UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2011.**

☐ **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 ☒

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 ☒

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 ☒ 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 ☒

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: $1,957,226 as of June 30, 2011, based upon 21,746,954 shares at $.09 per share as reported on the OTC Bulletin Board.

APPLICABLE ONLY TO REGISTRANTS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. ☐ Yes ☐ No

(APPLICABLE ONLY TO CORPORATE REGISTRANTS)

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the last practicable date: 38,573,928 shares of common stock as of April 10, 2012.

DOCUMENTS INCORPORATED BY REFERENCE

Information in Part III is incorporated by reference to the definitive proxy statement for the Company's 2012 annual meeting, which will be filed within 120 days after the end of fiscal 2011.

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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. We 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 have made limited sales to date. 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. The information on our website is not part of this Form 10-K.

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.

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, there is 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 higher capacity containers.

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 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.

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 two inflow ports positioned on the front of the device that effectively replace the current wall suction ports most commonly used to remove fluids during surgery. Additionally, a disposable external filter, which is provided as part of our disposable cleaning kit, allows for expansion to two inflow suction ports per filter.

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 undergone significant testing and has now been utilized in over 700 live surgeries. We do not currently have sufficient resources to fund the potential ramp-up in production and will need to raise a minimum of $2 million to fund this activity. We can provide no assurance that this funding will be available at attractive prices or at all. We currently utilize Miller Technical Services in Detroit, Michigan, an ISO 13485-certified outsource manufacturing organization, as our manufacturer and will continue this relationship 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 the BioDrain proprietary cleaning fluid for cleaning the internal tubing, pathways, and chamber within the FMS unit and a disposable external filter 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 or two filters, depending on the type of procedure, will be supplied with each bottle of cleaning fluid 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 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 . The estimated sales price to a hospital or surgery center is 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 consumable kit to the U.S. hospital market.

Patents and Intellectual Property

We spent approximately $0 in 2011 and approximately $10,000 in 2010 on research and development. We received a European patent in April 2007 (Patent No. EP1539580), a U.S. patent in December 2008 (U.S. Patent No. 7,469,727), and a Canadian patent in April 2011 (Number 2,495,747) (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 5-year warrant to purchase 150,000 shares of our common stock at a price of $.35 per share. The warrant expires 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. The first royalty payment of approximately $600 was issued in March 2011 for all revenue-to-date on the sales of Streamway™ systems.

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 was issued to the Company in April 2011.

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 that attaches to the FMS. The disposal cleaning kit also includes an in-line filter with two 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 kit is a critical component of our business model. The 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 kits are expected to be significantly higher over time than the revenues from the sales 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 that 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 disposable 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 strategy may also 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 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 about 1 pound. A canister and its gelled contents weigh about 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.

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, manufactures both single use canisters as well as a more automated fluid handling system that will compete with us. Accordingly, faced with this significant competition, we may have difficulty penetrating this market.

Solidifying Gel Powder

The market potential for solidifying gel was estimated by industry publications 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 habituated 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." According to the article, 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 "NeptuneTM" system, offering a combination of bio-aerosol and fluid management in a portable two-piece system; Waterstone Medical (now DeRoyal) introduced the "Aqua BoxTM" stationary system for fluid disposal; and Dornoch Medical Systems, Inc. introduced the "Red AwayTM" stationary system for fluid collection and disposal. All companies, regardless of size, have their own accessory kits.

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 may 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. We 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 troubleshooting 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 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. 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 disposable kit to the U.S. hospital market. By comparison, the disposal system of Stryker Instruments, one of our competitors, retails for approximately $25,000 plus an $8,000 docking station and requires a disposable component with an approximate cost of $25 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 in-house engineering at an estimated price of $1,000, 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 our sterilization kit.

Engineering and Manufacturing

We have manufacturing arrangements with Miller Technical Services ("MTS"), a contract manufacturer with ISO 13485 certification, to manufacture the FMS. Although we are in the early stages of manufacturing the FMS with MTS, their capabilities appear to be adequate to serve our future needs.

The disposable kit, including a bottle of proprietary cleaning solution and an in-line filter will be sourced through Oculus Innovative Sciences (cleaning solution) and through AETAS Corporation (filter), both of whom have long term vender agreements with the Company.

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 U.S., there are 3 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. Pre-market 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 have 3 employees, all of whom are full-time. We also have 2 external consultants who dedicate a substantial amount of time to the Company.

Executive Officers and Directors of the Registrant

The following table identifies our current executive officers and directors:

Name	Age	Position Held
Lawrence W. Gadbaw	74	Chairman of the Board of Directors
Kevin R. Davidson	52	President, Chief Executive Officer, Chief Financial Officer and Director
Chad A. Ruwe	47	Director
Peter L. Morawetz	84	Director
Thomas J. McGoldrick	70	Director
Andrew P. Reding	42	Director
Albert Emola	61	Director
Jeffrey Galitz	54	Director
Josh Kornberg	38	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.

Andrew Reding is the step-brother-in-law to Kevin Davidson. There are no other family relationships among our directors and 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.

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, Director. Mr. Ruwe became our Executive Vice President of Operations in 2008 and was promoted to Chief Operating Officer and a director in 2009. He left the position of COO in December 2011. 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, from March 2002 to December 2003, Vice President of the Fluid Handling Systems business, Vice President of Corporate Marketing from August 2005 to January 2006, Vice President of the Semiconductor business and Vice President & General Manager of the Liquid Micro-Contamination business from January 2006 to December 2008. From March 1996 to February 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.

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 30 years and was co-founder and Chief Executive Officer of Fastitch Surgical in 2000. Fastitch is a start-up 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 start-up 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.

Albert Emola, Director. Mr. Emola was elected to the Board of Directors on December 12, 2011. Mr. Emola has been in the healthcare industry for over thirty years and has served as President and CEO at both private and public companies, including StentTech Inc (2003-2008), Vital Images Inc (1999-2002) and FlexMedics Inc (1995-1999). Prior to this he was Vice President, Business Development for St. Jude Medical Inc (1985-1991). Mr. Emola began his career in marketing at Bristol-Myers/Squibb followed by marketing, strategic planning and business development positions at American Hospital Supply Corporation. He has served on the Boards of DesignWise Medical, Vital Images Inc, StentTech Inc, Medafor Corporation and Enpath Medical Inc. He holds an MBA from Indiana University's Kelley School of Business and a BS degree from the State University of New York. He is currently consulting with medical device start-ups and turnarounds.

Jeffrey Galitz, Director. Dr. Galitz was elected to the Board of Directors on January 3, 2012. He is a nationally renowned Board Certified Foot and Ankle surgeon based in South Florida. Dr Galitz has the unique distinction of being both a licensed Physician and Podiatrist. Dr. Galitz is the founding partner and Chairman of the Wound Technology Network. WTN is the most award winning wound management company in the country and the nation's leader in Telehealth Services covering over 9 million lives nationally. In addition to WTN, Dr Galitz is the founder and President of Podicare, Inc. one of the largest podiatric physician networks with over 125 locations which has been providing services to managed care companies for close to 20 years. Dr Galitz is also cofounder of PodiCare Purchasing Co-op, an online medical supply company. He has served as Director of the Podiatric surgical residency at Memorial Hospital in Hollywood in addition to serving on the hospital's Medical Executive committee. Dr. Galitz has served on the Healthcare Industry Liaison committee for the American College of Foot and Ankle Surgeon. In addition, he has been a Medical Advisor to many of the largest pharmaceutical companies and has lectured on a national scale.

Josh Kornberg, Director. Mr. Kornberg was elected to the Board on March 9, 2012. Mr. Kornberg was appointed to the Board in March 2012 at the direction of Dr. Samuel Herschkowitz, pursuant to the terms of the note purchase agreement executed with Dr. Herschkowitz in December 2011. As long as any amount payable under the note remains outstanding, Dr. Herschkowitz or his designee is entitled to appoint a special advisor to the Company's Board of Directors, who will be appointed as a member of the Board upon request. Pursuant to this authority, Josh Kornberg was appointed to the Board on March 9, 2012. Mr. Kornberg is President and founding partner of GPF, a private equity fund based in New York. Prior to founding GPF, Mr. Kornberg served as Chief Investment Officer of The Lightstone Group, a national private equity firm and Director of the Lightstone Value Plus REIT, a public company focused on commercial real estate. Mr. Kornberg served as Director of Acquisitions and Development at ARK Realty Investors, a real estate investment and development firm. He worked in the capital markets group at Morgan Stanley, and also served as Vice President at The RREEF Funds, one of the leading global pension fund advisors.

ITEM 1A. RISK FACTORS.

You should carefully consider the risks described below before making an investment decision. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Form 10-K, including our financial statements and related notes.

We will require additional financing to sustain our operation, and if adequate financing is not available, we may be forced to go out of business. Such financing will be dilutive and feature restricted terms. Our independent public accounting firm has indicated in their audit opinion, contained in our financial statements, that they have serious doubts about our ability to remain a going concern.

We incurred a net loss of $4,486,879 and $1,352,709, respectively, for the years ended December 31, 2011 and 2010, respectively. We have never earned a profit and we anticipate that we will continue to incur losses for at least the next 12 months. We continue to operate on a negative cash flow basis. We have generated only minimal revenues and are still developing our planned principal operations.

We are currently incurring operating expenses of approximately $100,000 per month. Although we are attempting to curtail our expenses, there is no guarantee that we will be able to reduce these expenses significantly, and expenses for some periods may be higher as we prepare our product for broader sales, increase our sales efforts and maintain adequate inventories. Further, we have approximately $2,382,000 in debts, liabilities and cash obligations that become due in the second and third quarters of calendar 2012. We are currently receiving advances on a convertible promissory note from an investment fund affiliated with one of our directors, up to an aggregate amount of $600,000. We believe that we will need to raise at least an aggregate of $2 million from future financing in order to have sufficient financial resources to fund our operations for the next 12 months because of our cash flow deficit. We will attempt to raise these funds through equity or debt financing, alternative offerings or other means, and we will also endeavor to convert existing obligations into equity, settle such obligations or otherwise reduce their amounts. We are not planning on any significant capital or equipment investments, and we will only have a few human resource additions over the next 12 months.

Although we have been able to fund our current working capital requirements, principally through debt and equity financing, there is no assurance that we will be able to do so in the future. If financing is available, it may be highly dilutive to our existing shareholders and may otherwise include burdensome or onerous terms. Our independent registered public accounting firm has indicated in their audit opinion, contained in our financial statements that they have serious doubts about our ability to continue as a going concern.
Our inability to raise additional working capital at all or to raise it in a timely manner would negatively impact our ability to fund our operations, to generate revenues, and to otherwise execute our business plan, leading to the reduction or suspension of our operations and ultimately forcing us to declare bankruptcy, reorganize or go out of business. Should this occur, the value of any investment in our securities could be adversely affected, and an investor would likely lose all or a significant portion of their investment.

We currently have a significant amount of debt past due, and we may not be able to negotiate conversions or restructurings of such debt or repay it.

As of April 10, 2012, we have $682,000 in principal and accrued interest on debts that are past due and in default. We are attempting to persuade the holders of a portion of debt to convert it into common stock or to negotiate a restructuring of such debt. The holders of debt representing $382,000 in principal and accrued interest have threatened legal action against the company. If the Company cannot repay or restructure the indebtedness and if such holders commence legal action, the Company may be subject to litigation expense and possible judgments against the Company, and the holders could assert various remedies including forcing the Company into involuntary bankruptcy proceedings.

Our limited operating history makes evaluation of our business difficult.

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

- Raise capital;
- Develop and implement our business plan in a timely and effective manner;
- Be successful in uncertain markets;
- Respond effectively to competitive pressures;

- Successfully address intellectual property issues of others;
- Protect and expand our intellectual property rights; and
- Continue to develop and upgrade our products.

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

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

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

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

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

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

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

Our revenues would be adversely affected if our intellectual property were found to infringe the intellectual property rights of others. Two individuals, Jay D. Nord and Jeffrey K. Drogue, filed a provisional patent application disclosing a particular embodiment for a medical waste fluid collection system (the "Nord/Drogue Embodiment"). We engaged the services of Marshall C. Ryan to further develop the medical waste fluid collection system for commercialization. Mr. Ryan conceived of an alternative embodiment for the medical waste fluid collection system (the "Ryan Embodiment"). An international (PCT) patent application was subsequently filed claiming priority to the earlier filed provisional application of Nord and Drogue and disclosing and claiming both the Nord/Drogue Embodiment and the Ryan Embodiment. The national stage applications were filed in the U.S., Europe and Canada based on the PCT application. During the national stage prosecutions, the European and U.S. patent offices each rejected the patent claims covering the Nord/Drogue Embodiment as being unpatentable over the prior art. The Canadian patent office has not yet examined the Canadian national stage application. The claims were amended in both the U.S. and European applications to claim only the subject matter of the Ryan Embodiment and Mr. Ryan was added as a named inventor. As required under U.S. law, we removed Nord and Drogue as named inventors from the U.S. application because they were no longer inventors to the subject matter of the remaining patent claims. A U.S. patent was granted to us in December 2008 (U.S. Patent No. 7,469,727). A European patent was granted to us in April 2007 (Patent No. EP1539580), and a Canadian patent was granted in April 2011 (number 2,495,747).

