in 2007 to reflect the amortization of \$67,833 in debt discount, that had previously been expensed in 2008, the amortization of debt discount in 2008 declined from \$66,765 to \$38,948. The decline in interest expense in the restated 2008 financials compared to that originally reported was only \$27,819 because the Company also recomputed the valuation of the warrants issued in connection with its convertible bridge loan debt using a 63% expected volatility and a three year expected term compared to a 45% expected volatility and 1 ½ year expected term as originally reported.

Additionally, the Company recomputed the value of other options and warrants using a range of volatilities from 53% to 66% and expected terms ranging from 2.5 to 7.5 years, resulting in a \$96,000 increase in the total valuation of options and warrants and an additional \$28,931 was expensed as compensation and consulting expense in 2008. The Company relied upon the guidance of SAB 79 to record expense in 2008 for officer/shareholder salaries in the amount of \$129,685, to record a capital contribution as waived salaries in an equal amount and accrued \$25,000 that will be paid to Mr. Gadbow, in addition to the remaining balance of the \$46,000 he is being paid at \$2,000 per month, upon raising an additional \$3 million.

**2009**

The Company is required, under terms of a financing agreement reached in 2008, to register 4,552,862 shares of stock sold in a private placement offering. The registration rights agreement allows the Company 180 days to register the shares after the August 31, 2008 closing date without incurring any penalty. For each 30 day period after the 180 days has passed the Company is obligated to issue 91,057 additional shares, up to a maximum of 728,458 shares, until the registration is declared effective. As of June 30, 2009 the Company has determined that the total liability for additional shares can reasonably be estimated to be 637,401 shares and we accrued \$318,701 for the value of these shares, at \$.50 per share as of June 30, 2009. The Company relied upon FSP EITF 00-19-2 (ASC 825-20-30-5 in the codification literature) in making this determination. Since the June 30, 2009 financial statements originally reported did not contain this expense accrual the enclosed financial statements are restated.

A recap of the amounts originally reported, amounts as restated and the net change for the 2007, 2008 and 2009 financial statements is shown below. The numbers in ( ) after the balance sheet and statement of operations category in 2007 and 2008 correspond to the adjustments that are itemized below following the recaps.

	<b>2007 Restatement</b>		
	As Originally Reported	As Restated	Net Change
<b>Balance Sheet</b>			
Current portion of convertible debt, net of discounts (4)(5)	\$ 170,000	\$ 139,101	\$ (30,899)
Accrued expenses (3)	\$ 226,429	\$ 341,429	\$ 115,000

Long-term debt and convertible debt, (6)(7) net of discounts	\$	136,508	\$	102,302	\$	(34,206)
Additional paid-in capital (1)(2)(4)(6)	\$	117,833	\$	660,430	\$	542,597
Deficit accumulated during development stage (1)(2)(3)(5)(7)	\$	(788,701)	\$	(1,381,164)	\$	(592,492)

		<u>As Originally Reported</u>		<u>As Restated</u>		<u>Net Change</u>
<u>Statement of Operations</u>						
General and administrative expense (1)(2)(3)		111,858		636,517		524,659
Interest expense (5)(7)		33,238		101,071		67,833
Total	\$	159,922	\$	752,414	\$	592,492
Loss per share	\$	(0.19)	\$	(0.91)	\$	(0.72)
Weighted average shares used in the computation of basic and diluted loss per share		823,627		823,627		-

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	<b>2008 Restatement</b>		
	<u>As Originally Reported</u>	<u>As Restated</u>	<u>Net Change</u>
<b>Balance Sheet</b>			
Accrued expenses (9)(14)	\$ 280,248	\$ 305,248	\$ 25,000
Long-term debt and convertible debt, (10)(11)(12)(13) net of discounts	\$ 99,608	\$ 98,406	\$ (1,202)
Additional paid-in capital (8)(10)(12)(15)(16)	\$ 2,171,080	\$ 2,753,039	\$ 581,959
Deficit accumulated during development stage (8)(9)(11)(13)(14)(15)(16)	\$ (2,538,035)	\$ (3,143,792)	\$ (605,756)
	<u>As Originally Reported</u>	<u>As Restated</u>	<u>Net Change</u>
<b>Statement of Operations</b>			
Operations expense (16)	\$ 318,066	\$ 321,205	\$ 3,139
Sales and marketing expense (16)	35,199	35,682	483
General and administrative expense (8)(9)(14)(15)(16)	1,278,937	1,316,398	37,461
Interest expense (11)(13)	117,162	89,343	(27,819)
Total	\$ 1,749,364	\$ 1,762,628	\$ 13,264
Loss per share	\$ (0.40)	\$ (0.41)	\$ (0.01)
Weighted average shares used in the computation of basic and diluted loss per share	4,335,162	4,335,162	-
	<b>Period ended June 30, 2009 Restatement</b>		
	<u>As Originally Reported</u>	<u>As Restated</u>	<u>Net Change</u>
<b>Balance Sheet</b>			
Accrued expense	\$ 274,642	\$ 593,343	\$ 318,701
Deficit accumulated during development stage	\$ (4,560,862)	\$ (4,879,563)	\$ (318,701)
<b>Statement of Operations</b>			
General and administrative expense	\$ 552,839	\$ 871,540	\$ 318,701
Net loss	\$ (1,423,724)	\$ (1,742,425)	\$ (318,701)
Net loss per common share, basic and diluted	\$ (0.17)	\$ (0.20)	\$ (0.03)
Weighted average shares used in the computation	\$ 8,531,200	\$ 8,531,200	-

The following table itemizes the adjustments made to the originally reported 2007 and 2008 financial statements that resulted in the restatements:

<b>2007</b>	<u>Paid-in Capital</u>	<u>Accrued Expenses</u>	<u>Debt</u>	<u>Accumulated Deficit</u>	
	\$ (346,714)			\$ 346,714	(1) Reverse credit to salary expense for waived salaries, credit this amount as a capital contribution.
	(62,945)			62,945	(2) Record FAS 123R value of stock options granted to Gadbow, Rice and Davidson
		(115,000)		115,000	(3) Accrue salary expense for the estimated payout to Gadbow, Rice and Davidson upon raising \$3 million
	(92,696)		92,696		(4) Record the Black-Scholes value of the debt discount computed on the July 2007 convertible bridge loan
			(61,797)	61,797	(5) Record amortization of interest expense for July 2007 through December 2007 on bridge loan debt discount
	(40,242)		40,242		(6) Record the Black-Scholes value of the debt discount computed on the March 2007 Moore loans
			(6,036)	6,036	(7) Record amortization of interest expense for March 2007 through December 2007 on Moore loan debt discount
Total net change	<u>\$ (542,597)</u>	<u>\$ (115,000)</u>	<u>\$ 65,105</u>	<u>\$ 592,492</u>	



