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, 2012.**

☐ **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.)

2915 Commers Drive, Suite 900
Eagan, Minnesota 55121
(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: $2,951,423 as of June 30, 2012, based upon 45,406,505 shares at $.065 per share as reported by the OTCQB 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: 120,303,418 shares of common stock as of March 20, 2013.

DOCUMENTS INCORPORATED BY REFERENCE

Except as otherwise stated in Part III, information in Part III is incorporated by reference to the definitive proxy statement for the Company's 2013 annual meeting, which will be filed within 120 days after the end of fiscal 2012.

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PART I

ITEM 1. BUSINESS.

Overview

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

We were founded as a Minnesota corporation in 2002 by Lawrence Gadbaw, who has over 40 years of experience in the medical devices field, Peter L. Morawetz, who has extensive experience consulting with development-stage companies in the medical and high technology field, and Jeffery K. Drogue. Our address is 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121. Our telephone number is (651)-389-4800, and our website address is www.biodrainmedical.com.

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.

The majority of these procedures produce potentially infectious materials that must be disposed with the lowest possible risk of cross-contamination to healthcare workers. Current standards of care allow for these fluids to be retained in canisters, are located in the operating room where they can be monitored throughout the surgical procedure. Once the procedure is complete these canisters and their contents are disposed using a variety of methods all of which include manual handling and result in a heightened risk to healthcare workers for exposure to their contents. A publically available Frost & Sullivan research report from April 24, 2006 estimates that 60,000,000 suction canisters are sold each year and the estimated market value of canisters is upwards of $120,000,000.

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 2007, 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 direct-to-drain 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. (Zimmer) 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 procedures 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. Each procedure requires the use of a disposable filter. At 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. The filter and 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, continuous suction, unlimited capacity 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 direct-to-drain 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 area, 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. (Zimmer)	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	No	No	No	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 must be installed in each room where it is intended to be used.

Once installed, the FMS has 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 additional inflow suction ports by utilizing one or two filters.

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 temporarily cause inconvenience and lost productivity as the operating rooms will need to be taken off line temporarily.

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.

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 allows the fluid to pass through a flowmeter that 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 7000 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 $1 million to fund this activity. We can provide no assurance that this funding will be available at attractive prices or at all. We currently are manufacturing the FMS system to revised specifications in low quantities in our facility. We are following GMP regulations to ensure FDA compliance to our operational activities. As FMS system sales rise we will analyze partnering with a qualified contract manufacturer versus expanding our operations to accommodate higher production capabilities.

We filed a 510(k) submission in March 2009 and received written FDA clearance on April 1, 2009 (K090759). 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 filter is also proprietary to the FMS and is designed to allow supply only from BioDrain. The cleaning fluid and filter are 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, local plumbers, 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 $15,000 in 2012 and $0 in 2011 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), a U.S. patent in February 2012 (U.S. Patent No. 8,123,731) and a Canadian patent in April 2011 (Number 2,495,747) (collectively, the "Patents"). These Patents will begin to 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. 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.

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. However, our patent attorney has recently analyzed and reviewed the Patents concluding that we maintain a strong position to defend our patents.

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 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 use in the cleaning kit for our FMS. The distribution agreement allows use of the fluid in connection with our devices; we expect to acquire ownership of any patent rights or claims pertaining to such fluid.

The Disposable Kit

The disposable 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 single or multiple 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. Our disposable, single use filter is designed specifically for use only on our FMS. The filter is used only once per procedure followed by immediate disposal. Our operation instructions and warranty require that a BioDrain filter is used for every procedure. There are no known off the shelf filters that will fit our FMS. We are currently developing a more effective and cost efficient filter, with intent to patent. 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 fits in the specially designed container holder on the FMS and perform testing to demonstrate that any other fluid would not damage the FMS. We believe that these barriers and the warranty control will allow us to achieve substantial revenue from our cleaning fluid. The instructions for use 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 either a hospital appointed service technician or 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 that may incorporate an on-board vacuum supply.

- *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.

- *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.

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 manufacturing experience of our management team to develop sources of supply and manufacturing to reduce costs 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 enhance the success of our after-market disposable products.*

Technology and Competition

Fluid Management for Surgical Procedures

The management of surgical waste 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, and the typical cost to dispose of medical waste is approximately $.30 per pound.

- The canister filled with gelled fluid must be disposed; it cannot be cleaned and re-sterilized for future use.

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

Drainage Systems

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

Existing competitors, that already have products on the market, have a competitive advantage in terms of brand recognition and market exposure. In addition, the aforementioned companies have extensive marketing and development budgets that could overpower an early stage company like ours.

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

Current Competition, Technology, and Costs

Single Use Canisters

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

Our FMS would replace the use of canisters and render them unnecessary, as storage and disposal would be performed automatically by the FMS. It should be noted that these canisters are manufactured by companies with substantially more resources than our Company. Cardinal Health, a very significant competitor, 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. Our true competitive advantage, however, is our unlimited capacity, eliminating the need for any high volume cases to be interrupted for canister changeover.

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.

In 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.

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 worse 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 and disposable filter 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; Cardinal Health introduced the Orwell Fluid Collection and Disposal System; and Dornoch Medical Systems, Inc. (Zimmer) 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 are completely direct-to-drain and 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 procedure kits through various methods that may include a direct sales force, independent distributors and manufacturer's representatives covering the vast majority of major U.S. and outside U.S. markets. Currently our Vice–President of Sales and an independent rep are selling, and demoing the FMS for prospective customers and distributors, as well as, supporting our current customer base for kit resupply. 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, imaging, 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 feature information on protection of the healthcare worker on our website 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 procedure 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 are currently manufacturing the FMS in our own facility. We have the capability to manufacture, test, house, ship and receive from our warehouse. We are in the process of negotiating with a manufacturing company that meets our standards and requirements as sales increase.

The disposable kit, including a bottle of proprietary cleaning solution and an in-line filter is sourced through National Purity (cleaning solution) and a local company that is currently tooling to manufacture our own newly designed disposable filter. Both these companies have the potential for long term vendor agreements with the Company. We are pursuing Intellectual Property protection for these disposable products as well.

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)

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 expect to contract 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).

FDA Clearance 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.

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. The FMS is a Class II device, which is less stringently reviewed as that of a Class III device. Our COO has numerous years' significant experience in the FDA clearance process and has a team of regulatory consultants with significant experience in the FDA clearance process.

We filed the 510(k) submission for 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.

Following this 510(k) clearance by the FDA, we continue to 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.

Employees

We have 8 employees, seven of whom are full-time, and one who is part-time.

Executive Officers and Directors of the Registrant

The following table identifies our current executive officers and directors:

Name	Age	Position Held
Lawrence W. Gadbaw	75	Chairman of the Board of Directors
Josh Kornberg	39	President, Chief Executive Officer, and Director
David O. Johnson	60	Chief Operating Officer
Bob Myers	58	Chief Financial Officer
Thomas J. McGoldrick	71	Director
Andrew P. Reding	43	Director
Peter L. Morawetz	85	Director
Ricardo Koenigsberger	46	Director

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

There are no family relationships among our directors and executive officers. Our executive officers are appointed by our Board of Directors and serve at the board's discretion. 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. Ricardo Koenigsberger was appointed to the Board under this authority in June 2012. See Item 13, "Certain Relationships and Related Transactions, and Director Independence".

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.

Josh Kornberg, President, Chief Executive Officer and Director. Effective July 22, 2012, Joshua Kornberg was appointed by the Board of Directors of BioDrain Medical, Inc. (the "Company") as the Chief Executive Officer and President of the Company. Mr. Kornberg was elected Interim President, Chief Executive Officer and Chief Financial Officer by the Board on April 23, 2012. 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. See Item 13, "Certain Relationships and Related Transactions, and Director Independence." Mr. Kornberg is President and founding partner of APA, a private equity fund based in New York. Prior to founding APA, 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 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.

David O. Johnson, Chief Operating Officer. Effective July 1, 2012, David O. Johnson was appointed as the Chief Operating Officer of BioDrain Medical, Inc. (the "Company"). Mr. Johnson, age 60, was previously the Acting Chief Operating Officer for the Company since December 2011 and had been a consultant to medical device companies since October 2010. Mr. Johnson has over 30 years' experience in executive, operations and management positions in rapid growth medical device organizations, directing growth domestically and internationally with products ranging from consumer based disposable commodity items to Class III implantable devices. His experience includes executive management, training, product development, business development, regulatory and quality assurance, operations, supplier development and technology acquisitions. From August 2007 to September 2010 Mr. Johnson was President and CEO of Spring Forest Qigong, an alternative healthcare organization. Prior to August 2007 he had been a co-founder and Vice President of Operations at Epitek, Inc. since January 2005, and prior to that time he was a co-founder and President of Timm Medical Technologies. He also held positions including Vice President-Operations/Technology at UroHealth/Imagyn, Vice-President Operations at Dacomed Corporation and various technical, operations and training positions at American Medical Systems and Pfizer Corporation. He also holds a number of patents in the medical device field and the exercise fitness industry.

Bob Myers, Chief Financial Officer. Effective July 1, 2012 Bob Myers was appointed as the Chief Financial Officer of the Company. Mr. Myers, age 58, was the Acting Chief Financial Officer and Corporate Secretary for the Company since December 2011. He has over 30 years' experience in multiple industries focusing on medical device, service and manufacturing and for the ten years prior to being appointed as our CFO, he was a financial contractor represented by various contracting firms in the Minneapolis area. He has spent much of his career as a Chief Financial Officer and/or Controller. Mr. Myers was a contract CFO at Disetronic Medical, contract Corporate Controller for Diametric Medical Devices and contract CFO for Cannon Equipment. Previously he held executive positions with American Express, Capitol Distributors, and International Creative Management and was a public accountant with the international firm of Laventhol & Horwath. Mr. Myers has an MBA in Finance from Adelphi University and a BBA in Public Accounting from Hofstra University.

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

Thomas J. McGoldrick, Director. Mr. McGoldrick has served as a director of the Company since 2005. Prior to that, he served as Chief Executive Officer of Monteris Medical Inc. from November 2002 to November 2005. He has been in the medical device industry for over 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 bachelor's degree from Marquette University and an MBA from The University of South Carolina.