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

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

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

We estimate that the total market for surgical suction canisters is approximately $100 million and has a compound annual growth rate of 5%. We estimate the total cost of using surgical canisters is a multiple of $100 million because this amount does not include the labor to handle the canisters, disposal costs and solidifying compounds commonly used to minimize exposure to health care workers. Cardinal Health, Inc., a $90 billion plus medical manufacturer and distributor, is a leading competitor. Another one of our competitors is Stryker Instruments, a wholly owned subsidiary of Stryker Corporation, which is a publicly traded company with revenues of approximately $8 billion, and has a leading position in this market. Cardinal Health, Inc. has recently begun advertising a powered device similar to that which Stryker currently markets. Both of these competitors are better capitalized than we are.

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

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

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

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

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

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

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

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

The BioDrain FMS is currently being launched into the fluid management market. We engaged Miller Technical Services, a medical product contract manufacturing entity, and we finalized the product design. We anticipate that the product will be attractive to the target market, but other unknown or unforeseen market requirements may arise. There is no assurance that such a product can be produced in sufficient volume to satisfy projected sales volumes.

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

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

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

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

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

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

Our success is dependent on our ability to attract and retain technical personnel, sales and marketing personnel, and other skilled management.

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

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

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

Costs incurred because we are a public company may affect our profitability.

As a public company, we incur significant legal, accounting, and other expenses, and we are subject to the SEC's rules and regulations relating to public disclosure that generally involve a substantial expenditure of financial resources. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC, requires changes in corporate governance practices of public companies. We expect that full compliance with such rules and regulations will significantly increase our legal and financial compliance costs and make some activities more time-consuming and costly, which may negatively impact our financial results. To the extent our earnings suffer as a result of the financial impact of our SEC reporting or compliance costs, our ability to develop an active trading market for our securities could be harmed.

Risks Related to Our Securities

There is currently a limited public trading market for our common stock and we cannot assure you that an active public trading market for our common stock will develop or be sustained. Even if a market further develops, you may be unable to sell at or near ask prices or at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares.

There is currently a limited public trading market for our registered common stock. An application for quotation on the OTC Bulletin Board was submitted by a market maker who agreed to sponsor the security and who demonstrated compliance with Rule 15c2-11 of the Securities Exchange Act of 1934 (the "Exchange Act"). The application for quotation of our registered common stock on the OTC Bulletin Board was accepted on November 13, 2009. We also caused a different market maker to submit an application in April 2010, on our behalf to the Depository Trust Corporation (DTC) to become eligible for electronic trading ("DTC eligible"). We are waiting for DTC to approve our application.

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

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

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

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

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

Even though our application for quotation on the OTC Bulletin Board has been accepted our stock may be thinly traded, so you may be unable to sell at or near ask prices or at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares.

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

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

In order for our registered common stock to be eligible to trade on the Nasdaq Capital Market, we would need, among other things, a bid price of $4.00, $5 million in stockholders' equity, and $15 million market value of publicly held shares. In order for our registered common stock to be eligible to trade on the NYSE Alternext U.S. LLC, which is a market for small and mid-sized companies, we would need, among other things, at least $3 million market value of public float, a minimum price of $3.00 and $4 million in stockholders' equity.

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

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

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

As long as the trading price of our common stock is below $5.00 per share, the open-market trading of our common stock will be subject to the "penny stock" rules, unless we otherwise qualify for an exemption from the "penny stock" definition. The "penny stock" rules impose additional sales practice requirements on certain broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with net assets in excess of $1,000,000 or annual income exceeding $200,000 or $300,000 together with their spouse). These regulations, if they apply, require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the associated risks. Under these regulations, certain brokers who recommend such securities to persons other than established customers or certain accredited investors must make a special written suitability determination regarding such a purchaser and receive such purchaser's written agreement to a transaction prior to sale. These regulations may have the effect of limiting the trading activity of our common stock, reducing the liquidity of an investment in our common stock and increasing the transaction costs for sales and purchases of our common stock as compared to other securities.

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

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

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

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

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

Shares eligible for future sale may adversely affect the market.

From time to time, certain of our shareholders may be eligible to sell some or all of their shares of common stock pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, (the "Securities Act") subject to certain limitations. In general, pursuant to Rule 144 as in effect as of the date of this Form 10-K, a shareholder (or shareholders whose shares are aggregated) who has satisfied the applicable holding period and is not deemed to have been one of our affiliates at the time of sale, or at any time during the three months preceding a sale, may sell their shares of common stock. Any substantial sale, or cumulative sales, of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our securities.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable

ITEM 2. PROPERTIES.

Our corporate offices are located at 2060 Centre Pointe Boulevard, Suite 7, Mendota Heights, Minnesota 55120. We lease about 3,600 square feet with possible expansion to 4,700 square feet of office space at this location. Our monthly base rent is $3,000 for months 1-12, $2,395 for months 13-24, $2,467 for months 25-36, $2,541 for months 37-48, and $2,617 for months 49-60. In addition, we 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 13-60. The common area maintenance expense was not payable in months 1-12. The lease term began on November 1, 2008 and ends on October 31, 2013. We expect that this space will be adequate for our office needs for the term of the lease. We are in discussions with our landlord about a possible move to equivalent space at the same rent.

ITEM 3. LEGAL PROCEEDINGS.

In January 2012, Ms. Kirsten Doerfert, the former Vice President, Sales and Marketing of the Company, brought an action against the Company in the District Court for Dakota County, Minnesota. The action relates to the Company's termination of Ms. Doerfert in February 2010. Plaintiff alleges breach of her employment contract and defamation. The action seeks compensation due arising from the alleged breach, attorneys fees and related costs, and injunctive release regarding future statements by the Company. In February 2012, the Company filed its answer, requesting that the court dismiss plaintiff's complaint and deny all release requested in plaintiff's complaint. The Company intends to vigorously defend this action.

ITEM 4. MINE SAFETY DISCLOSURES.

None

PART II

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

Market Information

Our common stock is quoted under the symbol "BIOR" on the OTCQB since November 16, 2009, and was quoted on the OTCBB from November 16, 2009 through July 21, 2010 and from December 29, 2010 through the present date. The following table sets forth, for the periods indicated, the reported high and low closing bid quotations for our common stock as reported on the OTCBB and OTCQB. The sale prices reflect inter-dealer quotations, do not include retail markups, markdowns, or commissions, and do not necessarily reflect actual transactions.

Quarter Ended	High Bid	Low Bid
December 31, 2011	$ 0.50	$ 0.15
September 30, 2011	$ 1.01	$ 0.08
June 30, 2011	$ 0.11	$ 0.05
March 31, 2011	$ 0.32	$ 0.07
December 31, 2010	$ 0.17	$ 0.10
September 30, 2010	$ 0.38	$ 0.12
June 30, 2010	$ 0.90	$ 0.12
March 31, 2010	*	*

* Our common stock had no active trading market until April 2010.

As of April 9, 2012, the closing bid price for shares of our common stock was $.05 per share on the OTCBB.

Holders

As of April 10, 2012, there were approximately 131 shareholders of record of our Common Stock. Our Common Stock is traded on the Over The Counter Bulletin Board (OTCBB) and the OTCQB segment of Pink Markets, Inc.

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 2012 Annual Meeting of Shareholders. Also see Item 12 below.

Purchases of Equity Securities by the Company

None.

Recent Sales of Unregistered Securities

The following is a summary of our transactions during the last three years involving sales of our securities that were not registered under the Securities Act:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

On September 8, 2009, we issued 100,000 common shares to a consulting firm for their consulting services.

On September 8, 2009, we issued 10,000 common shares and a warrant to purchase 10,000 shares at $.65 per share to an investor for his $5,000 investment in the Company.

On September 8, 2009, we issued 10,000 common shares and a warrant to purchase 10,000 shares at $.65 per share to an investor for her $5,000 investment in the Company.

On September 25, 2009, we issued 20,000 common shares and a warrant to purchase 20,000 shares at $.65 per share to an investor for her $10,000 investment in the Company.

On September 25, 2009, we issued 30,000 common shares and a warrant to purchase 30,000 shares at $.65 per share to co-investors for their $15,000 investment in the Company.

On September 30, 2009, we issued 80,000 common shares and a warrant to purchase 80,000 shares at $.65 per share to an investor for his $40,000 investment in the Company. On March 5, 2012, the warrants were re-issued at $.13 per share to consultants for their consulting services.

On October 2, 2009, we issued 30,000 common shares and a warrant to purchase 30,000 common shares at $.65 per share to a consultant for their consulting services. On March 5, 2012, the warrants were re-issued at $.13 per share to consultants for their consulting services.

On October 15, 2009, we issued 3,000 common shares and a warrant to purchase 3,000 common shares at $.65 per share to consultants for their consulting services.

On October 15, 2009, we issued 2,000 common shares and a warrant to purchase 2,000 common shares at $.65 per share to a consultant for her consulting services.

On October 26, 2009, we issued a note, convertible into 200,000 common shares, and a warrant to purchase 200,000 shares at $.65 per share to co-investors for their $100,000 investment in the Company.

On November 10, 2009, we 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 an investor for his $25,000 investment in the Company.

In January 2010, we issued 19,090 restricted shares of common stock under the 2008 Equity Incentive Plan to a consultant as partial payment for his services.

In March 2010, we issued 350,000 shares of common stock as payment to three consultants for their investor relations consulting services.

In March and April 2010, we issued 274,550 shares of common stock and warrants for 274,550 shares of common stock, at an exercise price of $.65 per share, to 9 investors for their $137,275 investment in the Company.

In April 2010, we raised $90,000 from the sale of 180,000 Units under a private placement at $.50 per Unit. Each Unit consists of one share of common stock and a warrant to purchase one share of common stock at $.65 per share.

In June 2010, we raised $200,000 from the issuance of convertible debt to the parents of one of our officers. The debt bears interest at 12%, is due March 31, 2012 and is convertible into share of common stock at $.25 per share. We also issued a warrant to purchase 800,000 shares at an exercise price of $.46 per share in connection with this debt. The proceeds of this debt were used, in part, to pay off a $100,000 note plus interest and prepayment penalty totaling $43,600 to Asher Enterprises.

In July 2010, we issued 225,000 shares of common stock to four consultants in connection with fundraising and investor relations activities on behalf of the Company.

In July 2010, we issued 13,860 shares of restricted stock under the 2008 Equity Incentive Plan to our acting CFO in partial payment for his consulting services for the quarter ended June 30, 2010.

In July 2010, we issued 238,860 shares of common stock, with a value of $.22 per share, to five consultants in exchange for fund raising, financial consulting and investor relations services.

In August 2010, we issued a $50,000 Convertible Promissory Note to an investor. The note bears interest at 8%, matures in May 2011, and is convertible into shares of common stock at 50% of the average of the three lowest closing prices in any 10 day trading period.

In September 2010, we issued a $100,000 Convertible Promissory Note to an investor. The note bears interest at 10%, matures in March 2012, and is convertible into shares of common stock at $.18 per share.

In September 2010, we issued a $32,000 Convertible Debenture to the parents of one of our officers. The note bears interest at 12%, matures in March 2012 and is convertible into shares of common stock at $.10 per share. We also issued a warrant to purchase 320,000 shares at $.46 per share, amended the note dated in June 2010 to reduce the conversion price from $.25 to $.18 per share and issued a new warrant to purchase 1,111,112 shares at $.46 per share to replace the initial warrant for 800,000 shares at $.46 per share.

In September 2010, we issued 250,000 common shares with a value of $.22 per share to an investment banker as partial compensation for their fund raising activities.

In September 2010, we issued 250,000 common shares to an investor in connection with his $25,000 investment in the Company. We also issued a warrant to purchase 250,000 common shares at $.17 per share. On March 5, 2012, the warrants were re-issued at $.13 per share to consultants for their consulting services.

On November 16, 2010, we issued 75,000 restricted shares, with a value of $.15 per share, to each of four members of the Board of Directors and also issued an option to purchase 85,000 shares at $.15 per share to the Chairman of the Board as compensation for their services on the board.

On January 7, 2011, we issued three convertible notes in the amount of $50,000 each to three individuals who had lent the Company $50,000 each. The notes bear interest at 10%, are convertible into shares of common stock at $.084 to $.10 per share and have a 24 month maturity date. We also issued warrants to purchase 1,595,239 shares of common stock at $.20 per share in connection with this financing arrangement.

On February 7, 2011, we issued 150,000 shares of common stock and a warrant to purchase 150,000 shares of common stock at $.20 per share to an investor in return for his $15,000 investment in the Company.

