UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2009.**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

COMMISSION FILE NUMBER: 333-155299

BIODRAIN MEDICAL, INC.
(Exact name of registrant as specified in its charter)

Minnesota	**33-1007393**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

2060 Centre Pointe Boulevard, Suite 7
Mendota Heights, Minnesota 55120
(Address and Zip Code of principal executive offices)

(Registrant's telephone number, including area code): **(651) 389-4800**

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered under Section 12(g) of the Act: None.

Common Stock $.01 par value	None
(Title of each class)	(Name of each exchange on which registered)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No x

Indicated by checkmark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark if disclosures of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated Filer ☐ Non-accelerated filer ☐ Smaller Reporting Company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No x.

As of June 30, 2009, no market price existed for the voting and non-voting common equity held by non-affiliates of the registrant.

There were 11,757,211 shares of the registrant's common stock outstanding as of March 31, 2010.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's definitive proxy statement for its 2010 annual meeting are incorporated by reference into Part III of this Form 10-K.

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PART I

ITEM 1. BUSINESS.

Overview

We are an early-stage medical device company and our mission is to provide hospitals and surgical centers 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 healthcare workers from exposure and is environmentally friendly. We own patent rights to our products 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, we believe our technologies will provide cost savings to facilities over the aggregate costs incurred today using the traditional canister method of collection, neutralization and disposal. We intend to sell our products through independent distributors and manufacturer's 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 Gadbaw, 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, and Jeffery K. Drogue. 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.

We currently file reports with the Securities and Exchange Commission (the "SEC"). Upon the October 19, 2009 effectiveness of the registration statement we filed with the SEC, we became subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended, and we intend to continue filing periodic reports, proxy statements and other information with the SEC.

Industry and Market Analysis

Infectious and Bio-hazardous Waste Management

There has long been recognition of the collective potential for ill effects to healthcare workers from exposure to infectious/bio-hazardous materials. Federal and state regulatory agencies have issued mandatory guidelines for the control of such materials, and 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, 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) Hospital Statistics, 2008 edition, America's hospitals performed 70 million surgeries. This number does not include the many procedures performed at surgery centers across the country. In a recent publicly-available Gallup survey, it was found that "on average, operating room directors report their hospitals have approximately six operating rooms."

The majority of these procedures produce potentially infectious materials that must be disposed 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 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 publicly-available Frost & Sullivan research report from April 24, 2006 estimates that 60,000,000 suction canisters are sold each year and the estimated market value of canisters is upwards of $120,000,000.

With an average cost of $2.00 per canister, $2.00 per container of solidification powder and an average disposal cost of $0.30/lb of infectious waste at approximately 7.5 lbs per canister, the estimated disposal cost to the hospitals who use solidifiers is $6.25 per canister. This cost increases significantly for disposal of high capacity containers according to the average estimate of three manufacturers and three different solidifiers as reported in a research report by Frost & Sullivan in 2003 and in an article titled “Liquid Waste Management & Disposal” that was published in *Infection Control Today* in 2006.

A study by the Lewin Group, prepared for the Health Industry Group Purchasing Association in April, reports that infectious fluid waste accounts for more than 75% of U.S. hospitals biohazard disposal costs. The study 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 American Institute of Architects Consensus Construction Forecast, “Health care is expected to see even stronger growth. With recent emphasis on increasing health-care coverage, including several state mandates for universal or near-universal coverage, health-care construction has become one of the fastest growing institutional construction categories. Panel members are projecting an 8.5 percent increase in spending in 2009, followed by an additional 5 percent gain in 2010.”

There are currently approximately 40,000 operating rooms and surgical centers in the U.S. (AHA, *Hospital Statistics*, 2008). 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 heavily dependent on the state of the economy. We benefit by having our products address both the procedure market of nearly 70 million procedures (AHA, *Beyond Health Care*, January 2009) as well as the hospital operating room market (approximately 40,000 operating rooms).

Current Techniques of Collecting Infectious Fluids

Typically, during the course of the procedure, fluids are continuously removed from the surgical 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 no 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 is typically 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 powder is poured into the canister, rendering the material gelatinous. These gelled canisters are then red-bagged in their entirety and removed to a bio-hazardous/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 piecemeal approach 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 his or her 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 his or her 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. We believe 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 (d) 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 it has recently started advertising. Most of these competing products 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 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. We believe that Stryker Instruments has the dominant market share position. We do not believe Cardinal Health, Inc., though having FDA concurrence, has made significant sales into the market.

Products

The Streamway™ Fluid Management System ("FMS")

The 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 will 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 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.

We believe our product provides substantial cost savings and improvements in safety in facilities that still use manual processes. 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 any operating room floor space and it does not require the use of any 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., the FMS will be the only known 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, after the surgery is complete, and use canisters, which still require processing or require a secondary device (such as a docking station) 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

Feature	BioDrain Medical, Inc.	Stryker Instruments	DeRoyal	Dornoch Medical Systems, Inc.	MD Technologies, Inc.
Portable to Bedside vs. Fixed Installation	Fixed	Portable	Fixed	Portable	Fixed
Uses Canisters	No	Yes	Yes	Yes	No
Secondary Installed Device Required for Fluid Disposal	No	Yes	Yes	Yes	No
Numeric Fluid Volume Measurement	Yes	Yes	No	Yes	Optional
Unlimited Fluid Capacity	Yes	No	No	No	Yes
Continuous, Uninterrupted Vacuum	Yes	No	No	No	No
Installation Requirements					
☐Water	No	Yes	Yes	Yes	No
☐ Sewer	Yes	Yes	Yes	Yes	Yes
☐Vacuum	Yes	Yes	Yes	Yes	Yes

The FMS system may be installed on or in 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 our consultations 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 information gathered from third parties at an average of 6 hours but will vary depending on the actual drain and suction systems already resident in the hospital.

By comparison, 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 potentially purchase less than one mobile unit for each operating room. With the FMS, a unit much be 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 is provided as part of our disposable cleaning kit, allows for expansion to three inflow suction ports.

Although the 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 the system may outweigh the expected savings and/or lengthen the expected return on investment time.

One of the current techniques utilized by Stryker, Cardinal Health and other smaller companies typically utilizes 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 to infectious waste fluids generated by the operating room procedure. Handling infectious waste in this manner is also more costly.

The FMS suctions potentially infectious fluid from the patient through standard surgical tubing into the FMS. There the fluid is separated from the air stream and deposited into a fluid chamber 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 chamber 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 at that point in the procedure. The fluid removed from the fluid chamber is passed through the pump and transported directly to the hospital sanitary sewer.

The FMS has had four prototype iterations completed. The product has undergone significant testing, including being utilized in veterinary cases. We are currently finalizing specifications for the final 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 filed a 510(k) submission in March 2009 and received written FDA clearance on April 1, 2009. The unit is classified as a Class II device by the FDA.

A summary of the features of the wall unit include:

- Minimal Human Interaction. The wall-mounted FMS provides 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.

- 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 in-line filter 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 is expected to 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. We will arrange installation of the FMS products through a partnership or group of partnerships. Such partnerships will include, but not be limited to, 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-mounted units allowing for quick start-up post-installation.

