# Prospectus Supplement (To the Prospectus dated September 8, 2014)

#### SKYLINE MEDICAL INC.

## 1,049,467 shares of common stock

This Prospectus Supplement supplements and amends the prospectus dated September 8, 2014, which we refer to as the "Prospectus." The Prospectus covers the resale by certain selling stockholders of up to 1,049,467 shares of our common stock, \$.01 par value, including 210,770 shares issuable upon conversion of our preferred stock, 5,648 shares to be issued as dividends on shares of preferred stock, 480,637 shares issuable upon the conversion of convertible promissory notes, and 352,414 shares issuable upon the exercise of warrants. We will not receive any of the proceeds from the sale of the common stock by the selling stockholders. However, we will receive the proceeds of any cash exercise of the warrants, and the conversion of any notes will reduce the outstanding principal and/or interest amount of certain indebtedness. Any proceeds received from the exercise of the warrants will be used for working capital and general corporate purposes. All share numbers listed in this Prospectus Supplement reflect the 1-for-75 reverse stock split effective October 24, 2014.

This Prospectus Supplement is filed for the purpose of including in the Prospectus our Annual Report on Form 10-K for the annual period ended December 31, 2014, which was filed with the Securities and Exchange Commission on April 30, 2015. A copy of such Form 10-K is attached (although the exhibits to such report have been omitted). The information set forth on the attachment supplements and amends the information contained in the Prospectus.

This Prospectus Supplement should be read in conjunction with, and is to be delivered with, the Prospectus and is qualified by reference to the Prospectus except to the extent that the information in this Prospectus Supplement supersedes the information contained in the Prospectus.

Our securities are not listed on any national securities exchange. Our common stock is currently quoted on the OTCQB marketplace under the symbol "SKLN.QB." The last reported per share price for our common stock was \$6.25, as quoted by the OTCQB marketplace on April 29, 2015.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 3 OF THE PROSPECTUS.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this Prospectus Supplement is May 1, 2015.

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549

# FORM 10-K

$\boxtimes$	ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE YEAR ENDED DECEMBER 31, 2014.	HE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL					
	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) O TRANSITION PERIOD FROM TO	F THE SECURITIES EXCHANGE ACT OF 1934 FOR THE					
	COMMISSION FILE NUMBER: 000-54361						
SKYLINE MEDICAL INC. (Exact name of registrant as specified in its charter)							
	<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	33-1007393 (IRS Employer Identification No.)					
2915 Commers Drive, Suite 900  Eagan, Minnesota 55121  (Address and Zip Code of principal executive offices)							
	(Registrant's telephone number, includir	ng area code): (651) 389-4800					
	Securities registered pursuant to Sect	ion 12(b) of the Act: None					
	Securities registered under Section Common Stock \$.01 par value (Title of each class)	12(g) of the Act: None.  None (Name of each exchange on which registered)					
Indicate by c	heck mark if the registrant is a well-known seasoned issuer, as defined it	n Rule 405 of the Securities Act. Yes □ No 区					
Indicate by c	heck mark if the registrant is not required to file reports pursuant to Sec	tion 13 or Section 15(d) of the Act. Yes □ No 図					
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 $\boxtimes$ No $\square$							
not be contain		gulation S-K (§229.405 of this chapter) is not contained herein, and will ation statements incorporated by reference in Part III of this Form 10-K or					
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):							
Larg	ge accelerated filer   Accelerated Filer   Non-accelerated filer	l Smaller Reporting Company ⊠					
Indicate by c	heck mark whether the registrant is a shell company (as defined in Rule	12b-2 of the Act). Yes □ No ☒.					
common equ	regate market value of the voting and non-voting common equity held ity was last sold, or the average bid and asked price of such common eq cond fiscal quarter: \$22,064,456 as of June 30, 2014, based upon 1,961	uity, as of the last business day of the registrant's most recently					
	APPLICABLE ONLY TO REGISTRANTS PROCEEDINGS DURING THE PRI						
	heck mark whether the registrant has filed all documents and reports recubsequent to the distribution of securities under a plan confirmed by a						
	(APPLICABLE ONLY TO CORPO	RATE REGISTRANTS)					

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the last practicable date: As of April 24, 2015, the

registrant had 3,142,736 shares of common stock, par value \$.01 per share outstanding, adjusted for a 1-for-75 reverse stock split effective October 24, 2104, as described in Note 1 to the Condensed Financial Statements under "Nature of Operations and Continuance of Operations." In this report all number of shares, and per share amounts, as appropriate, have been restated to reflect the reverse stock split.

DOCUMENTS INCORPORATED BY REFERENCE

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#### PART I

## ITEM 1. BUSINESS.

#### Overview

Skyline Medical Inc. is a medical device company that develops and manufactures The STREAMWAY® System, a safe, environmentally conscious, innovative and cost-effective solution for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. Skyline owns patent rights to its products, has previously received 510(k) approval from the FDA, and distributes these products to hospitals, surgical centers, and other medical facilities where bodily and irrigation fluids produced during surgical procedures must be contained, measured, documented, and disposed. Skyline's products minimize the exposure potential to the healthcare workers who handle such fluids. Skyline's 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, Skyline believes its technologies provide cost savings to facilities over the aggregate costs incurred today using the traditional canister method of collection, neutralization, and disposal. Skyline currently sells its products through an experienced in-house sales force and independent distributors located throughout the United States. Skyline also intends to seek the necessary approvals to distribute its products in Europe, Asia, Latin America, Canada, and other areas outside of the U.S.

The STREAMWAY FMS is a wall mounted fully automated system that disposes of an unlimited amount of suctioned fluid providing uninterrupted performance for surgeons while virtually eliminating healthcare workers exposure to potentially infectious fluids found in the surgical environment. The system also provides an innovative way to dispose of ascetic fluid with no evac bottles, suction canisters, transport or risk of exposure. The Company also manufactures and sells two disposable products required for system operation: a bifurcated single procedure filter and tissue trap and a single use bottle of cleaning solution. Both items are used on a single procedure basis and must be discarded after use.

Skyline's virtually hands free direct-to-drain technology (a) significantly reduce the risk of healthcare worker exposure to these infectious fluids by replacing canisters, (b) further reduces 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.

Skyline believes that the STREAMWAY FMS is unique to the industry in that it allows for continuous suction to the surgical field and provides unlimited capacity to the user so no surgical procedure will ever have to be interrupted to change canisters. It is wall mounted and takes up no valuable operating room space. 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.

Skyline believes its products provide 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, continuous flow, unlimited capacity and efficiency in removal of infectious waste with minimal exposure of operating room personnel to potentially infectious material.

The Company was originally incorporated on April 23, 2002 in Minnesota as BioDrain Medical, Inc. Effective August 6, 2013, the Company changed its name to Skyline Medical Inc. Effective December 16, 2013, the Company reincorporated in Delaware through a merger with and into a Delaware Corporation with the same name that was its wholly-owned subsidiary, with such Delaware Corporation as the surviving corporation of the merger. Our address is 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121. Our telephone number is 651-389-4800, and our website address is www.skylinemedical.com. Information on our website is not included or incorporated by reference in this report.

#### **Industry and Market Analysis**

# Infectious and Bio-hazardous Waste Management

Due to the 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 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.

According to the American Hospital Association's (AHA) Hospital Statistics, 2013 edition, America's hospitals performed 86 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, 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.

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 51.6 million inpatient procedures (CDC, National Hospital Discharge Survey: 2010 table) as well as the hospital operating room market (approximately 40,000 operating rooms).

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. 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.

## Typical 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. Traditio

We believe that our virtually hands free direct-to-drain technology (a) significantly reduces the risk of healthcare worker exposure to these infectious fluids by replacing canisters, (b) further reduces the risk of worker exposure when compared to powered canister technology that requires transport to and from the operating room, (c) reduces the cost per procedure for handling these fluids, and (d) enhances 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), Cardinal Health, Inc. and Stryker Instruments have all developed systems that provide for disposal into the sanitary sewer without pouring the infectious fluids directly through a hopper disposal or using expensive gel powders and most are sold with 510(k) concurrence from the FDA. 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. 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 Automated Surgical Fluid Waste Management System suctions surgical waste fluid from the patient using standard surgical tubing. The surgical waste fluid passes through our proprietary disposable filters and into the STREAMWAY System. The STREAMWAY System maintains continuous suction to the surgical field at all times. A simple, easy to use Human Interface Display screen guides the user through the set up process, ensuring that a safe vacuum level is identified and set by the user for each procedure and additionally guides them through the cleaning process.

Fluid is collected utilizing negative pressure and passes through one tank and into another during the collection process. After a predetermined amount of fluid is sensed, a valve is activated that insulates one tank from the other, the volume of fluid is identified and recorded and the tank is emptied into the facilities sewer drainage system. During this relief, measuring and draining process, negative pressure remains constant to the field. The STREAMWAY System constantly updates and displays the fluid volume removed during the procedure which allows the surgical team to immediately assess the total amount of fluid removed from the patient at any point during the procedure.

We believe that the STREAMWAY System is unique to the industry in that it allows for continuous suction to the surgical field and provides unlimited capacity to the user so no surgical procedure will ever have to be interrupted to change canisters. It is wall mounted and takes up no valuable operating room space.

The FMS replaces 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 we believe 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 further penetrate its market segment due to its virtually hands free operation, simple design, ease of use, continuous suction, continuous flow, 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. The FMS is 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** 

				Dornoch Medical	
Feature	Skyline Medical Inc.	Stryker Instruments	DeRoval	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 dual port 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.

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 STREAMWAY System 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 is 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 also view in real time the color of the extracted or evacuated fluid through the viewing window on the system.
- Cleaning Solution. A bottle of cleaning solution, proprietary to and sold by Skyline Medical, is used for the automated cleaning cycle at the conclusion of each procedure and prepares the STREAMWAY System for the next use, reducing operating room turnover time. The cleaning solution is intended to clean the internal tubing, pathways, and chamber within the system. The cleaning solution bottle is easily attached to the STREAMWAY System by inserting the bottle into the mount located on the front of the unit and inverting the bottle. The automated cleaning process takes less than five minutes and requires minimal staff intervention. 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 Skyline Medical cleaning fluid, and only the Skyline Medical cleaning fluid, must be used with the STREAMWAY System following each surgical case. The warranty is voided if any other solution is used.
- The Disposable Kit The Skyline disposables are a critical component of our business model. The disposable kit consists of a proprietary, premeasured 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. The disposables have 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, dual 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 Skyline filter is used for every procedure. We have exclusive distribution rights to the disposable 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.
- <u>Ease of Use</u>. 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 enacts a step by step instruction with safety questions ensuring that the correct amount of suction is generated 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. The FMS is 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 Skyline. We plan to maintain exclusive agreements between Skyline 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 Skyline based on certain specified conditions.

• <u>Competitive Pricing</u>. The list sales price to a hospital or surgery center is \$21,900 per system (one per operating room - installation extra) and \$24 per unit retail for the proprietary consumable kit to the U.S. hospital market.

## **Intellectual Property**

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain protection of the proprietary aspects of our technology. We rely on a combination of patent, trade secret and other intellectual property rights and measures to protect our intellectual property.

We spent approximately \$394,000 in 2014 and \$235,000 in 2013 on research and development. On January 25, 2014 the Company filed a non-provisional PCT Application No. PCT/US2014/013081 claiming priority from the U.S. Provisional Patent Application, number 61756763 which was filed one year earlier on January 25, 2013. The Patent Cooperation Treaty ("PCT") allows an applicant to file a single patent application to seek patent protection for an invention simultaneously in each of the 148 member countries of the PCT, including the United States. By filing this single "international" patent application through the PCT system, it is easier and more cost effective than filing separate applications directly with each national or regional patent office in the various countries in which patent protection is desired.