On February 8, 2011, we issued 200,000 shares of common stock and a warrant to purchase 200,000 shares of common stock at $.20 per share to an investor in return for his $18,000 investment in the Company.

On February 11, 2011, we issued 666,667 shares of common stock and a warrant to purchase 666,667 shares of common stock at $.15 per share to an investor in return for his $50,000 investment in the Company. On March 5, 2012, the warrants were re-issued at $.075 per share to consultants for their consulting services

On February 14, 2011, we issued a warrant to purchase 500,000 shares of common stock at $.15 per share to a consultant in return for their help in arranging financing.

On February 17, 2011, we issued 3,333,334 shares of common stock and a warrant to purchase 3,333,334 shares of common stock at $.15 per share (assigned to an affiliate of the investors) to two investors in return for their $250,000 investment in the Company. On March 5, 2012, the warrants were re-issued at $.075 per share to consultants for their consulting services.

On February 17, 2011, we issued a warrant to purchase 400,000 shares at $.075 per share to a consultant in return for their help in raising funds.

On February 23, 2011, we issued 181,818 shares of common stock as a result of an institutional lender converting $10,000 in debt into shares of common stock at a price determined by a formula in the loan agreement.

On March 3, 2011, we issued a warrant to purchase 100,000 shares at $.10 per share to a consultant for their support in selling the Company's products.

On March 7, 2011, we issued warrants to purchase 600,000 shares of common stock at $.10 per share to three individuals in return for their consulting services.

On March 15, 2011, we issued a warrant to purchase 200,000 shares at $.10 per share to a consultant as a partial payment of his prior executive recruiting services.

On March 15, 2011, we issued 588,235 shares of common stock and a warrant to purchase 588,235 shares of common stock at $.17 per share to an investor in return for his $50,000 investment in the Company.

On March 17, 2011, we issued 416,010 shares of common stock as a result of an institutional lender converting $20,000 in debt into shares of common stock at a price determined by a formula in the loan agreement.

On March 23, 2011, we issued 117,647 shares of common stock and a warrant to purchase 117,647 shares of common stock at $.17 per share to an investor in return for his $10,000 investment in the Company.

On March 23, 2011, we issued 1,333,333 shares of common stock and a warrant to purchase 1,333,333 shares of common stock at $.15 per share to an investor in return for his $100,000 investment in the Company.

On March 25, 2011, we issued a warrant to purchase 100,000 shares of common stock at $.16 per share to a consultant in exchange for investor relations services.

On March 28, 2011, we issued 588,235 shares of common stock and a warrant to purchase 588,235 shares of common stock at $.17 per share to an investor in return for his $50,000 investment in the Company.

On April 14, 2011, we issued 83,333 shares of common stock to the holder of a $100,000 convertible note as payment of prepaid interest as required under terms of the note.

On April 19, 2011, we issued 204,604 shares of common stock as a result of an institutional lender converting $8,000 of debt into shares of common stock at a price determined by a formula in the loan agreement.

On April 21, 2011, we issued 294,118 shares of common stock and a warrant to purchase 294,118 shares at $.17 per share to an investor in return for his $25,000 investment in the Company.

On April 22, 2011, we issued 75,000 shares of common stock to the holder of a $50,000 convertible note as payment of prepaid interest as required under terms of the note.

On May 2, 2011, we issued 294,118 shares of common stock and a warrant to purchase 294,118 shares at $.085 per share to an investor in return for his $25,000 investment in the Company.

On May 16, 2011, we issued 485,437 shares of common stock as a result of an institutional lender converting $15,000 in debt into shares of common stock at a price determined by a formula in the loan agreement

On May 23, 2011, we issued 250,696 shares of common stock as a result of an institutional lender converting $7,000 in debt and $2,000 of accrued interest into shares of common stock at a price determined by a formula in the loan agreement

On May 24, 2011, we issued 500,000 shares of common stock and a warrant to purchase 500,000 shares at $.12 per share to an investor in return for his $35,000 investment in the Company.

On July 1, 2011, we issued 250,000 shares of common stock and a warrant to purchase 250,000 shares at $.075 per share to an investor in return for his $15,000 investment in the Company.

On July 5, 2011 and July 11, 2011, we issued 333,334 total shares of common stock and a warrant to purchase 333,334 shares at $.075 per share to an investor in return for his $20,000 investment in the Company.

On July 12, 2011, we issued 571,429 shares of common stock and a warrant to purchase 571,149 shares at $.10 per share to an investor in return for his $40,000 investment in the Company.

On July 14, 2011, we issued 57,423 shares of common stock and a warrant to purchase 57,423 shares of common stock at $.10 per share to a consultant for his consulting services.

On July 26, 2011, we issued 1,250,000 shares of common stock and a warrant to purchase 1,250,000 shares at $.075 per share to an investor in return for his $75,000 investment in the Company.

On July 26, 2011, we issued 333,333 shares of common stock and a warrant to purchase 333,333 shares at $.075 per share to an investor in return for his $20,000 investment in the Company.

On July 26, 2011, we issued 333,333 shares of common stock and a warrant to purchase 333,333 shares at $.075 per share to an additional investor in return for his $20,000 investment in the Company.

On July 27, 2011, we issued 833,333 shares of common stock and a warrant to purchase 833,333 shares at $.075 per share to an investor in return for his $50,000 investment in the Company.

On August 2, 2011, we issued 166,667 shares of common stock and a warrant to purchase 166,667 shares at $.075 per share to an investor in return for his $10,000 investment in the Company.

On August 2, 2011, we issued 100,000 shares of common stock to an officer of the Company in connection with an exercise under a stock option agreement dated June 14, 2011.

On August 17, 2011, the Company issued 62,500 shares of common stock and a warrant to purchase 62,500 shares of common stock at $.25 per share to an investor in return for his $12,500 investment in the Company.

On August 31, 2011, the Company issued 475,000 shares of common stock and a warrant to purchase 475,000 shares of common stock at $.075 per share to a fund raising consultant.

On August 31, 2011, the Company issued 290,699 shares of common stock to a consultant as partial compensation for investor relations consulting work.

On September 15, 2011, the Company issued 500,000 shares of common stock and a warrant to purchase 500,000 shares of common stock at $.25 per share to an investor in return for his $100,000 investment in the Company.

On October 3, 2011, the Company issued 500,000 shares of common stock and a warrant to purchase 500,000 shares of common stock at $.25 per share to an investor in return for his $100,000 investment in the Company.

On October 6, 2011, the Company issued 100,000 shares of common stock and a warrant to purchase 100,000 shares of common stock at $.25 per share to an investor in return for his $20,000 investment in the Company.

On October 6, 2011, the Company issued 50,000 shares of common stock and a warrant to purchase 50,000 shares of common stock at $.25 per share to an investor in return for his $10,000 investment in the Company.

On October 11, 2011, the Company issued 575,000 shares of common stock to a consultant as sole compensation for investor relations consulting work.

On November 3, 2011, the Company issued 62,500 shares of common stock and a warrant to purchase 62,500 shares of common stock at $.20 per share to an investor in return for his $12,500 investment in the Company.

On November 8, 2011, the Company issued 100,000 shares of common stock and a warrant to purchase 100,000 shares of common stock at $.20 per share to an investor in return for his $20,000 investment in the Company.

On December 20, 2011, the Company issued 1,546,667 shares of common stock at $0.15 per share to Dr. Samuel Herschkowitz in return for his $225,000 investment in the Company, and $7,000 Board Meeting Fees.

On February 3, 2012, the Company issued 87,500 shares of common stock to a consultant as compensation for consulting work.

On March 5, 2012, the Company re-issued a warrant to purchase 100,000 shares of common stock at $.13 per share to an investor for consulting services. The original warrant was issued on June 23, 2008.

On March 6, 2012, the Company re-issued a warrant to purchase 100,000 shares of common stock at $.13 per share to an investor for consulting services. The original warrant was issued on June 11, 2008.

On March 6, 2012, the Company re-issued a warrant to purchase 71,429 shares of common stock at $.13 per share to an investor for consulting services. The original warrant was issued on June 11, 2008.

On March 26, 2012, the Company issued 300,000 shares of common stock at $.065 per share to Josh Kornberg, currently a Director of the Company for consulting services.

On March 28, 2012, the Company entered into a Convertible Note Purchase Agreement, dated as of March 28, 2012 between the Company and SOK Partners, LLC (“SOK Partners”), an investment partnership. Josh Kornberg, is an affiliate of SOK Partners. Pursuant to the Purchase Agreement, the Company issued a 20% convertible note due August 2012 in the principal amount of up to $600,000. Principal and accrued interest on the note are due and payable on August 28, 2012. On March 28, 2012, the Company received an advance of $84,657 under the note, including a cash advance of $60,000 net of a prepayment of interest on the first $300,000 in advances under the note. The holder of the note is entitled to convert the note into shares of common stock of the Company at an initial conversion price per share of $0.065 per share, subject to adjustment in the event of (1) certain issuances of common stock or convertible securities at a price lower than the conversion price of the note, and (2) recapitalizations, stock splits, reorganizations and similar events. In addition, the Company is required to issue two installments of an equity bonus to SOK Partners in the form of common stock valued at the rate of $0.065 per share. In April 2012, the Company issued the first equity bonus to SOK Partners, consisting of 4,615,385 shares of common stock, with a second installment due within five business days after SOK Partners has made aggregate advances under the note of at least $300,000. Until the maturity date of the note, if the Company obtains financing from any other source without the consent of SOK Partners, then the Company is required to issue additional bonus equity in an amount equal to $600,000 less the aggregate advances on the note made prior to the breach. As long as any amount payable under the note remains outstanding, SOK Partners or its designee is entitled to appoint a special advisor to the Company’s Board of Directors, who will be appointed as a member of the Board upon request.

On March 28, 2012, the Company signed an Amended and Restated Note Purchase Agreement, dated as of December 20, 2011, with Dr. Samuel Herschkowitz (as amended, the "Herschkowitz Purchase Agreement"). Pursuant to the Herschkowitz Purchase Agreement, the Company issued a 20.0% convertible note due June 20, 2012 in the principal amount of $240,000 for previous advances under the note. The Company's obligations under the note are secured by the grant of a security interest in substantially all tangible and intangible assets of the Company. The Company has previously issued to Dr. Herschkowitz an equity bonus consisting of 1,546,667 shares of common stock. An additional 7,500,000 shares are required to be transferred to Dr. Herschkowitz upon the occurrence of an event of default on the note. As long as any amount payable under the note remains outstanding, Dr. Herschkowitz or his designee is entitled to appoint a special advisor to the Company's Board of Directors, who will be appointed as a member of the Board upon request. Pursuant to this authority, Josh Kornberg was appointed to the Board on March 9, 2012.

On April 3, 2012, the Company issued 4,615,385 shares of common stock at $.065 per share to SOK Partners in exchange for their investment in a convertible note.

In April 2012, a private investor elected to convert a $63,000 convertible note into shares of common stock. The investor also elected to convert $29,000 of a $37,500 convertible note into shares of common stock.

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

ITEM 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 this Form 10-K 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 net losses of approximately $4.5 million and $1.4 million in 2011 and 2010, respectively. As of December 31, 2011 and December 31, 2010, we had an accumulated deficit of approximately $11.9 million and $7.4 million, respectively. 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. We obtained FDA final clearance 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 have signed agreements with independent sales representatives and product installation organizations and are conducting training sessions, but we continue to recruit more independent sales representatives and installation companies to meet our potential future needs. We achieved our first billable shipment in June 2009 and sold five Streamway™ units in 2011. 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 did not generate sufficient revenues in 2011 to fund our capital requirements, our capital needs for the next 12 months are expected to be approximately $2 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.

As of December 31, 2011, 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 our 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. In 2010, we raised approximately $605,000 from the issuance of convertible debt and approximately $220,000 from the sale of units of stock and warrants. The conversion price on the debt and the unit price of the stock and warrants ranged from $.10 to $.65 per share. In 2011 we funded our operations through private investors, largely consisting of convertible debt and notes, equaling $525,500, and by $1,386,000 from the issuance of common stock. . In 2012, we are currently receiving advances on a convertible promissory note from an investment fund affiliated with one of our directors, up to an aggregate amount of $600,000. Advances have totaled $110,000 through April 10, 2012.

We are currently incurring operating expenses of approximately $100,000 per month. Although we are attempting to curtail our expenses, there is no guarantee that we will be able to reduce these expenses significantly, and expenses for some periods may be higher as we prepare our product for broader sales, increase our sales efforts and maintain adequate inventories. Further, we have approximately $2,382,000 in debts, liabilities and cash obligations that become due in the second and third quarters of calendar 2012.