2008	Paid-in Capital	Accrued Expenses	Debt	Accumulated Deficit	
	27,533			(27,533)	(8) Reverse FAS 123R compensation expense previously expensed in 2008 on an amortization schedule, entire amount has been expensed in restated 2007 financial statements
		115,000		(115,000)	(9) Reverse accrued expense for Gadbow, Rice and Davidson, this amount is expensed in restated 2007 financials
	53,328		(53,328)		(10) Reverse portion of debt discount on convertible bridge loan that was applied to 2007 restated financials
			22,430	(22,430)	(11) Reverse the portion of interest expense on debt discount amortization that applies to 2007 restatement
	38,392		(38,392)		(12) Reverse portion of debt discount on Moore loan that was applied to 2007 restated financials
			5,389	(5,389)	(13) Reverse the portion of interest expense on Moore loan debt discount that was applied to 2007 restatement
		(25,000)		25,000	(14) Accrue the additional \$25,000 that Gadbow will receive upon raising \$3 million in new equity
	(129,685)			129,685	(15) Record capital contribution and salary expense for waived 2008 salaries for Gadbow, Rice and Davidson
	(28,931)			28,931	(16) Record additional stock based compensation and consulting expense due to revised expected volatility and revised expected term inputs to the Black-Scholes model
			(2)		Rounding
Total net change	\$ (39,362)	\$ 90,000	\$ (63,903)	\$ 13,264	
Cumulative change	\$ (581,959)	\$ (25,000)	\$ 1,202	\$ 605,756	

#### NOTE 12 – LIABILITY FOR EQUITY-LINKED FINANCIAL INSTRUMENTS

The Company adopted Emerging Issues Task Force (EITF) Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock*, on January 1, 2009.

EITF 07-5 mandates a two-step process for evaluating whether an equity-linked financial instrument or embedded feature is indexed to the entity's own stock. It is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, which is our first quarter of 2009. Most of the warrants issued by the Company contain a strike price adjustment feature, which upon adoption of EITF 07-5, changed the current classification (from equity to liability) and the related accounting for warrants with a \$479,910 estimated fair value of as of January 1, 2009.

The Company determined that the fair value on January 1, 2009 of 4,689,291 warrants was \$479,910, or \$.1023 per share. An adjustment was made to remove \$486,564 from paid-in capital (the cumulative value of the warrants on their grant dates), booked a positive adjustment of \$6,654 to accumulated deficit, representing the gain on valuation from the grant date to January 1, 2009, and booked the net of \$479,910 as a liability. The January 1, 2009 valuation was computed using the Black-Scholes valuation model based upon a 2.5 year expected term, an expected volatility of 63%, an exercise price of \$.46 per share, a stock price of \$.35, a zero dividend rate and a 1.37% risk free interest rate. On March 31, 2009 the company recomputed the value of the warrants using the Black-Scholes valuation model with an expected volatility of 66%, an expected term of 2.25 years, a stock price of \$.50 per share and a risk free interest rate of .895%. Primarily due to the increase in the underlying stock price the valuation per share was \$.2082 or a total of \$976,412. The \$496,502 increase in the liability is reflected as a Loss on the valuation of the liability for equity-linked instruments, on a separate line in the Income Statement for the three months ended March 31, 2009. On June 30, 2009 the Company again recomputed the value of the warrants using the Black-Scholes valuation model with an expected volatility of 66%, an expected term of 2 years, a risk free interest rate of 1.11%, a zero dividend rate and a stock price of \$.50. The computed value per share of \$.1967 produced a liability of \$922,344 as of June 30, 2009 for a net gain of \$54,067. In addition, the Company placed a valuation on their grant date, on warrants issued during the second quarter of \$169,654 and recomputed their value as of June 30, 2009. The value on June 30, 2009 was \$163,842 for a net gain of \$6,012. The June 30, 2009 valuation of the warrants issued during the second quarter was \$.1689 per share using a 63% expected volatility, a 2.83 year expected term, a zero dividend rate, an exercise price of \$.65 per share, a stock price of \$.50 per share and a 1.26% risk free interest rate. The combination of the net gains during the second quarter resulting from these new valuations was \$60,079 and reduced the loss for the six month period ended June 30, 2009 to \$436,423. This loss on valuation of equity-linked financial instruments is shown as a separate line on the statement of operations.

## Part II

### Item 24. Indemnification of Directors and Officers.

We are a Minnesota corporation and certain provisions of the Minnesota Statutes and our Bylaws provide for indemnification of our officers and directors against liabilities which they may incur in such capacities. A summary of the circumstances in which indemnification is provided is discussed below, but this description is qualified in its entirety by reference to our Bylaws and to the statutory provisions.

Section 302A.521, Subd. 2 of the Minnesota Statutes requires a corporation to indemnify a person made or threatened to be made a party to a proceeding by reason of the former or present official capacity of the person against judgments, penalties, fines, including, without limitation, excise taxes assessed against the person with respect to an employee benefit plan, settlements, and reasonable expenses, including attorneys' fees and disbursements, incurred by the person in connection with the proceeding, if, with respect to the acts or omissions of the person complained of in the proceeding, the person:

- (1) has not been indemnified by another organization or employee benefit plan for the same judgments, penalties, fines, including, without limitation, excise taxes assessed against the person with respect to an employee benefit plan, settlements, and reasonable expenses, including attorneys' fees and disbursements, incurred by the person in connection with the proceeding with respect to the same acts or omissions;
- (2) acted in good faith;
- (3) received no improper personal benefit and Section 302A.255, if applicable, has been satisfied;
- (4) in the case of a criminal proceeding, had no reasonable cause to believe the conduct was unlawful; and
- (5) in the case of acts or omissions occurring in the person's performance in the official capacity of director or, for a person not a director, in the official capacity of officer, board committee member or employee, reasonably believed that the conduct was in the best interests of the corporation or, in the case of performance by a director, officer or employee of the corporation involving service as a director, officer, partner, trustee, employee or agent of another organization or employee benefit plan, reasonably believed that the conduct was not opposed to the best interests of the corporation. If the person's acts or omissions complained of in the proceeding relate to conduct as a director, officer, trustee, employee, or agent of an employee benefit plan, the conduct is not considered to be opposed to the best interests of the corporation if the person reasonably believed that the conduct was in the best interests of the participants or beneficiaries of the employee benefit plan.