Our PCT patent application is for an enhanced model of the surgical fluid waste management system. We utilize this enhanced technology in the updated version of the STREAMWAY FMS unit we began selling in the first quarter of 2014. We obtained a favorable International Search Report from the PCT searching authority indicating that the claims in our PCT application are patentable (i.e., novel and non-obvious) over the cited prior art. A feature claimed in the PCT application is the ability to maintain continuous suction to the surgical field while simultaneously measuring, recording and evacuating fluid to the facilities sewer drainage system. This provides for continuous operation of the STREAMWAY FMS unit in suctioning waste fluids, which means that suction is not interrupted 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 and unlimited capacity feature provides us with a significant competitive advantage, particularly on large fluid generating procedures. All competing products, except certain models of 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 while some of their models may have an unlimited capacity the process is not truly continuous like the Company's system because it requires switching the vacuum containers when one becomes full. For example, when the first container becomes full, the vacuum is switched over to a second container in order to collect the fluid in the second container while the fluid in the first container is drained. When the second container becomes full, the vacuum between containers is automated in certain MD Technology models, the automated switching is still believed to result in brief interruptions or reductions in suction during the surgical procedure.

The Company holds the following granted patents in the United States, and a pending application in the United States on its earlier models: US7469727, US8123731 and US Publication No. US20090216205 (collectively, the "Patents"). These Patents will begin to expire on August 8, 2023.

In general, the Patents are directed to a system and method for collecting waste fluid from a surgical procedure while ensuring there is no interruption of suction during the surgical procedure and no limit on the volume of waste fluid which can be collected. More particularly, the Patents claim a system and method in which waste fluid is suctioned or drawn into holding tanks connected to a vacuum source which maintains a constant negative pressure in the holding tanks. When the waste fluid collected in the holding tanks reaches a predetermined level, the waste fluid is measured and pumped from the holding tanks while maintaining the negative pressure. Therefore, because the negative pressure is maintained in the holding tanks, waste fluid will continue to be drawn into the holding tanks while the waste fluid is being pumped from the holding tanks. Thus, there is no limit to the volume of waste fluid which can be collected, and the suction at the surgical site is never interrupted during the surgical procedure.

We also rely upon trade secrets, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We seek to protect our trade secrets and proprietary know-how, in part, with confidentiality agreements with consultants, vendors and employees, although we cannot be certain that the agreements will not be breached, or that we will have adequate remedies for any breach.

#### 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 dual 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 and a small installed pump, 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 Skyline disposables are a critical component of our business model. The disposables have 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, dual 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 Skyline filter is used for every procedure. There are no known off the shelf filters that will fit our FMS. We have developed a more effective and cost efficient filter, with intent to patent. We have exclusive distribution rights to the disposable 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 are 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 expect to reach agreements to perform this function in the second quarter of 2015. 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 hospital operating rooms, radiological rooms 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, the STREAMWAY System has achieved market acceptance through the installation of more than seventy-nine (79) FMS systems. The product has received numerous references from users and was also recognized by LifeScience Alley as a top ten finalist in their new technology showcase. Additionally, Skyline has become a member of Practice Greenhealth; highlighting the positive environmental impact of the STREAMWAY System.

Other strategy may also include:

- o 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.
- o Providing a leasing program and/or "pay per use" program as alternatives to purchasing.
- o Providing service contracts to establish an additional revenue stream.
- o 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.
- o 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 resterilization (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 \$.50 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 glass canister costs roughly \$8.00 each while the high impact plastic canisters cost \$2.00 - \$3.00 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 biohazardous/infectious waste sites. Previously many hospitals used incineration as the primary means of disposal, but environmental concerns at the international, domestic and local level have resulted in a systematic decrease in incineration worldwide as a viable method for disposing of blood, organs or materials saturated with bodily fluids. When landfill disposal is used, canisters are included in the general red-bag disposal and, when gel is used, comprise a significant weight factor. Where hopper disposal is still in use, most of the contents of the red-bag consist only of outer packaging of supplies used in surgery and small amounts of absorbent materials impregnated with blood and other waste fluid. These, incidentally, are retained and measured at the end of the procedure to provide a more accurate assessment of fluid loss or retention. Once at the landfill site, the red-bagged material is often steam-sterilized with the remaining waste being ground up and interred into a specially segregated waste dumpsite.

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 Skyline. 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 sell the FMS and procedure disposables through various methods that 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 we have three Regional Managers selling, and demoing the FMS for prospective customers and distributors, as well as, supporting our current customer base for disposable resupply. Our targeted customer base includes nursing administration, operating room managers, CFOs, CEOs, 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 is to introduce the FMS to potential customers 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 hired 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, a troubleshooting manual and an on-board PLC controlling an intuitive touch screen with step by step instruction and safety features.

We have structured 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 are leveraging this medical awareness and concern with education of regulatory agencies at the local, state and federal levels about the advantages of the FMS.

We supplement our sales efforts with a promotional mix that include a number of printed materials, electronic media 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 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 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 focus on education, the awareness of the hazards of infectious waste fluids and the Company's innovative solution to the problem. We have focused our efforts initially on the Association of Operating Room Nurses ("AORN") meetings, where the largest concentration of potential buyers and influencers are in attendance and the Radiological Society of North America Scientific Assembly and Annual Meeting. We feature information on protection of the healthcare worker on our website as well as links to other relevant sites. We have invested in limited journal advertising for targeted audiences that have been fully identified. The initial thrust focuses 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 using traditional canisters. Our pricing strategy ensures 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 continues 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 \$21,900 per system (one per operating room – installation extra) and \$24 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 - \$3.00 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 is done by distributors, independent contractors, or in-house engineering at an estimated price of \$300 - \$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 has an industry standard warranty period that can be extended through documented use of our disposables: one filter and one bottle of cleaning solution per procedure.

#### **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 have contracted with a manufacturing company, Wair Products in Bloomington, Minnesota that meets our standards and requirements that can produce six times the amount of FMS systems produced in-house at our facility on a monthly basis as sales increase.

The disposables, including a bottle of proprietary cleaning solution and an in-line filter, are sourced through Diversified Manufacturing Corporation (cleaning solution) situated in Newport, Minnesota and MPP Corporation (filters), located in Osceola, Wisconsin that has tooled 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 and achieved testing and certification to the IEC 60606-1 and IEC 60606-1-2, two internationally recognized standards.

The 6060101 & 60601-2 2<sup>nd</sup> edition certification for our STREAMWAY System is valid and enables us to continue to market and sell our product domestically.

A new standard; IEC 60601-1 3rd Edition Medical Device Safety Testing was adopted by the International Organization of Standards in 2005 and had a compliance date of June 2012 for OUS and Dec 31, 2013 for the U.S. This standard, which is now recognized by the U.S. FDA, includes a provision of risk management which the 2<sup>nd</sup> edition did not require. The purpose of these rules is to ensure that equipment manufacturers have safety, performance, and risk management control measures in place.

The EU & Canada required 60601-1 3<sup>rd</sup> Edition compliance for all product sold or currently on the market after June 2013. Any product that had previously been certified to the 60601-1 2<sup>nd</sup> generation standard was no longer allowed for use as the old standard was no longer recognized. This did not affect Skyline Medical as the company did not sell internationally.

The U.S. FDA compliance date to meet the new standard was Dec 31, 2013. The major difference between the U.S. and the EU & Canadian market transition to the new standard is that the U.S. allows the 60601-1 2<sup>nd</sup> edition testing to be grandfathered in, allowing previously certified product to remain on the market. Any new product that will be tested after December 31, 2013 should be certified to the new 60601-1 3<sup>rd</sup> generation standard.

## 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 12 employees, ten of whom are full-time, and two who are part-time.

## **Executive Officers and Directors of the Registrant**

The following table identifies our current executive officers and directors:

Name	Age	Position Held
Josh Komberg	41	President, Chief Executive Officer, and Interim Chairman of the Board
David O. Johnson	62	Chief Operating Officer
Bob Myers	60	Chief Financial Officer
Thomas J. McGoldrick	73	Director
Andrew P. Reding	45	Director
Ricardo Koenigsberger	48	Director
Frank Mancuso, Jr.	56	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. Komberg was appointed Interim Chairman of the Board on August 21, 2013. Ricardo Koenigsberger is a holder of membership units of SOK Partners.

#### **Business Experience**

Josh Kornberg, President, Chief Executive Officer and Interim Chairman of the Board. Effective July 22, 2012, Joshua Kornberg was appointed as the Chief Executive Officer and President of the Company. Mr. Kornberg was appointed Interim Chairman of the Board on August 21, 2013. Mr. Kornberg was elected Interim President and Chief Executive Officer by the Board on April 23, 2012. Mr. Kornberg was elected to the Board on March 9, 2012. Mr. Kornberg is President and founding partner of Atlantic Partners Alliance (APA), a private equity fund based in New York. APA and its affiliates are controlling stockholders of the Company. 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. In December 2013 Mr. Kornberg was appointed to the Board of Directors of Prospect Park Capital Corporation a business development company currently trading on the Canadian TSX exchange.

David O. Johnson, Chief Operating Officer. Mr. Johnson has been Chief Operating Officer since July 2012. He was previously the Acting Chief Operating Officer 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. Mr. Myers has been Chief Financial Officer since July 2012. Previously, he 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 representing 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.

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 Skyline Medical Inc. (the "Company"). Mr. Koenigsberger is currently co-CEO of CV Holdings, Inc. a publically held REIT. In addition he is a managing partner of ROCA Management, a private investment fund focused on the REIT industry. 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.

Frank Mancuso, Jr., Director. Mr. Mancuso is a veteran of the film production industry with more than 30 years of industry experience. He is currently the President of Boss Media, LLC, which he co-founded in 2010. Prior to joining Boss Media, Mr. Mancuso was the President of 360 Pictures, LLC and FGM Entertainment Inc. Mr. Mancuso also has an extensive background in healthcare and has served on the Boards of multiple public companies. Mr. Mancuso has been a director of Prospect Park Capital Corp. (TSX VENTURE: PPK.P), a company whose strategy is to invest in early to mid-stage healthcare companies. Previously, he was a director at Delcath Systems, Inc. (NASDAQ: DCTH), a healthcare device company dedicated to the infusion of high dose chemotherapy to targeted areas of the body for the treatment of cancer. Mr. Mancuso obtained a Bachelor of Arts degree in business and graduated with honors from Upsala College in 1980.

#### 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 at least through the first two quarters of 2015. We had revenues of \$952,000 in 2014, but we had negative operating cash flows of \$3.4 million. As a result of our continued losses, our cash resources have not been sufficient to sustain our operations, and we have continued to depend on financing transactions to generate sufficient cash to stay in operation. Our private offerings of preferred stock and convertible debt in 2014 yielded aggregate gross proceeds of \$3,555,000; however, our cash balance was only \$16,000 as of December 31, 2014. As we manage our cash resources, our cash balance continues to fluctuate depending on the timing of receipt of product revenues and the proceeds of continued financing transactions, as well as the timing of our needs to pay for essential services and supplies to stay in operation. In April 2015 we raised gross proceeds of \$100,000 from another private sale of convertible notes. These proceeds were used almost immediately, or will be used, to pay essential resources, in order to stay in operation. We are currently incurring negative operating cash flows of approximately \$250,000 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.

With limited cash available to fund our operating expenses, we have deferred or delayed payments to vendors, suppliers and service providers, opting instead to prioritize payments for personnel and essential resources. Our balance of debts, liabilities and cash obligations that are either considered past due or that will become due in calendar 2015 was approximately \$6,417,000 as of December 31, 2014 and has continued to increase. We have negotiated payment arrangements with some of the parties to whom we owe payments, and in some cases we incur interest, late fees and penalties that cause our balance of obligations to increase further. Our outstanding debt at December 31, 2014 included \$1,131,000 in principal amounts of convertible notes that are due and payable July 23, 2015, if not yet converted or redeemed.

In September 2014, we filed a registration statement with the SEC in connection with a proposed public offering of common stock and warrants. To date, this offering has not been completed. Although we continue to pursue this public offering, we may not be able to complete the offering, or the offering proceeds may not be sufficient to allow us to list our common stock on NASDAQ or any other exchange, or the offering proceeds may not be sufficient to fund our operations until we have positive cash flow or operate profitably. If we do not complete this public offering, we will continue to seek to raise sufficient capital to operate our business. If financing is available, it may be highly dilutive to our existing shareholders and may otherwise include burdensome or onerous terms.