As of April 10, 2012, we have $682,000 in principal and accrued interest on debts that are past due and in default. We are attempting to persuade the holders of a portion of debt to convert it into common stock or to negotiate a restructuring of such debt. The holders of debt representing $382,000 in principal and accrued interest have threatened legal action against the company. If the Company cannot repay or restructure the indebtedness and if such holders commence legal action, the Company may be subject to litigation expense and possible judgments against the Company, and the holders could assert various remedies including forcing the Company into involuntary bankruptcy proceedings

We believe that we will need to raise at least an aggregate of $2 million from future financing in order to have sufficient financial resources to fund our operations for the next 12 months because of our cash flow deficit. We will attempt to raise these funds through equity or debt financing, alternative offerings or other means, and we will also endeavor to convert existing obligations into equity, settle such obligations or otherwise reduce their amounts. We are not planning on any significant capital or equipment investments, and we will only have a few human resource additions over the next 12 months.

Although we have been able to fund our current working capital requirements, principally through debt and equity financing, there is no assurance that we will be able to do so in the future. If financing is available, it may be highly dilutive to our existing shareholders and may otherwise include burdensome or onerous terms. Our independent registered public accounting firm has indicated in their audit opinion, contained in our financial statements, that they have serious doubts about our ability to continue as a going concern. Our inability to raise additional working capital at all or to raise it in a timely manner would negatively impact our ability to fund our operations, to generate revenues, and to otherwise execute our business plan, leading to the reduction or suspension of our operations and ultimately forcing us to declare bankruptcy, reorganize or go out of business. Should this occur, the value of any investment in our securities could be adversely affected, and an investor would likely lose all or a significant portion of their investment.

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 $12,000 remains in accounts payable as of December 31, 2011. 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.

On March 28, 2012, the Company, entered into a Convertible Note Purchase Agreement, dated as of March 28, 2012 (the "SOK Purchase Agreement") with SOK Partners, LLC ("SOK Partners"), an investment partnership. Josh Kornberg, who is a member of the Company's Board of Directors, and Dr. Samuel Herschkowitz are affiliates of the manager of SOK Partners. Pursuant to the SOK Purchase Agreement, the Company issued a 20.0% convertible note due August 2012 in the principal amount of up to $600,000. Principal and accrued interest on the note are due and payable on August 28, 2012. The Company's obligations under the note are secured by the grant of a security interest in substantially all tangible and intangible assets of the Company. The SOK Purchase Agreement and the note include customary events of default that include, among other things, non-payment defaults, covenant defaults, inaccuracy of representations and warranties, cross-defaults to other indebtedness and bankruptcy and insolvency defaults. The occurrence of an event of default could result in the acceleration of the Company's obligations under the note, and interest rate of twenty-four (24%) percent per annum accrues if the note is not paid when due.

On March 28, 2012, the Company received an advance of $84,657 under the note, including a cash advance of $60,000 net of a prepayment of interest on the first $300,000 in advances under the note. The holder of the note is entitled to convert the note into shares of common stock of the Company at an initial conversion price per share of $0.065 per share, subject to adjustment in the event of (1) certain issuances of common stock or convertible securities at a price lower than the conversion price of the note, and (2) recapitalizations, stock splits, reorganizations and similar events. In addition, the Company is required to issue two installments of an equity bonus to SOK Partners in the form of common stock valued at the rate of $0.065 per share. In April 2012, the Company issued the first equity bonus to SOK Partners, consisting of 4,615,385 shares of common stock, with a second installment due within five business days after SOK Partners has made aggregate advances under the note of at least $300,000. Until the maturity date of the note, if the Company obtains financing from any other source without the consent of SOK Partners, then the Company is required to issue additional bonus equity in an amount equal to $600,000 less the aggregate advances on the note made prior to the breach.

As long as any amount payable under the note remains outstanding, SOK Partners or its designee is entitled to appoint a special advisor to the Company's Board of Directors, who will be appointed as a member of the Board upon request.

On March 28, 2012, the Company signed an Amended and Restated Note Purchase Agreement, dated as of December 20, 2011, with Dr. Samuel Herschkowitz (as amended, the "Herschkowitz Purchase Agreement"). Pursuant to the Herschkowitz Purchase Agreement, the Company issued a 20.0% convertible note due June 20, 2012 in the principal amount of $240,000 for previous advances under the note. The Company's obligations under the note are secured by the grant of a security interest in substantially all tangible and intangible assets of the Company. The Company has previously issued to Dr. Herschkowitz an equity bonus consisting of 1,546,667 shares of common stock. An additional 7,500,000 shares are required to be transferred to Dr. Herschkowitz upon the occurrence of an event of default on the note.

As long as any amount payable under the note remains outstanding, Dr. Herschkowitz or his designee is entitled to appoint a special advisor to the Company's Board of Directors, who will be appointed as a member of the Board upon request. Pursuant to this authority, Josh Kornberg was appointed to the Board on March 9, 2012.

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 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 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 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, 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 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 significant 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 quoted by the OTC Bulletin Board 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 – Stockholders' Deficit, Stock Options and Warrants" 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 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 significant 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 to 7 years of 10 small-cap medical companies traded on major exchanges and 15 medical companies in the middle of the market cap size range on the OTC Bulletin Board and combined the results using a weighted average approach. In the case of standard options to employees we determined the expected life to be the midpoint between the vesting term and the legal term. In the case of options or warrants granted to non-employees, we estimated the life to be the legal term unless there was a compelling reason to make it shorter.

Valuation of Intangible Assets. We review identifiable intangible assets for impairment in accordance with 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.

Recent Accounting Developments

See "Note 1 - Summary of Significant Accounting Policies - Recent Accounting Developments" in Notes to Financial Statements of this Annual Report on Form 10-K.

Results of Operations

Comparison of Year Ended December 31, 2011 with Year Ended December 31, 2010

Revenue. We recorded revenue of $96,637 in 2011 compared to $288 in 2010. We received approval from the FDA on April 1, 2009 to commence sales and marketing activities of the 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 or prior years, and there was no significant revenue in 2010 primarily due to lack of funds to build and ship the products. The revenue in 2011 included the sale of five Streamway™ systems and disposable supplies to operate the Streamway™. Revenue in 2010 was solely for disposable supplies for an evaluation unit. The Company has recently begun installing Streamway™ units in hospitals for evaluation purposes and, in one case, for production purposes, and expects the revenue for Streamway™ units to increase significantly at such time as the hospitals approve the use of the unit for their application and place orders for billable units.

Cost of sales. Cost of sales was $56,080 in 2011 compared to $140 in 2010. The gross profit margin was 42% for the system and the procedure kits in 2011.

General and Administrative expense. General and administrative (G&A) expense primarily consists of management salaries, professional fees, consulting fees, travel expense, administrative fees and general office expenses.

G&A expense increased to $3,562,000 for 2011 from $1,874,000 for 2010. The $1,688,000 increase in G&A expenses for 2011, compared to 2010, is primarily due to a $1,466,000 increase in consulting expense, a $272,000 increase in Investor Relation expenses, offset somewhat by $114,000 reduction in legal expense. Although we have continued to compensate consulting with stock-based instruments, the total value of the stock and the number of shares has decreased. Salary expense declined in 2011 in comparison to 2010 due to a $70,000 charge to expense in 2010 to estimate the costs to settle a termination matter with a former officer. Total G&A expenses are expected to increase due to increased insurance premiums, investor relations expenses and audit and legal fees, resulting from becoming a public company, but otherwise remain relatively constant over the next several quarters.

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

Operations expense increased to $352,000 in 2011 compared to $277,000 in 2010. The $75,000 increase in operations expense in 2011 is primarily due to an increase of $76,000 in stock-based compensation and an increase in manufacturing supplies and components expense of $19,000 for the year as the operations department continued to revise and adjust various parts and components in the Streamway™ unit to respond to results of operating the equipment in live surgical settings. Operations expense in the next several quarters is expected to increase significantly as the Company expects to increase shipments of the Streamway™ unit as customers complete their evaluations and place orders for billable units. Although we are attempting to curtail our expenses, there is no guarantee that we will be able to reduce these expenses significantly, and expenses for some periods may be higher as we prepare our product for broader sales, increase our sales efforts and maintain adequate inventories.

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 increased to $233,000 in 2011 compared to $200,000 in 2010. During the last several quarters, we have operated on a very slim marketing budget as a result of limited funding. The increase in 2011 is primarily the result of a decrease of $67,000 in salary expense offset, in part, by an increase of $87,000 in stock-based compensation and an increase of $43,000 in sales commissions. Sales and marketing expense is expected to increase significantly in the future as we expect to hire a Vice President of Sales and we expect to hire additional sales and sales support personnel and increase our trade show, promotion and travel expense significantly after we receive significant funding.

Interest expense. Interest expense increased to $230,000 in 2011 from $147,000 in 2010. The increase in interest expense was due to a higher level of interest-bearing debt and amortization of larger debt discounts attributable to new convertible debt issued with warrants.

Loss (gain) on valuation of equity-linked financial instruments. The Company realized a loss of $151,000 on valuation of equity-linked financial instruments in 2011 compared to a gain of $1,145,000 in 2010. The loss in 2011 resulted primarily from an extension of terms on warrants. The gain or loss in this account in the future will largely depend on the price performance of our stock in the future.

Liquidity and Capital Resources

Cash Flows for the Year Ended December 31, 2011

We had a cash balance of $122,985 as of December 31, 2011 and $9,383 as of December 31, 2010. Since our inception, we have incurred significant losses. As of December 31, 2011, we had an accumulated deficit of approximately $11,869,000. We have not achieved profitability and anticipate that we will continue to incur net losses for the foreseeable future. We expect that our operations, sales and marketing, and general and administrative expenses will increase, and as a result we will need to generate significant revenue to achieve profitability.

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

To date, our operations have been funded through a bank loan and private convertible debt of approximately $1,584,000 and equity investments totaling approximately $3,923,000. As of December 31, 2011, we had accounts payable of $731,000 and accrued liabilities of $567,000. Account payable has declined to $731,000 as of December 31, 2011 from $769,000 as of December 31, 2010 primarily due to the issuance of a convertible note in the amount of $89,300 to one of our law firms as full settlement of the accounts payable balance as of January 1, 2011.

Net cash used in operating activities was $1,781,631 for 2011 compared with net cash used of $821,000 for 2010. The $961,000 increase in cash used in operating activities was largely due to a $3,134,000 increase in the net loss in 2011, compared to 2010, offset by an increase of $3,137,000 in non-cash expenses compared to 2010.

Cash flows used in investing activities was zero for 2011 and 2010. There have been no investing activities since we invested in new furniture and patents in 2008. We will likely increase our cash used in investing activities in the next several quarters as we prepare to support the expected growth in sales.

Net cash provided by financing activities was $1,895,000 for 2011 compared to net cash provided of $813,000 for 2010. The increase in 2011 was primarily the result of selling $1,386,000 in common stock in 2011 compared to $220,000 in 2010. We expect to show additional cash provided by financing activities in the next few quarters provided we are successful in raising money with our investment banker.

Capital Resources

Based on our current operating plan we believe that we have sufficient cash, cash equivalents and short-term investment balances to last approximately through June 30, 2012 after which additional financing will be needed to continue to satisfy our obligations. While holders of our warrants could exercise and provide cash to us during that time frame, we are not depending on that in our fundraising efforts.

The funds from our October 2008 offering allowed us to complete the testing and certification of our FMS unit and to receive, on April 1, 2009, final FDA clearance. Management hired an investment banker in 2010 to raise an additional $3 to $5 million in new equity. The banker was unable to raise the expected $500,000 by September 30, 2010 and the balance within three months, but we raised approximately $1,386,000 in equity and $525,500 in convertible debt in 2010, and $1,154,000 in equity and $533,000 in convertible debt in 2011 through alternative means.

We are currently incurring operating expenses of approximately $100,000 per month. Although we are attempting to curtail our expenses, there is no guarantee that we will be able to reduce these expenses significantly, and expenses for some periods may be higher as we prepare our product for broader sales, increase our sales efforts and maintain adequate inventories. Further, we have approximately $2,382,000 in debts, liabilities and cash obligations that become due in the second and third quarters of calendar 2012. We are currently receiving advances on a convertible promissory note from an investment fund affiliated with one of our directors, up to an aggregate amount of $600,000. We believe that we will need to raise at least an aggregate of $2 million from future financing in order to have sufficient financial resources to fund our operations for the next 12 months because of our cash flow deficit. We will attempt to raise these funds through equity or debt financing, alternative offerings or other means, and we will also endeavor to convert existing obligations into equity, settle such obligations or otherwise reduce their amounts. We are not planning on any significant capital or equipment investments, and we will only have a few human resource additions over the next 12 months.

Although we have been able to fund our current working capital requirements, principally through debt and equity financing, there is no assurance that we will be able to do so in the future. If financing is available, it may be highly dilutive to our existing shareholders and may otherwise include burdensome or onerous terms. Our independent registered public accounting firm has indicated in their audit opinion, contained in our financial statements that they have serious doubts about our ability to continue as a going concern. Our inability to raise additional working capital at all or to raise it in a timely manner would negatively impact our ability to fund our operations, to generate revenues, and to otherwise execute our business plan, leading to the reduction or suspension of our operations and ultimately forcing us to declare bankruptcy, reorganize or to go out of business. Should this occur, the value of any investment in our securities could be adversely affected, and an investor would likely lose all or a significant portion of their investment.