- Sales Channel Partners. We expect the FMS will be sold to end-users through a combination of independent stocking distributors, manufacturer's representatives and, possibly later, direct sales personnel. We intend for all personnel involved in direct contact with the end-user will have extensive training and will be approved by BioDrain. We plan to maintain exclusive agreements 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 expect that such agreements will contain provisions allowing them to be terminated at any time by BioDrain based on certain specified conditions.

- Competitive Pricing. Estimated selling price is expected to be in the range of $15,000 - $18,000 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 Property

The Company spent approximately $71,000 in the year ended December 31, 2009 and approximately $183,000 in the year ended December 31, 2008 on Research and Development Expense.

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"). These patents will expire on August 8, 2023. 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. All competing products, except for MD Technologies, have a finite fluid collection capacity necessitating that the device be emptied when capacity is reached during the surgical procedure. In the case of MD Technologies their system has an unlimited capacity but the process is not continuous because they have to interrupt the process to manually switch over to a new container and drain the original container in order to have it ready for use when the second container is full.

In June 2008, we completed and 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 Mid-State Stainless, Inc., a corporation wholly owned by Mr. Ryan, 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, 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 unpatentable of the 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 Messrs. 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 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 Messrs. 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.

Our system, based on our patents, includes a cleaning kit that contains a pre-measured amount of a cleaning solution for cleaning the suction unit before a subsequent use. We have obtained an exclusive distribution agreement with a manufacturer of the fluid we will use in the cleaning kit for our FMS. While the distribution agreement will allow use of the fluid in connection with our devices, we do not expect to acquire ownership of any patent rights or claims pertaining to such fluid.

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 bottle with a connection mechanism to attach to the FMS. The disposal cleaning kit also includes an in-line filter and 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 disposable cleaning kit is a critical component of our business model. The cleaning kit has the "razor blade business model" characteristic with an ongoing stream of revenue for every FMS unit installed, and revenues from the sale of the cleaning kit is expected to be significantly higher over time than the revenues from the sale of the unit. We have exclusive distribution rights to the fluid and facilitate the use of only our fluid for cleaning following procedures by incorporating a special adapter to connect the fluid to the 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 fit 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 accompanies 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 multiple providers and we have signed an agreement with Belimed to perform 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

We intend to succeed by deploying a strategy of focused expansion within our core product and market segments, while utilizing a progressive approach to manufacturing and marketing to ensure maximum flexibility and profitability.

Our strategy is to:

- ☐ *Develop a complete line of wall-mounted fluid evacuation systems 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.

- ☐ *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 only 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.

- ☐ *Utilize existing medical products independent distributors and manufacturer's representatives to achieve the desired market penetration.* Contacts have been established with several existing medical products distributors and manufacturer's representatives and interest has been generated regarding the sales of the FMS and cleaning kits. In addition to their normal sales practices, the distributors will carry a significant supply of cleaning kits for their current customers and could purchase an FMS for demonstration to new potential customers.

- ☐ *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.

- ☐ *Utilize a Medical Advisory Board to assist in market penetration.* We have a Medical Advisory Board consisting of a pioneering 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:

- ☐ 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.

- ☐ Providing a leasing program and/or "pay per use" program as alternatives to purchasing.

- ☐ Providing service contracts to establish an additional revenue stream.

- ☐ 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 long term.

- ☐ 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 disposal of that waste either via incineration or in segregated landfills.

Once the procedure has ended, the canisters currently being used in many cases, 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 glutalderhyde, 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 bio-hazardous/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:

    - It does not ensure protection for healthcare workers, as there remains the potential for splash when the top of the canister is opened.

    - Based on industry pricing data, the total cost per canister increases by approximately $2.00.

    - 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.

    - 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. 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 it has started advertising. Most of these competing products 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, we believe most have been successful in eliminating the need for expensive gel and its associated handling and disposal costs.

Existing competitors, that already have products on the market, have a 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. We believe that Stryker Instruments has the dominant market share position Cardinal Health, Inc., though having FDA concurrence, has only recently started advertising its product. We also believe competing products are used in select procedures and often in some, but not all, surgical procedures.

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 our Company. Cardinal Health, a very significant competitor, manufacturers 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. We are 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 the red-bag procedure is followed when using these products. One significant 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.

The FMS eliminates 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 bio-hazardous/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 habitated 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 dramatically reduce costs and the amount of canisters sent to landfills.

Handling Costs

Once the surgical team has finished 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.

The 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 spills that may occur due to manual handling.

A hidden but very real and considerable handling cost is the cost of an infectious fluid exposure. A July 2007 research article published in *Infection Control Hospital Epidemiology* concluded that "Management of occupational exposures to blood and bodily fluids is costly; the best way to avoid these costs is by prevention of exposures." The research shows that hospital management cost associated with occupational blood exposure can, conservatively, be more than $4,500 per exposure. Because of privacy laws, it is difficult to obtain estimates of exposure events at individual facilities; however, in each exposure the worker must be treated as a worst case event. This puts the healthcare worker through a tremendous amount of personal trauma, and the health care facility through considerable expense and exposure to liability and litigation.

Nursing Labor

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.

The FMS 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 (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. For instance, some competing products require transport of the mobile unit to a docking port and then emptying of the fluid, while others require that the canister be 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 included in the section headed as Products for a comparison of the key features of the devices currently marketed and 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 must be purchased and installed in each room where it is intended to be used.

Marketing and Sales

Distribution

We intend to sell the FMS and cleaning kit through independent distributors and manufacturer's representatives covering the vast majority of major U.S. markets. Our 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, nurses, biomedical engineering, anesthetists, anesthesiologists, human resources, legal, administration and housekeeping.

The major focus of our marketing efforts will be to introduce the FMS 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. We believe that the FMS provides a convenient and cost effective way to collect and dispose of this highly contaminated material.

Our distributors will have installation and service capability, or we will contract those functions with 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. We believe our current cost and price estimates are conservative and allow for reasonable profit margins for all entities in the FMS and the cleaning fluid supply chain.

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 levels 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 website. We believe our 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, use of scientific journal articles and a webpage 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 our trade show booths 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 initially on the Association of Operating Room Nurses ("AORN") meeting, 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 webpage or directly through postage paid cards or direct contact. Additionally, we will create a press release distribution to clinician-oriented periodicals for inclusion in their new product development columns. These periodicals will provide the reader with an overview of the FMS and will direct readers to pursue more information by direct contact with us by accessing our webpage.

Pricing

We believe prices for the FMS and its disposable cleaning kit reflect a substantial cost savings to hospitals compared to their long-term procedure costs. Our pricing strategy should ensure that the customer realizes actual cost savings when using the FMS versus 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 contrast, 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). 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 or disposed with the rest of the facility's plastics.

The FMS lists for approximately $18,000 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. Because we will sell our products through distributors and manufacturer's representatives we expect to sell the FMS for approximately $15,000 and the cleaning kit for approximately $15 per unit. 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 per procedure and a proprietary cleaning fluid (cost unknown per procedure). Per procedure cost of the traditional disposal process includes approximate costs of $2 per liter canister, plus solidifier at $2 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 disposal expenses.

Installation will be done by distributors, independent contractors or 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, while 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 approach is for the disposable cleaning kit to be priced at $15 - $20 per unit, and a commission to be paid to the distributor/independent representative upon each sale, thus creating an ongoing revenue stream to the distributor/representative as well as to BioDrain.