Unless and until we are able to raise sufficient capital, our lack of cash will continue to constrain our business and subject us to significant risks, including the following. First, we may be unable to make the necessary investment in personnel, equipment or other resources to effectively pursue our business plan. Second, our suppliers, vendors and service providers could slow down or stop supplying components or services or could stop extending credit in connection with commercial transactions, which could curtail our business. Third, we may be subject to lawsuits from claimants relating to past due balances, if we cannot work out or continue to renegotiate payment terms. There is no assurance that we will be able to successfully defend against such claims, and our creditors or claimants may seek to seize our assets or assert other judicial remedies. Ultimately, any or all of the above factors could lead to a possible reduction or suspension of our operations, ultimately forcing us to declare bankruptcy, reorganize or go out of business. Should this occur, the value of any investment in our securities could be adversely affected, and an investor would likely lose all or a significant portion of their investment.

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. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

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

We were formed on April 23, 2002 and to date have generated only moderate though increasing revenue year by year. 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 throughout the years 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 rely on a combination of patent, trade secret and other intellectual property rights and measures to protect our intellectual property. 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. Also, with respect to our trade secrets and proprietary know-how, we cannot be certain that the confidentiality agreements we have entered into with consultants, vendors and employees will not be breached, or that we will have adequate remedies for any breach. 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. In addition, many of our employees were previously employed at other medical device companies. We may be subject to claims that our employees have disclosed, or that we have used trade secrets or other proprietary information of our employees' former employers. 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.

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 the Saf-T Pump that accommodates Medi-Vac suction canisters draining infectious fluid into the hospital sanitary sewer; though the canisters must be brought to the system for draining. Both of these competitors are better capitalized than we are.

Although the Skyline 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 Skyline FMS has been launched into the fluid management market. We are currently manufacturing the Product, following GMP compliance regulations, at our own facility and anticipate the capability of producing the Skyline FMS in sufficient quantities for future near term sales. We have contracted with a manufacturing company that fits our standards and costs. We have sold and installed more than 79 FMS Systems to date and the product has been proven attractive to the target market due to its continuous suction and unlimited capacity ability, but other unknown or unforeseen market requirements may arise.

## 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 Skyline 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 heavily depend on our management team; Joshua Kornberg, our President, Chief Executive Officer and Interim Chairman of the Board, 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 may expand the relatively small number of executives in our company. Were we to lose one or more of these key individuals, we would be forced to expend significant time and money in the pursuit of a replacement, which could result in both a delay in the implementation of our business plan and the diversion of our limited working capital. We can give you no assurance that we can find satisfactory replacements for these key individuals at all, or on terms that are not unduly expensive or burdensome to our company. 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 had 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 common stock dividends for the foreseeable future, and we may never pay common stock dividends.

We currently intend to retain any future earnings to support the development and expansion of our business and do not anticipate paying common stock cash dividends in the foreseeable future. Our payment of any future common stock 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.

The Company completed a private offering in February 2014 issuing Series A Convertible Preferred Stock paying dividends at 6% of the Stated Value per annum on a quarterly basis (see "Subsequent Events" in Note 1 to the Consolidated Financial Statements included in this report).

#### 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 \$3.00, \$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 MKT: Std. #4, which is a market for small and mid-sized companies, we would need, among other things, at least \$75 million in market capitalization, a minimum price of \$3.00 and \$20 million in market value of public float.

Currently, our market capitalization, revenues and stockholders' equity are insufficient to qualify for these exchanges. 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 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.

# A stockholder group holds a majority of the outstanding common stock of the company and is able to effectively control our management and operations, and control by this group may create conflicts of interest.

A group consisting of Dr. Samuel Herschkowitz, Josh Kornberg (who is our Chief Executive Officer and Interim Chairman of the Board), SOK Partners, LLC and Atlantic Partners Alliance, currently owns more than 1.7 million shares of our outstanding common stock, representing approximately 51% of our voting power. As a result, this group controls the outcome of all matters requiring stockholder approval, including any future merger, consolidation or sale of all or substantially all of our assets. Further, this group indirectly controls our management through the power to elect and remove any members of the Board of Directors. This concentrated control could discourage others from initiating any potential merger, takeover or other change of control transaction that may otherwise be beneficial to our stockholders. As a result, the return on your investment in our common stock through the market price of our common stock or ultimate sale of our business could be adversely affected. Further, conflicts of interest may arise with respect to the interpretation, continuation, renewal or enforcement of our agreements with the members of this group and their affiliates, including the agreements described under "Item 13. Certain Relationships and Related Transactions, and Director Independence." The resolution of any such conflict in favor of any member of this group or any of their affiliates may materially harm our results of operations and the value of your shares of common stock.

# Our Board of Directors' ability to issue undesignated preferred stock and the existence of anti-takeover provisions may depress the value of our common stock.

Our authorized capital includes 10,000,000 shares of preferred stock. Of this amount, 20,550 shares have been designated as Series A Convertible Preferred Stock and the remaining authorized shares are undesignated preferred stock. Our Board of Directors has the power to issue any or all of the shares of undesignated preferred stock, including the authority to establish one or more series and to fix the powers, preferences, rights and limitations of such class or series, without seeking stockholder approval. Further, as a Delaware corporation, we are subject to provisions of the Delaware General Corporation Law regarding "business combinations." We may, in the future, consider adopting additional anti-takeover measures. The authority of our Board to issue undesignated stock and the anti-takeover provisions of Delaware law, as well as any future anti-takeover measures adopted by us, may, in certain circumstances, delay, deter or prevent takeover attempts and other changes in control of the company not approved by our Board of Directors. As a result, our stockholders may lose opportunities to dispose of their shares at favorable prices generally available in takeover attempts or that may be available under a merger proposal and the market price, voting and other rights of the holders of common stock may also be affected.

# Since our inception, a majority of our shares and other securities have been issued in violation of the preemptive rights of existing shareholders, which could result in claims against us.

In 2013, it was brought to the attention of our management and board of directors that our company was subject to preemptive rights prior to its reincorporation in Delaware. The Minnesota Business Corporation Act (the "Act") provides such rights to shareholders of a corporation, unless the corporation's articles of incorporation "opt out" and deny them. Our company's articles of incorporation never denied preemptive rights or mentioned them in any way. Since our inception in 2002, our company has issued shares of common stock and other equity securities on numerous occasions to raise capital and for other purposes and, to our knowledge; we have never complied with the Minnesota preemptive rights statute in connection with such issuances. On December 16, 2013, the reincorporation merger became effective. From that date, stockholders no longer have preemptive rights relating to any future issuances of securities. As described in our Form 10-Q report for the quarter ended September 30, 2013 in Part II, Item 1A, "Risk Factors," in connection with previous issuances of securities, we may be subject to the claims of previous and current shareholders based on violations of their preemptive rights; the risk and magnitude of these claims are uncertain, because there is little legal authority on the application of the Minnesota preemptive rights statute and if there are any future claims, we intend to vigorously defend based in part on numerous facts and circumstances described in such Form 10-Q report and other factors. However, if current or former shareholders bring claims against the company for violations of preemptive rights, there can be no assurance that our company will not be liable for damages, the amount of which cannot be predicted. Further, in connection with any such claims, a court may grant other remedies that will have a material adverse effect on our company's financial condition or results of operations, or that will result in dilution to some existing shareholders.

#### 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, of which 2,945 square feet is used for office space and 2,828 is used for manufacturing. Our lease is effective through January 31, 2018. We expect that this space will be adequate for our current office and manufacturing needs.

#### ITEM 3. LEGAL PROCEEDINGS.

None

#### 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 "SKLN" on the OTCQB since August 6, 2013 through the present date. Previously the stock had been quoted under the symbol "BIOR" on the OTCQB. 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, 2014	\$	10.88	\$	3.25
September 30, 2014	\$	18.00	\$	5.25
June 30, 2014	\$	14.25	\$	7.95
March 31, 2014	\$	21.75	\$	13.13
December 31, 2013	\$	26.25	\$	15.00
September 30, 2013	\$	35.25	\$	9.75
June 30, 2013	\$	21.00	\$	9.00
March 31, 2013	\$	10.50	\$	3.75

As of April 23, 2015, the closing bid price for shares of our common stock was \$6.15 per share on the OTCQB.

#### Holders

As of April 23, 2015, there were approximately 152 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 on common stock in the foreseeable future.

In February 2014 the company completed a private placement of Series A Convertible Preferred Stock on which the Company shall pay a 6% quarterly dividend on the stated value per annum commencing on the first day of each quarter. The dividends shall be payable quarterly in cash or in shares of Common Stock (calculated at the then applicable Conversion Price per share) and shall be payable on the day at the end of each Dividend Period (each such day being hereinafter called a "Dividend Payment Date"). No other dividends shall be paid on shares of Preferred Stock; and the Corporation shall pay no dividends (other than dividends in the form of Common Stock) on shares of the Common Stock unless it simultaneously complies with the previous sentence. Dividends shall be payable to holders of record as they appear in the stock records of the Corporation at the close of business on the applicable record date, which shall be the tenth (10<sup>th</sup>) day preceding the applicable Dividend Payment Date, or such other date designated by the Board of Directors or an officer of the Corporation duly authorized by the Board of Directors for the payment of dividends that is not more than 30 nor less than ten days prior to such Dividend Payment Date (each such date, a "Dividend Record Date").

# Securities Authorized for Issuance under Equity Compensation Plans

The information required by Item 5 is incorporated herein by reference to Item 11, under "Equity Compensation Plan Information," and Item 12 below.

## **Recent Sales of Unregistered Securities**

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

On February 3, 2012, the Company issued 1,167 shares of common stock to a consultant as compensation for consulting work.

On March 5, 2012, the Company re-issued a warrant to purchase 1,334 shares of common stock at \$9.75 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 1,334 shares of common stock at \$9.75 per share to an investor for consulting services. The original warrant was issued on June 11, 2008.

On March 26, 2012, the Company issued 4,000 shares of common stock at \$4.875 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 Komberg 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 61,539 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 20,623 shares of common stock. An additional 100,000 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, 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 4,662 shares of common stock.

In April 2012, the Company issued an equity bonus consisting of 1,334 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 2,178 shares of common stock as an equity bonus for \$24,500 Board meeting fees.

In May 2012, the Company issued 5,507 shares of common stock to a former Board member and Officer of the Company in exchange for exercising stock options at \$.75 per share.

In May 2012, the Company issued the second equity bonus to SOK Partners, consisting of 61,539 shares of common stock. See Item 13, "Certain Relationships and Related Transactions, and Director Independence."

In May 2012, the Company issued 43,901 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 38,011 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 19,520 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 7,545 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 20,965 shares of common stock to an individual investor to transfer debt to equity by an Election to Convert a convertible

In June 2012, an institutional investor elected to convert \$12,000 of a \$50,000 convertible note into 5,162 shares of common stock.

In June 2012, the Company issued 5,297 shares of common stock to a vendor to transfer debt to equity by a settlement agreement.

In June 2012, the Company issued 3,698 shares of common stock at \$6.75 per share to the Mr. Lawrence Gadbaw the Company's Chairman of the Board as consulting compensation.

In June 2012, the Company issued 34,284 shares of common stock at \$5.25 per share and warrants to purchase 34,284 shares of common stock at \$11.25 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 6,799 shares of common stock.

In June 2012, the Company issued 3,783 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 9,877 shares of common stock.

In June 2012, the Company issued 8,334 shares of common stock to an IR firm as sole compensation for investor relations consulting work.

In August 2012, the Company issued 48,278 shares of common stock at \$5.25 per share and warrants to purchase 48,278 shares of common stock at \$11.25 per share to 16 investors in return for their \$253,456.58 investment in the Company.

In August 2012, the Company issued 176,667 shares of stock to Dr. Sam Herschkowitz and 176,667 shares of stock to SOK Partners, per a settlement and forbearance agreement.

In August 2012, the Company issued 15,556 shares of common stock at \$11.25 per share as part of a settlement with our former COO.

In October 2012, the Company issued 4,000 shares of common stock at \$5.25 per share to an investor relations firm as compensation for investor relations consulting work.

In October 2012, the Company issued 2,095 shares of common stock at \$11.25 per share to a vendor as compensation for work completed.

In November 2012, the Company issued 36,191 shares of common stock at \$5.25 per share and warrants to purchase 36,191 shares of common stock at \$11.25 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 20,833 shares of common stock in consideration of placement of the notes.

In November 2012, the Company issued 958 shares of common stock at \$.75 per share to an investor exercising a warrant.