Ricardo Koenigsberger, Director. Effective June 25, 2012, Ricardo Koenigsberger, was elected to the Board of Directors of BioDrain Medical, Inc. (the "Company"). Mr. Koenigsberger is currently a managing partner of ROCA Management, a private investment fund focused on the REIT industry. In addition, he also serves as CEO of Realty Finance Corporation, a publicly held company. Previously, Mr. Koenigsberger was a partner of Apollo Real Estate, a large private equity firm, where he was responsible for new investments and investment management. At Apollo, he oversaw the investment of over $1+ billion in equity. Mr. Koenigsberger graduated summa cum laude from the Wharton School of the University of Pennsylvania.

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 operations, 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 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.

We are currently incurring operating expenses of approximately $125,000 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 $3,414,000 in debts, liabilities and cash obligations that become due in the first and second quarters of calendar 2013.

We may default on significant debt that becomes due on March 31, 2013 and may be unable to continue in business. We are currently indebted to Dr. Samuel Herschkowitz and SOK Partners, LLC pursuant to convertible promissory notes with balances of $240,000 and approximately $357,000, respectively, as of December 31, 2012. Pursuant to a Forbearance and Settlement Agreement with these parties dated August 15, 2012, as subsequently amended, the due date of these notes has been extended to March 31, 2013. Dr. Herschkowitz' note is secured by substantially all of the assets of the Company. If we are unable to repay these notes as of April 30, 2013 and these parties do not convert their notes, we will be in default under the notes. In that case Dr. Herschkowitz will have rights as a secured creditor with respect to the Company's assets, which would include the right to seize the Company's assets. Further, the Company also has other significant indebtedness. If the Company defaults on its debt, it may be forced to seek bankruptcy protection and may be unable to continue in business.

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 6 - 9 months because of our cash flow deficit. We will attempt to raise these funds through equity or debt financing, alternative offerings or other means. We will also continue to endeavor to negotiate to extend the maturity dates of our indebtedness, convert existing obligations into equity, settle such obligations or otherwise reduce their amounts. If successful we are planning significant capital investments, and we will have human resources additions over the next 12 months. If we are unable to obtain additional funds at reasonable rates or at all we will be required to substantially curtail our operations and could cease to operate in our current form.

The Company has suffered recurring losses from operations and has a stockholders' deficit. 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 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. These factors raise substantial doubt about our ability to continue as a going concern.

As a result of the above factors, our independent registered public accounting firm has indicated in their audit opinion, contained in our financial statements included in this annual report on Form 10-K that they have serious doubts about our ability to continue as a going concern. The financial statements have been prepared assuming the Company will continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 believe the increase in sales in December 2012 and January 2013 may indicate that our business plan is on the right track, but 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.

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) and in February 2012 (US Patent No 8,123,731). 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 technical innovations of unlimited suction and unlimited capacity capabilities, 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 has only recently entered the commercial market and, although we anticipate market acceptance, we do not have enough customer experience with it to predict future demands.

The BioDrain FMS has been launched into the fluid management market. We are currently developing the product for manufacture, following GMP compliance regulations, at our own facility and anticipate the capability of producing the BioDrain FMS in sufficient quantities for future near term sales. We are in the process of negotiating with a manufacturing company that fits our standards and costs. We anticipate that the product will be attractive to the target market due to its continuous suction and unlimited capacity ability, but other unknown or unforeseen market requirements may arise. The Company is in the process of finalizing a contract manufacturing partner that will be able to produce our product 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 rely on the continued services of Lawrence Gadbaw, the Chairman of our Board of Directors, and heavily depend on our management team; Joshua Kornberg, our President and Chief Executive Officer, and David Johnson our Chief Operating Officer and Bob Myers our Chief Financial Officer. We have entered into employment agreements with all members of our senior management team and we plan to expand the relatively small number of executives in our company. We have expanded our staff hiring a new Vice-President of Sales and an experienced medical device engineer. Both have entered into employment agreements with the company. Our Director of Product Management has also entered into a new employment agreement with the 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. However, we have issued stock options and other equity-based compensation to attract and retain employees, and are confident that our team is committed to the products success.

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 early management team had limited public company experience, which have impaired 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 substantially more responsibility for managing publicly traded companies. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. Our senior management team has been able to implement and affect programs and policies in an effective and timely manner that adequately responds to such increased legal, regulatory compliance and reporting requirements. However, 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.

There is currently a limited public trading market for our common stock and we cannot assure you that a more 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. The numbers 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.

Our stock may be thinly traded.

Our common stock has been thinly traded, 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 numbers 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. 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 shareholders' equity.

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

Our common stock is traded on the OTCQB Market, is illiquid and subject to price volatility unrelated to our operations.

Our shares of common stock are currently traded on the OTCQB Market. Many institutional investors have investment policies which prohibit them from trading in stocks on the OTCQB Market. As a result, stocks traded on the OTCQB Market generally have limited trading volume and exhibit a wide spread between the bid/ask quotations than stock traded on national exchanges.

In addition, the stock market is subject to extreme price and volume fluctuations. The market price of our common stock could fluctuate substantially due to a variety of factors, including market perception of our ability to achieve our planned growth, our quarterly operating results, operating results of our competitors, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our competitors or us. Certain of these factors can have a significant effect on the market price for our stock for reasons that are unrelated to our operating performance.

The application of the "penny stock" rules to our common stock could limit the trading and liquidity of the common stock and adversely affect the market price of our common stock.

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.

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 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121. On January 28, 2013, the Company signed an amendment to the month to month lease originally signed on April 30, 2012. The lease as amended has a five-year term effective February 1, 2013 ending January 31, 2018. We lease 5,773 square feet at this location. Our monthly base rent is $2,906, increasing 3% annually through the term of the lease, plus charges for common area maintenance, real estate taxes/assessments and certain other charges that will cost approximately an additional $1,712 monthly. We expect that this space will be adequate for our current office and manufacturing needs.

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 related to the Company's termination of Ms. Doerfert in February 2010. In December 2012, Ms. Kirsten Doerfert, the former Vice-President, Sales and Marketing of the Company entered into a final settlement agreement, which provides for dismissal of the action.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

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 has been quoted under the symbol "BIOR" on the OTCQB since November 16, 2009 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 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, 2012	$ 0.14	$ 0.07
September 30, 2012	$ 0.12	$ 0.05
June 30, 2012	$ 0.10	$ 0.03
March 31, 2012	$ 0.33	$ 0.05
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

As of March 18, 2013, the closing bid price for shares of our common stock was $.095 per share on the OTCQB.

Holders

As of March 18, 2013, there were approximately 189 shareholders of record of our Common Stock. Our Common Stock is traded on 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 2013 Annual Meeting of Shareholders. Also see Item 12 below.

Purchases of Equity Securities by the Company

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans	Maximum Number of Shares that May Yet Be Purchased Under the Plan
December 31, 2012	362,967.00(1)	0.09	N/A	N/A
Total	362,967.00	0.09	N/A	N/A

(1) Shares purchased from a former officer to pay withholding tax for compensation income pursuant to a settlement agreement.

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:

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.

In February, 2011, we issued 350,000 shares of common stock and a warrant to purchase 350,000 shares of common stock at $.20 per share to two investors in return for their $33,000 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 for 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 for 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.

In the first and second quarters of 2011, we issued 1,588,235 shares of common stock and warrants to purchase 1,588,235 shares of common stock at $.17 per share to four investors in return for their $135,000 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 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 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 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.

In July and August of 2011, we issued 3,500,000 shares of common stock and warrants to purchase 3,500,000 shares at $.075 per share to seven investors in return for their $210,000 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 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.

In the third and fourth quarters of 2011, the Company issued 1,212,500 shares of common stock and warrants to purchase 1,212,500 shares of common stock at $.25 per share to five investors in return for their $242,500 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 October 11, 2011, the Company issued 575,000 shares of common stock to a consultant as sole compensation for investor relations consulting work.

In November 2011, the Company issued 162,500 shares of common stock and warrants to purchase 162,500 shares of common stock at $.20 per share to two investors in return for their $32,500 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, we 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, we issued a 20% convertible note due August 2012 in the principal amount of up to $600,000. Advances have totaled approximately $357,000 through July 27, 2012. In April 2012, the Company issued the first equity bonus to SOK Partners, consisting of 4,615,385 shares of common stock. See Item 13, "Certain Relationships and Related Transactions, and Director Independence."

On March 28, 2012, we 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, we 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 has previously issued to Dr. Herschkowitz an equity bonus consisting of 1,546,667 shares of common stock. An additional 7,500,000 shares were transferred to Dr. Herschkowitz upon the occurrence of an event of default on the note. See Item 13, "Certain Relationships and Related Transactions, and Director Independence."

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.

In April 2012, an institutional investor elected to convert $8,500 remaining from an original convertible note of $37,500 into 349,650 shares of common stock.

In April 2012, the Company issued an equity bonus consisting of 100,000 shares of common stock to Dr. Samuel Herschkowitz for an additional $15,000 advance under the December 20, 2011 convertible note due June 20, 2012. Dr. Herschkowitz was also issued 163,333 shares of common stock as an equity bonus for $24,500 Board meeting fees.

In May 2012, the Company issued 412,963 shares of common stock to a former Board member and Officer of the Company in exchange for exercising stock options at $.01 per share.

In May 2012, the Company issued the second equity bonus to SOK Partners, consisting of 4,615,385 shares of common stock. See Item 13, "Certain Relationships and Related Transactions, and Director Independence."

In May 2012, the Company issued 3,292,557 shares of common stock to an institutional investor to transfer debt to equity by an Election to Convert a convertible note.

In May 2012, the Company issued 2,850,754 shares of common stock to a vendor to transfer debt to equity by an Election to Convert Accounts Payable.

In May 2012, the Company issued 1,463,976 shares of common stock to an individual investor to transfer debt to equity by an Election to Convert a convertible note.

In May 2012, the Company issued 565,834 shares of common stock to an individual investor to transfer debt to equity by an Election to Convert a convertible note.

In May 2012, the Company issued 1,572,327 shares of common stock to an individual investor to transfer debt to equity by an Election to Convert a convertible note.

In June 2012, an institutional investor elected to convert $12,000 of a $50,000 convertible note into 387,097 shares of common stock.