Section 302A.521 Subd. 2 further provides that the termination of a proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent does not, of itself, establish that the person did not meet the criteria set forth in this subdivision.

In addition, Section 302A.521, Subd. 3, requires that if a person is made or threatened to be made a party to a proceeding, the person is entitled, upon written request to the corporation, to payment or reimbursement by the corporation of reasonable expenses, including attorneys' fees and disbursements, incurred by the person in advance of the final disposition of the proceeding, (a) upon receipt by the corporation of a written affirmation by the person of a good faith belief that the criteria for indemnification set forth in Section 302A.521, Subd. 2 have been satisfied and a written undertaking by the person to repay all amounts so paid or reimbursed by the corporation, if it is ultimately determined that the criteria for indemnification have not been satisfied, and (b) after a determination that the facts then known to those making the determination would not preclude indemnification under this section. The written undertaking required by clause (a) is an unlimited general obligation of the person making it, but need not be secured and shall be accepted without reference to financial ability to make the repayment.

Section 302A.521 Subd. 4 provides that the articles of incorporation or bylaws of a corporation either may prohibit indemnification or advances of expenses otherwise required by Section 302A.521 or may impose conditions on indemnification or advances of expenses in addition to the conditions contained in Subd. 2 and 3 including, without limitation, monetary limits on indemnification or advances of expenses, if the prohibition or conditions apply equally to all persons or to all persons within a given class. A prohibition or limit on indemnification or advances may not apply to or affect the right of a person to indemnification or advances of expenses with respect to any acts or omissions of the person occurring prior to the effective date of a provision in the articles of incorporation or the date of adoption of a provision in the corporation's bylaws establishing the prohibition or limit on indemnification or advances.

Section 302A.521 Subd. 5 provides that Section 302A.521 does not require, or limit the ability of a corporation to reimburse expenses, including attorneys' fees and disbursements, incurred by a person in connection with an appearance as a witness in a proceeding at a time when the person has not been made or threatened to be made a party to a proceeding

Section 302A.521 Subd. 6 further provides that:

(a) all determinations whether indemnification of a person is required because the criteria set forth in Subd. 2 have been satisfied and whether a person is entitled to payment or reimbursement of expenses in advance of the final disposition of a proceeding as provided in Subd. 3 shall be made:

- (1) by the board by a majority of a quorum, if the directors who are at the time parties to the proceeding are not counted for determining either a majority or the presence of a quorum;
- (2) if a quorum under clause (1) cannot be obtained, by a majority of a committee of the board, consisting solely of two or more directors not at the time parties to the proceeding, duly designated to act in the matter by a majority of the full board including directors who are parties;
- (3) if a determination is not made under clause (1) or (2), by special legal counsel, selected either by a majority of the board or a committee by vote pursuant to clause (1) or (2) or, if the requisite quorum of the full board cannot be obtained and the committee cannot be established, by a majority of the full board including directors who are parties;
- (4) if a determination is not made under clauses (1) to (3), by the affirmative vote of the shareholders required by Section 302A.437 of the Minnesota Statutes, but the shares held by parties to the proceeding must not be counted in determining the presence of a quorum and are not considered to be present and entitled to vote on the determination; or
- (5) if an adverse determination is made under clauses (1) to (4) or under paragraph (b), or if no determination is made under clauses (1) to (4) or under paragraph (b) within 60 days after (i) the later to occur of the termination of a proceeding or a written request for indemnification to the corporation or (ii) a written request for an advance of expenses, as the case may be, by a court in this state, which may be the same court in which the proceeding involving the person's liability took place, upon application of the person and any notice the court requires. The person seeking indemnification or payment or reimbursement of expenses pursuant to this clause has the burden of establishing that the person is entitled to indemnification or payment or reimbursement of expenses.

(b) With respect to a person who is not, and was not at the time of the acts or omissions complained of in the proceedings, a director, officer, or person possessing, directly or indirectly, the power to direct or cause the direction of the management or policies of the corporation, the determination whether indemnification of this person is required because the criteria set forth in Subd. 2 have been satisfied and whether this person is entitled to payment or reimbursement of expenses in advance of the final disposition of a proceeding as provided in Subd. 3 may be made by an annually appointed committee of the board, having at least one member who is a director. The committee shall report at least annually to the board concerning its actions.

Section 302A.521 Subd 7 allows a corporation to purchase and maintain insurance on behalf of a person in that person's official capacity against any liability asserted against and incurred by the person in or arising from that capacity, whether or not the corporation would have been required to indemnify the person against the liability under the provisions of section 302A.521 of the Minnesota Statutes.

Section 302A.521 Subd. 8 requires a corporation that indemnifies or advances expenses to a person in accordance with Section 302A.521 in connection with a proceeding by or on behalf of the corporation to report to the shareholders in writing the amount of the indemnification or advance and to whom and on whose behalf it was paid not later than the next meeting of shareholders.

Section 302A.521 Subd. 9 provides that nothing in Section 302A.521 shall be construed to limit the power of the corporation to indemnify persons other than a director, officer, employee, or member of a committee of the board of the corporation by contract or otherwise.

Pursuant to our Bylaws, we may indemnify our directors and executive officers to the fullest extent not prohibited by any applicable law; provided, however, that we may modify the extent of such indemnification by individual contracts with our directors and executive officers; and, provided, further, that we shall not be required to indemnify any director or executive officer in connection with any proceeding (or part thereof) initiated by such person unless: (i) such indemnification is expressly required to be made by law; (ii) the proceeding was authorized by our Board of Directors; (iii) such indemnification is provided by the Company, in our sole discretion, pursuant to the powers vested in the Company under any applicable law. We shall have the power to indemnify our other officers, employees and other agents as set forth in any other applicable law. Our Board of Directors shall have the power to delegate the determination of whether indemnification shall be given to any such person to such officers or other persons as our Board of Directors shall determine.

In addition, our Bylaws provide that we will advance to any person who was or is a party to a threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he is or was a director or executive officer, of the Company, prior to the final disposition of the proceeding, promptly following request therefore, all expenses incurred by any director or executive officer in connection with such proceeding; provided, however, that the advancement of expenses shall be made only upon delivery to the Company of an undertaking by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal that such indemnitee is not entitled to be indemnified for such expenses. Notwithstanding the foregoing, unless otherwise determined, no advance shall be made by the Company to an officer of the Company (except by reason of the fact that such officer is or was a director of the Company in which event this paragraph shall not apply) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, if a determination is reasonably and promptly made: (i) by a majority vote of directors who are not parties to the proceeding; (ii) by a committee of such directors designated by a majority vote of such directors; or (iii) if there are no such directors, or such directors so direct, by a written opinion from independent legal counsel, that the facts known to the decision making party at the time such determination is made demonstrate clearly and convincingly that such person acted in bad faith or in a manner that such person did not believe to be in the best interests of the Company.