In December 2012, the Company issued 12,858 shares of common stock at \$5.25 per share and warrants to purchase 12,858 shares of common stock at \$11.25 per share to 2 investors in return for their \$67,500 investment in the Company.

In December 2012 the Company issued 3,148 shares of common stock at \$5.25 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 4,840 shares of common stock at \$6.75 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 convertible one year promissory notes that bear interest at 8%, in an aggregate principal amount of \$300,000 convertible into 33,334 shares of common stock assuming a conversion rate of \$9.00 per share and five year warrants to purchase up to an aggregate of 33,334 shares of the corporation's common stock at an exercise price of \$11.25 per share. The value of the notes are net discounts of \$45,517 in 2013; due in January 2014. In addition, we issued to the placement agent for these sales five year warrants to purchase an aggregate of 2,667 shares of common stock at an exercise price of \$11.25 per share. All of the notes were converted in September 2013 resulting in 35,168 shares of common stock issued at \$9.00 per share.

In January and March, 2013, in connection with a separate and new private placement offering we issued 95,239 shares of common stock at \$5.25 per share and warrants to purchase 95,239 shares of common stock at \$11.25 per share to 5 investors in return for their \$500,000 investment in the Company.

In January 2013, the Company issued 3,869 shares of common stock at \$11.25 per share in payment to a vendor for \$43,521.39 including principal and interest.

In February 2013, the Company issued 13,334 shares of common stock to an escrow account to secure a settlement agreement with a former note holder. The escrow agent releases 1/3 of the stock back to the Company once per year until the settlement is paid in full. If the Company prepays the balance due then all the stock remaining in escrow is released back to the Company. If the Company defaults, and cannot cure the default within the contracted time period, then the stock is released to the note holder toward payment of the settlement.

In February 2013, the Company issued 3,334 shares of common stock in agreement with an investor relations firm canceling their services.

In March 2013, the Company issued 3,072 shares of common stock to a vendor as part of a cash/stock settlement of their long term note with the Company.

In March 2013, the Company issued 95,239 shares of common stock as an equity bonus. Includes a warrant to purchase 95,239 shares of common stock at \$6.00 per share. Includes a warrant to purchase 47,620 shares of common stock at \$11.25 per share. Includes a warrant to purchase 2,540 shares of common stock at \$6.00 per share. Includes a warrant to purchase 5,080 shares of common stock at \$6.00 per share.

On April 22, 2013, the Company issued 2,667 shares of common stock to a former consultant exercising stock options with an exercise price of \$.75.

On April 25, 2013, the Company issued 4,445 shares of common stock to the former CEO exercising stock options with an exercise price of \$.75.

On May 7, 2013 the Company converted the notes issuing 14,882 aggregate shares of common stock at \$11.25 per share to the note holders. One of the note holder's is Dr. Herschkowitz, a related party, who received 4,763 shares of common stock.

In May and June 2013, in connection with a private placement offering we issued convertible one year promissory notes that bear interest at 8%, in an aggregate principal amount of \$1,000,000 convertible into 80,000 shares of common stock assuming a conversion rate of \$13.50 per share and five year warrants to purchase up to an aggregate of 61,482 shares of the corporation's common stock at an exercise price of \$14.85 per share. The value of the notes is net discounts of \$275,640 in 2013; due in May and June 2014. In addition, we issued to the placement agent for these sales five year warrants to purchase an aggregate of 5,926 shares of common stock at an exercise price of \$13.50 per share. All of the notes were converted in September 2013 resulting in 75,777 shares of common stock issued at \$13.50 per share.

In August and September 2013 some warrant holders opted for a cashless warrant exercise resulting in issuing 87,118 shares of common stock pursuant to the warrant instruction for cashless exercise. The Company has entered into a settlement agreement with holders of certain of these warrants resulting in a net reduction of 16,867 shares.

In September 2013 the Company offered a limited amount of large warrant holders to exercise at a reduced rate of \$7.50 per share. Twenty-four warrants were exercised for a total of 139,266 shares for \$1,044,490.

In September 2013 the Company issued 2,000 shares of common stock at \$28.50 per share for consulting to a public relation/investor relations company.

In September 2013 the Company issued 299,509 shares of common stock at \$10.50 per share upon conversion of a secured note, which is no longer outstanding.

In September 2013 the Company issued 648,043 shares of common stock at \$10.50 per share to a secured note holder converting the debt to equity. The security interest held by the noteholder has been returned to the Company. UCC forms were filed appropriately.

In September 2013, two directors resigned from the Board. Both received 667 shares of common stock each at \$24.375 per share; 267 of these shares were for compensation from serving as Board members and the remaining 400 shares were issued to satisfy previous contractual agreements.

In October 2013, the Company issued to Wisconsin Rural Enterprise Fund, LLC ("WREF") 5,040 shares of the Company's common stock in full and final settlement of all of WREF's claims against the Company related to a certain Stock Purchase and Sale Agreement entered into by and between the Company and WREF on December 2, 2006.

In October 2013 the Company issued 546 shares of the Company's common stock to two noteholders for missed interest payments when the notes were converted in September 2013. The shares were issued at \$13.50 per share.

In October 2013 an employee exercised vested options at \$4.875 per share to receive 134 shares of the Company's common stock.

In October a warrant holder exercised at a reduced rate of \$9.375 per share. The warrant was exercised for a total of 13,334 shares for \$125,000.

In November 2013 a vendor exercised a portion of options received in payment for executive placement. He received 227 shares of common stock at \$5.25 per share.

In December 2013 a warrant holder opted for a cashless warrant exercise resulting in issuing 1,556 shares of common stock pursuant to the warrant instruction for cashless exercise.

In January 2014 a warrant holder opted for a cashless warrant exercise resulting in issuing 1,729 shares of common stock pursuant to the warrant instruction for cashless exercise.

On January 6, 2014, the Company issued 4,336 shares of common stock to the former CEO exercising stock options with an exercise price of \$.75.

In January 2014 a vendor received 2,000 shares of common stock at \$20.625 per share in payment for public relations services.

In January 2014 a warrant holder opted for a cashless warrant exercise resulting in issuing 3,324 shares of common stock pursuant to the warrant instruction for cashless exercise.

In January 2014 a vendor exercised a portion of options received in payment for executive placement. He received 267 shares of common stock at \$5.25 per share.

On February 4, 2014 the Company entered into a Securities Purchase Agreement with certain investors issuing 20,550 shares of Series A Convertible Preferred Stock, par value \$.01, and warrants to acquire an aggregate of approximately 21,334 shares of the Company's common stock, par value \$.01. The preferred shares are convertible into shares of common stock at an initial conversion price of \$19.50 per share of common stock. The warrants are exercisable at an exercise price of \$24.375 per share and expire five years from the closing date. The Company received gross proceeds of \$2,055,000, before offering expenses. See ("Subsequent Events" in Note 1 to the Consolidated Financial Statements included in this report).

In February 2014 two warrant holders opted for a cashless warrant exercise resulting in issuing 2,175 shares of common stock pursuant to the warrant instruction for cashless exercise.

In February 2014 a warrant holder exercised his warrant resulting in issuing 2,667 shares of common stock at an exercise price of \$13.50 per share for \$36,000.

In February 2014 the Company issued 1,334 shares of common stock at \$18.75 per share to a vendor as part of a contract for investor relations consulting.

In February 2014, as a result of completing payments for the first of three years pursuant to a settlement agreement, 13,334 shares of common stock held in escrow was canceled and reissued for 8,889 shares. The shares held in escrow will reduce by 4,445 shares in February 2015 and then again for the remaining 4,444 shares in February 2016 as the settlement is paid without default.

In March 2014 four warrant holders opted for a cashless warrant exercise resulting in issuing 7,918 shares of common stock pursuant to the warrant instruction for cashless exercise.

In May 2014, the Company issued 2,134 shares of common stock at \$11.25 per share to a vendor as part of a contract for investor relations consulting.

In May 2014, the Company issued 1,334 shares of common stock at \$18.75 per share to a vendor as part of a contract for investor relations consulting.

In May 2014, a warrant holder opted for a cashless warrant exercise resulting in issuing 3,725 shares of common stock pursuant to the warrant instruction for cashless exercise.

In July 2014, a warrant holder opted for a cashless warrant exercise resulting in issuing 1,411 shares of common stock pursuant to the warrant instruction for cashless exercise. The warrant holder notified the Company at the close of the second quarter that the original warrant had been lost in a fire. The warrant holder wanted to exercise his warrant but needed a replacement warrant to do so. The Company had already reported that the warrant had expired at the end of the second quarter. The Company issued a replacement warrant early in the third quarter and the warrant holder immediately opted for a cashless exercise.

In July, August and September 2014, the Company sold convertible notes and warrants for an aggregate purchase price of \$1.475 million. The convertible notes originally had an aggregate principal amount of \$1.802 million, which was reduced to \$1.603 million in the aggregate on September 9, 2014 as a result of the effectiveness of the Resale Registration Statement. The warrants were originally for 81,465 shares, subsequently reduced to 71,257 shares, at an exercise price of \$12.38 per share.

In August 2014, a warrant holder exercised his warrant resulting in issuing 11,112 shares of common stock at an exercise price of \$5.63 per share for \$62,500.

In August 2014 a vendor exercised a portion of options received in payment for executive placement. He received 334 shares of common stock at \$5.25 per share.

In November 2014, the Company issued 13,700 shares of common stock previously held in escrow pursuant to a settlement agreement.

In January 2015, the Company released 13,700 shares of common stock from the escrow account pursuant to a settlement agreement.

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.

# 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; 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 Skyline 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 under the name BioDrain Medical, Inc. Effective August 6, 2013, the Company changed its name to Skyline Medical Inc. Pursuant to an Agreement and Plan of Merger dated effective December 16, 2013, the Company merged with and into a Delaware corporation with the same name that was its wholly-owned subsidiary, with such Delaware Corporation as the surviving corporation of the merger. 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 currently have three Regional Sales Managers. In the first quarter of 2015 we have renewed a contract with an Independent Distributor covering New York and surrounding areas.

Since inception, we have been unprofitable. We incurred net losses of approximately \$6.8 million and \$9.4 million in 2014 and 2013, respectively. As of December 31, 2014 and December 31, 2013, we had an accumulated deficit of approximately \$35.6 million and \$28.7 million, respectively. We received approval from the FDA in April 2009 to commence sales and marketing activities of the STREAMWAY 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 have sold seventy-nine STREAMWAY units to date. We expect the revenue for STREAMWAY units to increase significantly at such time as the hospitals approve the use of the unit for their application and place orders for billable units. 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 future cash requirements and the adequacy of available funds depend on our ability to sell our products. See "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, 2014 with Year Ended December 31, 2013

Revenue. We recorded revenue of \$952,000 in 2014, compared to \$468,000 in 2013. Revenue in 2014 included the sale of forty-four STREAMWAY systems and disposable supplies to operate the STREAMWAY. The revenue in 2013 included the sale of twenty-one STREAMWAY systems and disposable supplies to operate the STREAMWAY.

Cost of sales. Cost of sales was \$385,000 in 2014 compared to \$189,000 in 2013. The gross profit margin was 60% in 2014 and 59% in 2013. As our revenue has increased and we honed in on parts for the STREAMWAY, we were better able to maximize our margins through advanced purchasing at larger volumes. The Company also developed ways to reduce cost through tooling parts and purchasing different components that improved the STREAMWAY Systems while costing less. The Company had an offset to the increased margin absorbing the cost of replacing eleven units of the original STREAMWAY generation model with its newer iteration rolled out in the second quarter of 2014.

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 decreased to \$4,883,000, for 2014 from \$7,530,000 in 2013. The \$2,647,000 decrease in G&A expenses for 2014, compared to 2013, is primarily due to reductions of \$3,139,000 in stock based and investors stock compensation as a result of different structure of our private placements; \$662,000 due to lower bonuses predominantly in the form of stock options; \$71,000 less consulting expenses and no intellectual property amortization expense in 2014 (there was a write-off of \$141,000 in 2013 for the generation one STREAMWAY patents). There are some offsets by increased expenses of \$161,000 in salaries and payroll taxes; \$179,000 in legal fees mostly for proceeding with an attempted public offering; \$48,000 in corporate insurance; \$55,000 in depreciation expenses; \$500,000 in settlement costs; and \$234,000 for finders fees associated with fund raising.