Engineering and Manufacturing

We are currently in negotiations to finalize our relationship and execute a manufacturing supply agreement with TriVirix, Inc. for the engineering and manufacturing of the FMS, which does not include the cleaning fluid, cleaning fluid packaging, external manifold or any other accessories. TriVirix is ISO 13485:2003 and GMP-certified and has the necessary expertise and experience to build our product in a cost-effective manner.

We anticipate that the manufacturing supply agreement with TriVirix will specify the quantities for production of our product, which we expect 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 would be considered our primary supplier of the FMS device. As part of a broader manufacturing sourcing strategy, we plan to identify at most two second sources of production for the FMS device. Except for the custom made stainless steel cabinet, all of the components in the FMS are off-the-shelf products readily available from a number of suppliers. Likewise, the custom designed cabinet can be produced by a variety of suppliers with expertise in machining stainless steel.

The disposable cleaning kit, including 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), an in-line filter and a multi-port external, non-sterile manifold, will be sourced through alternative suppliers segregated as primary and secondary suppliers. 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 and components.

To further our manufacturing sourcing strategy we hired, in July 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. Mr. Ruwe was promoted to Chief Operating Officer in 2009.

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)
- State, county, hospital and other institutions

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 the FMS device. We issued request for quotes to two of the three 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 requires, 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 have 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 SE 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), (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 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 Pacific Rim, as well as product design changes necessitated by laws, regulations and directives.

Employees

We currently have four full-time employees: a Chief Executive Officer/Chief Financial Officer; a Vice President of Sales; 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. We believe that our relations with our employees are good.

ITEM 1A. RISK FACTORS.

Not required.

ITEM 2. PROPERTIES.

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 one through twelve; $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 was not payable in months one through twelve. The lease term began on November 1, 2008 and will extend for a period of five 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.

ITEM 3. LEGAL PROCEEDINGS.

In April 2009 Gerald Rice, 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. Settlement discussions commenced but the parties were unable to reach an agreement. Thereafter, the former officer filed a lawsuit in Minnesota State Court, Dakota County alleging claims for breach of contract and unpaid wages. The Company answered the complaint and denied the allegations therein. The Company believes that the claims are without merit and continues to defend the claims. We are not otherwise 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 the Company. To our knowledge, we are not otherwise a party to any pending civil or criminal action or investigation.

ITEM 4. REMOVED AND RESERVED.

Executive Officers of the Registrant

The following table identifies our current executive officers and directors:

Name	Age	Position Held
Lawrence W. Gadbaw	72	Chairman of the Board of Directors
Kevin R. Davidson	50	President, Chief Executive Officer, Chief Financial Officer and Director
Chad A. Ruwe	45	Chief Operating Officer and Director
Jess R. Carsello	47	Vice President of Sales
James E. Dauwalter	58	Director
Peter L. Morawetz	82	Director
Thomas J. McGoldrick	68	Director
Andrew P. Reding	40	Director

We have not set a term of office for 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,

1) 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,

2) had been convicted in a criminal proceeding and none of our directors or executive officers is subject to a pending criminal proceeding,

3) has 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

4) has 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. Gadbaw, Chairman of the Board of Directors. Mr. Gadbaw has served as a director and Chairman of the Board 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. Gadbaw 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. Gadbaw 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. Gadbaw 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. He has over 20 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 Micro-Contamination 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, Huntsville, and he received his Bachelor of Science degree in Mechanical Engineering, specializing in Fluid Dynamics, from The Ohio State University in Columbus, Ohio.

Jess R. Carsello, Vice President of Sales. Mr. Carsello became our Vice President of Sales in 2010. He has over 20 years of sales and management experience in the medical industry, the majority of which has been in selling single-use disposables and capital equipment for operating room applications. From 2004 to 2009 Mr. Carsello served as VP of Sales for Aspen Surgical with primary focus on sales into distribution concentrating on Private Label sales for large distributors nationwide. From 2002 to 2004 Mr. Casello served as VP of Sales for Sterion Inc. where he was responsible for managing worldwide sales of Sterilization Container Systems and Wound Care products. Mr. Carsello served as the VP of Sales for Barriermed Inc, from 2001 to 2002 where he introduced a new technology in Polyisoprene Surgical Gloves. From 1991 to 2001 he was with Regent Medical/SSL Americas, (now Mölnlycke Health Care) where he was Director of Distributor Relations for North America, Regional Manager covering 13 Midwest states, Sales Rep and Sales Trainer. He began his career as a Sales Representative for Vital Signs selling products into Anesthesia, Respiratory Care and all Critical Care areas of the hospital. Mr. Carsello holds a Bachelor of Science degree from the University of Wisconsin, Eau Claire.

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 was co-founder 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 was 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 set up 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 (UM) 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 Wangensteen 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.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCK HOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Holders

As of March 15, 2010, there were approximately 125 shareholders of record of our Common Stock. Our Common Stock is not traded on a public market.

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.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by Item 5 is incorporated herein by reference to the sections entitled "Principal Shareholders and Management Shareholdings" and "Equity Compensation Plan Information," which appear in our definitive proxy statement for our 2010 Annual Meeting of Shareholders. Also see Item 12 below.

Purchases of Equity Securities by the Company

None.

Recent Sales of Unregistered Securities

On November 10, 2009, the Company issued 50,000 shares of its Common Stock and a warrant to purchase 50,000 shares of Common Stock at an exercise price of $.65 per share to Russell H. Yaucher for his $25,000 investment in the Company.

ITEM 6. SELECTED FINANCIAL DATA.

Not Required.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing under Item 8 of this Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and expected financial results, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" in our Registration Statement on Form S-1 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We were 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-mounted Fluid Management System ("FMS") and use of our proprietary cleaning fluid.

Since inception, we have been unprofitable. We incurred a net loss of approximately $1,763,000 for the fiscal year ended 2008 and a net loss of approximately $2,892,000 for the fiscal year ended December 31, 2009. As of December 31, 2009, we had an accumulated deficit of approximately $6,029,000. 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 have focused on finalizing our production processes and obtaining final FDA clearance to sell our product to the medical facilities market. FDA final clearance was obtained on April 1, 2009. We intend to sell the FMS through experienced, independent medical distributors and manufacturer's representatives, who we believe will enhance acceptability of the FMS in the market. We are currently in the process of signing agreements with independent sales representatives and product installation organizations and conducting training sessions. We achieved our first billable shipment in June 2009 and anticipate several orders during the first half of 2010. 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 2010 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, 2009, 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 our 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 raised approximately $1.6 million through our October 2008 financing. The $170,000 convertible bridge loan and the $4,000 in officer and director loans were converted into shares of the Company's Common Stock in October 2009. During 2009 we raised an additional $725,000 in a private placement of stock units and/or convertible debt, with each stock or debt unit consisting of, or converting into, respectively, one share of our Common Stock, and a warrant to purchase one share of our Common Stock at $.65 per share.