Our Bylaws also provide that without the necessity of entering into an express contract, all rights to indemnification and advances to our directors and executive officers shall be deemed to be contractual rights and to be effective to the same extent and as if provided for in a contract between the Company and the director or executive officer. Any right to indemnification or advances granted to a director or executive officer shall be enforceable by or on behalf of the person holding such right in any court of competent jurisdiction if: (i) the claim for indemnification or advances is denied, in whole or in part; or (ii) no disposition of such claim is made within ninety (90) days of request therefore. The claimant in such enforcement action, if successful, shall be entitled to be paid also the expense of prosecuting the claim. In connection with any claim for indemnification, the Company shall be entitled to raise as a defense to any such action that the claimant has not met the standards of conduct that make it permissible under applicable law for the Company to indemnify the claimant for the amount claimed. In connection with any claim by an executive officer of the Company (except in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such executive officer is or was a director of the Company) for advances, the Company shall be entitled to raise a defense as to any such action clear and convincing evidence that such person acted in bad faith or in a manner that such person did not believe to be in the best interests of the Company, or with respect to any criminal action or proceeding that such person acted without reasonable cause to believe that his conduct was lawful. A determination by the Company (including the Board of Directors, independent legal counsel or the stockholders) that indemnification of the claimant is proper because he has met the applicable standard of conduct or that the claimant has not met such applicable standard of conduct shall not be a defense to the action nor shall it create a presumption that claimant has not met the applicable standard of conduct.

**Item 25. Other Expenses of Issuance and Distribution.**

The following table sets forth an estimate of the costs and expenses payable by us in connection with the registration of the common stock offered hereby. All of the amounts shown are estimates except the Securities and Exchange Commission Registration Fee:

	<u>Amount</u>
SEC Registration Fee	\$ 200
Printing Fees	\$ 30,000
Legal Fees and Expenses	\$ 80,000
Accounting Fees and Expenses	\$ 60,000
Miscellaneous	\$ 55,000
Total	<u>\$ 225,200</u>

**Item 26. Recent Sales of Unregistered Securities.**

During the past four years, the Company has issued the following securities without registration under the Securities Act of 1933, as amended. The discussions below take into account the June 6, 2008 and October 20, 2008 reverse stock splits.

On August 22, 2005, we issued an option agreement to purchase 17,957 shares (30,000 shares at \$1 pre-split) of our common stock at \$1.67 per share to Thomas McGoldrick, for his services as a director. In addition to the initial grant the option agreement specifies that he will be granted an option for 5,985 shares per year, on his anniversary date of joining the board, at the market price on the grant date. On August 22, 2006, we issued an option to purchase 5,985 shares of common stock at \$1.67 per share to Mr. McGoldrick. This transaction was effected under Rule 701 promulgated under the Act on the basis that the transaction was pursuant to a contract relating to compensation provided under Rule 701. The recipient of the securities in this transaction represented his intentions to acquire the securities for investment only and not with a view towards distribution thereof. He had access, through his relationship with the Company, to information about us.

On August 31, 2005, we issued a warrant to purchase 2,993 shares of our common stock at \$1.67 per share to each of three members of our Medical Advisory Board, Debbie Heitzman, Mary Wells Gorman and David Feroe, for their services on the Medical Advisory Board.

On December 14, 2005, we issued 7,482 shares of common stock to officers Lawrence Gadbow and Gerald Rice as compensation for personal guarantees on Company loans.

On May 16, 2006, we issued 71,906 shares of our common stock to the inventor of our intellectual property, Marshall Ryan, for the development work he performed with respect to our product.

On June 12, 2006, we issued a warrant to purchase 35,913 shares of our common stock at \$.02 per share to Dr. Arnold Leonard for his services on the Medical Advisory Board. The warrant agreement contained an anti-dilution clause that would add another 35,913 shares upon any large, dilutionary offering. The second warrant to purchase 35,913 shares of our common stock was granted to Mr. Leonard in June 2008 when we achieved 2 million in outstanding shares of common stock through the October 2008 financing.

On August 8, 2006, we issued 14,964 shares of our common stock to Andcor Companies, Inc. in partial payment of an invoice. Also in 2006, we issued warrants to purchase 5,985 shares of common stock at \$1.67 per share to Andcor Companies, Inc. as part of a convertible loan agreement.

On October 4, 2006, we entered into an employment agreement with Kevin Davidson, our Chief Executive Officer. As part of this agreement, we agreed to issue 50,000 shares of our common stock to Mr. Davidson. The grant under the employment agreement contained an anti-dilution protection amounting to 3.81% of the fully-diluted outstanding common stock of the Company up to the completion of the first \$1,000,000 raised by the Company. On June 5, 2008, pursuant to a stock option agreement with the Company, which amended Mr. Davidson's employment agreement, Mr. Davidson opted to receive an option to purchase 543,292 shares of common stock, exercisable at \$.01, in lieu of obtaining the shares to which he was entitled under his employment agreement.

On October 23, 2006, we issued 8,979 shares of our common stock to a former employee as a part of his compensation package in his employment agreement. This transaction was effected under Rule 701 promulgated under the Act on the basis that the transaction was pursuant to a contract relating to compensation provided under Rule 701. The recipient of securities in this transaction represented his intentions to acquire the securities for investment only and not with a view towards distribution thereof. He had access, through his relationship with the Company, to information about us.

On November 11, 2006 we issued an option agreement to purchase 17,957 shares (30,000 at \$1 pre-split) of common stock at \$1.67 per share to Andrew Reding, for his services as a director. In addition to the initial grant the option agreement specifies that he will be granted an option for 5,985 shares per year, on his anniversary date of joining the board, at the market price on the grant date. On November 11, 2007, we issued an option to purchase 5,985 shares of common stock at \$1.67 per share to Mr. Reding. This transaction was effected under Rule 701 promulgated under the Act on the basis that the transaction was pursuant to a contract relating to compensation provided under Rule 701. The recipient of securities in this transaction represented his intentions to acquire the securities for investment only and not with a view towards distribution thereof. He had access, through his relationship with the Company, to information about us.

On December 1, 2006, we fully repaid two of our three loans, in the combined amount of \$37,500, due to Wisconsin Rural Enterprise Fund ("WREF"). To pay the outstanding loan to WREF, the Company issued warrants to purchase 20,949 shares of common stock at \$1.67 per share to WREF.