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

Operations expense decreased to \$973,000 in 2014 compared to \$1,097,000 in 2013. The \$124,000 decrease in operations expense in 2014 is primarily due to decreases of \$154,000 in salaries and payroll taxes; \$157,000 in bonuses predominantly in the form of stock options; and \$71,000 in reduced stock based compensation also as a result of fewer employee stock options. There were increased expenses for \$159,000 in research and development from a concentrated effort extended toward rolling out the enhanced STREAMWAY; \$68,000 in consulting expenses for engineering alterations; and \$51,000 in higher shipping expenses.

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

Sales and marketing expenses increased to \$1,178,000 in 2014 compared to \$579,000 in 2013. The \$600,000 increase is a result of a \$462,000 increase in salaries, payroll taxes and benefits due to hiring four additional regional sales managers; \$65,000 increased commissions for higher sales in 2014; \$138,000 for bonuses attained by the sales managers; and \$43,000 in travel expenses. The Company did reduce public relations expenses by \$115,000.

Interest Expense. Interest expense decreased to \$377,000 in 2014 compared to \$637,000 in 2013. The \$260,000 was a result of reduced financing efforts through private placements.

Loss (gain) on valuation of equity-linked financial instruments. The Company realized a gain of \$12,000 on valuation of equity-linked financial instruments in 2014 compared to a gain of \$158,000 in 2013. The gain resulted from older warrants expiring.

## **Liquidity and Capital Resources**

#### Cash Flows for the Year Ended December 31, 2014

Net cash used in operating activities was \$3,371,000 for 2014, compared with net cash used of \$3,855,000 for 2013. The \$484,000 decrease in cash used in operating activities was largely due to an increase in accounts payable and accrued expenses. The Company received more favorable terms from vendors extending payouts. Accrued Liabilities increased as 2012, 2013 and 2014 bonuses have not been paid out; payroll and payroll tax liability accounts were higher as well. Offsets were for increased research and development, a decrease in accounts receivable and an increase in our prepaid accounts.

Cash flows used in investing activities was \$121,000 for 2014 and \$216,000 in 2013. As we have grown our fixed asset acquisitions have increased as well. We have purchased furniture, computers, software and have incurred leasehold improvements.

Net cash provided by financing activities was \$3,407,000 for 2014 compared to net cash provided of \$4,160,000 for 2013. The decrease in 2014 was primarily the result of less proceeds from private placements of common stock by \$2,180,000, principal payment on debt of \$305,000 offset by \$2,055,000 resulting from the issuance of preferred stock.

## Liquidity, Plan of Financing and Going Concern Qualification

Since our inception, we have incurred significant losses, and our accumulated deficit was approximately \$35.6 million as of December 31, 2014. Our operations from inception have been funded with private placements of convertible debt securities and equity securities, in addition to a past bank loan (not currently outstanding). We currently have no outstanding bank debt and no secured indebtedness.

We received \$952,000 in revenues from product sales in 2014; however, our operating losses and negative cash flow have continued, including operating cash flows of a negative \$3.4 million in 2014, compared to a negative \$3.9 million in 2013. We anticipate that we will continue to incur net losses at least through the first two quarters of 2015. Our private offerings of preferred stock and convertible debt in 2014 yielded aggregate gross proceeds of \$3,555,000; however, our cash balance was only \$16,000 as of December 31, 2014.

As we manage our cash resources, our cash balance continues to fluctuate depending on the timing of receipts of product revenues and continued financing transactions, as well as our need to pay for essential services and supplies to stay in operation. In April 2015, we raised gross proceeds of \$100,000 from a private sale of convertible notes as described under "Historical Financing" below. These proceeds were used almost immediately, or will be used, to pay essential resources, in order to stay in operation. We are currently incurring negative operating cash flows of approximately \$250,000 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.

With limited cash available to fund our operating expenses, we have deferred or delayed payments to vendors, suppliers and service providers, opting instead to prioritize payments for personnel and essential resources. Our balance of debts, liabilities and cash obligations that are either considered past due or that will become due in calendar 2015 was approximately \$6,417,000 as of December 31, 2014 and has continued to increase. We have negotiated payment arrangements with some of the parties to whom we owe payments, and in some cases we incur interest, late fees and penalties that cause our balance of obligations to increase further. Our outstanding debt at December 31, 2014 included \$1,131,000 in principal amounts of convertible notes that are due and payable July 23, 2015, if not yet converted or redeemed. These notes are not subject to automatic conversion upon the completion of a qualified public offering. In connection with the contemplated public offering described below, the holders of a portion of such notes previously agreed, on a voluntary basis, to convert their notes at closing; however, this agreement to convert is no longer binding on the holders of the convertible notes.

In September 2014, we filed a registration statement with the SEC in connection with a proposed public offering of common stock and warrants. To date, this offering has not been completed. Although we continue to pursue this public offering, we may not be able to complete the offering, or the offering proceeds may not be sufficient to allow us to list our common stock on NASDAQ or any other exchange, or the offering proceeds may not be sufficient to fund our operations until we have positive cash flow or operate profitably. If we do not complete this public offering, we will continue to seek to raise sufficient capital to operate our business. If financing is available, it may be highly dilutive to our existing shareholders and may otherwise include burdensome or onerous terms.

Unless and until we are able to raise sufficient capital, our lack of cash will continue to constrain our business and subject us to significant risks, including the following. First, we may be unable to make the necessary investment in personnel, equipment or other resources to effectively pursue our business plan. Second, our suppliers, vendors and service providers could slow down or stop supplying components or services or could stop extending credit in connection with commercial transactions, which could curtail our business. Third, we may be subject to lawsuits from claimants relating to past due balances, if we cannot work out or continue to renegotiate payment terms. There is no assurance that we will be able to successfully defend against such claims, and our creditors or claimants may seek to seize our assets or assert other judicial remedies. Ultimately, any or all of the above factors could lead to a possible reduction or suspension of our operations, ultimately forcing us to declare bankruptcy, reorganize or go out of business. Should this occur, the value of any investment in our securities could be adversely affected, and an investor would likely lose all or a significant portion of their investment.

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.

## 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 20,833 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.

Equity and Debt Financing in 2013. 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. In June 2013, the Company raised an additional \$1,000,000 from the sale of convertible notes. See Note 3 to the Financial Statements. In the third quarter we also borrowed the remaining \$243,000 principal amount of our convertible note payable to SOK, Partners, LLC. During the third quarter of 2013, the holders of convertible notes, including Dr. Samuel Herschkowitz and SOK Partners, LLC, converted \$1,506,000 of outstanding debt, including principal and interest, into equity. The Company converted the promissory notes totaling \$314,484 and \$680,444, respectively, including principal and interest, on September 11, 2013 for 299,509 and 648,043 shares, respectively, at \$1.05 per share. Also during the third quarter of 2013, we raised approximately \$1,044,000 through the cash exercise of warrants by investors who were offered a reduction in the exercise in connection with the exercise. In December 2013 the Company raised \$280,000 in the form of a short term non-convertible note with 10% interest based on a 365 day year from SOK Partners, LLC. In January 2014 an additional \$20,000 was raised and added to the original note to SOK, Partners, LLC. Josh Komberg the CEO, is a 50% managing partner in SOK Partners, LLC.

2014 Convertible Preferred Financing. On February 4, 2014, (the "Closing Date") we raised \$2,055,000 in gross proceeds from a private placement of Series A Convertible Preferred Stock, par value \$0.01 (the "Preferred Shares") pursuant to a Securities Purchase Agreement with certain investors (the "Purchasers") who purchased 20,550 Preferred Shares, and warrants (the "Warrants") to acquire an aggregate of approximately 285 shares of Common Stock. The Preferred Shares are convertible into shares of Common Stock at a conversion price that was \$19.50 per share of Common Stock, subject to adjustment. The Warrants are exercisable at an exercise price of \$24.38 per share and expire five years from the Closing Date. If the Common Stock is not listed on the NASDAQ Stock Market, the New York Stock Exchange, or the NYSE MKT within 180 days of the Closing, the Company shall issue additional Warrants to purchase additional shares of Common Stock, equal to 30% of the shares of Common Stock which the Preferred Shares each Purchaser purchased are convertible into. As of August 4, 2014, the Company issued additional warrants to purchase 61,539 shares to the Purchasers in connection with this provision.

The Securities Purchase Agreement requires the Company to register the resale of the shares of Common Stock underlying the Preferred Shares (the "Underlying Shares") and the Common Stock underlying the Warrants (the "Warrant Shares"). The Company is required to prepare and file a registration statement with the Securities and Exchange Commission within 132 days of the Closing Date (as extended by subsequent consent of the Purchasers), and to use commercially reasonable efforts to have the registration statement declared effective within 147 days if there is no review by the Securities and Exchange Commission, and within 192 days in the event of such review.

The Preferred Shares are convertible at the option of the holder into the number of shares of Common Stock determined by dividing the stated value of the Preferred Shares being converted by the conversion price of \$19.50, subject to adjustment for stock splits, reverse stock splits and similar recapitalization events. If the Company issues additional shares of Common Stock, other than certain stock that is excluded under the terms of the Securities Purchase Agreement, in one or more capital raising transactions with an aggregate purchase price of at least \$100,000 for a price less than the then existing conversion price for the Preferred Shares (the "New Issuance Price"), then the then existing conversion price shall be reduced to the New Issuance Price, provided, however, that under no circumstances shall the New Issuance Price be less than \$9.75 or reduced to a price level that would be in breach of the listing rules of any stock exchange or that would have material adverse effect on the Corporation's ability to list its Common Stock on a stock exchange, including but not limited to the change of accounting treatment of the Preferred Stock. In July 2014, in connection with the issuance of certain convertible notes, the conversion price of the Preferred Stock was adjusted to \$9.75 per share. Further, the Company has agreed to additional shares of Common Stock to holders of the Preferred Stock in certain circumstances, as described in the description of the Consent and Waiver below. The Preferred Shares contain certain limitations on conversion so that the holder will not own more than 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon conversion of Preferred Shares held by the applicable holder, with the percentage subject to increase in certain circumstances. The Preferred Shares are eligible to vote with the Common Stock on an as-converted basis, but only to the extent that the Preferred Shares are eligible for conversion without exceeding the Beneficial Ownership Limitation. The Preferred Shares are entitled to receive dividends on a pari passu basis with the Common Stock, when, and if declared. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary (a "Liquidation"), after the satisfaction in full of the debts of the Company and the payment of any liquidation preference owed to the holders of shares of Common Stock ranking prior to the Preferred Shares upon liquidation, the holders of the Preferred Shares shall receive, prior and in preference to the holders of any junior securities, an amount equal to \$2,055,000 times 1.2, plus all declared but unpaid dividends.

The Warrants issued in the offering of Preferred Shares are exercisable on any day on or after the date of issuance, have an exercise price of \$24.38 per share, subject to adjustment, and a term of five years from the date they are first exercisable. However, a holder will be prohibited from exercising a Warrant if, as a result of such exercise, the holder, together with its affiliates, would exceed the Beneficial Ownership Limitation as described above for the Preferred Shares. If any Warrant has not been fully exercised prior to the first anniversary of the Closing and if during such period the Company has not installed or received firm purchase orders (accepted by the Company) for at least 500 STREAMWAY ® Automated Surgical Fluid Disposal Systems, then, the number of shares of Common Stock for which such Warrant may be exercised shall be increased 2.5 times.