In June 2012, the Company issued 397,267 shares of common stock to a vendor to transfer debt to equity by a settlement agreement.

In June 2012, the Company issued 277,278 shares of common stock at $.09 per share to the Mr. Lawrence Gadbaw the Company's Chairman of the Board as consulting compensation.

In June 2012, the Company issued 2,571,285 shares of common stock at $.07 per share and warrants to purchase 2,571,285 shares of common stock at $.15 per share to 8 investors in return for their $179,990 investment in the Company.

In June 2012, an institutional investor elected to convert $18,000 of a $50,000 convertible note into 509,915 shares of common stock.

In June 2012, the Company issued 283,718 shares of common stock to an individual investor to transfer debt to equity by an Election to Convert a convertible note.

In June 2012, an institutional investor elected to convert $20,000 remaining of a $50,000 convertible note, plus $2,000 interest, into 740,741 shares of common stock.

In June 2012, the Company issued 625,000 shares of common stock to an IR firm as sole compensation for investor relations consulting work.

In August 2012, the Company issued 3,620,809 shares of common stock at $.07 per share and warrants to purchase 3,620,809 shares of common stock at $.15 per share to 16 investors in return for their $253,456.58 investment in the Company.

In August 2012, the Company issued 13,250,000 shares of stock to Dr. Sam Herschkowitz and 13,250,000 shares of stock to SOK Partners, per a settlement and forbearance agreement.

In August 2012, the Company issued 1,166,667 shares of common stock at $.15 per share as part of a settlement with our former COO.

In October 2012, the Company issued 300,000 shares of common stock at $.07 per share to an investor relations firm as compensation for investor relations consulting work.

In October 2012, the Company issued 157,088 shares of common stock at $.15 per share to a vendor as compensation for work completed.

In November 2012, the Company issued 2,714,286 shares of common stock at $.07 per share and warrants to purchase 2,714,286 shares of common stock at $.15 per share to 5 investors in return for their $190,000 investment in the Company.

On November 6, 2012, we issued and sold convertible promissory notes in the total principal amount of $156,243 to Dr. Herschkowitz and certain of his assignees. Pursuant to the note purchase agreements, we issued to these parties an aggregate 1,562,430 shares of common stock in consideration of placement of the notes.

In November 2012, the Company issued 71,826 shares of common stock at $.01 per share to an investor exercising a warrant.

In December 2012, the Company issued 964,286 shares of common stock at $.07 per share and warrants to purchase 964,286 shares of common stock at $.15 per share to 2 investors in return for their $67,500 investment in the Company.

In December 2012 the Company issued 236,092 shares of common stock at $.07 per share in exchanged for a promissory note without restrictive legend; the note totaled $16,526.40 including principal and interest.

In December 2012 the Company purchased back 362,966 shares of common stock at $.09 per share from a former COO. The Company remitted payment for the shares directly to the federal and state taxing authorities for payroll taxes pertaining directly to the former COO.

In January, 2013, in connection with a private placement offering we issued 8% convertible one year promissory notes in an aggregate principal amount of $300,000 convertible into 2,500,000 shares of common stock assuming a conversion rate of $.12 per share and five year warrants to purchase up to an aggregate of 2,500,000 shares of the corporation's common stock at an exercise price of $0.15 per share. In addition, we issued to the placement agent for these sales five year warrants to purchase an aggregate of 200,000 shares of Common Stock at an exercise price of $.12 per share.

In January and March, 2013, in connection with a separate and new private placement offering we issued 7,142,857 shares of common stock at $.07 per share and warrants to purchase 7,142,857 shares of common stock at $.15 per share to 5 investors in return for their $500,000 investment in the Company.

In January 2013, the Company issued 290,143 shares of common stock at $.15 per share in payment to a vendor for $43,521.39 including principal and interest.

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.

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:

- Inability to raise sufficient additional capital to operate our business;
- Uncertainty of market acceptance of our products and the impact of competitive products;
- Risk that we will be unable to protect our intellectual property or claims that we are infringing on others' intellectual property;
- Possible impact of government regulation and scrutiny;
- 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.

Overview

We were incorporated in Minnesota in April 2002. We are a development company manufacturing an environmentally conscientious system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. Since our inception in 2002, we have invested significant resources into product development. 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 and filter kit.

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 have brought the manufacturing process in house and plan to supplement through outside third party contract manufacturers. Our VP of Sales is actively selling with independent and national sales organizations /people and training both.

Since inception, we have been unprofitable. We incurred net losses of approximately $7.4 million and $4.5 million in 2012 and 2011, respectively. As of December 31, 2012 and December 31, 2011, we had an accumulated deficit of approximately $19.3 million and $11.9 million, respectively. We received approval from the FDA in April 2009 to commence sales and marketing activities of the Streamway^{TM} FMS system and shipped the first system in 2009. However, there was no significant revenue prior to 2011, primarily due to lack of funds to build and ship the product. We sold five Streamway^{TM} units in 2011, and another thirteen to date. The Company has been installing Streamway^{TM} units in hospitals for evaluation purposes, selling 100% of those installed for trial. We expect the revenue for Streamway^{TM} 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. Trial basis units are either installed in or hung on the hospital room wall. The unit is connected to the hospital plumbing and sewer systems, as well as, the hospital vacuum system. The unit remains on the customer site for 2 – 4 weeks, as contracted, at no cost to the customer. However, the customer does purchase the disposable kits necessary to effectively operate the units. Once the trial period has expired the unit is either returned to the Company or purchased by the customer. If purchased, at that time, the Company invoices the customer based upon a contracted price negotiated prior to the trial.

We have never generated sufficient revenues to fund our capital requirements. We have funded our operations through a variety of debt and equity instruments. See "Liquidity and Capital Resources – Historical Financing" below. Our capital needs for the next 6 - 9 months are expected to be approximately $2 million because of our cash flow deficit. We will attempt to raise these funds through equity or debt financing, alternative offerings or other means. Our future cash requirements and the adequacy of available funds depend on our ability to sell our products. We will also continue to endeavor to negotiate to extend the maturity dates of our indebtedness, convert existing obligations into equity, settle such obligations or otherwise reduce their amounts. See "Liquidity and Capital Resources – Plan of Financing; Going Concern Qualification" below.

As a company still in 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.

Results of Operations

Comparison of Year Ended December 31, 2012 with Year Ended December 31, 2011

Revenue. We recorded revenue of $188,772 in 2012, compared to $96,637 in 2011. Revenue in 2012 included the sale of nine Streamway^{TM} systems and disposable supplies to operate the Streamway^{TM}. The revenue in 2011 included the sale of five Streamway^{TM} systems and disposable supplies to operate the Streamway^{TM}. The Company has been installing Streamway^{TM} units in hospitals for evaluation purposes, selling 100% of those installed for trial. We expect the revenue for Streamway^{TM} 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 $128,540 in 2012 compared to $56,080 in 2011. The gross profit margin was 32% in 2012 and 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 $6,286,000, for 2012 from $3,562,000 in 2011. The $2,724,000 increase in G&A expenses for 2012, compared to 2011, is primarily due to a $3,795,000 expense for investor stock compensation and $737,000 non-cash expense for stock based compensation, methods of remuneration to an investor in lieu of cash by issuing stock and/or warrants in an amount equal to the expense that was recorded in the twelve months ended December 31, 2012. Bonuses of $485,000, in stock and cash, were approved by the Board. This was partially offset by reductions in stock based consulting expenses of $2,117,000, consulting expenses of $193,000, and investor relations of $279,000. We have significantly decreased the practice of compensating consultants with stock-based instruments, in order to lessen dilution to the shareholders. Expenses may increase in 2013 if sales continue to rise as the Company will ramp up employees and office equipment as needed.

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 $761,000 in 2012 compared to $352,000 in 2011. The $409,000 increase in operations expense in 2012 is primarily due to increases of $149,000 in salaries mostly due to a severance agreement with the former COO, $77,000 in stock-based compensation and $100,000 in consulting. Bonuses of $200,000, in stock and cash, were approved by the Board. There were moderate offsets with a $120,000 reduction in manufacturing supplies as more expense was directed to research and development. Operations expense in the next several quarters is expected to increase as the Company expects to increase shipments of the Streamway™ unit as customers complete their evaluations and place orders for billable units. We expect to incur more expense in research and development as we continue to improve our product for future generation models. 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 decreased to $173,000 in 2012 compared to $233,000 in 2011. During the last several quarters, we have operated on a very slim marketing budget as a result of limited funding. The decline in 2012 is primarily the result of $94,000 in stock based compensation expense and $25,000 in commissions. Sales and marketing expense is expected to increase in the future as we expect to hire additional sales and sales support personnel and increase our trade show, promotion and travel expense significantly after in order to promote sales and train personnel.

Interest expense. Interest expense increased slightly in 2012, with $259,000 compared to $230,000 in 2011. The increase is due to additional notes incurred in 2012.

Loss (gain) on valuation of equity-linked financial instruments. The Company realized a loss of $3,100 on valuation of equity-linked financial instruments in 2012 compared to a loss of $151,000 in 2011. The loss in 2012 resulted primarily from the extension of 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, 2012

Net cash used in operating activities was $1,184,000 for 2012, compared with net cash used of $1,782,000 for 2011. The $597,000 decrease in cash used in operating activities was largely due to an increase of $3,413,000 in non-cash expenses related to equity instruments issued for management and consulting and investments, which more than offset the $2,935,000 increase in the net loss in 2012. As of December 31, 2012, we had accounts payable of $734,000 and accrued liabilities of $1,600,000. Account payable has remained virtually equal to the $731,000 of December 31, 2011. Accrued Expenses rose by $947,000 predominately due to a convertible note settled for a monthly cash payout, and performance bonuses; officer cash bonuses accounted for $497,500. Payroll Liabilities also increased as employees are owed for missed payrolls.

Cash flows used in investing activities was zero for 2012 and 2011 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 $1,074,000 for 2012 compared to net cash provided of $1,895,000 for 2011. The decrease in 2012 was primarily the result of a reduction in common stock issuance of approximately $690,000 compared to 2011. We expect to show additional cash provided by financing activities in the next few quarters provided we are successful in raising money through our investment banking firm.