On December 1, 2006, we issued 3,986 shares of our common stock to pay a consulting fee to Wisconsin Business Innovation Corporation, a related firm of WREF.

On December 7, 2006 and December 20, 2006 we issued warrants to purchase 2,993 shares of our common stock at \$1.67 per share to each of Karen Ventura, Nancy Kolb and Kim Shelquist for their sales and marketing advisory services.

On January 30, 2007 we fully repaid a Company loan of \$1,000 due one of our former employees by issuing him 599 shares of our common stock.

In February 2007, Messrs. Davidson, Morawetz, Reding and McGoldrick loaned the Company \$1,000 each and obtained an 8.25% convertible promissory note in the principal amount of \$1,000. Each note matured on July 31, 2007 and the note was convertible into common stock at the lower of (i) \$1.00 per share or (ii) the price of the sale of common stock the next financing which ultimately was \$0.35 per share.

On March 1, 2007, we entered into a convertible debenture agreement with two individuals, Roy Moore and Carl Moore, who loaned us \$50,000 each, whereby we granted warrants to purchase up to an aggregate of 28,502 to them at \$.46 per share. There were no special terms contained in the warrant other than that the two individuals would pay a per share price equal to that of the October 2008 financing when exercising their warrants.

On July 23, 2007, we entered into a convertible debenture with certain investors who loaned us \$170,000. Such securities are convertible into 620,095 shares and the lenders were also entitled to receive warrants to purchase 620,095 shares at \$.35 per share. The Company issued the warrants February 24, 2009.

From July 2007 to October 2008, we issued 4,552,862 shares of our common stock at a price per share of \$0.35 to a number of investors pursuant to a private placement, and raised gross proceeds of approximately \$1.6 million. The transaction was a unit offering, pursuant to which each investor received a unit including one share of common stock and one warrant to purchase common stock at \$0.46 per share. Thirty-three investors, including one of our officers, Chad Ruwe, participated in the transaction, which we completed in October 2008. The transaction is described further in "Description of Business" Section. This transaction was in reliance upon the exemption from registration set forth in Rule 506 of Regulation D. Each and all of the investors in this financing qualified as an "accredited investor," as that term is defined in the Act. The following conditions were all met with respect to this transaction: (1) the registrant did not advertise this issuance in any public medium or forum; (2) the registrant did not solicit any investors with respect to this issuance; (3) the registrant did not publicize any portion of the purchase or sale of the shares issued; (4) none of the shares issued were offered in conjunction with any public offering; and (5) neither the registrant nor the investors paid any fees to any finder or broker-dealer in conjunction with this issuance. In July 2007, we entered into a binding term sheet with a consultant pursuant to which the consultant would assist us in obtaining bridge financing and subsequent equity financing and such term sheet provided that the consultant and its assigns would receive 13.3% of the Company's anticipated issued and outstanding common stock following the proposed bridge and equity financing on a fully-diluted basis. The parties subsequently agreed that we would issue 2,001,119 shares to such parties in satisfaction of such obligation.

On November 11, 2007, pursuant to a stock option agreement with Andrew Reding, a member of our board of directors, we issued an option to purchase 5,985 shares of our common stock at \$.46 per share to Mr. Reding. This transaction was effected under Rule 701 promulgated under the Act on the basis that the transaction was pursuant to a contract relating to compensation provided under Rule 701. The recipient of securities in this transaction represented his intentions to acquire the securities for investment only and not with a view towards distribution thereof. He had access, through his relationship with the Company, to information about us.

On February 29, 2008, we entered into a consulting agreement with Jeremy Roll for referral services for the Company's funding that was completed in October 2008. Under the agreement, in addition to a cash referral fee, Mr. Roll was entitled to receive warrants to purchase our common stock at \$.35 per share equal to 10% of his gross proceeds of the funds raised for us. As a result, in July 7, 2008 Mr. Roll received warrants to purchase 11,429 shares of our common stock.

On March 10, 2008, we entered into a finder agreement for referral services for the Company's funding that was completed in October 2008. This agreement also covered the following finders: Thomas Pronesti, Craig Kulman, Caron Partners, LP and Bellajule Partners, LP. Under the agreement, in addition to a cash referral fee, the finders were entitled to receive 10% of their gross proceeds raised for us with a fair market value of our common stock, or \$.35 per share. As a result, on June 23, 2008, the group of finders received an aggregate of 155,142 shares of our common stock.

On April 15, 2008, we entered into an agreement with Kulman IR, LLC for investor relations services. Under the agreement, in addition to cash fees, Kulman was entitled to receive 250,000 shares of our common stock. On June 23, 2008 Kulman and Cross Street Partners, Inc., a party related to Kulman, each received 125,000 shares of our common stock.

On June 16, 2008, we entered into an employment agreement with Chad Ruwe, Executive Vice President of Operations, pursuant to which we granted him an option to purchase 250,000 shares of common stock with 50,000 shares vested immediately and increments of 50,000 shares vesting upon achievement of certain milestones related to obtaining FDA clearance and achieving commercial sales of our Streamway™ Fluid Management System. This transaction was effected under Rule 701 promulgated under the Act on the basis that the transaction was pursuant to a contract relating to compensation provided under Rule 701. The recipient of securities in this transaction represented his intentions to acquire the securities for investment only and not with a view towards distribution thereof. He had access, through his relationship with the Company, to information about us.

On June 30, 2008, we entered into a consulting agreement with Namaste Financial, Inc. for a one-year period of general business, strategic and growth advisory services. Under the agreement, Namaste received 125,000 shares of common stock and a warrant to purchase 125,000 shares of common stock at \$.46 per share. This firm was engaged to arrange new equity financing and the warrants and shares. The shares were valued at \$43,750 and the warrants were valued at \$12,800 using a Black-Scholes valuation model. The total value of \$56,550 is shown as a net reduction of paid in capital as they were treated as an incremental cost of raising capital under the guidance of SAB Topic 5-A.

On August 11, 2008, we entered into an employment agreement with David Dauwalter, Director of Sales, pursuant to which we granted him an option to purchase 50,000 shares of common stock with 10,000 shares vested immediately and increments of 10,000 shares vesting upon reaching certain performance milestones.

On August 15, 2008, we issued warrants to purchase 75,000 shares each of our common stock at \$.46 per share to Taylor & Associates, Inc. and Andcor Corporation for their HR services in selecting a Vice President of Sales and Marketing.

On August 26, 2008, we issued a warrant to purchase 50,000 shares of our common stock at \$.46 per share to a regulatory consultant, Thomas Bachinski, for his past services.