As of July 23, 2014, in connection with the offering of convertible notes and warrants described below, the Company and the holders of at least the minimum number of Preferred Shares required to (i) waive certain covenants under the Securities Purchase Agreement for the Preferred Shares, dated February 4, 2014 (the "Preferred Stock SPA"), and (ii) consent to the automatic conversion of all outstanding Preferred Shares pursuant to Section 6(d) of the Certificate of Designation, filed January 27, 2014, setting forth the preferences, rights and limitations of the Preferred Shares (the "Certificate of Designation"), agreed to the following (the "Consent and Waiver"):

- a waiver of the Company's obligation under Section 6.12 of the Preferred Stock SPA to not enter into any contract, transaction or arrangement or issue any security or instrument that provides for forward pricing of shares of Common Stock (the "Forward Pricing Transaction Restriction") with respect to the offering of convertible notes and, following a Qualified Public Offering (as defined below), a waiver of the Forward Pricing Transaction Restriction for any subsequent offering of securities by the Company;
- a consent to the inclusion of the registration of the Additional Shares (as defined below) on a registration statement or registration statements of the Company to be filed under the Securities Act of 1933, as amended, pursuant to Section 10 of the Preferred Stock SPA (the "Registration Statement"), covering the "Registrable Securities" as defined under the Preferred Stock SPA (the "Preferred Stockholders Registrable Securities");
- a consent to further extend the Filing Deadline and the Effectiveness Deadline (each as defined in the Certificate of Designation) pursuant to Section 10.1 of the Preferred Stock SPA such that the deadlines for the filing and effectiveness of the Registration Statement shall be the same as the applicable deadlines for the Convertible Notes Offering;
- an agreement by the Preferred Stockholders to a 90-day lock-up beginning from the date of closing of an underwritten public offering of the Common Stock with gross offering proceeds of at least \$6.0 million and the concurrent listing of the Common Stock on a national securities exchange (a "Qualified Public Offering") (the "Purchaser Lock-Up"); and
- a consent to automatically convert all outstanding Preferred Shares upon a Qualified Public Offering pursuant to the Certificate of Designation as described further below.

In consideration of the waiver and consents provided by the Preferred Stockholders, the Company agreed:

- to issue additional shares of Common Stock to the Preferred Stockholders (the "Additional Shares") (A) automatically upon the closing of a Qualified Public Offering, to the extent that (i) the Qualified Public Offering closes within six (6) months of the first closing of the Convertible Notes Offering ("Qualified Public Offering Deadline") and (ii) 70% of the public offering price per share of the Common Stock in the Qualified Public Offering (the "QPO Discount Price") is less than the Conversion Price floor contained in Section 7(e)(i) of the Certificate of Designation (the "Conversion Price Floor"), or (B) if a Qualified Public Offering has not been consummated by the Qualified Public Offering Deadline, upon the Preferred Stockholders' conversion of their shares of Preferred Stock to the extent that 70% of the volume weighted average price of the Common Stock on the principal Trading Market (as defined in the Certificate of Designation) of the Common Stock during the ten Trading Days (as defined in the Certificate of Designation) immediately preceding the Qualified Public Offering Deadline (the "Non-QPO Discount Price") is less than the Conversion Price Floor;
- to provide the Preferred Stockholders with the right to participate in the Affiliate Convertible Notes Offering (as defined below) pro rata up to an aggregate of \$500,000 based on their respective interests in the Preferred Shares; and
- to provide the Preferred Stockholders with the right to participate in the Affiliate Convertible Notes Offering pro rata up to an aggregate of \$500,000 based on their respective interests in the Preferred Shares; and
- to pay reasonable attorneys' fees and expenses of the Preferred Stockholders in connection with certain transactions as described further in the waiver and consent of, and notice to, holders of Preferred Shares.

On February 2, 2015, the Consent and Waiver was amended such that it applies for an expanded set of qualified offerings, and modifying certain of its terms. The terms of this amended Consent and Waiver were described in our Form 8-K report filed on February 4, 2015.

2014 Sales of Convertible Notes and Warrants. On July 23, 2014, the Company entered into a Securities Purchase Agreement (the "SOK Securities Purchase Agreement") with SOK Partners, LLC, an affiliate of the Company ("SOK"), pursuant to which the Company agreed to issue and sell (i) a senior convertible note, in an original principal amount of \$122,195.60 (the "SOK Note"), which SOK Note shall be convertible into a certain amount of shares (the "SOK Conversion Shares") of Common Stock, in accordance with the terms of the SOK Note, and (ii) a warrant (the "SOK Warrant") to initially acquire up to 5,431 additional shares of Common Stock (the "SOK Warrant Shares", and collectively with the SOK Note, the SOK Warrant and the SOK Conversion Shares, the "SOK Securities") for an aggregate purchase price of \$100,000 (with the reduced principal amount as described below representing an approximately 8.7% original issue discount) (the "SOK Convertible Notes Offering"). Upon effectiveness of the Resale Registration Statement (as defined below) on September 9, 2014, the principal amount of the note was reduced to \$108,695 and the number of warrants was reduced to 4,831 shares.

Also, on July 23, 2014, the Company entered into a Securities Purchase Agreement with 31 Group, LLC (an affiliate of Aegis Capital Corp., the underwriter for the Company's pending public offering), pursuant to which the Company agreed to issue and sell (i) a senior convertible note, in an original principal amount of \$610,978 (subsequently reduced to \$543,478) (the "31 Group Note"), which shall be convertible into a certain amount of shares of Common Stock, in accordance with the terms of the 31 Group Note, (ii) a warrant (the "31 Group Warrant") to initially acquire up to 27,155 additional shares of Common Stock (subsequently reduced to 24,155 shares) (the "31 Group Conversion Shares", and collectively with the 31 Group Note, the 31 Group Warrant and the 31 Conversion Shares, the "31 Group Securities") for an aggregate purchase price of \$500,000 (representing an approximately 8.7% original issue discount) (the "31 Group Convertible Notes Offering").

On July 31, 2014, August 8, 2014, August 12, 2014, September 4, 2014 and September 5, 2014, the Company entered into Securities Purchase Agreements (collectively, the "Affiliate Securities Purchase Agreements") with certain affiliates of the Company and certain persons with whom the Company was required to have a pre-existing relationship (the "Affiliates") pursuant to which the Company agreed to issue and sell (i) senior convertible notes, in an original aggregate principal amount of \$1,069,221 (subsequently reduced to \$951,086) (the "Affiliate Notes"), which Affiliate Notes shall be convertible into a certain amount of shares (the "Affiliate Conversion Shares") of the Company's Common Stock in accordance with the terms of the Affiliate Notes, and (ii) warrants (the "Affiliate Warrants") to initially acquire up to 48,879 additional shares of Common Stock (subsequently reduced to 42,271 shares) (the "Affiliate Warrant Shares", and collectively with the Affiliate Notes, the Affiliate Warrants and the Affiliate Conversion Shares, the "Affiliate Securities") for an aggregate purchase price of \$875,000 (representing an approximately 8.7% original issue discount) (the "Affiliate Convertible Notes Offering").

In this section, the SOK Note, 31 Group Note and the Affiliate Notes are referred to as the "2014 Convertible Notes." Certain of the terms of the 2014 Convertible Notes and the accompanying Warrants are described below.

On December 31, 2014, the SOK Note, 31 Group Note and the Affiliate Notes had a combined amortization of \$137,470. At the same point in time the SOK Note, the 31 Group Note and the Affiliate Notes had a combined original issue discount of \$56,627. Additionally, as of December 31, 2014, the 31 Group, LLC converted \$80,000 of their note. One of the affiliate investors also converted \$120,000 of their note by December 31, 2014. As of December 31, 2014 another of the affiliate investors converted \$280,616 comprising the balance of their note.

Under the terms of the Registration Rights Agreements and Affiliates Registration Rights Agreements, the Company was required to file a registration statement on Form S-1 to cover the resale of the Original Conversion Shares, the Original Warrant Shares, the Issued Affiliate Conversion Shares and the Issued Affiliate Warrant Shares (the "Resale Registration Statement") and have the Resale Registration Statement declared effective by the Securities and Exchange Commission (the "SEC"). The Company filed the Resale Registration Statement on August 25, 2014 (as amended on September 8, 2014), and the Resale Registration Statement was declared effective on September 8, 2014. As a result of the Company filing the Resale Registration Statement and the SEC declaring it effective within the time periods specified in the Registration Rights Agreements and Affiliates Registration Rights Agreements, (1) the outstanding principal amount of the Notes was reduced from \$1,802,395 to \$1,603,270 (without any cash payment by the Company) and any accrued and unpaid interest with respect to such portion of the principal amount of the Notes that was extinguished was similarly extinguished, and (2) the number of shares of Common Stock issuable upon the exercise of the Warrants was reduced from 80,106 shares of Common Stock to 71,256 shares of Common Stock (without any cash payment by the Company).

Certain Terms of the 2014 Convertible Notes. The 2014 Convertible Notes mature on July 23, 2015 (subject to extension as provided in the 2014 Convertible Notes) and, in addition to the approximately 8.7% original issue discount (after the reduction of the principal amount in September 2014), accrue interest at a rate of 12.0% per annum. The holders have no voting rights as the holders of the 2014 Convertible Notes. Upon conversion of the 2014 Convertible Notes, the holders are entitled to receive such dividends paid and distributions made to the holders of Common Stock from and after the initial issuance date of the 2014 Convertible Notes to the same extent as if the holders had effected such conversion and had held such shares of Common Stock on the record date for such dividends and distributions.

The 2014 Convertible Notes are convertible at any time after issuance, in whole or in part, at the holder's option into shares of Common Stock, at a conversion price equal to the lesser of (i) the product of (x) the arithmetic average of the lowest three volume weighted average prices of the Common Stock during the ten consecutive trading days ending and including the trading day immediately preceding the applicable conversion date and (y) 72.5% (or if an event of default has occurred and is continuing, 70%), and (ii) \$11.25 (as adjusted for stock splits, stock dividends, recapitalizations or similar events).

The 2014 Convertible Notes include customary events of default provisions. The 2014 Convertible Notes provides for a default interest rate of 15% per annum. Upon the occurrence of an event of default, the holder may require the Company to pay in cash the "Event of Default Redemption Price" which is defined in the 2014 Convertible Notes to mean the greater of (i) the product of (A) the amount to be redeemed multiplied by (B) 125% (or 100% if an insolvency related event of default) and (ii) the product of (X) the conversion price in effect at that time multiplied by (Y) the product of (1) 125% (or 100% if an insolvency related event of default) multiplied by (2) the greatest closing sale price of the Common Stock on any trading day during the period commencing on the date immediately preceding such event of default and ending on the date the Company makes the entire payment required to be made under this provision.

With respect to the 2014 Convertible Notes, the Company has the right at any time to redeem, in whole or in part, the outstanding amount then remaining under such 2014 Convertible Note (the "Remaining Amount") at a price equal to the greater of (i) 125% of the Remaining Amount and (ii) the product of (X) the conversion price in effect at that time multiplied by (Y) the product of (1) 135% multiplied by (2) the greatest closing sale price of the Common Stock on any trading day during the period commencing on the Company option redemption notice date and ending on the date immediately prior to the date that the Company makes the entire payment required to be made under this provision. The Company is also required to initially reserve 10 million shares of Common Stock, and will take all action necessary to reserve and keep available 150% of the number of shares of Common Stock as shall from time to time be necessary to effect the conversion of such portion of the 2014 Convertible Notes then outstanding.

Certain Terms of the Warrants Issued to Purchasers of 2014 Convertible Notes. The Warrants issued to the purchasers of the 2014 Convertible Notes are exercisable on any day on or after the date of issuance and have an exercise price of \$12.38 per share, subject to adjustment, and a term of five years from the date of issuance. The holders, will not be entitled, by virtue of being holders of the Warrants, to vote, to consent, to receive dividends, to receive notice as shareholders with respect to any meeting of shareholders for the election of the Company's directors or any other matter, or to exercise any rights whatsoever as our shareholders. If, however, the Company decides to declare a dividend or make distributions of its assets (the "Distribution"), the holders will be entitled to such Distribution to the same extent that the holder's would have participated therein if the holder's had held the number of share of Common Stock acquirable upon complete exercise of the Warrants.

At any time commencing on the earliest to occur of (x) the public disclosure of any change of control, (y) the consummation of any change of control and (z) the holder first becoming aware of any change of control through the date that is ninety (90) days after the public disclosure of the consummation of such change of control by the Company pursuant to a Current Report on Form 8-K filed with the SEC, the Company or the successor entity (as the case may be) may have to purchase the Warrants from the holder in an amount equal to the Black Scholes Value (as defined in the Warrants).

Convertible Notes Issued in 2015. On April 8, 2015, the Company entered into a securities purchase agreement with a private investor, pursuant to which the Company agreed to issue and sell (i) a senior convertible note, in an original principal amount of \$125,000 (the "April 2015 Note"), which shall be convertible into a certain amount of shares of Common Stock, in accordance with the terms of the April 2015 Note, for an aggregate purchase price of \$125,000 (representing an approximately 20% original issue discount (the "April 2015 Convertible Notes Offering"). The terms of the April 2015 Note are substantially similar to those of the 2014 Convertible Notes.