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, 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 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 is 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 statements.

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-12 of this report.

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

None.

ITEM 9A. 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 Officer/Chief Financial Officer evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covering this report. Based on this evaluation, our Chief Executive Officer/Chief Financial Officer concluded that, as of December 31, 2011, our disclosure controls and procedures were not effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in the rules promulgated under the Securities Exchange Act of 1934. Under the supervision and with the participation of our management, including our Chief Executive Officer/Chief Financial Officer, we have conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in "Internal Control-Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis by our internal controls. In connection with our assessment of our internal control over financial reporting as required under Section 404 of the Sarbanes-Oxley Act of 2002, we identified the following material weakness in our internal control structure over financial reporting as of December 31, 2011;

> In the 4th quarter of 2011, there was an improper gap in maintaining issuance of stock options and warrants discovered in account reconciliations at December 31, 2011. In particular there was a large adjustment converting equity value into compensation expense. These audit adjustments did materially affect our financial position and results of operations for the year ended December 31, 2011.

Remediation of Material Weakness in Internal Control Structure over Financial Reporting

We are in the process of implementing remediation efforts with respect to our control environment and the material weakness noted above as follows:

> We plan over the next quarter, to implement corrections to ensure that stock option and warrants are effectively recorded, filed, maintained and reconciled and reviewed for any discrepancies to avoid misstatements of our financial position or results of operations.

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 in 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 2012 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," "2011 Director Compensation," and "Compensation Committee," all of which will appear in our definitive proxy statement for our 2012 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 will appear in our definitive proxy statement for our 2012 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 will appear in our definitive proxy statement for our 2012 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 will appear in our definitive proxy statement for our 2012 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 April 16, 2012;
- Balance Sheets as of December 31, 2011 and December 31, 2010;
- Statements of Operations for the Years Ended December 31, 2011 and December 31, 2010 and from April 23, 2002 (Inception) to December 31, 2011;
- Statements of Stockholders' Deficit from April 23, 2002 (Inception) to December 31, 2011;
- Statements of Cash Flows for the Years Ended December 31, 2011 and December 31, 2010 and from April 23, 2002 (Inception) to December 31, 2011; 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: April 16, 2012

BioDrain Medical, Inc.

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

POWER OF ATTORNEY

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	April 16, 2012
/s/ Kevin R. Davidson	President, Chief Executive Officer, Chief Financial Officer and Director (principal executive officer and principal financial and accounting officer)	April 16, 2012
/s/ Albert Emola	Director	April 16, 2012
/s/ Jeffrey Galitz	Director	April 16, 2012
/s/ Josh Kornberg	Director	April 16, 2012
/s/ Thomas J. McGoldrick	Director	April 16, 2012
/s/ Peter L. Morawetz	Director	April 16, 2012
/s/ Andrew P. Reding	Director	April 16, 2012
/s/ Chad A. Ruwe	Director	April 16, 2012

EXHIBIT INDEX
BIODRAIN MEDICAL, INC.
FORM 10-K

Exhibit Number	Description
3.1	Articles of Incorporation, as amended (6)
3.2	Bylaws, as amended (8)
10.1	Employment Agreement between the Registrant and Kevin R. Davidson, dated October 4, 2006 (1)**
10.2	Confidential Separation Agreement and Release between the registrant and Lawrence W. Gadbaw, dated August 13, 2008 (1)**
10.3	Stock Option Agreement between the registrant and Kevin R. Davidson, dated June 5, 2008 (1)**
10.4	Director Stock Option Agreement between the registrant and Thomas McGoldrick, dated August 22, 2006 (1)**
10.5	Director Stock Option Agreement between the registrant and Andrew P. Reding, dated November 11, 2006 (1)**
10.6	Consulting Agreement between the registrant and Marshall C. Ryan and Mid-State Stainless, Inc., dated June 2008 (1)
10.7	Patent Assignment by Marshall C. Ryan in favor of the registrant, dated June 18, 2008 (1)
10.8	Convertible Debenture between the registrant and Kevin R. Davidson, dated February 2, 2007 (1)
10.9	Convertible Debenture between the registrant and Peter L. Morawetz, dated February 2, 2007 (1)
10.10	Convertible Debenture between the registrant and Andrew P. Reding, dated February 2, 2007 (1)
10.11	Convertible Debenture between the registrant and Thomas McGoldrick, dated January 30, 2007 (1)
10.12	Convertible Debenture between the registrant and Andcor Companies, Inc., dated September 29, 2006 (1)
10.13	Convertible Debenture between the registrant and Carl Moore, dated March 1, 2007 (1)
10.14	Convertible Debenture between the registrant and Roy Moore, dated March 1, 2007 (1)
10.15	Form of Subscription Agreement (1)
10.16	Form of Registration Rights Agreement (1)
10.17	Form of Escrow Agreement (1)
10.18	Form of Warrant (1)
10.19	2008 Equity Incentive Plan (1)**
10.20	Office Lease Agreement between the registrant and Roseville Properties Management Company, as agent for Lexington Business Park, LLC (1)
10.21	Employment Agreement between the registrant and David Dauwalter, dated August 11, 2008 (2)**
10.22	Amendment No. 1 to Employment Agreement between the registrant and David Dauwalter, dated September 11, 2008 (2)**
10.23	Consulting Agreement by and between the registrant and Andcor Companies, Inc., dated September 15, 2008 (2)
10.24	Consulting Agreement by and between the registrant and Taylor & Associates, Inc., dated August 15, 2008 (2)
10.25	Independent Contractor Agreement between Belimed, Inc. and the registrant, dated February 2, 2009 (3)

10.26	Supply Agreement between Oculus Innovative Sciences, Inc., and the registrant, dated February 20, 2009 (4)
10.27	Agreement between the registrant and Peter Morawetz, dated May 15, 2009 (5)
10.28	Amendment No. 1 to BioDrain Medical, Inc. 2008 Equity Incentive Plan (7)**
10.29	Convertible Note Purchase Agreement between the Company and SOK Partners, LLC dated March 28, 2012, including the form of Convertible Promissory Grid Note (9)
10.30	Amended and Restated Note Purchase Agreement between the Company and Dr. Samuel Herschkowitz dated as of December 20, 2011, including the form of Convertible Promissory Note (issued in the amount of $240,000) (9)
14.1*	Code of ethics
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of principal executive officer required by Rule 13a-14(a)
31.2*	Certification of principal financial officer required by Rule 13a-14(a)
32.1*	Section 1350 Certification

*Filed herewith.
**Compensatory Plan or arrangement required to be filed pursuant to Item 15(b) of Form 10-K.

(1) Filed on November 12, 2008 as an exhibit to our Registration Statement on Form S-1 and incorporated herein by reference.

(2) Filed on January 12, 2009 as an exhibit to Amendment No. 1 to our Registration Statement on Form S-1and incorporated herein by reference.

(3) Filed on April 6, 2009 as an exhibit to our Amendment No. 3 to our Registration Statement on Form S-1and incorporated herein by reference.

(4) Filed on July 1, 2009 as an exhibit to our Amendment No. 5 to our Registration Statement on Form S-1and incorporated herein by reference.

(5) Filed on August 12, 2009 as an exhibit to Amendment No. 7 to our Registration Statement on Form S-1and incorporated herein by reference.

(6) Filed on March 31, 2011 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference.

(7) Filed on June 15, 2011 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(8) Filed on November 23, 2011 as an exhibit to Amendment No. 1 to our Quarterly Report on Form 10-Q and incorporated herein by reference.

(9) Filed on April 3, 2012 as an exhibit to our Current report on Form 8-K and incorporated herein by reference.

The audited financial statements for the periods ended December 31, 2011, December 31, 2010 and Inception through December 31, 2011 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, 2011 and 2010 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, 2011. 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, 2011 and 2010, and the results of its operations and its cash flows for the years then ended and from April 23, 2002 (inception) to December 31, 2011, 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
April 16, 2012

PART 1. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	December 31, 2011	December 31, 2010
ASSETS		
Current Assets:		
Cash	$ 122,985	$ 9,383
Accounts receivable	50,294	-
Inventories	97,605	-
Prepaid expense and other assets	30,148	8,126
Total Current Assets	301,032	17,509
Fixed assets, net	4,600	6,831
Intangibles, net	140,588	141,532
Total Assets	$ 446,220	$ 165,872
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Current portion of long-term debt (See Note 8)	$ -	$ 10,267
Current portion of convertible debt, net of discounts of $28,741 and $0 (See Notes 6, 7 and 8)	1,055,559	56,000
Accounts payable	731,135	768,720
Accrued expenses	566,574	498,707
Total Current Liabilities	2,353,268	1,333,694
Long-term debt and convertible debt, net of discounts of $16,446 and $109,310 (See Note 8)	630,153	1,006,789
Liability for equity-linked financial instruments (See Note 10)	166,063	14,946
Stockholders' Deficit:		
Common stock, $.01 par value, 200,000,000 authorized, 32,074,000 and 14,002,290 outstanding	320,740	140,023
Additional paid-in capital	8,844,952	5,052,497
Deficit accumulated during development stage	(11,868,956)	(7,382,077)
Total Stockholders' Deficit	(2,703,264)	(2,189,557)
Total Liabilities and Stockholders' Deficit	$ 446,220	$ 165,872

See Notes to Financial Statements

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

	Year Ended December 31,		Period From April 23, 2002 (Inception) To December 31,
	2011	2010	2011
Revenue	$ 96,637	$ 288	$ 112,662
Cost of goods sold	56,080	140	63,220
Gross margin	40,557	148	49,442
General and administrative expense	3,561,566	1,874,465	9,464,458
Operations expense	351,662	276,998	1,529,534
Sales and marketing expense	232,716	199,593	888,485
Interest expense	230,374	147,093	667,107
Loss (gain) on valuation of equity-linked financial instruments	151,118	(1,145,292)	(631,186)
Total expense	4,527,436	1,352,857	11,918,398
Net loss available to common shareholders	$ (4,486,879)	$ (1,352,709)	$ (11,868,956)
Loss per common share - basic and diluted	$ (0.18)	$ (0.11)	$ (2.04)
Weighted average shares used in computation - basic and diluted	24,282,433	12,771,683	5,820,397

See Notes to Financial Statements

BIODRAIN MEDICAL, INC.
(A DEVELOPMENT STAGE COMPANY)
STATEMENTS OF STOCKHOLDERS' DEFICIT
PERIOD FROM APRIL 23, 2002 (INCEPTION)
To December 31, 2011