On October 20, 2008, we entered into an agreement with Gregory Sachs, a regulatory consultant, pursuant to which the Company granted an agreement to purchase up to 50,000 shares of our common stock contingent upon reaching certain performance goals from April 1, 2009 to June 30, 2009. Mr. Sachs assisted the Company in obtaining FDA 510(k) clearance. The purpose of the performance goal provision was to help to ensure a timely clearance of the 510(k). Upon reaching FDA clearance on April 1, 2009, Mr. Sachs received a warrant to purchase 50,000 shares of our common stock. The warrant has a 5 year term and an exercise price of \$.46 per share.

On February 1, 2009, we entered into an employment agreement with Kirsten Doerfert, Vice President of Sales and Marketing, pursuant to which we granted her an option to purchase 100,000 shares of common stock at \$.35 per share with 20,000 shares vested immediately and increments of 20,000 shares vesting upon reaching certain performance milestones. In addition, we granted Ms. Doerfert a warrant, vested immediately, to purchase 15,000 shares at \$.46 per share as compensation for her consulting services prior to becoming an employee.

On March 27, 2009 we issued 125,000 shares of common stock to Cross Street Partners/Morrie Rubin as compensation in connection with raising up to \$500,000 in new equity prior to June 30, 2009.

On April 6, 2009 we issued 50,000 shares and a warrant to purchase 50,000 shares at \$.65 to Russell H. Yaucher for his \$25,000 investment in the Company.



On April 14, 2009 we issued 50,000 shares and a warrant to purchase 50,000 shares at \$.65 to Chad A. and Marianne K. Ruwe for their \$25,000 investment in the Company.

On April 20, 2009 we issued 200,000 shares and a warrant to purchase 200,000 shares at \$.65 to Dean M. and Carol L. Ruwe for their \$100,000 investment in the Company.

On April 21, 2009 we issued 200,000 shares and a warrant to purchase 200,000 shares at \$.65 to Richard J. Butler for his \$100,000 investment in the Company.

On April 30, 2009 we issued 200,000 shares and a warrant to purchase 200,000 shares at \$.65 to James Dauwalter for his \$100,000 investment in the Company.

On May 5, 2009 we issued 20,000 shares and a warrant to purchase 20,000 shares at \$.65 to Gregory B. Graves for his \$10,000 investment in the Company.

On May 15, 2009 we entered into an agreement with Peter Morawetz, a co-founder of the Company, a significant shareholder and a member of the board of directors, whereby Mr. Morawetz agreed to waive unpaid consulting fees in the amount of \$84,600, relating to 2006 and prior years and, in exchange, would receive a cash payment of \$30,000 and an option to purchase 75,000 shares at \$.35 per share upon the Company raising an additional \$3 million in equity. Mr. Morawetz is not required to participate in any way in the effort to raise \$3 million.

On May 21, 2009 we issued 200,000 shares and a warrant to purchase 200,000 shares at \$.65 to Richard J. Butler for his additional \$100,000 investment in the Company.

On June 10, 2009 we issued 50,000 shares and a warrant to purchase 50,000 shares to Citigroup FBO John Villas for his \$25,000 investment in the Company.

On August 5, 2009 we issued 50,000 common shares and a warrant to purchase 50,000 shares at \$.65 per share to Arnold A. Angeloni for his \$25,000 investment in the Company.

On August 18, 2009 we issued 30,000 common shares and a warrant to purchase 30,000 shares at \$.65 per share to Peter G. Kertes for his \$15,000 investment in the Company.

On August 24, 2009 we issued restricted shares under the 2008 Equity Incentive Plan to certain management and directors of the Company to reward them for past service and to incentivize them for future service. The shares are subject to forfeiture until the earlier of a Change in Control, as defined in the Plan, attainment of 6 consecutive quarters of a minimum of \$250,000 in net income or attainment of a 30 day average trading volume of not less than 25,000 shares of stock. The shares will be forfeited to the Company if none of these "acceleration events" occurs by the 10<sup>th</sup> anniversary of the grant date. The shares granted are as follows:

Peter Morawetz, Director	100,000 shares
Thomas McGoldrick, Director	40,000 shares
Andrew Reding, Director	20,000 shares
Kevin Davidson, Chief Executive Officer	300,000 shares
Chad Ruwe, Chief Operating Officer	200,000 shares
Kirsten Doerfert, VP Sales and Marketing	75,000 shares
David Dauwalter, Direct of Product Management	50,000 shares

The value of these shares was determined to be \$.50 per share and the expense for their grant was recorded in August 2009.

In addition, on August 24, 2009 the Company issued 12,810 shares of restricted stock under the 2008 Equity Incentive Plan and a warrant to purchase 18,207 common shares at \$.46 per share to Alan Shuler as partial compensation under his consulting arrangement with the Company. The warrant has a term of 5 years and the shares are subject to forfeiture until the earlier of a Change in Control, as defined in the Plan, attainment of 6 consecutive quarters of a minimum of \$250,000 in net income or attainment of a 30 day average trading volume of not less than 25,000 shares of stock. The shares will be forfeited to the Company if none of these "acceleration events" occurs by the 10<sup>th</sup> anniversary of the grant date. The value of the warrant was determined to be \$4,943 using the Black-Scholes valuation model with an expected term of 5 years, an expected volatility of 59%, a dividend rate of zero and a risk free interest rate of 2.5%. The value of the restricted shares was determined to be \$6,405 at \$.50 per share. These expenses were recorded in August 2009.

Unless otherwise specified above, the Company believes that all of the above transactions were transactions not involving any public offering within the meaning of Section 4(2) of the Securities Act, since (a) each of the transactions involved the offering of such securities to a substantially limited number of persons; (b) each person took the securities as an investment for his/her/its own account and not with a view to distribution; (c) each person had access to information equivalent to that which would be included in a registration statement on the applicable form under the Securities Act; (d) each person had knowledge and experience in business and financial matters to understand the merits and risk of the investment; therefore no registration statement needed to be in effect prior to such issuances.