# **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 Skyline and we will, therefore, recognize revenue upon shipment in most cases. This revenue recognition policy applies to shipments of our STREAMWAY FMS units as well as shipments of cleaning solution and filters. 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 STREAMWAY FMS unit or significant quantities of cleaning solution and/or filters may be returned. Currently we manufacture, test and ship the STREAMWAY 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. In 2013 the Company experienced significant exercises of options and warrants. The options raised \$6,500 in capital. Warrants exercised for cash produced \$1,330,000 of capital. 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 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. The Company wrote off the entire original STREAMWAY product patent of \$140,588 in June 2013. The balance represented intellectual property in the form of patents for our original STREAMWAY product. The Company's enhanced STREAMWAY product has a new patent pending, see "Patents and Intellectual Property."

# **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 and Procedures**

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

With the participation of the Chief Executive Officer and the Chief Financial Officer, management has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934). Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2014.

# 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 defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) as of December 31, 2014 based on the criteria in ["Internal Control - Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in 2013]. Based upon this evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2014.

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.

The Board may be increased or decreased from time to time by resolution of the stockholders or the Board. The Company's Board presently consists of five directors. Directors are elected at each annual meeting, and each director shall serve until his or her term expires, his or her earlier death, or a successor is elected and qualified or until the director resigns or is removed. Directors are elected by the highest number of votes cast at a meeting at which a quorum is present. Any vacancies may be filled by the vote of a majority of the Board of Directors, although less than a quorum, and any such person elected to fill a vacancy shall serve as a director until the next annual meeting of stockholders.

The Board does not intend to alter the manner in which it evaluates candidates based on whether or not the candidate was recommended by a shareholder. To submit a candidate for consideration for nomination, shareholders must submit such nomination in writing to our Secretary at 2915 Commers Drive, Suite 900, Eagan, MN 55121.

To view a brief biography for each director please see, "Executive Officers and Directors of the Registrant," in this Annual Report on Form 10-K for additional information.

Name	Age	Position
Directors:		
Joshua Kornberg	41	President, Chief Executive Officer and Interim Chairman of the Board of
		Directors
Frank Mancuso (2)	56	Director
Thomas J. McGoldrick (1) (2) (3)	73	Director
Andrew P. Reding (1)	45	Director
Ricardo Koenigsberger (1) (3)	48	Director

- (1) Member of the Audit Committee
- (2) Member of the Compensation Committee
- (3) Member of the Governance/Nominating Committee

Below is a description of each committee of the Board of Directors as such committees are presently constituted. The Board of Directors has determined that each current member of each committee meets the applicable SEC and NASDAQ rules and regulations regarding "independence" and that each member is free of any relationship that would impair his individual exercise of independent judgment with regard to the Company.

#### **Audit Committee**

The Audit Committee of the Board of Directors was established by the Board in accordance with Section 3(a)(58)(A) of the Exchange Act to oversee the Company's corporate accounting and financial reporting processes and audits of its financial statements.

The functions of the Audit Committee include, among other things:

- serving as an independent and objective party to monitor the Company's financial reporting process and internal control system;
- coordinating, reviewing and appraising the audit efforts of the Company's independent auditors and management and, to the extent the Company has an internal auditing or similar department or persons performing the functions of such department ("internal auditing department" or "internal auditors"), the internal auditing department; and
- communicating directly with the independent auditors, financial and senior management, the internal auditing department, and the Board of Directors regarding the matters related to the committee's responsibilities and duties.

Both our independent registered public accounting firm and management periodically meet privately with the Audit Committee.

Our Audit Committee currently consists of Mr. Koenigsberger, as the chairperson, Mr. McGoldrick and Mr. Reding. Each Audit Committee member is a non-employee director of the Board. The Board of Directors reviews the NASDAQ listing standards definition of independence for Audit Committee members on an annual basis and has determined that all current members of our Audit Committee are independent (as independence is currently defined in Rule 5605(a) (2) of the NASDAQ listing standards). The Audit Committee met four times in fiscal 2014.

#### **Audit Committee Financial Expert**

The Board has determined that Mr. Koenigsberger meets the criteria as an "audit committee financial expert," as defined in Item 407(d)(5)(ii) of Regulation S-K under the Securities Act of 1933, as amended (the "Securities Act"). As noted above, Mr. Koenigsberger, Mr. McGoldrick and Mr. Reding are independent within the meaning of NASDAQ's listing standards.

# Report of the Audit Committee of the Board of Directors

The Audit Committee assists the Board of Directors with fulfilling its oversight responsibility regarding the quality and integrity of the accounting, auditing and financial reporting practices of the Company. In discharging its oversight responsibilities regarding the audit process, the Audit Committee:

- (1) reviewed and discussed the audited financial statements with management and the independent auditors;
- (2) discussed with the independent auditors the material required to be discussed by Statement on Auditing Standards No. 114, as amended (AICPA, Professional Standards, Vol. 1, AU section 380), as adopted by the Public Company Accounting Oversight Board in Rule 3200T, with and without management present; and
- (3) received the written disclosures and the letter from the independent auditors required by applicable requirements of the Public Company Accounting Oversight Board regarding the independent accountant's communications with the Audit Committee concerning independence, and discussed with the independent accountant the independent accountant's independence.

Based upon the review and discussions referred to above, the Audit Committee recommended to the Board of Directors that the audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, as filed with the Securities and Exchange Commission.

Ricardo Koenigsberger, Chair Andrew P. Reding Thomas McGoldrick

# **Compensation Committee**

The Compensation Committee of the Board of Directors currently consists of two directors, Mr. McGoldrick, as the chairperson, and Mr. Mancuso. All members of the Compensation Committee were appointed by the Board of Directors, and consist entirely of directors who are "outside directors" for purposes of Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Code"), "non-employee directors" for purposes of Rule 16b-3 under the Exchange Act and "independent" as independence is currently defined in Rule 4200(a) (15) of the NASDAQ listing standards. In fiscal 2014, the Compensation Committee met two times. The functions of the Compensation Committee include, among other things:

- approving the annual compensation packages, including base salaries, incentive compensation, deferred compensation and stock-based compensation, for our executive officers;
- administering our stock incentive plans, and subject to Board approval in the case of executive officers, approving grants of stock, stock options and other equity awards under such plans;
- approving the terms of employment agreements for our executive officers;
- developing, recommending, reviewing and administering compensation plans for members of the Board of Directors;
- reviewing and discussing the compensation discussion and analysis with management; and
- preparing any compensation committee report required to be included in the annual proxy statement.

All Compensation Committee approvals regarding compensation to be paid or awarded to our executive officers are rendered with the full power of the Board, though not necessarily reviewed by the full Board.

Our Chief Executive Officer may not be present during any Board or Compensation Committee voting or deliberations with respect to his compensation. Our Chief Executive Officer may, however, be present during any other voting or deliberations regarding compensation of our other executive officers, but may not vote on such items of business.

# **Compensation Committee Interlocks and Insider Participation**

As indicated above, the Compensation Committee consists of Mr. McGoldrick and Mr. Mancuso. No member of the Compensation Committee has ever been an executive officer or employee of ours. None of our officers currently serves, or has served during the last completed year, on the compensation committee or the Board of Directors of any other entity that has one or more officers serving as a member of the Board of Directors or the Compensation Committee.

# Governance/Nominating Committee

The Governance/Nominating Committee of the Board of Directors currently consists of Mr. McGoldrick, as the chairperson, and Mr. Koenigsberger. Each of whom is an "independent director," as such term is defined by The NASDAQ Market Listing Rule 5605(a)(2), and free from any relationship that, in the opinion of the Board, would interfere with the exercise of his or her independent judgment as a member of the Committee.

The members of the Committee shall be elected annually by the Board. Committee members may be removed for any reason or no reason at the discretion of the Board, and the Board may fill any Committee vacancy that is created by such removal or otherwise. The Committee's chairperson shall be designated by the full Board or, if it does not do so, the Committee members shall elect a chairperson upon the affirmative vote of a majority of the directors serving on the Committee

The Committee may form and delegate authority to subcommittees as it may deem appropriate in its sole discretion.

In furtherance of its purposes, the Committee:

- Evaluates the composition, organization and governance of the Board, determines future requirements and make recommendations to the Board for approval;
- Determines desired Board and committee skills and attributes and criteria for selecting new directors;
- Reviews candidates for Board membership consistent with the Committee's criteria for selecting new directors and annually recommend a slate of nominees to the Board for consideration at the Company's annual shareholders' meeting;
- Reviews candidates for Board membership, if any, recommended by the Company's shareholders;
- Conducts the appropriate and necessary inquiries into the backgrounds and qualifications of possible director candidates;
- Evaluates and considers matters relating to the qualifications and retirement of directors;
- Develops a plan for, and consults with the Board regarding, management succession; and
- Advises the Board generally on corporate governance matters.

In addition, the Committee, if and when deemed appropriate by the Board or the Committee, develop and recommend to the Board a set of corporate governance principles applicable to the Company, and review and reassess the adequacy of such guidelines annually and recommend to the Board any changes deemed appropriate. The Committee also advises the Board on (a) committee member qualifications, (b) appointments, removals and rotation of committee members, (c) committee structure and operations (including authority to delegate to subcommittees), and (d) committee reporting to the Board. Finally, the Committee performs any other activities consistent with this Charter, the Company's Articles of Incorporation, Bylaws and governing law as the Committee or the Board deems appropriate.

The Committee will review and reassess at least annually the adequacy of the Charter and recommend any proposed changes to the Board for approval.

The Committee has the authority to obtain advice and seek assistance from internal or external legal, accounting or other advisors. The Committee has the sole authority to retain and terminate any search firm to be used to identify director candidates, including sole authority to approve such search firm's fees and other retention terms.

#### **Diversity**

The Board of Directors does not currently have a policy regarding attaining diversity on the Board.

# Compliance With Section 16(a) of the Exchange Act

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires the Company's officers and directors, and persons who own more than ten percent of a registered class of the Company's equity securities, to file reports of ownership and changes in ownership of such securities with the Securities and Exchange Commission. Officers, directors and greater than ten percent stockholders are required by Securities and Exchange Commission regulations to furnish the Company with copies of all Section 16(a) forms they file. Based solely on review of the copies of Forms 3 and 4 and amendments thereto furnished to the Company during the fiscal year ended December 31, 2014 and Forms 5 and amendments thereto furnished to the Company with respect to such fiscal year, or written representations that no Forms 5 were required, the Company believes that the following is the list of its officers, directors and greater than ten percent beneficial owners who have failed to file on a timely basis all Section 16(a) filing requirements during the fiscal year ended December 31, 2014: Samuel Herschkowitz, 2 late reports covering 2 transactions; Ricardo Koenigsberger, 3 late reports, 4 transactions; Joshua Komberg, 2 late reports, 5 transactions; Frank G. Mancuso, 3 late reports, 6 transactions; Thomas J. McGoldrick, 3 late reports, 6 transactions; Andrew P. Reding, 4 late reports, 6 transactions; and Amon Dreyfuss, 3 late reports, 5 transactions.

# ITEM 11. EXECUTIVE COMPENSATION.

#### Overview

This section describes the material elements of the compensation awarded to, earned by or paid to our Chief Executive Officer and our two most highly compensated executive officers other than our Chief Executive Officer, as determined in accordance with SEC rules, collectively referred to as the "Named Executive Officers."