	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 10/23/02, $1.67/share	2,993	30	4,970		5,000
Net loss				(51,057)	(51,057)
Balance 12/31/02	601,542	$ 6,015	$ 8,985	$ (51,057)	$ (36,057)
Issuance of common 2/12/03, $.0167 (2)	23,942	239	161		400
Issuance of common 6/11&12,$1.67 (3)	21,548	216	34,784		35,000
Net loss				(90,461)	(90,461)
Balance 12/31/03	647,032	$ 6,470	$ 43,930	$ (141,518)	$ (91,118)
Issuance of common 5/25/04, $.0167 (4)	6,567	66	44		110
Net loss				(90,353)	(90,353)
Balance 12/31/04	653,599	$ 6,536	$ 43,974	$ (231,871)	$ (181,361)
Issuance of common 12/14/05, $.0167 (5)	14,964	150	100		250
Vested stock options and warrants			2,793		2,793
Net loss				(123,852)	(123,852)
Balance 12/31/05	668,563	$ 6,686	$ 46,867	$ (355,723)	$ (302,170)
Issuance of common 5/16 & 8/8, $.0167 (6)	86,869	869	582		1,451
Issuance of common 10/19 & 23, $.0167 (7)	38,906	389	261		650
Issuance of common 12/01, $1.67 (8)	28,739	287	44,523		44,810
Vested stock options and warrants			13,644		13,644
Net loss				(273,026)	(273,026)
Balance 12/31/06	823,077	$ 8,231	$ 105,877	$ (628,749)	$ (514,641)
Issuance of common 1/30/07 @ 1.67 (9)	599	6	994		1,000
Value of equity instruments issued with debt			132,938		132,938
Capital contributions resulting from waivers of debt			346,714		346,714
Vested stock options and warrants			73,907		73,907
Net loss				(752,415)	(752,415)
Balance 12/31/07	823,676	$ 8,237	$ 660,430	$ (1,381,164)	$ (712,497)
Issuance of common 6/11 to 9/30, $.35 (10)	4,552,862	45,528	1,547,974		1,593,502
Shares issued to finders, agents	2,012,690	20,127	(20,127)		-
Shares issued to pay direct legal fees	285,714	2,857	(2,857)		
Issuance of common due to 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 waivers of debt			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 PMM 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
Capital contributions resulting from waivers of debt			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 under PPM in November 2009, $.50	50,000	500	24,500		25,000
Shares issued upon conversion of debt and interest, $.27	935,446	9,354	247,100		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	$ 113,830	$ 3,573,507	$ (6,029,368)	$ (2,342,030)
Shares issued in March 2010 under PPM, $.50	174,550	1,746	85,529		87,275
Shares issued to consultants for IR and consulting, $.50	374,090	3,741	183,304		187,045
Value of equity instruments issued for consulting services			354,602		354,602
Vested stock options and warrants			11,382		11,382
Value of equity-linked financial instruments issued in connection with PPM in first quarter			(25,553)		(25,553)
Shares issued in April 2010 under PPM, $.50	180,000	1,800	88,200		90,000
Shares issued in May 2010 to consultant, $.50	12,850	129	6,296		6,425
Shares issued in May 2010 to 2008 investors as a penalty for late registration of 4,552,862 shares, $.50	710,248	7,102	348,022		355,124
Value of equity instruments issued with debt			119,474		119,474
Value of equity-linked financial instruments issued in connection with PPM in second quarter			(31,332)		(31,332)
Value of equity-linked financial instruments issued in connection with PPM in third quarter			(31,506)		(31,506)
Shares issued in September 2010 under PPM, $.10	250,000	2,500	22,500		25,000
Shares issued to consultants in third quarter at $.22 per share	488,860	4,889	102,660		107,549
Shares issued in November 2010 upon exercise of warrants at $.135 per share	128,571	1,286	16,071		17,357
Shares issued in November 2010 to directors as compensation at $.15 per share	300,000	3,000	42,000		45,000
Vested stock options in fourth quarter			161,107		161,107
Equity instruments issued to consultants in fourth quarter			26,234		26,234
Net loss				(1,352,709)	(1,352,709)
Balance 12/31/2010	14,002,290	$ 140,023	$ 5,052,497	$ (7,382,077)	$ (2,189,557)
Value of equity instruments issued with debt in first quarter			47,908		47,908
Shares issued in first quarter at $.075 per share under PPM	5,333,334	53,334	346,666		400,000
Shares issued in first quarter at $.085 per share under PPM	1,294,117	12,941	97,059		110,000
Shares issued in first quarter at $.09 per share under PPM	200,000	2,000	16,000		18,000
Shares issued in first quarter at $.10 per share under PPM	150,000	1,500	13,500		15,000
Vested stock options and warrants in first quarter			268,549		268,549
Equity instruments issued to consultants in first quarter			91,504		91,504
Stock issued upon conversion of debt in first quarter	416,010	4,160	15,840		20,000
Stock issued to pay interest on debt in second quarter	158,036	1,580	20,920		22,500
Shares issued in second quarter at $.085 per share under PPM	588,236	5,882	44,118		50,000
Shares issued in second quarter at $.07 per share under PPM	500,000	5,000	30,000		35,000
Stock issued upon conversion of debt and interest	941,034	9,410	22,590		32,000
Vested stock options and warrants in second quarter			82,463		82,463
Equity instruments issued to consultants in second quarter			12,256		12,256
Vested stock options and warrants in third quarter			1,357,494		1,357,494
Equity instruments issued to consultants in third quarter			147,116		147,116
Restricted stock issued to consultants in third quarter	822,842	8,228	46,772		55,000
Shares issued in third quarter at $.06 per share under PPM	3,500,000	35,000	175,000		210,000
Shares issued in third quarter at $.07 per share under PPM	571,429	5,715	34,285		40,000
Shares issued in third quarter at $.20 per share under PPM	562,500	5,625	106,875		112,500
Shares issued upon exercise of stock options at $.01	100,000	1,000			1,000
Shares issued in fourth quarter at $.35 per share IR compensation	575,000	5,750	195,500		201,250
Shares issued in fourth quarter at $.20 per share under PPM	812,500	8,125	154,375		162,500
Equity instruments upon conversion of Accounts Payable in first quarter			20,000		20,000
Vested stock options and warrants in fourth quarter			229,132		229,132
Shares issued to private investor in fourth quarter at $.15 per share	1,546,667	15,467	216,533		232,000
Net loss				(4,486,879)	(4,486,879)
Balance 12/31/2011	32,074,000	$ 320,740	$ 8,844,952	$ (11,868,956)	$ (2,703,264)

(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

	Year Ended December 31,		April 23, 2002 (Inception) To December 31,
	2011	2010	2011
Cash flow from operating activities:			
Net loss	$ (4,486,879)	$ (1,352,709)	$ (11,868,956)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,175	2,429	9,565
Vested stock options and warrants	1,937,638	172,489	2,667,300
Equity instruments issued for management and consulting	507,126	726,854	1,869,940
Stock-based registration payments	-	-	355,124
Capital contributions resulting from waivers of debt	-	-	476,398
Amortization of debt discount	112,031	55,037	285,284
(Gain) loss on valuation of equity-linked instruments	151,118	(1,145,292)	(631,186)
Changes in assets and liabilities:			
Accounts receivable	(50,294)	15,737	(50,294)
Inventories	(97,605)	-	(97,605)
Prepaid expense and other assets	(22,022)	(4,325)	(30,148)
Notes payable to shareholders	-	-	(14,957)
Accounts payable	71,714	411,883	1,297,735
Accrued expenses	92,367	297,216	678,434
Net cash used in operating activities:	(1,781,631)	(820,681)	(5,053,366)
Cash flow from investing activities:			
Purchase of fixed assets	-	-	(12,258)
Purchase of intangibles	-	-	(142,495)
Net cash used in investing activities	-	-	(154,753)
Cash flow from financing activities:			
Proceeds from long-term and convertible debt	525,500	604,800	1,583,966
Repayment of convertible debt	-	(100,000)	(100,000)
Principal payments on long-term debt	(16,267)	(14,334)	(75,667)
Restricted cash in escrow	-	103,333	-
Issuance of common stock	1,386,000	219,632	3,922,805
Net cash provided by (used in) financing activities	1,895,233	813,431	5,331,104
Net increase (decrease) in cash	113,602	(7,249)	122,985
Cash at beginning of period	9,383	16,632	-
Cash at end of period	$ 122,985	$ 9,383	$ 122,985
Non cash transactions:			
Common stock issued for accrued interest	24,500	-	111,860
Conversion of accounts payable to convertible debt	89,300	457,300	546,600
Common stock issued to satisfy debt	50,000	-	224,000
Stock warrant issued to satisfy accounts payable	20,000	-	20,000

See Notes to Financial Statements

NOTE 1 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations and Continuance of Operations

BioDrain Medical, Inc. (the "Company") 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 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 2010 to raise an additional $3 to $5 million in new equity. The banker was unable to raise the expected $500,000 by September 30, 2010 and the balance within three months, but the Company raised approximately $229,000 in equity and $605,000 in convertible debt in 2010 and $1,154,000 in equity and $533,000 in convertible debt in 2011 through alternative means. The Company's April 1, 2009 510(k) clearance from the FDA to authorize the Company to market and sell its FMS products is being received very positively. The Company has a private investor that has committed $300,000 to $600,000 in 2012 with potential additional investment subsequent to June 2012.

Recent Accounting Developments

In the first quarter of 2011 we adopted new guidance on separating consideration in multiple-deliverable arrangements. The guidance addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how the consideration should be allocated among the separate units of accounting. The adoption of this guidance did not have a material impact on our financial statements.

We reviewed all other significant newly issued accounting pronouncements and determined they are either not applicable to our business or that no material effect is expected on our financial position and results of our operations.

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 economic downturn 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.

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. There were no advertising expenses for 2011 or 2010.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs were $0 and approximately $10,000 for 2011 and 2010, respectively.

Revenue Recognition

The Company recognizes 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. The Company's standard terms specify that shipment is FOB BioDrain and the Company will, therefore, recognize revenue upon shipment in most cases. This revenue recognition policy applies to shipments of the FMS units as well as shipments of cleaning solution kits. When these conditions are satisfied, the Company recognizes gross product revenue, which is the price it charges generally to its customers for a particular product. Under the Company's 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 the Company's standard one-year warranty whereby the Company replaces or repairs, at its option, and it would be rare that the FMS unit or significant quantities of cleaning solution kits may be returned. Additionally, since the Company buys both the FMS units and cleaning solution kits from "turnkey" suppliers, the Company 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. The Company has determined there will be no losses on balances outstanding at December 31, 2011.

Inventories

Inventories are stated at the lower of cost or market, with cost determined on a first-in, first-out basis. Inventory balances are as follows:

	December 31, 2011	December 31, 2010
Finished goods	$ 94,331	$ -
Raw materials	3,274	-
Total	$ 97,605	$ -

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 trademarks and 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 carryforwards 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.

The Company reviews income tax positions expected to be taken in income tax returns to determine if there are any income tax uncertainties. The Company recognizes tax benefits from uncertain tax positions only if it is more likely than not that the tax positions will be sustained on examination by taxing authorities, based on technical merits of the positions. The Company has identified no income tax uncertainties.

Tax years subsequent to 2007 remain open to examination by federal and state tax authorities.

Patents and Intellectual Property

In June 2008, the Company 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 $95.00 per hour.

Mr. Ryan also received a warrant, with immediate vesting, to purchase 150,000 shares of the Company's common stock at a price of $.35 per share. The warrant has a five-year term ending on June 30, 2013 and was assigned a value of $28,060 using a Black-Scholes formula. This amount was expensed as consulting expense in 2008 using a five-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

The Company has evaluated subsequent events through the date of this filing. On March 28, 2012, BioDrain Medical, Inc. (the "Company"), entered into a Convertible Note Purchase Agreement, dated as of March 28, 2012 (the "SOK Purchase Agreement") between the Company and SOK Partners, LLC ("SOK Partners"), an investment partnership. Josh Kornberg, who is a member of the Company's Board of Directors, and Dr. Samuel Herschkowitz are affiliates of the manager of SOK Partners. Pursuant to the SOK Purchase Agreement, the Company issued a 20.0% convertible note due August 2012 in the principal amount of up to $600,000. Principal and accrued interest on the note are due and payable on August 28, 2012. The Company's obligations under the note are secured by the grant of a security interest in substantially all tangible and intangible assets of the Company. The SOK Purchase Agreement and the note include customary events of default that include, among other things, non-payment defaults, covenant defaults, inaccuracy of representations and warranties, cross-defaults to other indebtedness and bankruptcy and insolvency defaults. The occurrence of an event of default could result in the acceleration of the Company's obligations under the note, and interest rate of twenty-four (24%) percent per annum accrues if the note is not paid when due.

On March 28, 2012, the Company received an advance of $84,657 under the note, including a cash advance of $60,000 net of a prepayment of interest on the first $300,000 in advances under the note. The holder of the note is entitled to convert the note into shares of common stock of the Company at an initial conversion price per share of $0.065 per share, subject to adjustment in the event of (1) certain issuances of common stock or convertible securities at a price lower than the conversion price of the note, and (2) recapitalizations, stock splits, reorganizations and similar events. In addition, the Company is required to issue two installments of an equity bonus to SOK Partners in the form of common stock valued at the rate of $0.065 per share. In April 2012, the Company issued the first equity bonus to SOK Partners, consisting of 4,615,385 shares of common stock, with a second installment due within five business days after SOK Partners has made aggregate advances under the note of at least $300,000. Until the maturity date of the note, if the Company obtains financing from any other source without the consent of SOK Partners, then the Company is required to issue additional bonus equity in an amount equal to $600,000 less the aggregate advances on the note made prior to the breach.

As long as any amount payable under the note remains outstanding, SOK Partners or its designee is entitled to appoint a special advisor to the Company's Board of Directors, who will be appointed as a member of the Board upon request.

The foregoing description does not purport to be complete and is qualified in its entirety by the terms and conditions of the SOK Purchase Agreement, including the form of note, which is filed as an exhibit to this Annual Report on Form 10-K.

On March 28, 2012, the Company signed an Amended and Restated Note Purchase Agreement, dated as of December 20, 2011, with Dr. Samuel Herschkowitz (as amended, the "Herschkowitz Purchase Agreement"). Pursuant to the Herschkowitz Purchase Agreement, the Company issued a 20.0% convertible note due June 20, 2012 in the principal amount of $240,000 for previous advances under the note. The Company's obligations under the note are secured by the grant of a security interest in substantially all tangible and intangible assets of the Company. The Company has previously issued to Dr. Herschkowitz an equity bonus consisting of 1,546,667 shares of common stock. An additional 7,500,000 shares are required to be transferred to Dr. Herschkowitz upon the occurrence of an event of default on the note.

As long as any amount payable under the note remains outstanding, Dr. Herschkowitz or his designee is entitled to appoint a special advisor to the Company's Board of Directors, who will be appointed as a member of the Board upon request. Pursuant to this authority, Josh Kornberg was appointed to the Board on March 9, 2012. The Company does not believe there are other subsequent events that require disclosure.