Related Party Transactions

The Company entered into agreements in 2008, with our Chairman of the Board Lawrence Gadbaw, and in 2009 with board member, Peter Morawetz, to pay Mr. Gadbaw $25,000 and Mr. Morawetz $30,000 upon the Company raising $3 million in new equity. Mr. Gadbaw will also be paid the balance, if any, due under his separation agreement from 2008. This amount was $46,000 upon signing the agreement in 2008, is payable at $2,000 per month, and $16,000 remains in accounts payable as of December 31, 2009. Mr. Morawetz will also receive a stock option for 75,000 shares at $.35 per share and Mr. Gadbaw will receive a stock option for 160,000 shares at $.35 per share upon the Company raising $3 million.

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 Annual Report on Form 10-K. We believe that the following discussion addresses our critical accounting policies and reflects 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 ASC 605-*Revenue Recognition*.

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. We believe it would be rare that the FMS 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) which replaced SFAS No. 123, and superseded Accounting Principles Board (APB) Opinion No. 25, all codified as ASC 718-*Compensation-Stock Compensation* ("ASC 718"). Under ASC 718 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 ASC 718 under which prior periods are not retroactively restated.

ASC 718 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 Common 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 was 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 Annual Report on Form 10-K 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 recognizes that. Since we have no trading history in our Common Stock and no first-hand experience with how our 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 Common 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 ten medical companies in the middle of the market cap size range on the OTC Bulletin Board (“OTCBB”) 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 ASC 360-*Property Plant and Equipment* (“ASC 360”), 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, now codified under ASC 815-*Derivatives and Hedging* (“ASC 815”). ASC 815 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 ASC 815, 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, June 30, 2009, September 30, 2009 and December 31, 2009 and recorded a loss of $369,642 in the 12-month period ended December 31, 2009 as a result of the increase in the valuation of the liability. See “Note 10 – Liability for Equity-Linked Financial Instrument” to the Notes to Financial Statements of this Annual Report on Form 10-K.

Issued in January 2010, ASU Update 2010-06, Fair Value Measures and Disclosures, provides amendments to Topic 820 that will provide more robust disclosures about (1) the different classes of assets and liabilities measured at fair value, (2) the valuation techniques and inputs used, (3) the activity in level 3 fair value measurements, and (4) the transfers between levels 1, 2, and 3. ASC Update 2010-06 is effective for fiscal years beginning after December 15, 2010. We do not expect adoption of ASU Update 2010-06 to have a material effect to our financial statements or our disclosures.

Issued in October 2009, ASU Update 2009-13, Revenue Recognition Topic 605 - Multiple-Deliverable Revenue Arrangements provides guidance for separating consideration in multiple-deliverable arrangements. ASC Number 2009-13 is effective for fiscal years beginning on or after June 15, 2010. We do not expect adoption of ASU Update 2009-13 to have a material effect on our financial statements.

Effective February 2010, we adopted ASU Update 2010-09, Subsequent Events,which provides amendments to Topic 855 removing the requirement for SEC filers to disclose the date through which an entity has evaluated subsequent events. The adoption of ASU Update 2010-09 did not have a significant impact on our disclosures.

Effective October 1, 2009, we adopted ASU Update 2009-05, Fair Value Measurement and Disclosures Topic 820 which provides further guidance on the fair value measurement of liabilities. The adoption of ASU 2009-05 did not have a material effect on our consolidated financial statements.

Effective September 15, 2009, we adopted ASC 105 making the FASB Accounting Standards Codification, (“Codification”) the single source of authoritative nongovernmental U.S. generally accepted accounting principles. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. All other accounting literature not included in the Codification is non-authoritative.

Effective June 15, 2009, we adopted requirements within ASC 855 which establishes general standards of accounting for and disclosure of events that occur after the balance sheet date, but before financial statements are issued or are available to be issued. ASC 855 sets forth (1) the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, (2) the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and (3) the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. The adoption of the

requirements within ASC 855 did not have a material effect on our consolidated financial statements. Subsequent events have been evaluated through the filing date of this Annual Report on Form 10-K.

Results of Operations

Comparison of Fiscal Year Ended December 31, 2009 with Fiscal Year Ended December 31, 2008

Revenue. We recorded revenue of $15,737 in 2009 compared to none in 2008. We received approval from the FDA on April 1, 2009 to commence sales and marketing activities of its patented Streamway FMS system and recorded its first shipment in June 2009. Since the system was first approved for sale during 2009 there was no revenue in 2008.

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 $1,598,000 for the year ended December 31, 2009 from $1,316,000 for the year ended December 31, 2008. General and administrative expense increased primarily due to an increase of $54,000 in stock-based compensation expense, a $48,000 increase in audit and accounting expense, a $355,000 increase in stock-based registration payments and a $119,000 increase in consulting expense offset, in part, by a $66,000 reduction in legal fees and a $119,000 reduction in stock-based consulting. The increase in stock-based compensation expense resulted from a significant grant of restricted stock to officers and directors in 2009. The large increase in registration payments was due to the monthly penalty arising from our inability to obtain effective registration of our Common Stock within 180 days of the closing date of the October 2008 financing. Legal fees decreased when our Registration Statement on Form S-1 became effective. We anticipate that general and administrative expense will increase in absolute dollars in 2010 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 complying with public reporting obligations.

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 $447,000 in the year ended December 31, 2009 compared to $321,000 in the year ended December 31, 2008, primarily due to a $31,000 increase in salaries and a $86,000 increase in stock-based compensation. The increase in salaries was due to the Chief Operating Officer being employed for the entire year, compared to only 7 months in 2008, and the increase in stock-based compensation resulted from a significant grant of restricted stock to officers and directors in 2009.

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 expense grew to $407,000 in the year ended December 31, 2009 compared to $36,000 in the year ended December 31, 2008, primarily as a result of an increase of $195,000 in salaries and benefits, a $75,000 increase in stock-based compensation, a $21,000 increase in travel and a $73,000 increase in trade show, promotion and marketing supplies expenses. On February 1, 2009, the Company 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 2010 to exceed, by a significant amount, the expenses incurred in 2009.

Interest expense. Interest expense, including loss on valuation of equity-linked financial instruments, increased to $449,000 in the year ended December 31, 2009 from $89,000 in the year ended December 31, 2008, primarily due to adoption of ASC 815 which, beginning January 1, 2009, requires the Company to re-compute the value of equity-linked financial instruments on each balance sheet date resulting in a $370,000 (non-cash) loss on valuation of equity-linked financial instruments during 2009.

Liquidity and Capital Resources

We had a cash balance of $16,632 as of December 31, 2009 and $463,838 as of December 31, 2008. Since our inception, we have incurred significant losses, and as of December 31, 2009, we had an accumulated deficit of approximately $6,029,000. 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.

Through December 31, 2009, our operations have been funded through a bank loan in the original amount of $41,400, a private party loan totaling $10,000, convertible debt in the amounts of $170,000 and $100,000 and equity investments totaling approximately $2,317,000. The $170,000 in convertible debt was converted into 620,095 shares of our Common Stock as of October 19, 2009. As of December 31, 2009, we had accounts payable of $814,000 and accrued liabilities of $201,000.

Net cash used in operating activities was $1,310,000 for 2009 as compared with net cash used of $901,000 for 2008. The increased use of cash was due primarily to an increase to $2,892,000 in net loss offset, in part, by an increase of $317,000 in accounts payable and the net loss including $399,000 in stock issued for management and consulting services, $355,000 in stock-based registration payments and a $370,000 loss on equity-linked financial instruments that did not consume cash.