Capital Resources

We had a cash balance of $13,139 as of December 31, 2012 and $122,985 as of December 31, 2011. Since our inception, we have incurred significant losses. As of December 31, 2012, we had an accumulated deficit of approximately $19,291,000.

From inception to December 31, 2012, our operations have been funded through a bank loan and private convertible debt of approximately $2,113,000 and equity investments totaling approximately $4,618,000. See "Historical Financing" below. Also, in January 2013, the Company raised an additional $300,000 from the sales of convertible notes and an additional $500,000 from the private sales of equity securities in January and March 2013.

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 $229,000 in equity and $605,000 in convertible debt in 2010, and $1,386,000 in equity and $525,000 in convertible debt in 2011 through alternative means. In 2012, the Company converted $818,000 of debt into equity, raised $3,764,000 in equity and $1,053,000 in convertible debt.

We are currently incurring operating expenses of approximately $125,000 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 $3,414,000 in debts, liabilities and cash obligations that become due in the first and second quarters of calendar 2013. 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 6 – 9 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. If successful we are planning significant capital investments, and we will have 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.

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, 2013 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.

Historical Financing

We have funded our operations through a combination of debt and equity instruments. We funded our early 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 a private common stock offering completed in October 2008. 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 $229,000 in equity and $605,000 in convertible debt.

In 2011, we raised $1,386,000 in equity and $525,000 in convertible debt, including the convertible debt investment by Dr. Sam Herschkowitz described under Item 13, "Certain Relationships and Related Party Transactions, and Director Independence."

In 2012, the Company raised $696,000 in equity and $529,000 in convertible debt, and $818,000 of debt was converted into equity. This convertible debt included advances on a convertible promissory note from SOK Partners, LLC, and an investment fund affiliated with one of our directors, for approximately $357,000. See Item 13, "Certain Relationships and Related Party Transactions, and Director Independence." On November 6, 2012, we entered into additional note purchase agreements with Dr. Samuel Herschkowitz, pursuant to which on the same date, we issued and sold convertible promissory notes in the total principal amount of $156,243 to Dr. Herschkowitz and certain of his assignees. Pursuant to the note purchase agreements, we issued to these parties an aggregate 1,562,430 shares of common stock in consideration of placement of the notes. The convertible notes bear interest at a rate of 20% per annum and are secured by a security interest in the Company's accounts receivable, patents and certain patent rights and are convertible into common stock upon certain mergers or other fundamental transactions at a conversion price based on the trading price prior to the transaction. The proceeds from this financing were used to pay off approximately $155,000 in principal amount of secured indebtedness.

The Company also raised an additional $300,000 from the sale of convertible notes in January 2013. Also, in January and March 2013, the Company raised an additional $500,000 from a second private sale of equity securities. In addition, in March 2013, the Company completed a further private sale of common stock for an aggregate purchase price of $500,000. See Note 2 to the Financial Statements.

Plan of Financing; Going Concern Qualification

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.

We are currently incurring operating expenses of approximately $125,000 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 $2,834,000 in debts, liabilities and cash obligations that become due in the first and second quarters of calendar 2013.

We may default on significant debt that becomes due on March 31, 2013 and may be unable to continue in business. We are currently indebted to Dr. Samuel Herschkowitz and SOK Partners, LLC pursuant to convertible promissory notes with balances of $240,000 and approximately $357,000, respectively, as of December 31, 2012. Pursuant to a Forbearance and Settlement Agreement with these parties dated August 15, 2012, as subsequently amended, the due date of these notes has been extended to April 30, 2013. Dr. Herschkowitz' note is secured by substantially all of the assets of the Company. If we are unable to repay these notes as of April 30, 2013 and these parties do not convert their notes, we will be in default under the notes. In that case, Dr. Herschkowitz will have rights as a secured creditor with respect to the Company's assets, which would include the right to seize the Company's assets. Further, the Company also has other significant indebtedness. If the Company defaults on its debt, it may be forced to seek bankruptcy protection and may be unable to continue in business.

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 6 - 9 months because of our cash flow deficit. We will attempt to raise these funds through equity or debt financing, alternative offerings or other means. We will also continue to endeavor to negotiate to extend the maturity dates of our indebtedness, convert existing obligations into equity, settle such obligations or otherwise reduce their amounts. If we are planning significant capital investments, and we will have human resources additions over the next 12 months. If we are unable to attend additional funds at reasonable rates or at all we will be required to substantially curtail our operations and could cease to operate in our current form.

The Company has suffered recurring losses from operations and has a stockholders' deficit. 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 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. These factors raise substantial doubt about our ability to continue as a going concern.

As a result of the above factors, our independent registered public accountant firm has indicated in their audit opinion, contained in our financial statements included in this annual report on Form 10-K that they have serious doubts about our ability to continue as a going concern. The financial statements have been prepared assuming the Company will continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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. The Company recognizes revenue in accordance with the SEC's Staff Account Bulletin Topic 13 Revenue Recognition 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. Currently we manufacture, test and ship the FMS units from our own warehouse and can easily replace or repair units as needed. Additionally, since we buy the cleaning solution/filter 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.

Off-Balance Sheet Transactions

We have 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 and Chief Financial Officer evaluated the effectiveness of our disclosure and procedures as of the end of the period covering this report. Based on this evaluation our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2012, our disclosure controls and procedures were effective.

Remediation of Material Weakness in Internal Control Structure over Financial Reporting

The material weakness that was previously disclosed as of December 31, 2011 was remediated as of June 30, 2012. See "Item 9A. Controls and Procedures - Management's Report on Internal Control Over Financial Reporting" and "Item 9A. Controls and Procedures - Remediation of Material Weakness in Internal Control Structure Over Financial Reporting" contained in the Company's report on Form 10-K for the fiscal year ended December 31, 2011 and "Item 4. Controls and Procedures" contained in the Company's subsequent quarterly reports on Form 10-Q during 2011, for disclosure of information about the material weakness that was reported as a result of the Company's annual assessment as of December 31, 2011 and remediation of that material weakness. As disclosed in the quarterly reports on Form 10-Q for the first quarter of 2011, the Company has implemented and executed the Company's remediation plans, and as of June 30, 2012, are believed to be successful in remediating.

Management's Report on Internal Control Over Financial Reporting

We are responsible for establishing and maintaining adequate internal control over financial reporting. As defined in the securities laws, internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officer and effected by our Board of Directors, management, and other personnel, 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 and includes those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the acquisitions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we carried out an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2012 based on the criteria in "Internal Control - Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based upon this evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2012.

This annual report does not include an attestation report of Olsen, Thielen & Co., Ltd., our independent registered public accounting firm, regarding internal control over financial reporting. Our management report was not subject to attestation by our independent registered public accounting firm pursuant to Section 989G of the Dodd-Frank Wall Street Reform and Consumer Protection Act, which exempts smaller reporting companies from the independent registered public accounting firm attestation requirement.

Changes in Internal Control Over Financial Reporting

There has not been any change in our internal control over financial reporting during our fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Other than the information included below and 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 2013 Annual Meeting of Shareholders.

Our Board of Directors has adopted a Code of Ethics applicable to all directors, officers and employees, including our CEO and senior financial officers. The Code of Ethics is available in print to any stockholder requesting a copy in writing from our corporate secretary at our executive offices set forth on the cover page of this Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by Item 11 is incorporated herein by reference to the sections entitled "Executive Compensation," 2012 Director Compensation," and "Compensation Committee," all of which will appear in our definitive proxy statement for our 2013 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 2013Annual Meeting of Shareholders.

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

The information required under Item 404 of Regulation S-K is included below. The information required under Item 407(a) of Regulation S-K 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 2013 Annual Meeting of Shareholders.

Certain Transactions

The Company entered into agreements, in 2008, with our Chairman of the Board, Lawrence Gadbaw, and in 2009 with a 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 received 277,778 shares at $.09 per share in June 2012 as compensation in lieu of the $25,000 cash for raising $3 million in new equity. Mr. Gadbaw was paid the balance due under his separation agreement from 2008. This amount was $46,000 upon signing the agreement in 2008 payable at $2,000 per month; the payments to Mr. Gadbaw are complete. Mr. Gadbaw is due $10,000 in accounts payable as of December 31, 2012 pertaining to his monthly fee as Chairman of the Board of Directors. Mr. Gadbaw also received a warrant for 30,000 shares at $.15 per share in June 30, 2012 as compensation for service as Chairman.

Convertible Note Purchase Agreements with Dr. Samuel Herschkowitz and SOK Partners, LLC

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 and Ricardo Koenigsberger, a director, is a holder of membership units 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 is 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. The balances of the Samuel Herschkowitz and SOK Partners notes are $240,000 and $357,282, respectively.

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 new member to the Company's Board of Directors, who will be appointed upon request. Mr. Koenigsberger was appointed to the Board by SOK Partners on June 25, 2012.

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. Further, on December 22, 2011 in agreement with Dr. Herschkowitz, the Company had issued 7,500,000 shares for him to hold should the Company default on his original Note Purchase Agreement. Due to the occurrence of an "event of default" under Dr. Herschkowitz's convertible promissory note, on April 24, 2012, and in accord with the forbearance and settlement agreement described below, we conceded the 7,500,000 shares to Dr. Herschkowitz as penalty shares pursuant to his Note Purchase Agreement with the Company. Effective August 15, 2012 the Company entered into a settlement and forbearance agreement relating to the defaults under the note and other matters. Among other things, the Company issued 26.5 million shares of common stock to Dr. Herschkowitz and SOK Partners and adjusted the conversion price of the notes held by such parties, in exchange for forbearance from Dr. Herschkowitz asserting his rights as a secured creditor, an extension of the due dates of the notes and other consideration. See "Letter Agreement With Investors Regarding Forbearance and Dilution Protection" below.

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 was appointed the Interim CEO, President and CFO on April 24, 2012. On July 22, 2012 Mr. Kornberg was approved by the Board of Directors as the Company's CEO/President. Both the Samuel Herschkowitz and SOK Partners agreements have been extended until March 31, 2013. The agreement was amended a second time the due date extended to April 30, 2013.

Letter Agreement With Affiliates of Dr. Herschkowitz and SOK Partners Regarding Forbearance and Dilution Protection.