Subsequent to year end an institutional investor converted $92,000 of Convertible Debt to 1,647,048 shares of common stock

Reclassifications

Certain amounts in the prior periods financial statements have been reclassified to conform with the 2011 presentation. These reclassifications had no effect on the net loss or stockholders' deficit for any period.

NOTE 2 – DEVELOPMENT STAGE OPERATIONS

The Company was formed April 23, 2002. Since inception through December 31, 2011, 32,074,000 shares of common stock have been issued between par value and $1.67. Operations since incorporation have primarily 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

The Company has adopted 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, using a straight-line method. We elected the modified-prospective method 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. The Company uses 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 the Company's 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 the Company uses in calculating the fair value of stock-based payment awards represent the Company's best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and the Company uses different assumptions, the Company's equity-based compensation expense could be materially different in the future.

Since the Company's common stock has no significant public trading history, and the Company has experienced no significant option exercises in its history, the Company is required to take an alternative approach to estimating future volatility and estimated life and the future results could vary significantly from the Company's estimates. The Company compiled historical volatilities over a period of 2 to 7 years of 15 small-cap medical companies traded on major exchanges and 10 mid-range medical companies on the OTC Bulletin Board and combined the results using a weighted average approach. In the case of ordinary options to employees the Company 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, the Company 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, the Company deems 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 the Company also uses the Black-Scholes 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 the Company's 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 the Company has limited trading history in its stock and no first-hand experience with how its investors and consultants have acted in similar circumstances, the assumptions the Company uses in calculating the fair value of stock-based payment awards represent its best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and the Company uses different assumptions, the Company's 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 option valuation model based upon assumptions regarding risk-free interest rate, expected dividend rate, volatility and estimated term. For grants issued during 2008, the Company 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 them to be treated as a liability (See Note 10) and warrants granted in connection 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 that 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 convertible "bridge" debt that 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 of common stock at $.65 per share. The Company determined that the warrant had an initial value of $30,150 that was treated as a debt discount and amortized as additional interest expense over the 24-month term of the note.

The Company also issued $200,000 in convertible debt in June 2010 and issued a warrant, in connection with the debt, to purchase 1,111,112 shares of common stock at $.46 per share. The Company determined that the value of the June 2010 warrant is $96,613.This value is treated as a debt discount and amortized as additional interest expense over the 22-month term of the note. The Company also issued $32,000 in convertible debt in September 2010 and issued a warrant to purchase 320,000 shares of common stock at $.18 per share. The Company determined that this warrant has a value of $15,553 that was treated as a debt discount and amortized as additional interest expense over the 18-month term of the note.

The Company also issued $16,800 in convertible debt in December 2010 and issued a warrant to purchase 200,000 shares of common stock at $.084 per share. The Company determined that this warrant has a value of $7,232 that was treated as a debt discount and amortized as additional interest expense over the 24- month term of the note.

In January 2011, the Company issued three convertible notes of $50,000 each and also issued warrants to purchase 1,595,239 common shares at $.20 per share. The value of the warrants was determined to be $47,908 and is being treated as a debt discount and amortized as additional interest expense over the 24-month term of the notes.

For grants of stock options and warrants in 2011 the Company used a 0.34 to 2.44% risk-free interest rate, 0% dividend rate, 54-66% volatility and estimated term of 3 to 10 years. Values computed using these assumptions ranged from $0.0126 to $0.3412 per share.

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
Issued	2,210,000	0.17	3,435,662	0.34
Expired	(207,956)	0.43	(8,979)	1.67
Exercised			(128,571)	0.46
Outstanding at December 31, 2010	3,498,218	0.19	10,670,925	0.44
Issued	2,483,334	0.01	18,222,243	0.14
Expired	(83,941)	0.73	(2,010,917)	0.48
Exercised	(100,000)	0.01		
Outstanding at December 31, 2011	5,797,611	$ 0.11	26,882,251	$ 0.23

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

At December 31, 2011, 4,888,660 stock options are fully vested and currently exercisable with a weighted average exercise price of $0.13 and a weighted average remaining term of 9.24 years. There are 26,882,251 warrants that are fully vested and exercisable. Stock-based compensation recognized in 2011 and 2010 was $1,937,638 and $172,489, respectively. The Company has $130,123 of unrecognized compensation expense related to non-vested stock options that are expected to be recognized over a weighted average period of approximately 2 years.

The following summarizes the status of options and warrants outstanding at December 31, 2011:

	Range of Exercise Prices	Shares	Weighted Average Remaining Life
Options:			
$	0.01	2,926,626	8.97
$	0.15	2,060,000	8.60
$	0.35	775,000	1.55
$	0.50	30,000	0.87
$	1.67	5,985	0.87
Total		5,797,611	
Warrants:			
$	0.01	200,000	3.94
$	0.02	71,826	2.45
$	0.075	4,657,745	2.52
$	0.10	2,328,572	1.93
$	0.12	500,000	2.33
$	0.13	631,429	1.78
$	0.15	5,333,334	2.16
$	0.16	500,000	2.27
$	0.17	1,882,353	2.27
$	0.18	200,000	2.11
$	0.20	2,445,239	2.05
$	0.25	1,375,000	2.74
$	0.35	998,597	0.49
$	0.46	4,028,606	0.95
$	0.65	1,729,550	0.66
Total		26,882,251	

Stock options and warrants expire on various dates from February 2012 to July 2021.

Under the terms of the Company's agreement with investors in the October 2008 financing, 1,920,000 shares of common stock were the maximum number of shares allocated to the Company's existing shareholders at the time of the offering (also referred to as the original shareholders or the "Founders"). Since the total of the Company's fully diluted shares of common stock was greater than 1,920,000 shares, in order for the Company to proceed with the offering, the 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 shares. 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 split was 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 shares of common stock of 20,000,000 was proportionately divided by 1.2545 to arrive at 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 arrive at 11,970,994 shares and (ii) approved a resolution to increase the number of authorized shares of the Company's common stock from 11,970,994 to 40,000,000, which was approved by the Company's shareholders holding a majority of the shares entitled to vote thereon at a special meeting of shareholders held on December 3, 2008.

The shareholders approved an increase in authorized shares to 80 million shares in an annual shareholder meeting held on June 22, 2010 and approved an increase in authorized shares to 200 million shares in a special shareholder meeting held on September 7, 2011.

Stock Options and Warrants Granted by the Company

The following table is the listing of stock options and warrants as of December 31, 2011 by year of grant:

Stock Options:

Year	Shares	Price
2006	-	$ -
2007	5,985	1.67
2008	1,243,292	.01-.35
2009	105,000	.35-.50
2010	2,060,000	.15
2011	2,383,334	.01
Total	5,797,611	$ .01-1.67

Warrants:

Year	Shares	Price
2006	35,913	$ .02
2007	28,502	.35
2008	2,971,629	.02-.46
2009	2,188,302	.13-.65
2010	3,435,662	.01-.65
2011	18,222,243	.075-.25
Total	26,882,251	$ .01-1.67

NOTE 4 - LOSS PER SHARE

The following table presents the shares used in the basic and diluted loss per common share computations:

	Year Ended December 31, 2011	2010	From April 23, 2002 (Inception) To December 31, 2011
Numerator:			
Net loss available in basic and diluted calculation	$ (4,486,879)	$ (1,352,709)	$ (11,868,956)
Denominator:			
Weighted average common shares outstanding-basic	24,282,433	12,771,683	5,805,714
Effect of dilutive stock options and warrants (1)	-	-	-
Weighted average common shares outstanding-diluted	24,282,433	12,771,683	5,805,714
Loss per common share-basic and diluted	$ (0.18)	$ (0.11)	$ (2.04)

(1) The number of shares underlying options and warrants outstanding as of December 31, 2011 and December 31, 2010 are 32,679,862 and 14,169,143, respectively. The effect of the shares that would be issued upon exercise of such options and warrants has been excluded from the calculation of diluted loss per share because those shares are anti-dilutive.

NOTE 5 – 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 statements 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, 2011, were approximately $11,254,000 and will begin to expire in 2017.

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

The components of deferred income taxes at December 31, 2011 and December 31, 2010 are as follows:

	December 31, 2011	December 31, 2010
Deferred Tax Asset:		
Net Operating Loss	$ 2,626,000	$ 1,579,000
Other	49,000	56,000
Total Deferred Tax Asset	2,675,000	1,635,000
Less Valuation Allowance	2,675,000	1,635,000
Net Deferred Income Taxes	$ —	$ —

NOTE 6 – CONVERTIBLE DEBENTURE

The Company issued a convertible debenture to Andcor Companies, Inc. (“Andcor”) with principal of $10,000 and interest at 10.25% that originally matured in 2007. The debenture is convertible into shares of 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 $0.35 per share. The convertible debenture has not yet been paid, but the maturity of the note was extended, in May 2010, to March 31, 2012.

NOTE 7 – NOTES PAYABLE

On December 20, 2011, the Company signed a Note Purchase Agreement, with Dr. Samuel Herschkowitz. Pursuant to this agreement, Dr. Herschkowitz purchased a 20.0% note due June 20, 2012 in the principal amount of $225,000. The Company’s obligations under the note are secured by the grant of a security interest in substantially all tangible and intangible assets of the Company. The Company issued to Dr. Herschkowitz an equity bonus consisting of 1,546,667 shares of common stock. An additional 7,500,000 shares are required to be transferred to Dr. Herschkowitz upon the occurrence of an event of default on the note.

As long as any amount payable under the note remains outstanding, Dr. Herschkowitz or his designee is entitled to appoint a special advisor to the Company’s Board of Directors, who will be appointed as a member of the Board upon request. Pursuant to this authority, Josh Kornberg was appointed to the Board on March 9, 2012.

NOTE 8 – LONG-TERM DEBT

Long-term debt is as follows:

	December 31, 2011	December 31, 2010
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, 2010). The final payment under the note was made in September 2011. The note was personally guaranteed by former executives of the Company.	$ —	$ 10,267
Notes payable to two individuals, net of discounts of $1,341 and $9,390 with interest only payments at 12% to March 2012 when the remaining balance is payable. The notes are convertible into 285,715 shares of common stock in the Company at $.35 per share.	98,659	90,610
Note payable issued on October 26, 2009 to the parents of one of the Company's directors, net of a discount of $0 and $12,360 discount, with interest at 8% to March 31, 2012 when the remaining balance is payable and convertible into shares of common stock at $.35 per share.	100,000	87,640
Notes payable issued to two individuals in January 2010. The notes bear interest at 8%, mature March 31, 2012 and are convertible into shares of common stock at 50% of the weighted average closing bid price over any 10 consecutive days of trading.	100,000	100,000
Note payable issued on June 12, 2010 to the parents of one of the Company's directors, net of a discount of $14,931 and $67,629. The note bears interest at 12% to March 31, 2012 when the remaining balance is payable, and is convertible into shares of common stock at $.18 per share.	185,069	132,371
Note payable issued on August 2, 2010 to an institutional investor. The note accrued interest at 8%, matured May 4, 2011 and was convertible into shares of common stock at 50% of the average of the three lowest closing prices in any 10 day trading period. $20,000 was converted in the three months ended March 31, 2011 and $30,000, plus accrued interest, was converted in the three months ended June 30, 2011.	—	50,000
Note payable issued on June 14, 2011 to an institutional investor. The note bears interest at 8%, matures June 14, 2012 and is convertible into shares of common stock at 55% of the average of the five lowest closing prices in any 10 day trading period.	63,000	—
Note payable issued on July 12, 2011 to an institutional investor. The note bears interest at 8%, matures April 16, 2012 and is convertible into shares of common stock at 60% of the average of the five lowest closing prices in any 10 day trading period.	37,500	—
Note payable issued on September 16, 2010 to an institutional investor. The note bears interest at 10%, matures March 15, 2012 and is convertible into shares of common stock at $.18 per share.	100,000	100,000
Note payable issued on December 23, 2010 to the parents of one of the Company's directors, net of a discount of $4,960 and $7,229. The note bears interest at 10%, matures December 23, 2012 and is convertible into shares of common stock at $.084 per share.	11,840	9,571
Note payable issued on December 31, 2010 to a law firm that accepted this note in full payment of their past due legal fees. The note bears interest at 6%, matures December 31, 2014 and is convertible into shares of common stock at $.15 per share.	457,300	457,300
Note payable issued on December 23, 2010 to a private investor. The note matured April 30, 2011, is paid, and accrued interest at 10%.	-	6,000
Note payable issued on September 21, 2010 to the parents of one of the Company's directors, net of a discount of $0 and $12,702. The note bears interest at 12%, matures March 30, 2012 and is convertible into shares of common stock at $.18 per share.	32,000	19,298
Notes payable issued in January 2011 to three individuals, net of a debt discount of $23,954. The notes bear interest at 10%, have a 24-month term and are convertible into shares of common stock at $0.084 to $0.10 per share.	126,046	—
Note payable issued January 1, 2011 to a law firm that accepted this note in full payment of their past due legal fees. The note bears interest at 6%, matures January 1, 2015 and is convertible into shares of common stock at $.15 per share.	89,300	—
On November 18, 2011 the Company issued a convertible note with an institutional investor at 8% interest convertible into common stock at 60% of the average of the five lowest closing prices in any ten day trading period. The note matures on August 21, 2012.	50,000	—
Total	1,450,714	1,063,056
Less amount due within one year	820,561	66,267
Long-Term Debt	$ 630,153	$ 996,789

Cash payments for interest were $280 and $967 for 2011 and 2010, respectively.