Cash flows used in investing activities was zero for 2009 as compared to $42,000 cash used in investing activities for 2008. The amount in 2008 represented $30,000 in investments in intellectual property and $12,000 in purchases of furniture.

Net cash provided by financing activities was $863,000 for 2009 as compared to net cash provided by financing activities of $1,402,000 for 2008. The decrease in 2009 was primarily the result of selling approximately $1,600,000 in stock in 2008, compared to $625,000 in 2009 although the Company was also successful in arranging a $100,000 convertible debt loan, converting $87,000 in accrued interest into shares of our Common Stock and utilizing $60,000 from the restricted cash in escrow account in 2009.

Information Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements" that indicate certain risks and uncertainties related to the Company and this Offering, many of which are beyond the Company's control. The Company's actual results could differ materially and adversely from those anticipated in such forward-looking statements as a result of certain factors, including those set forth below and elsewhere in this report. Important factors that may cause actual results to differ from projections include:

- Adverse economic conditions;
- Inability to raise sufficient additional capital to operate our business;
- Unexpected costs and operating deficits, and lower than expected sales and revenues, if any;
- Adverse results of any legal proceedings;
- The volatility of our operating results and financial condition;
- Inability to attract or retain qualified senior management personnel, including sales and marketing personnel; and
- Other specific risks that may be alluded to in this report.

All statements, other than statements of historical facts, included in this report regarding the Company's growth strategy, future operations, financial position, estimated revenue or losses, projected costs, prospects and plans and objectives of management are forward-looking statements. When used in this report, the words "will," "may," "believe," "anticipate," "intend," "estimate," "expect," "project," "plan" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain such identifying words. All forward-looking statements speak only as of the date of this report. The Company does not undertake any obligation to update any forward-looking statements or other information contained herein. Potential investors should not place undue reliance on these forward-looking statements. Although BioDrain believes that its plans, intentions and expectations reflected in or suggested by the forward-looking statements in this report are reasonable, the Company cannot assure potential investors that these plans, intentions or expectations will be achieved. The Company discloses important factors that could cause the Company's actual results to differ materially from its expectations in the "Risk Factors" section of our Registration Statement on Form S-1 and elsewhere in this report. These cautionary statements qualify all forward-looking statements attributable to the Company or persons acting on its behalf.

Information regarding market and industry statistics contained in this report are included based on information available to the Company that it believes is accurate. It is generally based on academic and other publications that are not produced for purposes of securities offerings or economic analysis. The Company has not reviewed or included data from all sources, and the Company cannot assure potential investors of the accuracy or completeness of the data included in this report. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and the additional uncertainties accompanying any estimates of future market size, revenue and market acceptance of products and services. The Company has no obligation to update forward-looking information to reflect actual results or changes in assumptions or other factors that could affect those statement

Off-Balance Sheet Transactions

BioDrain Medical, Inc. has no off-balance sheet transactions.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not required.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our financial statements and supplementary data are included on pages F-1 to F-14 of this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A(T). CONTROLS AND PROCEDURES.

Disclosure Controls

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our Chief Executive Office/Chief Financial Officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) as of the end of the period covering this report. Based on this evaluation, our Chief Executive Officer/Chief Financial Officer concluded that our disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed in the reports that are filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified by the Securities and Exchange Commission's rules and forms and that our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management including our Chief Executive Officer/Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Limitations on Controls

Our management, including our Chief Executive Officer/Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. In addition, the design of any system of controls is based in part on certain assumptions about the likelihood of future events, and controls may become inadequate if conditions change. There can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Changes in Internal Controls

There were no changes in our internal controls over financial reporting during the fourth quarter of fiscal year 2009 that may have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Other than the information included in this Form 10-K under the heading "Executive Officers of the Registrant," which is set forth at the end of Part I, the information required by Item 10 is incorporated by reference to the sections labeled "Election of Directors," "Corporate Governance" and "Section 16(a) Beneficial Ownership Reporting Compliance," all of which appear in our definitive proxy statement for our 2010 Annual Meeting of Shareholders.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by Item 11 is incorporated herein by reference to the sections entitled "Executive Compensation," "2009 Director Compensation," and "Compensation Committee," all of which appear in our definitive proxy statement for our 2010 Annual Meeting of Shareholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by Item 12 is incorporated herein by reference to the sections entitled "Principal Shareholders and Management Shareholdings" and "Equity Compensation Plan Information," which appear in our definitive proxy statement for our 2010 Annual Meeting of Shareholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by Item 13 is incorporated herein by reference to the sections entitled "Corporate Governance — Independence" and "Certain Transactions," which appear in our definitive proxy statement for our 2010 Annual Meeting of Shareholders.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by Item 14 is incorporated herein by reference to the section entitled "Audit Fees," which appears in our definitive proxy statement for our 2010 Annual Meeting of Shareholders.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

The following exhibits and financial statements are filed as part of, or are incorporated by reference into, this report:

(1) Financial Statements

The following financial statements are filed with this Annual Report and can be found beginning at page F-1 of this report:

- Report of Independent Registered Public Accounting Firm dated March 31, 2010;
- Balance Sheets as of December 31, 2009 and December 31, 2008;
- Statements of Operations for the Fiscal Years Ended December 31, 2009 and December 31, 2008 and from Inception to December 31, 2009;
- Statements of Stockholders' Equity from Inception to December 31, 2009;
- Statements of Cash Flows for the Fiscal Years Ended December 31, 2009 and December 31, 2008 and from Inception to December 31, 2009; and
- Notes to Financial Statements.

(2) Financial Statement Schedules

The following financial statement schedule is filed with this Annual Report on Form 10-K and can be found following the Notes to Financial Statements:

- Schedule II—Valuation and Qualifying Accounts.

All other schedules have been omitted because the information required to be shown in the schedules is not applicable or is included elsewhere in the financial statements and Notes to Financial Statements.

(3) Exhibits

See “Exhibit Index” following the signature page of this Form 10-K for a description of the documents that are filed as Exhibits to this Annual Report on Form 10-K or incorporated by reference herein.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 31, 2010

BioDrain Medical, Inc.

By /s/ Kevin R. Davidson
President, Chief Executive Officer and Chief Financial Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes KEVIN R. DAVIDSON his true and lawful attorneys-in-fact and agents, each acting alone, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any or all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all said attorneys-in-fact and agents, each acting alone, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof. Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	Title	
/s/ Lawrence W. Gadbaw	Chairman of the Board of Directors	March 31, 2010
/s/ Kevin R. Davidson	President, Chief Executive Officer, Chief Financial Officer and Director (principal executive officer and principal financial and accounting officer)	March 31, 2010
/s/ James E. Dauwalter	Director	March 31, 2010
/s/ Thomas J. McGoldrick	Director	March 31, 2010
/s/ Peter L. Morawetz	Director	March 31, 2010
/s/ Andrew P. Reding	Director	March 31, 2010
/s/ Chad A. Ruwe	Director	March 31, 2010

EXHIBIT INDEX
BIODRAIN MEDICAL, INC.
FORM 10-K

Exhibit No.	Description
23.1*	Consent of Olsen Thielen & Co., Ltd.
31.1*	Certification of principal executive officer and principal financial officer required by Rule 13a-14(a).
32.1*	Section 1350 Certification.