Effective August 15, 2012, the Company entered into a letter agreement with Dr. Samuel Herschkowitz, his affiliate, Atlantic Partners Alliance ("APA"), and SOK Partners, LLC ("SOK"), an investment partnership. Dr. Herschkowitz and Joshua Kornberg, the Chief Executive Officer of the Company, are managers of APA and SOK Partners. The letter agreement modifies terms of the Herschkowitz Note Purchase Agreement and the SOK Note Purchase Agreement. Among other things, (i) Dr. Herschkowitz agreed to forbear from asserting his rights as a secured creditor to substantially all of the Company's assets, resulting from the Company's defaults; (ii) the Company agreed to issue shares of common stock to Dr. Herschkowitz and SOK and adjust the conversion price of their convertible notes to satisfy the Company's obligations to adjust for dilution; (iii) Dr. Herschkowitz and SOK agreed to extend the maturity of their notes; (iv) The Company agreed to pay certain compensation to Dr. Herschkowitz upon the achievement of financial milestones and (v) Dr. Herschkowitz clarified and waived certain of his rights, including the right to interest at a penalty rate upon default.

Dilution Protection. The Company and APA were parties to a letter agreement dated March 14, 2012, providing APA and its affiliates (including Dr. Herschkowitz and SOK) with rights to avoid dilution relating to additional issuances of equity securities by the Company through July 14, 2012, evidencing the parties' intent that APA would be provided with significant protection against dilution. This protection was in recognition of APA's investments in the Company involving a high degree of risk and the Company's contemplated need for restructuring its indebtedness, which were anticipated to result, and have resulted, in significant dilution. The parties acknowledged that Dr. Herschkowitz and SOK would not have made their historical cash investments in the Company to the same degree had the dilution protection not been provided, and the investments by these parties have enabled the Company to avoid insolvency. Since the respective dates of the Herschkowitz Note Purchase Agreement and the SOK Note Purchase Agreement, the Company has issued in excess of 16,000,000 shares of common stock to parties other than APA and its affiliates, resulting in significant dilution.

Default Notice. Pursuant to a letter dated April 20, 2012 and as disclosed in the Form 10-Q for the quarter ended March 31, 2012, Dr. Herschkowitz advised the Company of the occurrence of numerous events of default under the terms of the Herschkowitz Note and the Herschkowitz Note Purchase Agreement. As a result of such events of default, Dr. Herschkowitz asserted significant rights as a secured creditor of the Company, including his rights as a secured creditor with a security interest in substantially all assets of the Company. Without a settlement relating to the defaults and other matters, Dr. Herschkowitz could have taken action to levy upon the Company's assets, including patents and other intellectual property.

Terms of Letter Agreement Relating to Settlement.

Forbearance. In the letter agreement, Dr. Herschkowitz agrees to forbear from exercising any of his rights arising under the Herschkowitz Note or the Herschkowitz Note Purchase Agreement with respect to the existing defaults against the Company, subject to the limitations set forth in the letter agreement and without releasing or waiving any future breach of the letter agreement. He further agrees to forbear from exercising any rights with respect to events of default, security interests in the collateral and other similar remedies against the Company or his interests under the Herschkowitz Note or the Herschkowitz Note Purchase Agreement until the occurrence of an event of default in the Herschkowitz Note: (a) that does not constitute an existing default and (b) occurs and accrues after the effective date of the letter agreement.

Penalty Shares; No Penalty Interest. Dr. Herschkowitz and the Company acknowledge that 7.5 million shares of the Company's common stock, constituting the "penalty shares" under the Herschkowitz Note Purchase Agreement, were delivered to Dr. Herschkowitz in April 2012 as provided in the Herschkowitz Note Purchase Agreement upon an event of default. Notwithstanding a provision that would have increased the rate of interest from 20% to 24% upon an event of default, Dr. Herschkowitz agreed that the Company would not pay the increased rate of interest but would accrue interest at 20% until a subsequent event of default.

Extension of Due Dates and Other Amendments to Notes. The Herschkowitz Note and the SOK Note were amended as follows: (i) the due dates of the notes are extended to December 31, 2012, from the previous due dates of June 20, 2012 and August 28, 2012, respectively; (ii) Dr. Herschkowitz will release his security agreement after payment of all currently outstanding promissory notes to parties other than SOK; and (iii) the Herschkowitz Note was amended to add certain events of default relating to judgments against the Company or other creditors taking action with respect to the collateral. In December 2012, Dr. Herschkowitz and SOK Partners agreed to further extend the due date of the Herschkowitz Note and the SOK Note, respectively, through March 31, 2013. In March 2013, the due date was extended to April 30, 2013.

Adjustment for Dilution. APA and its affiliates agreed to terminate the letter agreement regarding dilution dated March 14, 2012. In consideration of the various provisions of the letter agreement and in recognition of the understanding of the parties regarding dilution and the agreements of APA and its affiliates to forebear and to extend the due dates of the notes, the Company (i) issued 13,250,000 shares to Dr. Herschkowitz, (ii) issued 13,250,000 shares to SOK, and (iii) the conversion price of the Herschkowitz Note and the SOK Note were changed to $0.014 per share from $0.065 per share. Based on the principal balance and accrued interest through June 30, 2012 as a result of the adjusted conversion price, the Herschkowitz Note and the SOK Note in the aggregate were convertible into approximately 42.7 million shares of common stock.

Milestone Fees. In the event that the Company consummates the following series of transactions on or prior to June 30, 2013: (i) a merger or similar transaction with a public shell company, (ii) raising between $2 million and $4 million through an offering of the securities of the public shell company concurrent with or subsequent to the shell merger and (iii) listing the Company's shares on NASDAQ pursuant to an underwritten offering of the Company's securities resulting in gross proceeds of between $5 million and $30 million then the Company shall deliver to Dr. Herschkowitz the following compensation: (A) $75,000 upon consummating the shell merger, (B) $150,000 upon consummating the qualifying financing round and (C) 3% of the gross proceeds of the NASDAQ underwriting, which payment shall under no circumstances be less than $200,000 or greater than $1,000,000. The Company shall reimburse Dr. Herschkowitz at his actual out-of-pocket cost for reasonable expenses incurred in connection with the shell transactions but in no event in an amount greater than $10,000. On March 6, 2013 the due date for the convertible notes was extended to April 30, 2103. In consideration of the extension additional milestone fees were included in the agreement: (i) financing raising not less than $1 million, compensation of $75,000; (ii) a going private transaction, compensation of $200,000 and (iii) 3% of the gross proceeds of the NASDAQ underwriting, which payment shall under no circumstances be less than $200,000 or greater than $3,000,000.

Share Ownership and Control. As a result of the transactions under the letter agreement, Dr. Herschkowitz, SOK and their affiliates currently own 45,040,769 outstanding shares of common stock and hold derivative securities representing an additional 44,450,718 shares of common stock. Their beneficial ownership currently represents 66% of the Company's outstanding common stock, giving such parties significant control over election of the Board of Directors and other matters.

Additional Investments by Dr. Herschkowitz and Assignees

On November 6, 2012, we entered into additional note purchase agreements with Dr. Samuel Herschkowitz, pursuant to which on the same date, we issued and sold convertible promissory notes in the total principal amount of $156,243 to Dr. Herschkowitz and certain of his assignees. Pursuant to the note purchase agreements, we issued to these parties an aggregate 1,562,430 shares of common stock in consideration of the notes. The convertible notes bear interest at the rate of 20% per annum and are secured by a security interest in the Company's accounts receivable, patents and certain patent rights and are convertible into common stock upon certain mergers or other fundamental transactions at a conversion price based on the trading price prior to the transaction. The proceeds from the financing were used to pay off approximately $155,000 in principal amount of secured indebtedness.

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 2013 Annual Meeting of Shareholders.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

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

(1) Financial Statements

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

- Report of Independent Registered Public Accounting Firm dated March 22, 2013;
- Balance Sheets as of December 31, 2012 and December 31, 2011;

- Statements of Operations for the Years Ended December 31, 2012 and December 31, 2011and from April 23, 2002 (Inception) to December 31, 2012;
- Statements of Stockholders' Deficit from April 23, 2002 (Inception) to December 31, 2012;
- Statements of Cash Flows for the Years Ended December 31, 2012 and December 31, 2011 and from April 23, 2002 (Inception) to December 31, 2012; and
- Notes to Financial Statements.

(2) Financial Statement Schedules

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

(3) Exhibits

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

SIGNATURES

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

Dated: March 22, 2013

BioDrain Medical, Inc.

By /s/ Joshua Kornberg
Joshua Kornberg
President, Chief Executive Officer and Director

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/ Joshua Kornberg Joshua Kornberg	President, Chief Executive Officer and Director (principal executive officer)	March 22, 2013
/s/ Bob Myers Bob Myers	Chief Financial Officer (principal financial officer)	March 22, 2013
/s/ Lawrence W. Gadbaw Lawrence W. Gadbaw	Chairman of the Board	March 22, 2013
/s/ Andrew P. Reding Andrew P. Reding	Director	March 22, 2013
/s/ Peter L. Morawetz Peter L. Morawetz	Director	March 22, 2013
/s/ Ricardo Koenigsberger Ricardo Koenigsberger	Director	March 22, 2013
/s/ Thomas J. McGoldrick Thomas J. McGoldrick	Director	March 22, 2013

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	Note Purchase Agreement between the registrant and Dr. Samuel Herschkowitz, dated December 20, 2011 (9)
10.30	Amended and Restated Note Purchase Agreement between the registrant and Dr. Samuel Herschkowitz, effective December 20, 2011, including the form of Convertible Promissory Note (issued in the amount of $240,000) (10)
10.31	Convertible Note Purchase Agreement between the registrant and SOK Partners, LLC, dated March 28, 2012, including the form of Convertible Promissory Grid Note (10)
10.32	Forbearance and Settlement Agreement among the registrant, Dr. Samuel Herschkowitz and SOK Partners, LLC dated August 15, 2012 (13)
10.33	BioDrain Medical, Inc. 2012 Stock Incentive Plan, adopted on August 13, 2012 (12)**
10.34	Form of Non-Qualified Stock Option Agreement under the 2012 Stock Incentive Plan (13)**
10.35	Employment Agreement with Josh Kornberg dated August 13, 2012 (13)**
10.36	Non-Qualified Stock Option Agreement with Josh Kornberg dated August 13, 2012 (13)**
10.37	Employment Agreement with Robert Myers dated August 11, 2012 (13)**
10.38	Employment Agreement with David Johnson dated August 13, 2012 (13)**
10.39	Separation Agreement with Chad A. Ruwe dated August 21, 2012 (13)
10.40	Separation Agreement with Kevin Davidson effective October 11, 2012 (13)
10.41	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and BioDrain Medical, Inc. (14)
10.42	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and BioDrain Medical, Inc. (14)
10.43	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and BioDrain Medical, Inc. (14)
10.44	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and BioDrain Medical, Inc. (14)
10.45	Form of Warrants Issued on January 14, 2013 (15)
10.46	Form of Notes Issued on January 14, 2013 (15)
10.47	Amended Lease with Roseville Properties Management Company, Inc. dated January 28, 2013 (13)
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.