## Item 27. Exhibits.

### EXHIBIT INDEX

- 3.1 Articles of Incorporation of the Registrant, as amended\*\*
- 3.2 Bylaws of the Registrant, as amended\*\*
- 3.3 Amendment to Articles\*\*

- 5.1 Opinion of Richardson & Patel LLP\*
- 10.1 Form of Employment Agreement by and between the Registrant and Kevin R. Davidson dated October 4, 2006\*\*
- 10.2 Form of Employment Agreement by and between the Registrant and Gerald D. Rice dated October 18, 2006\*\*
- 10.3 Form of Employment Agreement by and between the Registrant and Chad A. Ruwe dated June 16, 2008\*\*
- 10.4 Form of Confidential Separation Agreement and Release by and between the Registrant and Lawrence W. Gadbaw dated August 13, 2008\*\*
- 10.5 Form of Nondisclosure and Non-compete Agreement by and between the Registrant and Lawrence W. Gadbaw dated October 18, 2006\*\*

- 10.6 Form of Stock Option Agreement by and between the Registrant and Kevin R. Davidson dated June 5, 2008\*\*
- 10.7 Form of Director Stock Option Agreement between the Registrant and Thomas McGoldrick dated August 22, 2006\*\*
- 10.8 Form of Director Stock Option Agreement between the Registrant and Andrew P. Reding dated November 11, 2006\*\*
- 10.9 Form of Consulting Agreement by and between the Registrant and Jeremy Roll dated February 29, 2008\*\*
- 10.10 Form of Consulting Agreement by and between the Registrant and Namaste Financial, Inc. dated June 30, 2008\*\*
- 10.11 Form of Consulting Agreement by and between the Registrant and Marshall C. Ryan and Mid-State Stainless, Inc. dated June 2008\*\*
- 10.12 Form of Investor Relations Agreement by and between the Registrant and Kulman IR, LLC dated April 15, 2008\*\*
- 10.13 Form of Finder Agreement by and between the Registrant and Thomas Pronesti dated March 10, 2008\*\*
- 10.14 Form of Patent Assignment by Marshall C. Ryan in favor of the Registrant dated June 18, 2008\*\*
- 10.15 Form of Convertible Debenture by and between the Registrant and Kevin R. Davidson dated February 2, 2007\*\*
- 10.16 Form of Convertible Debenture by and between the Registrant and Peter L. Morawetz dated February 2, 2007\*\*
- 10.17 Form of Convertible Debenture by and between the Registrant and Andrew P. Reding dated February 2, 2007\*\*
- 10.18 Form of Convertible Debenture by and between the Registrant and Thomas McGoldrick dated January 30, 2007\*\*
- 10.19 Form of Convertible Debenture by and between the Registrant and Andcor Companies, Inc. dated September 29, 2006\*\*
- 10.20 Form of Convertible Debenture by and between the Registrant and Carl Moore dated March 1, 2007\*\*
- 10.21 Form of Convertible Debenture by and between the Registrant and Roy Moore dated March 1, 2007\*\*
- 10.22 Form of Advisory Board Warrant Agreement by and between the Registrant and Debbie Heitzman dated August 31, 2005\*\*
- 10.23 Form of Advisory Board Warrant Agreement by and between the Registrant and Mary Wells Gorman dated August 31, 2005\*\*

- 10.24 Form of Advisory Board Warrant Agreement by and between the Registrant and David Feroe dated August 31, 2005\*\*
- 10.25 Form of Advisory Board Warrant Agreement by and between the Registrant and Dr. Arnold S. Leonard dated June 12, 2006\*\*
- 10.26 Form of Advisory Board Warrant Agreement by and between the Registrant and Karen A. Ventura dated December 7, 2006\*\*
- 10.27 Form of Advisory Board Warrant Agreement by and between the Registrant and Nancy A. Kolb dated December 20, 2006\*\*
- 10.28 Form of Advisory Board Warrant Agreement by and between the Registrant and Kim Shelquist dated December 20, 2006\*\*
- 10.29 Form of Warrant Agreement by and between the Registrant and Wisconsin Rural Enterprise Fund, LLC dated December 1, 2006\*\*
- 10.30 Form of Stock Purchase and Sale Agreement by and between the Registrant and Wisconsin Rural Enterprise Fund, LLC dated July 31, 2006\*\*
- 10.31 Form of Subscription Agreement\*\*
- 10.32 Form of Registration Rights Agreement\*\*
- 10.33 Form of Escrow Agreement\*\*
- 10.34 Form of Warrant\*\*
- 10.35 2008 Equity Incentive Plan\*\*
- 10.36 Office Lease Agreement by and between the Registrant and Roseville Properties Management Company, as agent for Lexington Business Park, LLC\*\*
- 10.37 Form of Employment Agreement by and between the Registrant and David Dauwalter dated August 11, 2008\*\*
- 10.38 Form of Amendment No. 1 to Employment Agreement by and between the Registrant and David Dauwalter dated September 11, 2008\*\*
- 10.39 Form of Consulting Agreement by and between the Registrant and Andcor Companies, Inc. dated September 15, 2008\*\*
- 10.40 Form of Consulting Agreement by and between the Registrant and Taylor & Associates, Inc. dated August 15, 2008\*\*
- 10.41 Form of Consulting Agreement by and between the Registrant and Gregory Sachs dated October 20, 2008\*\*
- 10.42 Form of Restructuring Agreement dated June 9, 2008\*\*
- 10.43 Form of Secured Convertible Note Purchase Agreement dated July 23, 2007\*\*
- 10.44 Form of Secured Convertible Note dated July 2007\*\*
- 10.45 Form of Secured Convertible Note Security Agreement dated July 2007\*\*

- 10.46 Independent Contractor Agreement dated as of February 2, 2009 by and between Belimed, Inc. and BioDrain Medical, Inc.\*\*(1)
- 10.47 Supply Agreement dated as of February 20, 2009 by and between Oculus Innovative Sciences, Inc., and BioDrain Medical, Inc.\*\*(1)
- 10.48 Employment Agreement made and entered into effective the 1st of February, 2009 by and between Kirsten Doerfert\*\*
- 10.49 Term Sheet by and among the Registrant and Longport Holdings, as amended\*\*
- 10.50 Agreement between the Company and Peter Morawetz dated May 15, 2009\*\*
- 14 Code of Ethics\*\*
- 21 Subsidiaries of the Registrant\*\*
- 23.1 Consent of Olsen Thielen & Co., Ltd.\*
- 23.2 Consent of Richardson & Patel LLP (See Exhibit 5.1)\* \*

\* Filed herewith.

\*\* Previously filed

\*\*\* To be filed by amendment.

(1) Portions of this Exhibit have been omitted and are subject to a request for confidential treatment.