Principal payments required during the years 2012 to 2015 are as follows:

2012	$ 1,084,300
2013	$ 100,000
2014	$ 457,300
2015	$ 89,300

NOTE 9 – RENT OBLIGATION

The Company leases its principal office under a non-cancelable lease that extends five years and expires October 2013. In addition to rent, the Company pays real estate taxes and repairs and maintenance on the leased property. Rent expense was $49,975 and $49,863 for 2011 and 2010, respectively.

The Company's rent obligation for the years 2012 and 2013 is as follows:

2012	$ 31,000
2013	$ 26,000

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 was effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, which was the Company's first quarter of 2009. Many 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 $479,910 was booked as a liability. The warrants issued in 2011 do not contain a strike price adjustment feature and, therefore, are not treated 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 re-valued 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 and 2010 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. A significant reduction in the liability was realized in 2010 primarily due to a reduction from $.50 to $.22 per share in the underlying stock price. The Company realized a slight increase in the liability for existing warrants during the first quarter of 2011 primarily due to a reduction in the spread between the exercise price and the market price of the underlying shares, additionally, there was an increase in the liability due to the extension of some existing warrants.

The inputs to the Black-Scholes model during 2009, 2010 and 2011 were as follows:

Stock price	$ .08 to $.50
Exercise price	$ .01 to $.65
Expected life	2.0 to 6.5 years
Expected volatility	54% to 68%
Assumed dividend rate	- %
Risk-free interest rate	.13% to 2.97%

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

	Initial Value	Annual Gain (Loss)	Value at 12/31/09	2010 Gain (Loss)	Value at 12/31/10	2011 Gain (Loss)	Value at 12/31/2011
January 1, 2009 adoption	$ 479,910	$ (390,368)	$ 870,278	$ 868,772	$ 1,506	(88,290)	$ 89,796
Warrants issued in quarter ended 6/30/2009	169,854	20,847	149,007	147,403	1,604	(4,689)	6,293
Warrants issued in quarter ended 9/30/2009	39,743	(738)	40,481	40,419	62	(1,562)	1,624
Warrants issued in quarter ended 12/31/2009	12,698	617	12,081	12.053	28	(724)	752
Subtotal	$ 702,205		$ 1,071,847				
Warrants issued in quarter ended 3/31/2010	25,553			25,014	539	(5,571)	6,109
Warrants issued in quarter ended 6/30/2010	31,332			30,740	592	(6,122)	6,714
Warrants issued in quarter ended 9/30/2010	31,506			20,811	10,615	(44,160)	54,775
Total	$ 790,596	$ (369,642)	$ 1,071,847	$ 1,145,292	$ 14,946	$ (151,118)	$ 166,072

NOTE 11 - 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 $12,000 remains in accounts payable as of December 31, 2011. 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 14.1

CODE OF ETHICS

OF

BIODRAIN MEDICAL, INC.

(as adopted November 14, 2008)

I. Introduction

The board of directors (the "**Board**") of BioDrain Medical, Inc., a Minnesota corporation, (the " **Company** "), has adopted this BioDrain Medical, Inc. Code of Ethics (this " **Code** "), which is applicable to all directors, officers and employees of the Company, to:

- promote honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- promote the full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with, or submits to, the Securities and Exchange Commission (the " **SEC** "), as well as in other public communications made by or on behalf of the Company;
- promote compliance with applicable governmental laws, rules and regulations;
- deter wrongdoing; and
- require prompt internal reporting of breaches of, and accountability for adherence to, this Code.

No code or policy can anticipate every situation that may arise. Accordingly, this Code is intended to serve as a source of guiding principles. Directors, officers and employees are encouraged to bring questions about particular circumstances that may involve one or more of the provisions of this Code to the attention of the Company's Chief Executive Officer or Chairman of the Board, who may consult with the Company's outside legal counsel as appropriate.

This Code may be amended only by unanimous resolution of the Board.

II. Honest, Ethical and Fair Conduct

Each director, officer and employee of the Company owes a duty to the Company to act with integrity. Integrity requires, among other things, being honest, fair and candid. Deceit, dishonesty and subordination of principle are inconsistent with integrity. Service to the Company should never be subordinated to personal gain and advantage.

Each director, officer and employee of the Company must:

1. act with integrity, including being honest and candid while still maintaining the confidentiality of the Company's information where required or in the Company's interests;
2. observe all applicable governmental laws, rules and regulations;

3. comply with the requirements of applicable accounting and auditing standards, as well as Company policies, in order to maintain a high standard of accuracy and completeness in the Company's financial records and other business-related information and data;

4. adhere to a high standard of business ethics and not seek competitive advantage through unlawful or unethical business practices;

5. deal fairly with the Company's customers, suppliers, competitors and employees;

6. refrain from taking advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts or any other unfair-dealing practice;

7. protect the assets (both tangible and intangible) of the Company and ensure their proper use;

8. refrain from taking personal opportunities that are discovered through the use of corporate assets or using corporate assets, information or position for personal gain outside the scope of employment or service with the Company;

9. refrain from trading in the Company's securities at any time when aware of material nonpublic information about the Company, or passing on to others material nonpublic information about the Company;

10. avoid conflicts of interest, wherever possible, except under guidelines or resolutions approved by the Board (or the appropriate committee of the Board). Anything that would be a conflict for a person subject to this Code also will be a conflict if it is related to a member of his or her family or a close relative.

    Examples of conflict of interest situations include, but are not limited to, the following:

    a. any significant ownership interest in any supplier or customer;

    b. any consulting or employment relationship with any customer, supplier or competitor;

    c. any outside business activity that detracts from an individual's ability to devote appropriate time and attention to his or her responsibilities with the Company;

    d. conducting business with, or competing with, an entity in which a director, officer or employee has an ownership interest or in which a close relative has an ownership or employment interest, unless such business relationship has been disclosed and authorized by a majority of the independent members of the Board;

    e. the receipt of any money, non-nominal gifts or excessive entertainment from any company with which the Company has current or prospective business dealings or from any entity if the money, gift or entertainment is for the purposes of influencing the director, officer or employee in his or her capacity as such;

f. being in the position of supervising, reviewing or having any influence on the job evaluation, pay or benefit of any close relative;

g. selling anything to the Company or buying anything from the Company, except on the same terms and conditions as comparable officers or directors are permitted to so purchase or sell; and

h. any other circumstance, event, relationship or situation in which the personal interest of a person subject to this Code interferes–or even appears to interfere–with the interests of the Company as a whole.

III. Disclosure

The Company strives to ensure that the contents of and the disclosures in the reports and documents that the Company files with the SEC and other public communications shall be full, fair, accurate, timely and understandable in accordance with applicable disclosure standards, including standards of materiality, where appropriate. Each director, officer and employee must:

1. not knowingly misrepresent, or cause others to misrepresent, facts about the Company to others, whether within or outside the Company, including to the Company's independent auditors, governmental regulators, self-regulating organizations and other governmental officials, as appropriate; and

2. in relation to his or her area of responsibility, properly review and critically analyze proposed disclosure for accuracy and completeness.

In addition to the foregoing, the Chief Executive Officer and Chief Financial Officer of the Company and each subsidiary of the Company (or persons performing similar functions), and each other person that typically is involved in the financial reporting of the Company must familiarize himself or herself with the disclosure requirements applicable to the Company as well as the business and financial operations of the Company.

Each director, officer and employee must promptly bring to the attention of the Chairman of the Audit Committee of the Board (or the Chairman of the Board) any information he or she may have concerning (i) significant deficiencies in the design or operation of internal and/or disclosure controls which could adversely affect the Company's ability to record, process, summarize and report financial data or (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's financial reporting, disclosures or internal controls.

IV. Compliance

It is the Company's obligation and policy to comply with all applicable governmental laws, rules and regulations. It is the personal responsibility of each person to, and each person must, adhere to the standards and restrictions imposed by those laws, rules and regulations, including those relating to accounting and auditing matters.

V. Reporting and Accountability

The Board or Audit Committee of the Board is responsible for applying this Code to specific situations in which questions are presented to it and has the authority to interpret this Code in any particular situation. Any director, officer or employee who becomes aware of any existing or potential breach of this Code is required to notify the Chairman of the Board or the Chairman of the Audit Committee promptly. Failure to do so is itself a breach of this Code.

1. Each director, officer and employee must:

a. notify the Chairman of the Board or the Chairman of the Audit Committee promptly of any existing or potential violation of this Code; and

b. not retaliate against any other person for reports of potential violations that are made in good faith.

2. The Company will follow the following procedures in investigating and enforcing this Code and in reporting on the Code:

a. The Board or Audit Committee will take all appropriate action to investigate any breaches reported to it.

b. If the Board or Audit Committee determines (by majority decision) that a breach has occurred, it will inform the entire Board.

c. Upon being notified that a breach has occurred, the Board (by majority decision) will take or authorize such disciplinary or preventive action as it deems appropriate, after consultation with the Audit Committee and/or the Company's counsel, up to and including dismissal or, in the event of criminal or other serious violations of law, notification of the SEC or other appropriate law enforcement authorities.

No person who reports an incident in accordance with the above procedure shall, as a result of following such procedure, be subject by the Company or any officer or employee thereof to discharge, demotion suspension, threat, harassment, or, in any manner, discrimination against such person in terms and conditions of employment.

VI. Waivers and Amendments

Any waiver, including an implicit waiver, from a provision of this Code or any amendment to this Code that applies to the principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, is required to be disclosed in a Report on Form 8-K filed with the SEC, unless the Company discloses the required information on its Internet website and has disclosed in its most recently filed annual report its Internet address and intention to provide disclosure in this manner.

A "waiver" means the approval by the Company's Board of a material departure from a provision of the Code. An "implicit waiver" means the Company's failure to take action within a reasonable period of time regarding a material departure from a provision of the Code that has been made known to an executive officer of the Company. An "amendment" means any amendment to this Code other than technical, administrative or other non-substantive amendments hereto.

All persons should note that it is not the Company's intention to grant or to permit waivers from the requirements of this Code. The Company expects full compliance with this Code.

VII. Other Policies and Procedures

Any other policy or procedure set out by the Company in writing or made generally known to employees, officers or directors of the Company prior to the date hereof or hereafter are separate requirements and remain in full force and effect.

VIII. Inquiries

All inquiries and questions in relation to this Code or its applicability to particular people or situations should be addressed to the Company's Chief Executive Officer, or such other compliance officer as shall be designated from time to time by the Company.

BIODRAIN MEDICAL, INC.

CODE OF ETHICS

ACKNOWLEDGEMENT FORM

All directors, officers and employees of BioDrain Medical, Inc. (the "Company") are required to read and follow the BioDrain Medical, Inc. Code of Ethics and complete this Acknowledgement Form.

Acknowledgement

I hereby acknowledge that I have received a copy of the BioDrain Medical, Inc. Code of Ethics and that I will be responsible for obtaining any and all future amendments and modifications thereto.

I further acknowledge that I have read, understand, and am in full compliance with all of my obligations, duties, and responsibilities under each provision of the BioDrain Medical, Inc. Code of Ethics.

I understand and agree that upon receipt of proof of a violation of the BioDrain Medical, Inc. Code of Ethics, the Board of Directors of the Company may proceed with an investigation and proper action may be taken.

Name (Print):_____

Signature:_____

Date:_____

Please complete the above and submit only this page to BioDrain Medical, Inc. at 2060 Centre Pointe Boulevard, Suite 7, Mendota Heights, Minnesota 55120, Phone Number (651) 389-4800.

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 and on Form S-8 of our report, dated April 16, 2012, 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, 2011.

Olsen Thielen & Co., Ltd.

St. Paul, Minnesota
April 16, 2012

EXHIBIT 31.1

CERTIFICATION

I, Kevin R. Davidson, certify that:

1. I have reviewed this annual report on Form 10-K 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. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15-d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) 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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: April 16, 2012

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

EXHIBIT 31.2

CERTIFICATION

I, Kevin R. Davidson, certify that:

1. I have reviewed this annual report on Form 10-K 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. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15-d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) 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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: April 16, 2012

/s/ Kevin R. Davidson
Kevin R. Davidson
Chief Financial Officer (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, 2011 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: April 16, 2012

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