(9) Filed on January 24, 2012 as an exhibit to our Registration Statement on Form S-1 (File No. 333-179145) and incorporated herein by reference.

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

(12) Filed on September 4, 2012 as Appendix A to our definitive Proxy Statement for the 2012 Annual Meeting and incorporated herein by reference.

(13) Filed on February 8, 2013 as an exhibit to Amendment No. 3 to our Registration Statement on Form S-1 (File No. 333-179145) and incorporated herein by reference.

(14) Filed on November 8, 2012 as an exhibit to Amendment No. 7 to the Schedule 13D report filed by Dr. Samuel Herschkowitz, et al. and incorporated herein by reference.

(15) Filed on January 15, 2013 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, 2012, December 31, 2011 and Inception through December 31, 2012 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.
Eagan, MN

We have audited the accompanying balance sheets of BioDrain Medical, Inc. (a development stage company) as of December 31, 2012 and 2011 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, 2012. BioDrain Medical, Inc.'s management is responsible for these financial statements. 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, 2012 and 2011, and the results of its operations and its cash flows for the years then ended and from April 23, 2002 (inception) to December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

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 is also described in Note 1. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Olsen Thielen & Co., Ltd.

St. Paul, Minnesota
March 22, 2013

PART 1. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	December 31, 2012	December 31, 2011
ASSETS		
Current Assets:		
Cash	$ 13,139	$ 122,985
Accounts receivable, net of Allowance for Doubtful Accounts of $4,073 and $0 in 2012 and 2011	39,711	50,294
Inventories	145,209	97,605
Prepaid expense and other assets	27,409	30,148
Total Current Assets	225,468	301,032
Fixed assets, net	3,521	4,600
Intangibles, net	140,588	140,588
Total Assets	$ 369,577	$ 446,220
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Current portion of long-term debt (See Note 6)	$ -	$ -
Current portion of convertible debt, net of discounts of $21,138 and $28,741 (See Note 6)	1,081,187	1,055,559
Accounts payable	733,595	731,135
Accrued expenses	1,599,519	566,574
Total Current Liabilities	3,414,301	2,353,268
Long-term debt and convertible debt, net of discounts of $0 and $16,446 (See Note 6)	89,300	630,153
Liability for equity-linked financial instruments (See Note 8)	169,179	166,063
Stockholders' Deficit:		
Common stock, $.01 par value, 300,000,000 authorized, 104,247,228 and 32,074,000 outstanding	1,042,473	320,740
Additional paid-in capital	14,945,435	8,844,952
Deficit accumulated during development stage	(19,291,111)	(11,868,956)
Total Stockholders' Deficit	(3,303,203)	(2,703,264)
Total Liabilities and Stockholders' Deficit	$ 369,577	$ 446,220

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,
	2012	2011	2012
Revenue	$ 188,772	$ 96,637	$ 301,434
Cost of goods sold	128,540	56,080	191,760
Gross margin	60,232	40,557	109,674
General and administrative expense	6,285,905	3,561,566	15,750,363
Operations expense	761,047	351,662	2,290,581
Sales and marketing expense	172,970	232,716	1,061,455
Interest expense	259,349	230,374	926,456
Loss (gain) on valuation of equity-linked financial instruments	3,116	151,118	(628,070)
Total expense	7,482,387	4,527,436	19,400,785
Net loss available to common shareholders	$ (7,422,155)	$ (4,486,879)	$ (19,291,111)
Loss per common share - basic and diluted	$ (0.11)	$ (0.18)	$ (1.59)
Weighted average shares used in computation - basic and diluted	69,587,814	24,282,433	12,143,184

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, 2012

	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 anti-dilution provisions	205,899	2,059	(2,059)		-
Shares issued to pay investor relations services 6/23/08, $.35	250,000	2,500	85,000		87,500
Vested stock options and warrants			354,994		354,994
Capital contributions resulting from waivers of debt			129,684		129,684
Net loss				(1,762,628)	(1,762,628)
Balance 12/31/08	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 2009, $.50	2,147,810	21,478	1,052,427		1,073,905
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 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 2010 under PPM, $.50	354,550	3,546	173,729		177,275
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 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, $.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 at $.075 per share under PPM	5,333,334	53,334	346,666		400,000
Shares issued at $.085 per share under PPM	1,882,353	18,823	141,177		160,000
Shares issued at $.09 per share under PPM	200,000	2,000	16,000		18,000
Shares issued at $.10 per share under PPM	150,000	1,500	13,500		15,000
Vested stock options and warrants in first quarter			1,937,638		1,937,638
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	158,036	1,580	20,920		22,500
Shares issued at $.07 per share under PPM	1,071,429	10,715	64,285		75,000
Stock issued upon conversion of debt and interest	941,034	9,410	22,590		32,000
Equity instruments issued to consultants			12,256		12,256
Equity instruments issued to consultants			147,116		147,116
Restricted stock issued to consultants	822,842	8,228	46,772		55,000
Shares issued at $.06 per share under PPM	3,500,000	35,000	175,000		210,000
Shares issued at $.20 per share under PPM	1,375,000	13,750	261,250		275,000
Shares issued upon exercise of stock options at $.01	100,000	1,000			1,000
Shares issued at $.35 per share IR compensation	575,000	5,750	195,500		201,250
Equity instruments upon conversion of Accounts Payable			20,000		20,000
Shares issued to private investor 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)
Shares issued to institutional investor upon conversion of Note Payable at $.1342 per share	59,613	596	7,404		8,000
Shares issued to institutional investor upon conversion of Note Payable at $.13 per share	107,692	1,077	12,923		14,000
Shares issued to institutional investor upon conversion of Note Payable at $.088 per share	170,455	1,705	13,295		15,000
Shares issued to institutional investor upon conversion of Note Payable at $.0446 per share	343,348	3,433	12,567		16,000
Shares issued to institutional investor upon conversion of Note Payable at $.0446 per share	269,058	2,690	9,310		12,000
Shares issued to institutional investor upon conversion of Note Payable at $.0446 per share	268,670	2,687	7,313		10,000
Shares issued to institutional investor upon conversion of Note Payable at $.0397 per share	428,212	4,282	4,218		8,500
Shares issued to a private investor at $.065 per share	9,230,770	92,308	507,692		600,000
Shares issued for consulting to the then interim CEO at $.065 per share	300,000	3,000	16,500		19,500
Vested stock options and warrants			830,372		830,372
Shares issued to an institutional investor upon conversion of Note Payable at $.0286 per share	349,650	3,497	6,503		10,000
Shares issued to a private investor per a convertible note default at $.15 per share	7,500,000	75,000	1,050,000		1,125,000
Shares issued to a private investor at $.15 per share	263,333	2,633	36,867		39,500
Shares issued upon exercise of options at $.01 per share	412,963	4,130			4,130
Stock issued upon conversion of debt at $.15 per share	3,292,557	32,926	460,958		493,884
Stock issued upon conversion of debt at $.065 per share	2,850,754	28,508	156,791		185,299
Shares issued to private investor upon conversion of Note Payable at $.18 per share	316,898	3,169	53,873		57,042
Shares issued to private investor upon conversion of Note Payable at $.052 per share	1,147,078	11,471	48,063		59,534
Shares issued to private investor upon conversion of Note Payable at $.10 per share	565,834	5,658	50,926		56,584
Shares issued to a private investor upon conversion of Note Payable at $.032 per share	1,572,327	15,723	34,277		50,000
Shares issued to an institutional investor upon conversion of Note Payable at $.031 per share	387,097	3,871	8,129		12,000
Stock issued upon conversion of debt at $.15 per share	397,267	3,973	55,617		59,590
Shares issued to a Director as compensation at $.09 per share	277,778	2,778	22,222		25,000
Shares issued under PPM at $.07 per share	9,870,666	98,707	592,239		690,946
Shares issued to institutional investor upon conversion of Note Payable at $.0353 per share	509,915	5,099	12,901		18,000
Shares issued to a private investor upon conversion of Note Payable at $.032 per share	283,718	2,837	6,185		9,022
Shares issued to an institutional investor upon conversion of Note Payable at $.0297 per share including $11,021 of interest.	740,741	7,407	25,614		33,021
Shares issued at $.15 per share as Investor Relations compensation	625,000	6,250	87,500		93,750

Shares issued as settlement to remove anti-dilution agreement at $.065 per share	26,500,000	265,000	1,457,500		1,722,500
Shares issued in settlement with former COO at $.15 per share less shares cancelled at $.09 per share	803,701	8,037	134,296		142,333
Equity value for options and warrants			150,189		150,189
Shares issued at $.07 per share as Investor Relations compensation	300,000	3,000	18,000		21,000
Shares issued at $.15 per share as conversion of debt	157,088	1,571	21,992		23,563
Shares issued to a private investor exercising options at $.01 per share	71,826	718			718
Shares issued to debtors as compensation at $.10 per share	1,563,031	15,630	140,613		156,243
Value of equity instruments issued with debt			33,469		33,469
Shares issued upon conversion of Note Payable at $.07 per share	236,092	2,361	14,165		16,526
Share true-up to certified shareholders list per the stock transfer agency	100	1			1
Net loss				(7,422,155)	(7,422,155)
Balance at 12/31/2012	104,247,228	$ 1,042,473	$ 14,945,435	$ (19,291,111)	$ (3,303,203)