* Filed herewith.

The audited financial statements for the periods ended December 31, 2009, December 31, 2008 and Inception through December 31, 2009 are included on the following pages:

INDEX TO FINANCIAL STATEMENTS

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, 2009 and 2008 and the related statements of operations, stockholders' deficit and cash flows for the years then ended and for the period from April 23, 2002 (inception), to December 31, 2009. 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.

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, 2009 and 2008, 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 significant 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
March 31, 2010

PART 1. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	December 31, 2009	December 31, 2008
ASSETS		
Current Assets:		
Cash	$ 16,632	$ 463,838
Accounts receivable	15,737	-
Prepaid expense and other assets	3,801	7,974
Restricted cash in escrow (See Note 4)	103,333	163,333
Total Current Assets	139,503	635,145
Fixed assets, net	9,260	11,689
Intangibles, net	141,532	142,145
Total Assets	$ 290,295	$ 788,979
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current Liabilities:		
Current portion of bank debt (See Note 8)	$ 13,620	$ 17,620
Current portion of convertible debt	50,000	170,000
Accounts payable	814,137	497,150
Shares due investors under registration payment arrangement	355,124	-
Accrued expenses	201,490	305,248
Convertible debenture	10,000	10,000
Total Current Liabilites	1,444,371	1,000,018
Long term debt and convertible debt, net of discounts of $44,873 and $26,157 (See Note 8)	116,108	98,406
Liability for equity-linked financial instruments (See Note 11)	1,071,847	-
Shareholders’ Deficit:		
Common stock, par value $.01, 40,000,000 authorized, 11,383,121 and 8,130,841 outstanding	113,831	81,308
Additional paid-in capital	3,573,506	2,753,039
Deficit accumulated during development stage	(6,029,368)	(3,143,792)
Total Shareholder' Deficit	(2,342,031)	(309,445)
Total Liabilities and Shareholders' Deficit	$ 290,295	$ 788,979

See Notes to Financial Statements

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

	Twelve Months Ended December 31,		Period From April 23, 2002 (Inception) To December 31,
	2009	**2008**	**2009**
Revenue	$ 15,737	$ -	$ 15,737
Cost of goods sold	7,000		7,000
Gross margin	8,737	-	8,737
General and administrative expense	1,598,286	1,316,398	4,028,427
Operations expense	447,000	321,205	900,874
Sales and marketing expense	407,101	35,682	456,176
Interest expense	78,938	89,343	289,640
Loss (gain) on valuation of equity-linked financial instruments	369,642	-	362,988
Total expense	2,900,967	1,762,628	6,038,105
Net loss available to common shareholders	$ 2,892,230	$ 1,762,628	$ 6,029,368
Loss per common share basic and diluted	$ 0.31	$ 0.41	$ 2.56
Weighted average shares used in computation, basic and diluted	9,475,369	4,335,162	2,355,376

See Notes to Financial Statements

BIODRAIN MEDICAL, INC.
(A DEVELOPMENT STAGE COMPANY)
STATEMENT OF STOCKHOLDERS' DEFICIT
PERIOD FROM APRIL 23, 2002 (INCEPTION)
TO DECEMBER 31, 2009

	Shares	Amount	Paid in Capital	Deficit	Total
Issuance of common stock 9/1/02, $.0167 (1)	598,549	$ 5,985	$ 4,015	$ -	$ 10,000
					-
Issuance of common stock 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 stock 2/12/03, $.0167 (2)	23,942	239	161		400
Issuance of common stock 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 stock 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 stock 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 stock 5/16 & 8/8, $.0167 (6)	86,869	869	582		1,451
Issuance of common stock 10/19 & 23, $.0167 (7)	38,906	389	261		650
Issuance of common stock 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 stock 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	823,676	$ 8,237	$ 660,430	$ (1,381,164)	$ (712,497)
Issuance of common stock 6/11 to 9/30, $.35 (10)	4,552,862	45,528	1,547,974		1,593,502
Shares issued to finders, agents and attorneys	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 antidilution 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 conversion of accrued liabilities			129,684		129,684
Net loss				(1,762,628)	(1,762,628)
Balance 12/31/08	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			111,835		111,835
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
Shares issued under PPM in August 2009, $.50	80,000	800	39,200		40,000
Shares issued under PPM in September 2009, $.50	150,000	1,500	73,500		75,000
Shares issued to directors, management and consultant in August 2009, $.50	797,810	7,978	390,927		398,905
Shares issued to finder in September 2009, $.50	100,000	1,000	49,000		50,000
Shares issued under PPM in November 2009, $.50	50,000	500	24,500		25,000
Capital contributions resulting from conversion of accrued liabilities			84,600		84,600
Value of equity-linked financial instruments issued in connection with PPMs			(222,296)		(222,296)
Value of equity instruments issued with debt			30,150		30,150
Shares issued to consultant for fund raising	30,000	300	(300)		-
Shares issued upon conversion of debt and interest, $.27	935,446	9,355	247,099		256,454
Shares issued upon conversion of shareholder note, $.35	14,024	140	4,766		4,906
Net Loss				$ (2,892,230)	(2,892,230)
Balance 12/31/09	11,383,121	$ 113,831	$ 3,573,506	$ (6,029,368)	$ (2,342,021)

(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 Notes to Financial Statements

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

	Twelve Months Ended December 31,		April 23, 2002 (Inception) To December 31,
	2009	2008	2009
Cash flow from operating activities:			
Net loss	$ (2,892,230)	$ (1,762,628)	$ (6,029,368)
Adjustments to reconcile net loss to			
net cash used in operating activities:			
Depreciation	3,042	569	3,961
Vested stock options and warrants	111,835	354,994	557,153
Stock issued for management and consulting services	448,905	87,500	536,405
Stock based registration payments	355,124		355,124
Conversion of accrued liabilites to capital	84,600	129,684	560,998
Amortization of debt discount	11,435	38,948	118,216
Loss on valuation of equity-linked instruments	369,642	-	362,988
Changes in assets and liabilities:			
Accounts receivable	(15,737)	-	(15,737)
Prepaid expense and other	4,173	(3,417)	(3,801)
Notes payable to shareholders	(4,000)	-	(14,973)
Accounts payable	316,987	290,003	814,137
Accrued expenses	(103,761)	(36,181)	201,491
Net cash used in operating activities:	(1,309,985)	(900,528)	(2,553,390)
Cash flow from investing activities:			
Purchase of fixed assets	-	(12,258)	(12,258)
Purchase of intangibles		(29,599)	(142,495)
Net cash used in investing activities	-	(41,857)	(154,753)
Cash flow from financing activities:			
Proceeds from long term debt	100,000	-	521,505
Principal payments on long term debt	(183,581)	(28,125)	(271,930)
Restricted cash in escrow	60,000	(163,333)	(103,333)
Debt converted to common stock	174,000	-	174,000
Accrued interest converted to stock	87,360		87,360
Issuance of common stock	625,000	1,593,502	2,317,173
Net cash provided by financing activities	862,779	1,402,044	2,724,775
Net increase (decrease) in cash	(447,206)	459,659	16,632
Cash at beginning of period	463,838	4,179	-
Cash at end of period	$ 16,632	$ 463,838	$ 16,632

See Notes to Financial Statements

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 an investment banker in January 2010 to raise an additional $3-$5 million in new equity with an interim closing of up to $500,000 expected by March 31, 2010. Although our ability to raise this new capital is in substantial doubt we received $725,000 through private placements of equity and convertible debt in 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, now codified under ASC 815-*Derivatives and Hedging* ("ASC 815"). ASC 815 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 ASC 815, 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, June 30, 2009, September 30, 2009 and December 31, 2009 and recorded a loss of $369,642 in the 12-month period ended December 31, 2009 as a result of the increase in the valuation of the liability. See "Note 10 – Liability for Equity-Linked Financial Instrument" to the Notes to Financial Statements of this Annual Report on Form 10-K.