## Item 28. Undertakings.

The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement to:
  - i. Include any prospectus required by section 10(a)(3) of the Securities Act of 1933;
  - ii. Reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
  - iii. Include any additional or changed material information on the plan of distribution.
2. For determining liability under the Securities Act of 1933, treat each post-effective amendment as a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
3. File a post-effective amendment to remove from registration any of the securities that remain unsold at the end of offering.
4. If the registrant is relying on Rule 430B:

Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons under the foregoing provisions or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. If a claim for indemnification against such liabilities (other than our payment of expenses incurred or paid by any of our directors, officers or controlling persons in the successful defense of any action, suit, or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by a controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

*[ The remainder of this page left blank intentionally ]*

**SIGNATURES**

In accordance with the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and authorized this registration statement to be signed on its behalf by the undersigned, in the City of Mendota Heights, State of Minnesota on October 8, 2009.

**BIODRAIN MEDICAL, INC.**

By: /s/ Kevin R. Davidson  
Kevin R. Davidson  
President, Chief Executive Officer (Principal Executive Officer), Chief Financial Officer (Principal Financial and Accounting Officer).

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>*</u> Lawrence W. Gadbaw	Chairman of the Board of Directors	October 8, 2009
<u>/s/ Kevin R. Davidson</u> Kevin R. Davidson	President, Chief Executive Officer (Principal Executive Officer), Chief Financial Officer (Principal Financial and Accounting Officer) and Director	October 8, 2009
<u>*</u> Chad A. Ruwe	Director	October 8, 2009
<u>*</u> Peter L. Morawetz	Director	October 8, 2009
<u>*</u> Thomas J. McGoldrick	Director	October 8, 2009
<u>*</u> Andrew P. Reding	Director	October 8, 2009
<u>* /s/ Kevin Davidson</u> Chief Executive Officer and Power of Attorney		



RICHARDSON & PATEL LLP  
10900 Wilshire Boulevard  
Suite 500  
Los Angeles, California 90024  
Telephone (310) 208-1182  
Facsimile (310) 208-1154

October 8, 2009

Biodrain Medical, Inc.  
2060 Centre Pointe Blvd, Suite 7  
Mendota Heights, Minnesota 55120

Re: Registration on Form S-1 (File No. 333-155299)

Ladies and Gentlemen:

We have acted as counsel to Biodrain Medical, Inc. (the "Company") in connection with the registration with the Securities and Exchange Commission on Form S-1 of 13,030,747 shares of the Company's common stock, par value \$0.01 (the "Shares"), 7,101,266 of which are issued, 5,309,386 of which may be issued to certain selling security holders upon the exercise of certain warrants (the "Warrant Shares") and up to 620,095 shares of common stock, \$0.01 par value, of the Company, as may be required for issuance upon conversion of the debentures (the "Conversion Shares"). In connection with this registration, we have reviewed the proceedings of the Board of Directors of the Company relating to the registration and the issuance (or the proposed issuance) of the Shares, the Company's Articles of Incorporation and all amendments thereto, the Bylaws of the Company and all amendments thereto, and such other documents and matters as we have deemed necessary to render the following opinion.

Based upon that review, it is our opinion that the Shares now issued are legally issued, fully paid, and nonassessable. We are of the further opinion that the Warrant Shares and Conversion Shares have been duly authorized and, when issued by the Company upon conversion of the applicable debentures or warrants in accordance with their terms, will be legally issued, fully paid and nonassessable.

This opinion opines upon Minnesota law including the statutory provisions, and reported judicial decisions interpreting those laws.

We do not find it necessary for the purposes of this opinion to cover, and accordingly we express no opinion as to, the application of the securities or blue sky laws of the various states as to the issuance and sale of the Shares.

We consent to the use of this opinion in the registration statement filed with the Securities and Exchange Commission in connection with the registration of the Shares, to the filing of this opinion as an exhibit, and to the reference to our firm under the heading "Legal Matters and Interests of Named Experts" in the registration statement and the prospectus included therein. In giving such consent, we do not admit that we are "experts" within the meaning of such term as used in the Securities Act of 1933, as amended, or the rules and regulations of the Securities and Exchange Commission issued thereunder, with respect to any part of the registration statement, including this opinion as an exhibit or otherwise.

Very truly yours,

/s/ RICHARDSON & PATEL LLP

RICHARDSON & PATEL LLP

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the use in this Registration Statement on Form S-1/A of our audit report, dated May 14, 2009, relating to the financial statements of BioDrain Medical, Inc. appearing in the Prospectus which are a part of this Registration Statement. We also consent to the reference to our Firm under captions "Experts" in the Prospectus.

Olsen Thielen & Co., Ltd.

/s/ Olsen Thielen & Co., Ltd.

St. Paul, Minnesota

October 8, 2009

**BioDrain Medical, Inc.**  
**2060 Centre Pointe Boulevard, Suite 7**  
**Mendota Heights, Minnesota 55120**

**VIA FEDERAL EXPRESS**

Securities and Exchange Commission  
Division of Corporation Finance  
100 F. Street, N.E.  
Washington, D.C. 20549-6010  
Attn: Geoffrey Kruczek, Attorney

**Re: *BioDrain Medical, Inc.***  
**Amendment No. 10 to Registration Statement on Form S-1**  
**Filed September 30, 2009**  
**File No. 333-155299**

Dear Mr. Kruczek:

On behalf of BioDrain Medical, Inc., (the "Company" or "BioDrain"), set forth below are the Company's responses to the comments received from the staff ("Staff") of the Securities and Exchange Commission in the letter dated October 6, 2009. We have reproduced the Staff's comments in bold type for your convenience and have followed the comment with the Company's response. References in this letter to "we", "our", or "us" mean the Company or its advisors, as the context may require.

**Exhibits**

**We are an early stage company... page 4**

- 1. Please provide a currently dated accountant's consent with the amendment to be declared effective.**

*Response:* We have attached an accountant's consent dated as of October 8, 2009

**Exhibit 5.1**

- 2. Refer to the last paragraph. The consent provided by counsel must include its consent to the filing of the opinion as an exhibit. Please file a revised opinion.**
-

*Response:* Our counsel has revised its opinion to provide that it consents to the filing of the opinion as an exhibit.

**3. While counsel may state that it “does not admit” that it is an expert, it is inappropriate for counsel to deny that it is an expert. Please have counsel revise the last sentence of its opinion accordingly.**

*Response:* The opinion has been revised to state that counsel does not admit to being an expert.

\* \* \* \* \*

We hope that the information contained in this letter satisfactorily addresses the comments by the Staff. Please do not hesitate to contact the undersigned by telephone at (651) 389-4802 or by facsimile at (651) 389-4803. You may also reach our outside counsel, Ryan Hong, Esq. of Richardson & Patel LLP at (310) 208-1182 extension 723, or by facsimile at (310) 208-1154.

Very truly yours,

/s/ Kevin Davidson

Kevin Davidson

Chief Executive Officer