(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% finder's 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)
	2012	2011	To December 31, 2012
Cash flow from operating activities:			
Net loss	(7,422,155)	(4,486,879)	(19,291,111)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,079	3,175	10,644
Vested stock options and warrants	830,372	1,937,638	3,497,672
Equity instruments issued for management and consulting	3,919,828	507,126	5,789,768
Stock-based registration payments	-	-	355,124
Capital contributions resulting from waivers of debt	-	-	476,398
Amortization of debt discount	57,518	112,031	342,802
(Gain) loss on valuation of equity-linked instruments	3,116	151,118	(628,070)
Changes in assets and liabilities:			
Accounts receivable	10,583	(50,294)	(39,711)
Inventories	(47,604)	(97,605)	(145,209)
Prepaid expense and other assets	2,739	(22,022)	(27,409)
Notes payable to shareholders	-	-	(14,957)
Accounts payable	421,104	71,714	1,718,839
Accrued expenses	1,039,255	92,367	1,717,689
Net cash used in operating activities:	(1,184,165)	(1,781,631)	(6,237,531)
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	528,525	525,500	2,112,491
Repayment of convertible debt	(150,000)	-	(250,000)
Principal payments on long-term debt	-	(16,267)	(75,667)
Issuance of common stock	695,794	1,386,000	4,618,599
Net cash provided by (used in) financing activities	1,074,319	1,895,233	6,405,423
Net increase (decrease) in cash	(109,846)	113,602	13,139
Cash at beginning of period	122,985	9,383	-
Cash at end of period	13,139	122,985	13,139
Non cash transactions:			
Conversion of debt to accrued liabilities	100,000	-	100,000
Common stock issued for accrued interest/bonus	106,310	24,500	218,170
Conversion of accounts payable to convertible debt	-	89,300	546,600
Common stock issued to satisfy debt	817,800	50,000	1,041,799
Stock/warrant issued to satisfy accounts payable/Liabilities	418,644	20,000	438,644

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 has developed an environmentally safe system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. The Company also makes ongoing sales of our proprietary cleaning fluid to users of our systems. In April 2009, the Company received 510(k) clearance from the FDA to authorize the Company to market and sell its STREAMWAY® FMS products.

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.

Since inception to December 31, 2012, the Company raised approximately $4,619,000 in equity and $2,112,000 in debt financing, including $696,000 in equity and $529,000 in convertible debt in 2012. The Company is currently engaged in a private placement of units of common stock and warrants. The Company is also engaged in a corporate restructuring, including actively seeking to convert indebtedness into equity. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources".

Recent Accounting Developments

We reviewed all 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 350- *Intangibles – Goodwill and Other*, 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 2012 and $1,100 in 2011.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs were approximately $15,000 and $0 for 2012 and 2011, respectively.

Revenue Recognition

The Company recognizes revenue in accordance with the SEC's Staff Accounting Bulletin Topic 13 Revenue Recognition and ASC 605- 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 STREAMWAY 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 STREAMWAY FMS unit or significant quantities of cleaning solution kits may be returned. Additionally, since the Company buys both the STREAMWAY 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 provides for probable uncollectible amounts through charges to earnings and credits to the valuation based on management's assessment of the current status of individual accounts, changes to the valuation allowance have not been material to the financial statements.

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, 2012	December 31, 2011
Finished goods	$ 91,008	$ 94,331
Raw materials	39,543	3,274
Work-In-Process	14,658	0
Total	$ 145,209	$ 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 2009 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 approximately $22,000 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 $8,980 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.

Subsequent Events

Other Restructuring and Financing. The Company has completed an ongoing restructuring process negotiating with a significant number of creditors other than Dr. Herschkowitz and SOK to convert their indebtedness into common stock. The Company has also made other private sales of securities. On January 13, 2013 the Company completed the private sale of 8% convertible one (1) year promissory notes in the aggregate principal amount of $300,000 and warrants to purchase up to an aggregate of 2,500,000 shares of the corporation's common stock at an exercise price of $0.15 per share. Also, in January 2013, the Company initiated a second private sale of securities selling common stock ($.01 par value) at $.07 price per share with a warrant for an equal number of shares at an exercise price of $.15 per share. The Company has raised $500,000 from this private placement. The Company has evaluated all other subsequent events through the date of this filing.

On March 15, 2013 the Company completed the private sale of 7,142,858 shares of the Company's common stock, par value $.01 per share, at $.07 per share for an aggregate purchase price of $500,000, warrants to purchase 7,142,858 shares of common stock at an exercise price of $0.08 per share, and warrants to purchase 3,571,429 shares at an exercise price of $0.15 per share.

NOTE 2 – DEVELOPMENT STAGE OPERATIONS

The Company was formed April 23, 2002. Since inception through December 31, 2012, 104,247,228 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 8) 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 was 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 was $96,613. This value was 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 had 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 had 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 was 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.

In November 2012, the Company issued four convertible notes of $27,500, $27,500, $51,243 and $50,000, respectively. The note holders were issued shares of our common stock at $.10 per share value in consideration for the notes. Though short term the value of the notes are being treated as a debt discount with an aggregate discount of $33,469 and amortized as additional interest expense over the six month term of the notes.

For grants of stock options and warrants in 2012 the Company used a 0.33% to 1.80% risk-free interest rate, 0% dividend rate, 54%, 59% or 66% volatility and estimated terms of 3, 5 or 10 years. Value computed using these assumptions ranged from $0.0111 to $0.096 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
Issued	9,514,286	0.08	11,688,166	0.15
Expired	(2,235,368)	0.11	(3,366,455)	0.50
Exercised	(412,963)	0.01	(71,826)	0.01
Outstanding at December 31, 2012	12,663,566	$ 0.09	35,132,136	$ 0.13

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

At December 31, 2012, 11,200,602 stock options are fully vested and currently exercisable with a weighted average exercise price of $0.09 and a weighted average remaining term of 7.63 years. There are 35,132,136 warrants that are fully vested and exercisable. Stock-based compensation recognized in 2012 and 2011was $830,372 and $1,937,638, respectively. The Company has $108,278 of unrecognized compensation expense related to non-vested stock options that are expected to be recognized over the next 19 months.

The following summarizes the status of options and warrants outstanding at December 31, 2012:

	Range of Exercise Prices	Shares	Weighted Average Remaining Life
Options:			
$	0.01	1,414,280	3.50
$	0.07	214,286	9.69
$	0.08	9,300,000	9.63
$	0.15	1,210,000	2.39
$	0.35	525,000	0.57
Total		12,663,566	
Warrants:			
$	0.01	200,000	3.46
$	0.075	8,657,746	1.34
$	0.10	3,128,572	1.35
$	0.12	500,000	1.33
$	0.13	631,429	1.38
$	0.15	12,133,999	4.30
$	0.16	500,000	1.27
$	0.17	1,882,353	1.27
$	0.18	200,000	1.11
$	0.20	2,532,739	1.08
$	0.25	1,375,000	1.74
$	0.35	150,000	0.50
$	0.46	2,685,748	0.41
$	0.65	554,550	0.19
Total		35,132,136	

Stock options and warrants expire on various dates from January 2013 to September 2022.

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.

The shareholders approved an increase in authorized shares to 300 million shares in a special shareholder meeting held on January 15, 2013.

Stock Options and Warrants Granted by the Company

The following table is the listing of stock options and warrants as of December 31, 2012 by year of grant:

Stock Options:

Year	Shares	Price
2008	993,292	$ .01-.35
2009	75,000	.35
2010	1,210,000	.15
2011	870,988	.01
2012	9,514,286	.07 - .08
Total	12,663,566	$ .01- .35

Warrants:

Year	Shares	Price
2008	1,592,858	$ .13-.46
2009	193,207	.13
2010	3,435,662	.01-.65
2011	18,222,243	.075-.25
2012	11,688,166	.10 -.20
Total	35,132,136	$ .01-.65

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, 2012	Year Ended December 31, 2011	From April 23, 2002 (Inception) To December 31, 2012
Numerator:			
Net loss available in basic and diluted calculation	$ (7,422,155)	$ (4,486,879)	$ (19,291,111)
Denominator:			
Weighted average common shares outstanding-basic	69,587,814	24,282,433	12,143,184
Effect of dilutive stock options and warrants (1)	-	-	-
Weighted average common shares outstanding-diluted	69,587,814	24,282,433	12,143,184
Loss per common share-basic and diluted	$ (0.11)	$ (0.18)	$ (1.59)

(1) The number of shares underlying options and warrants outstanding as of December 31, 2012 and December 31, 2011 are 47,795,702 and 32,679,862, 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, 2012, were approximately $9,470,000 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, 2012 and December 31, 2011are as follows:

	December 31, 2012	December 31, 2011
Deferred Tax Asset:		
Net Operating Loss	$ 2,209,000	$ 1,564,000
Other	73,000	49,000
Total Deferred Tax Asset	2,282,000	1,613,000
Less Valuation Allowance	2,282,000	1,613,000
Net Deferred Income Taxes	$ —	$ —

NOTE 6 – LONG-TERM DEBT

Long-term debt is as follows:

	December 31, 2012	December 31, 2011
Notes payable to two individuals, net of discounts of $0 and $1,341 with interest only payments at 12% to March 2012 when the remaining balance is payable. The notes were renegotiated on December 31, 2012.	—	98,659
Note payable issued on October 26, 2009, net of a discount of $0 and $0 discount, with interest at 8% to March 31, 2012 when the remaining balance was payable and convertible into shares of common stock at $.35 per share. The note was renegotiated in February 2013.	100,000	100,000
Notes payable issued to two individuals in January 2010. The notes bear interest at 8%, mature March 31, 2012 and were convertible into shares of common stock at 50% of the weighted average closing bid price over any 10 consecutive days of trading. Both notes were converted in May 2012, for 1,147,178 and 1,856,045 shares, respectively.	—	100,000
Note payable issued on June 12, 2010, net of a discount of $0 and $14,931. The note bears interest at 12% to March 31, 2012 when the remaining balance was payable, and is convertible into shares of common stock at $.18 per share. The note was renegotiated in February 2013.	200,000	185,069
Note payable issued on June 14, 2011 to an institutional investor. The note bears interest at 8%, matures June 14, 2012 and was convertible into shares of common stock at 55% of the average of the five lowest closing prices in any 10 day trading period. The note was converted in the first quarter of 2012 for 949,778 shares.	—	63,000
Note payable issued on July 12, 2011 to an institutional investor. The note bears interest at 8%, matures April 16, 2012 and was convertible into shares of common stock at 60% of the average of the five lowest closing prices in any 10 day trading period. The note was converted over the first two quarters of 2012 for 1,046,920 shares.	—	37,500
Note payable issued on September 16, 2010 to an institutional investor. The note bears interest at 10%, matures March 15, 2012 and was convertible into shares of common stock at $.18 per share. The note was paid off in November 2012, and replaced by four convertible notes due April 6, 2013; see below.	—	100,000
Note payable issued on December 23, 2010, net of a discount of $0 and $4,960. The note bears interest at 10%, matures December 23, 2012 and was convertible into shares of common stock at $.084 per share. The note was renegotiated in February 2013.	16,800	11,840
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. The note was converted in May 2012 along with a $185,299 Accounts Payable debt to the same note holder for 6,143,311 shares distributed to five shareholders.	—	457,300
Note payable issued on September 21, 2010 to the parents of one of the Company's directors, net of a discount of $0 and $0. The note bears interest at 12%, matures March 30, 2012 and was convertible into shares of common stock at $.18 per share. The note was renegotiated in February 2013.	32,000	32,000
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. Two of the notes have been converted into 565,834 and 316,898 shares, respectively. The third note was paid off and replaced by four convertible notes due April 6, 2013; see below.	—	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	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. The note was converted in June 2012 for 1,637,753 shares.	—	50,000
On November 6, 2012 the Company issued four convertible notes at 20% interest, each, net of an aggregate discount of $21,138, due on April 6, 2013.	122,774	—
Total	560,874	1,450,714
Less amount due within one year	471,574	820,561
Long-Term Debt	$ 89,300	$ 630,153

Cash payments for interest were $31,008 and $280 for 2012 and 2011, respectively.

Principal payments required during the years 2013 to 2015 are as follows:

2013	$	492,712
2014	$	0
2015	$	89,300

The four renegotiated notes above, totaling $450,958 in principal and interest, will be paid for the next three (3) years as follows: $67,500 in 2013, $90,000 in 2014 and $97,500 in 2015. The remaining balance including attorney's fees and interest is due on February 1, 2016. The debt is secured by 1 million shares of common stock held in escrow. The escrow account releases 1/3 or 333,333 shares per year to the Company if there is no default. If a default occurs the entire amount of stock left in escrow at the time of default is released to the former note holders.

NOTE 7 – RENT OBLIGATION

The Company leases its principal office under a lease that can be cancelled after three years with proper notice per the lease and an amortized schedule of adjustments that will be due to the landlord. The lease extends five years and expires January 2018. In addition to rent, the Company pays real estate taxes and repairs and maintenance on the leased property. Rent expense was $45,961 and $49,975 for 2012 and 2011, respectively.

The Company's rent obligation for the next five years are as follows:

2013	$	32,000
2014	$	36,000
2015	$	37,000
2016	$	38,000
2017	$	39,000

NOTE 8 – 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 2012 and 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 an increase in the liability for existing warrants during 2011 primarily due to a reduction in the spread between the exercise price and the market price of the underlying shares. In 2012, there was a slight increase to the liability due to the extension of warrants.

The inputs to the Black-Scholes model during 2009 through 2012 were as follows:

Stock price	$ .05 to $.50
Exercise price	$ .01 to $.65
Expected life	.50 to 9.67 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	2012 Gain (Loss)	Value at12/31/2012
January 1, 2009 adoption	$ 479,910	$ (390,368)	$ 870,278	$ 868,772	$ 1,506	$ (88,290)	$ 89,796	$ (21,856)	$ 111,652
Warrants issued in quarter ended 6/30/2009	169,854	20,847	149,007	147,403	1,604	(4,689)	6,293	6,293	-
Warrants issued in quarter ended 9/30/2009	39,743	(738)	40,481	40,419	62	(1,562)	1,624	910	714
Warrants issued in quarter ended 12/31/2009	12,698	617	12,081	12,053	28	(724)	752	415	337
Subtotal	702,205		1,071,847						
Warrants issued in quarter ended 3/31/2010	25,553			25,014	539	(5,571)	6,109	3,701	2,408
Warrants issued in quarter ended 6/30/2010	31,332			30,740	592	(6,122)	6,714	6,083	631
Warrants issued in quarter ended 9/30/2010	31,506			20,891	10,615	(44,160)	54,775	1,338	53,437
Total	$ 790,596	$ (369,642)	$ 1,071,847	$ 1,145,292	$ 14,946	$ (151,118)	$ 166,063	$ (3,116)	$ 169,179

NOTE 9 - RELATED PARTY TRANSACTIONS

The Company entered into agreements, in 2008, with our Chairman of the Board, Lawrence Gadbaw, and in 2009 with a 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 received 277,778 shares at $.09 per share in June 2012 as compensation in lieu of the $25,000 cash for raising $3 million in new equity. Mr. Gadbaw was paid the balance due under his separation agreement from 2008. This amount was $46,000 upon signing the agreement in 2008 payable at $2,000 per month; the payments to Mr. Gadbaw are complete. Mr. Gadbaw is due $10,000 in accounts payable as of December 31, 2012 pertaining to his monthly fee as Chairman of the Board of Directors. Mr. Gadbaw also received a warrant for 30,000 shares at $.15 per share in June 30, 2012 as compensation for service as Chairman.

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 and Ricardo Koenigsberger, a director, is a holder of membership units 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 is 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. The balances of the Samuel Herschkowitz and SOK Partners notes are $240,000 and $357,282, respectively, as of the month ended September 30, 2012. See “Part II Other Information; Item 5 Other Information”.

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 March 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. In May 2012 the Company issued the second installment consisting of 4,615,385 shares of common stock subsequent to SOK Partners surpassing the aggregate advances of $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 new member to the Company's Board of Directors, who will be appointed upon request. Mr. Koenigsberger was appointed to the Board by SOK Partners on June 25, 2012.

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 were transferred to Dr. Herschkowitz effective in April 2012, upon the occurrence of an event of default on the note. On August 13, 2012, the Company entered into a settlement and forbearance agreement (the "Forbearance Agreement") relating to the defaults under the note and other matters.

Under the Forbearance Agreement, among other things, (i) Dr. Herschkowitz agreed to forbear from asserting his rights as a secured creditor to substantially all of the Company's assets, resulting from the Company's defaults; (ii) the Company issued an aggregate 26.5 million shares of common stock to Dr. Herschkowitz and SOK and adjusted the conversion price of their convertible notes to $0.014 per share from $0.065 per share, to satisfy the Company's obligations to adjust for dilution; (iii) Dr. Herschkowitz and SOK agreed to extend the maturity of their notes to December 31, 2012; (iv) the Company agreed to pay certain compensation to Dr. Herschkowitz upon the achievement of financial milestones and (v) Dr. Herschkowitz clarified and waived certain of his rights, including the right to interest at a penalty rate upon default. Based on the principal balance and accrued interest through September 30, 2012, as a result of the adjusted conversion price, the notes held by Dr. Herschkowitz and SOK in the aggregate were convertible into approximately 42.7 million shares of common stock. The terms and conditions of the Forbearance Agreement are described in the Company's Form 10-Q report for the quarter ended June 30, 2012 under "Part II Other Information; Item 5 Other Information".

On March 6, 2013 the due date for the convertible notes was extended to April 30, 2103. In consideration of the extension additional milestone fees were included in the agreement: (i) financing raising not less than $1 million, compensation of $75,000; (ii) a going private transaction, compensation of $200,000 and (iii) 3% of the gross proceeds of the NASDAQ underwriting, which payment shall under no circumstances be less than $200,000 or greater than $3,000,000.

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 was appointed the Interim CEO, President and CFO on April 24, 2012. On July 22, 2012 Mr. Kornberg was approved by the Board of Directors as the Company's CEO/President.

On November 6, 2012, the Company issued and sold convertible promissory notes in the total principal amount of $156,243 to Dr. Herschkowitz and certain of his assignees. The Company issued to these parties an aggregate 1,562,430 shares of common stock in consideration of placement of the notes. The notes bear interest at a rate of 20% per annum and are secured by a security interest in the Company's accounts receivable, patents and certain patent rights and are convertible into common stock upon certain mergers or other fundamental transactions at a conversion price based on the trading price prior to the transaction. The proceeds from this transaction were used to pay off approximately $155,000 in principal amount of secured indebtedness.

NOTE 10 – RETIREMENT SAVINGS PLANS

We have a pre-tax salary reduction/profit-sharing plan under the provisions of Section 401(k) of the Internal Revenue Code, which covers employees meeting certain eligibility requirements. In fiscal 2012, its inception year, we matched 100%, of the employee's contribution up to 4.0% of their earnings. The employer contribution was $1,654 for fiscal 2012. There were no discretionary contributions to the plan in fiscal 2012.

Schedule II

Valuation and Qualifying Accounts

(None)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements of our report, dated March 22, 2013, 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, 2012.

Registration Statement on Form S-8 Nos. 333-169556 relating to the 2008 Equity Incentive Plan; 333-175565 relating to the 2008 Equity Incentive Plan, as amended; and 333-186464 relating to the 2012 Stock Incentive Plan.

Olsen Thielen & Co., Ltd.

St. Paul, Minnesota
March 22, 2013

EXHIBIT 31.1

CERTIFICATION

I, Joshua Kornberg, 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: March 22, 2013

/s/ Joshua Kornberg
Joshua Kornberg
Chief Executive Officer (Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Bob Myers, 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 March 22, 2013

/s/ Bob Myers

Bob Myers
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, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joshua Kornberg, Chief Executive Officer, and I, Bob Myers, Chief Financial Officer, of the Company, certify, pursuant to § 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1350, that to our knowledge:

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

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

Date: March 22, 2013

/s/ Joshua Kornberg
Joshua Kornberg
Chief Executive Officer
(Principal Executive Officer)

/s/ Bob Myers
Bob Myers
Chief Financial Officer (Principal Financial Officer)