Issued in January 2010, ASU Update 2010-06, Fair Value Measures and Disclosures, provides amendments to Topic 820 that will provide more robust disclosures about (1) the different classes of assets and liabilities measured at fair value, (2) the valuation techniques and inputs used, (3) the activity in level 3 fair value measurements, and (4) the transfers between levels 1, 2, and 3. ASC Update 2010-06 is effective for fiscal years beginning after December 15, 2010. We do not expect adoption of ASU Update 2010-06 to have a material effect to our financial statements or our disclosures.

Issued in October 2009, ASU Update 2009-13, Revenue Recognition Topic 605 - Multiple-Deliverable Revenue Arrangements provides guidance for separating consideration in multiple-deliverable arrangements. ASC Number 2009-13 is effective for fiscal years beginning on or after June 15, 2010. We do not expect adoption of ASU Update 2009-13 to have a material effect on our financial statements.

Effective February 2010, we adopted ASU Update 2010-09, Subsequent Events,which provides amendments to Topic 855 removing the requirement for SEC filers to disclose the date through which an entity has evaluated subsequent events. The adoption of ASU Update 2010-09 did not have a significant impact on our disclosures.

Effective October 1, 2009, we adopted ASU Update 2009-05, Fair Value Measurement and Disclosures Topic 820 which provides further guidance on the fair value measurement of liabilities. The adoption of ASU 2009-05 did not have a material effect on our consolidated financial statements.

Effective September 15, 2009, we adopted ASC 105 making the FASB Accounting Standards Codification, ("Codification") the single source of authoritative nongovernmental U.S. generally accepted accounting principles. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. All other accounting literature not included in the Codification is non-authoritative.

Effective June 15, 2009, we adopted requirements within ASC 855 which establishes general standards of accounting for and disclosure of events that occur after the balance sheet date, but before financial statements are issued or are available to be issued. ASC 855 sets forth (1) the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, (2) the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and (3) the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. The adoption of the requirements within ASC 855 did not have a material effect on our consolidated financial statements. Subsequent events have been evaluated through the filing date of this Annual Report on Form 10-K.

Accounting Policies and 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.

Presentation of Taxes Collected from Customers

Sales taxes are imposed on the Company's sales to nonexempt customers. The Company collects the taxes from customers and remits the entire amounts to the governmental authorities. The Company's accounting policy is to exclude the taxes collected and remitted from revenues and expenses.

Shipping and Handling

Shipping and handling charges billed to customers are recorded as revenue. Shipping and handling costs are recorded within cost of goods sold on the statement of operations.

Advertising

Advertising costs are expensed as incurred. Total advertising expenses were approximately $1,600 for 2009 and none in 2008.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs were approximately $71,000 and $183,000 in 2009 and 2008, respectively.

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 ASC 605 *Revenue Recognition.*

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable and collectability 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 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.

Receivables

Receivables are reported at the amount the Company expects to collect on balances outstanding at year end. The Company has concluded there will be no losses on balances outstanding at year end.

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:

	Years
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 ASC 740-*Income Taxes("ASC 740")*. Under ASC 740, 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, now included within ASC 740, addresses how tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740, 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 Company has identified no income tax uncertainties.

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.

Subsequent Events
In May 2009, Financial Accounting Standards Board issued ASC 855 *Subsequent Events*. This standard is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855 is effective for interim and annual periods ended after June 15, 2009. The Company adopted this standard effective June 15, 2009.

The Company has evaluated any subsequent events through the date of this filing. The Company does not believe there are subsequent events that require disclosure.

NOTE 2 – DEVELOPMENT STAGE OPERATIONS
The Company was formed April 23, 2002. Since inception to December 31, 2009, 11,383,121 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), all now codified under ASC 718-*Compensation-Stock Compensation* ("ASC 718). Under ASC 718 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 under which prior periods are not retroactively restated.

ASC 718 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 11) 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. The Company issued $100,000 in convertible debt in October 2009 and issued a warrant, in connection with the debt, for 200,000 shares at $.65 per share. The Company determined that the warrant had an initial value of $30,150 that is treated as a debt discount and amortized as additional interest expense over the 24 month term of the note. The value was determined using the Black-Scholes-Merton option valuation model with a 3 year expected life, a 54% expected volatility, a zero dividend rate and a 2.53% risk free interest rate.

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	205,000	0.37	2,188,302	0.65
Outstanding at December 31, 2009	1,496,174	0.27	7,372,813	0.49

(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 December 31, 2009 and the fair value of shares vesting in each year are as follows:

Year	Options	Fair Value	Fair value vested
2005	17,956	$ 0.671	$ 1,673
2006	23,942	$ 0.682	$ 12,919
2007	5,984	$ 0.687	$ 71,038
2008	1,243,292	$ 0.232	$ 220,287
2009	205,000	$ 0.243	$ 52,272
Total	1,496,174	$ 0.207	$ 358,189

At December 31, 2009, 1,496,174 stock options are fully vested and currently exercisable with a weighted average exercise price of $.27 and a weighted average remaining term of 6.7 years. There are 7,372,813 warrants that are fully vested and exercisable. Stock based compensation recognized in the year ended December 31, 2008 was $220,287 the year ended December 31, 2009 was $111,835.

The following summarizes the status of options and warrants outstanding at December 31, 2009:

Range of Exercise Prices	Shares	Weighted Average Remaining Life
Options		
$0.01	$ 543,292	$ 8.43
$0.35	875,000	3.61
$0.50	30,000	2.87
$1.67	47,882	1.50
Total	1,496,174	
Warrants		
$0.02	71,826	4.45
$0.35	798,597	2.40
$0.46	4,972,498	1.62
$0.65	1,485,000	2.48
$1.67	44,892	1.69
Total	7,372,813	

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.

Stock, Stock Options and Warrants Granted by the Company

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

Stock Options:

Year	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	205,000	.35-.50
Total	1,496,174	$ .01-$1.67

Warrants:

Year	Shares	Price
2005	8,979	$ 1.67
2006	71,826	.02-1.67
2007	28,502	.35
2008	5,075,204	.02-.46
2009	2,188,302	.35-.65
Total	7,372,813	$ .02-$1.67

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 commenced 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.

During the fourth quarter of 2009 $60,000 was released to pay for investor relations activities. The balance in this escrow account will be released to the Company if we should withdraw our public company registration 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 the shares used in the basic and diluted loss per common share computations:

	Twelve Months Ended December 31, 2009	Twelve Months Ended December 31, 2008	From April 23, 2002 (Inception) To December 31, 2009
Numerator			
Net Loss available in basic and diluted calculation	$ 2,892,230	$ 1,762,628	$ 6,029,368
Denominator			
Weighted average common shares oustanding-basic	9,475,369	4,335,162	2,355,376
Effect of dilutive stock options and warrants (1)	-	-	-
Weighted average common shares outstanding-diluted	9,475,369	4,335,162	2,355,376
Loss per common share-basic and diluted	$ 0.31	$ 0.41	$ 2.56

(1) The number of options and warrants outstanding as of December 31, 2009 and December 31, 2008 are 8,868,987 and 6,475,685 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, 2009, were approximately $5,415,000 and will begin to expire between 2017 and 2019.

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. Tax returns subsequent to 2005 are open for examination.

The components of deferred income taxes at December, 2009 and December 31, 2008 are as follows:

	December 31, 2009	December 31 , 2008
Deferred Tax Asset:		
Net Operating Loss	$ 1,278,000	$ 747,000
Total Deferred Tax Asset	1,278,000	747,000
Less Valuation Allowance	1,278,000	747,000
Net Deferred Income Taxes	$ —	$ —

NOTE 7 –NOTES PAYABLE

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 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.

NOTE 8 – LONG-TERM DEBT

Long-term debt is as follows:

	December 31, 2009	December 31, 2008
Notes payable to seven individuals due April 2008 including 8% fixed interest. The notes were convertible into 620,095 shares of the Company's common stock and automatically converted as of October 19, 2009, the effective date of the Company's registration statement.	$ 0	$ 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.	24,601	38,183
Notes payable to two individuals, net of discounts of $17,438 and $25,487 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.	82,562	73,843
Note payable issued on October 26, 2009 to the parents of one our officers, net of a $27,435 discount, with interest at 8% to October 26, 2011 and convertible into 200,000 shares of common stock at $.50 per share.	72,565	
Notes payable to four shareholders of the Company that are overdue. The notes converted into 11,432 shares of stock in the Company at $.35 per share on October 31, 2009.	-	4,000
Total	179,728	286,026
Less amount due within one year	63,620	187,620
Long-Term Debt	$ 116,108	$ 98,406

Cash payments for interest were $5,175 for the year ended December 31, 2008 and $1,718 for the year ended December 31, 2009. The convertible debenture of $10,000 (discussed in Note 7), is delinquent and could be called by the holders, putting additional strains on our liquidity. The note for $170,000 contained 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 accrued interest and penalty in the amount of $86,454 was converted into 315,351 shares of stock and the $170,000 principal balance was converted into 620,095 shares of common stock as of October 19, 2009. In addition, beginning March 2009 the Company was 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. The Company is obligated to issue 710,248 shares as a result of an effective registration on October 19, 2009.

Principal payments required during the years 2010 to 2014 are:

2010 -	$ 73,620
2011 -	$ 60,981
2012 -	$ 100,000
2013 -	$ 0
2014	$ 0

NOTE 9 – RENT OBLIGATION

The Company leases it 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 was $38,035 and $13,219 for 2009 and 2008, respectively.

The Company's rent obligation for the years 2010 to 2014 is as follows:

2010	29,000
2011	30,000
2012	30,000
2013	26,000
2014	0

NOTE 10 – LIABILITY FOR EQUITY-LINKED FINANCIAL INSTRUMENTS

The Company adopted ASC 815-*Derivatives and Hedging* ("ASC 815") on January 1, 2009. ASC 815 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 was our first quarter of 2009. Most of the warrants issued by the Company contain a strike price adjustment feature, which upon adoption of ASC 815, changed the classification (from equity to liability) and the related accounting for warrants with a $479,910 estimated fair value of as of January 1, 2009. An adjustment was made to remove $486,564 from paid-in capital (the cumulative values of the warrants on their grant dates), a positive adjustment of $6,654 was made to accumulated deficit, representing the gain on valuation from the grant date to January 1, 2009, and booked $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. Subsequent to January 1, 2009 these warrants were revalued at the end of each quarter and a gain or loss was recorded based upon their increase or decrease in value during the quarter. Likewise, new warrants that were issued during 2009 were valued, using the Black-Scholes valuation model on their date of grant and an entry was made to reduce paid-in capital and increase the liability for equity-linked financial instruments. These warrants were also re-valued at the end of each quarter based upon their expected life, the stock price, the exercise price, assumed dividend rate, expected volatility and risk free interest rate.

The inputs to the Black-Scholes model during 2009 were as follows:

Stock price	$.35 to $.50
Exercise price	$.46 to $.65
Expected life	2.00 to 3.00 years
Expected volatility	63% to 66%
Assumed dividend rate	-%
Risk free interest rate	.895% to 1.375%

The original valuations, annual gain/(loss) and end of year valuations are shown below:

	Initial Value	Annual Gain (Loss)	Value at 12/31/2009
January 1, 2009 Adoption	$ 479,910	$ (390,368)	$ 870,278
Warrants issued in quarter ended 6/30/09	169,854	20,847	149,007
Warrants issued in quarter ended 9/30/09	39,743	(738)	40,481
Warrants issued in quarter ended 12/31/09	12,698	617	12,081
Total	$ 702,205	$ (369,642)	$ 1,071,847

NOTE 11 - RELATED PARTY

The Company entered into agreements, in 2008, with our Chairman of the Board Lawrence Gadbaw, and in 2009 with board member, Peter Morawetz, to pay Mr. Gadbaw $25,000 and Mr. Morawetz $30,000 upon the Company raising $3 million in new equity. Mr. Gadbaw will also be paid the balance, if any, due under his separation agreement from 2008. This amount was $46,000 upon signing the agreement in 2008, is payable at $2,000 per month, and $16,000 remains in accounts payable as of December 31, 2009. Mr. Morawetz will also receive a stock option for 75,000 shares at $.35 per share and Mr. Gadbaw will receive a stock option for 160,000 shares at $.35 per share upon the Company raising $3 million.

Schedule II

Valuation and Qualifying Accounts

(None)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-155299 of BioDrain Medical, Inc. (the Company) on Form S-1/A of our report, dated March 31, 2010, which expresses an unqualified opinion and includes an explanatory paragraph relating to the Company's ability to continue as a going concern, appearing in this Annual Report on Form 10-K of BioDrain Medical, Inc. for the year ended December 31, 2009.

Olsen Thielen & Co., Ltd.

St. Paul, Minnesota
March 31, 2010

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Kevin R. Davidson, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ending December 31, 2009 of BioDrain Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. Acting as both the Principal Executive Officer and the Principal Financial Officer, I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant. This quarterly report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies. I have;

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the small business issuer is made known to me by others within this entity, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting;

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of small business issuer's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: March 31, 2010

/s/ Kevin R. Davidson
Kevin R. Davidson
Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of BioDrain Medical, Inc. (the "Company") for the year ended December 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kevin R. Davidson., Chief Executive Officer and Chief Financial Officer, of the Company, certify, pursuant to § 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1350, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2010

/s/ Kevin R. Davidson
Kevin R. Davidson
Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)