# **Summary Compensation Table for Fiscal 2014 and 2013**

The following table provides information regarding the compensation earned during the fiscal years ended December 31, 2014 and December 31, 2013 by each of the Named Executive Officers:

Name and Principal Position	Year	(5) Salary	Bonus <sup>(7)</sup>	Stock Awards	(1) Option Awards	(6) All Other Compensation	Total Compensation
Joshua Kornberg, CEO, President							
(2)	2014	\$ 275,000	\$ -	\$ -	\$ 428,708	\$ 33,000	\$ 736,708
	2013	\$ 238,691	\$ 187,500	\$ -	\$ 689,169	\$ 36,000	\$ 1,151,360
David O. Johnson, COO (3)	2014	\$ 180,000	\$ -	\$ -	\$ 52,910	\$ -	\$ 232,910
	2013	\$ 161,466	T. Comment	•	\$ 68,252	\$ 10,350	\$ 312,068
		<b>4</b> 202,100	,	*	+ 00,202	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	+,
Bob Myers, CFO <sup>(4)</sup>	2014	\$ 165,000	\$ -	\$ -	\$ 44,087	\$ -	\$ 209,087
• /	2013	\$ 40,561	\$ 60,000	\$ -	\$ 56,877	\$ 1,133	\$ 258,571

- (1) Represents the actual compensation cost recognized during 2014 and 2013 as determined pursuant to FASB ASC 718 Stock Compensation utilizing the assumptions discussed in Note 3, "Stock Options and Warrants," in the notes to the financial statements included in this prospectus.
- (2) Mr. Komberg's bonus earned in 2013 was 75% of his base salary, \$187,500, and will be paid in 2015. Mr. Komberg was also awarded 225% of his base salary in the form of options to purchase 32,609 shares of common stock at \$17.25. In 2014 he also received options to purchase 2,179 shares of common stock as fees for serving on the Board of Directors. In 2013 he also received options to purchase 457 shares of common stock as fees for serving on the Board of Directors. Mr. Komberg received options to purchase 192,000 shares at \$5.625 in 2013 as part of his 2012 bonus.
- (3) Mr. Johnson's bonus awarded by the Board in 2013 was fifty percent payable in cash (\$72,000) and fifty percent in the form of options to purchase 4,174 shares of common stock at \$17.25 per share.
- (4) Mr. Myers bonus awarded by the Board in 2013 was fifty percent payable in cash (\$60,000) and fifty percent in the form of options to purchase 3,479 shares of common stock at \$17.25 per share.
- (5) Salaries shown, where applicable are net of the 401(k) retirement plan put in place during 2013.
- (6) Mr. Kornberg's All Other Compensation consists of health insurance reimbursement for 2014 and 2013.
- (7) Bonuses shown for each year represent the amounts earned for the year, including amounts paid in later periods or accrued for payment in later periods. Bonuses for 2014 are not yet calculable, but are expected to be determined by the Compensation Committee in the first two quarters of 2015. The contractual minimum bonuses for the CEO, COO and CFO for 2014 are described under "Employment Contracts" below.

# Outstanding Equity Awards at Fiscal Year-end for Fiscal 2014

The following table sets forth certain information regarding outstanding equity awards held by the named executive officers as of December 31, 2014:

		Number of Securities Underlying Options	Number of Securities Underlying Options			
	Grant Date	Exercisable	Unexercisable	Option	Exercise Price	Option Expiration Date
Joshua Kornberg (1)	8/13/2012	80,000		\$	6.00	8/13/2022
	3/14/2013	192,000		\$	5.63	3/14/2023
	9/30/2013	210		\$	23.85	9/30/2018
	12/31/2013	247		\$	20.25	12/31/2018
	3/6/2014	32,609		\$	17.25	3/6/2024
	3/31/2014	360		\$	13.88	3/31/2024
	6/30/2014	444		\$	11.25	6/30/2024
	9/30/2014	606		\$	8.25	9/30/2024
	12/31/2014	769		\$	6.50	12/31/2024
David O. Johnson	8/13/2012	13,334		\$	6.00	8/13/2022
	3/18/2013	12,659		\$	5.93	3/18/2023
	3/6/2014	4,174		\$	17.25	3/6/2024
Bob Myers	8/13/2012	13,334		\$	6.00	8/13/2022
	3/18/2013	10,549		\$	5.93	3/18/2023
	3/6/2014	3,479		\$	17.25	3/6/2024

<sup>(1)</sup> Does not reflect an award of 66,667 shares of restricted stock which the Compensation Committee has approved. Such shares would vest upon certain changes in control of the Company.

# **Executive Compensation Components for Fiscal 2014**

Base Salary. Base salary is an important element of our executive compensation program as it provides executives with a fixed, regular, non-contingent earnings stream to support annual living and other expenses. As a component of total compensation, we generally set base salaries at levels believed to attract and retain an experienced management team that will successfully grow our business and create shareholder value. We also utilize base salaries to reward individual performance and contributions to our overall business objectives, but seek to do so in a manner that does not detract from the executives' incentive to realize additional compensation through our stock options and restricted stock awards.

The Compensation Committee reviews the Chief Executive Officer's salary at least annually. The Compensation Committee may recommend adjustments to the Chief Executive Officer's base salary based upon the Compensation Committee's review of his current base salary, incentive cash compensation and equity-based compensation, as well as his performance and comparative market data. The Compensation Committee also reviews other executives' salaries throughout the year, with input from the Chief Executive Officer. The Compensation Committee may recommend adjustments to other executives' base salary based upon the Chief Executive Officer's recommendation and the reviewed executives' responsibilities, experience and performance, as well as comparative market data.

In utilizing comparative data, the Compensation Committee seeks to recommend salaries for each executive at a level that is appropriate after giving consideration to experience for the relevant position and the executive's performance. The Compensation Committee reviews performance for both our Company (based upon achievement of strategic initiatives) and each individual executive. Based upon these factors, the Compensation Committee may recommend adjustments to base salaries to better align individual compensation with comparative market compensation, to provide merit-based increases based upon individual or company achievement, or to account for changes in roles and responsibilities.

Stock Options and Other Equity Grants. Consistent with our compensation philosophies related to performance-based compensation, long-term shareholder value creation and alignment of executive interests with those of shareholders, we make periodic grants of long-term compensation in the form of stock options or restricted stock to our executive officers, directors and others in the organization.

Stock options provide executive officers with the opportunity to purchase common stock at a price fixed on the grant date regardless of future market price. A stock option becomes valuable only if the common stock price increases above the option exercise price and the holder of the option remains employed during the period required for the option shares to vest. This provides an incentive for an option holder to remain employed by us. In addition, stock options link a significant portion of an employee's compensation to shareholders' interests by providing an incentive to achieve corporate goals and increase shareholder value. Under our Amended and Restated 2012 Stock Incentive Plan (the "2012 Plan"), we may also make grants of restricted stock awards, restricted stock units, performance share awards, performance unit awards and stock appreciation rights to officers and other employees. We adopted the 2012 Plan to give us flexibility in the types of awards that we could grant to our executive officers and other employees.

Limited Perquisites; Other Benefits. We provide our employees with a full complement of employee benefits, including health and dental insurance, short term and long term disability insurance, life insurance, a 401(k) plan, FSA flex plan and Section 125 plan. Mr. Komberg receives \$3,000 monthly as a health insurance reimbursement in lieu of accepting the Company medical plan benefits.

# **Employment Contracts**

Employment Agreement with Chief Executive Officer

Base Salary. Our employment agreement, dated March 14, 2013, with Joshua Komberg, President, Chief Executive Officer and Interim Chairman of the Board, provided that his initial annual base salary would be \$250,000 and that his base salary for subsequent years is to be determined by the Board. Effective in March 2014 Mr. Komberg's annualized base salary was increased to \$275,000. We offered this amount as part of a package of compensation to ensure that we retain Mr. Komberg in his current capacity with our Company. The compensation package for Mr. Komberg was designed to provide annual cash compensation, combined with the equity compensation described below, sufficient to induce him to remain with the Company and continue to incentivize him to create revenue growth and shareholder value. Based upon the recommendation of the Compensation Committee, the Board approved an increase to Mr. Komberg's base salary rate from \$180,000 to \$250,000 for calendar 2013.

Compensation and Related Matters. Notwithstanding the terms of the Existing Employment Agreement, in connection with the Mr. Komberg's employment with the Company from April 24, 2012 to December 31, 2012, the Executive shall receive, or has received, the following incentive compensation payments in lieu of the payments described in Section 2(b) of the Existing Employment Agreement:

2012 Annual Bonus. Mr. Komberg was entitled to receive a cash bonus equal to Three Hundred Sixty Thousand Dollars (\$360,000), which is equal to two hundred percent (200%) of the Executive's annual Base Salary in 2012, payable in a lump sum no later than the Company's first regularly scheduled payroll date after the Effective Date. In March 2014, for fiscal year 2013, Mr. Komberg was awarded a \$187,500 cash bonus equal to 75% of his base salary, and 225% of his base salary in the form of options to purchase 32,609 shares of common stock at \$17.25.

<u>Incentive Compensation.</u> In connection with his employment during the Term, Mr. Komberg shall be eligible to receive cash and/or equity incentive compensation as determined by the Board and/or the Compensation Committee from time to time, including, without limitation, the incentive compensation described below:

Annual Bonus. Mr. Komberg shall be eligible to receive with respect to each calendar year ending during the Term of the Executive's employment with the Company a bonus payment subject to the terms of this Section (the "Annual Bonus"). The amount of the Annual Bonus shall be determined based on the attainment of reasonable Company and/or individual performance metrics established and revised annually by the Compensation Committee and/or Board in consultation with Mr. Kornberg, which shall be set at or about the beginning of the given year to which the metrics relate. Mr. Kornberg's target Annual Bonus shall be one hundred fifty percent (150%) of his Base Salary (the "Target Annual Bonus"); provided, however, that the actual amount of the Annual Bonus for each calendar year shall be determined by the Compensation Committee and/or the Board based on relative level of achievement of the applicable metrics and which may be in an amount greater or less than the Target Annual Bonus but shall not be less than fifty percent (50%) of the Target Annual Bonus (the "Minimum Bonus"). The Annual Bonus shall be payable in a single lump sum in cash between January 1 and March 15 of the year following the calendar year to which such Annual Bonus relates. Except as otherwise provided in this Agreement, to eam and be entitled to payment of an Annual Bonus in respect of a given calendar year, Mr. Komberg must be employed by the Company on the last day (i.e., December 31st) of the calendar year to which the bonus relates. Notwithstanding the foregoing, Mr. Komberg (or his estate, if applicable) shall receive a pro-rata portion of the Calendar year during which the Executive was employed) (the "Pro-Rata Bonus") for the calendar year during which the Executive's employment terminates due to: (i) termination by the Company without Cause (as defined below); (ii) termination by the Executive's death or Disability (as defined below).

2012 Stock Option Award Grant. On March 14, 2013, the Company granted to Mr. Komberg 192,000 stock options, which is equal to (A) Three Hundred Sixty Thousand Dollars (\$360,000) (i.e., two hundred percent (200%) of the Executive's annual Base Salary in 2012); divided by (B) the price of a share of common stock of the Company on the day preceding the date of grant; multiplied by (C) three (3) (the "2012 Stock Option Award Grant"). The 2012 Stock Option Award Grant will be fully vested on the date of grant.

2012 Restricted Stock Award Grant. On March 14, 2013, the Company shall grant to Mr. Kornberg Five Million (66,667) shares of common stock, subject to the restrictions contained in the applicable award agreement (the "2012 Restricted Stock Award Grant"). The 2012 Restricted Stock Award Grant will fully vest on a Change in Control (as defined below), as provided in the applicable award agreement.

Equity Incentive Grants. Mr. Kornberg shall receive annual equity incentive grants (e.g., stock options, restricted stock or other stock-based awards) with respect to each calendar year ending during the Term of Mr. Kornberg's employment with the Company, which shall be granted on December 31st of the calendar year to which such grant pertains (each an "Annual Grant"). Each Annual Grant shall be granted in accordance with the terms and conditions of the applicable equity incentive plan or plans then in effect and will be evidenced by an award agreement issued under the applicable plan. The target aggregate grant date fair value of each such Annual Grant shall be two hundred percent (200%) of Mr. Kornberg's Base Salary (the "Target Grant"); provided, however, that the actual amount of any such award shall be determined in the reasonable discretion of the Compensation Committee and/or the Board and may be greater than the Target Grant but shall not be less than the Target Grant. Each Annual Grant shall be fully vested on the date of grant; provided, however, that any equity incentive grant Mr. Kornberg receives that is not an Annual Grant will be subject to the vesting provisions contained in the applicable award agreement.

Compensation Upon Termination.

Termination Generally. If Mr. Komberg's employment with the Company is terminated for any reason, the Company shall pay or provide to Mr. Komberg (or to his authorized representative or estate) (i) any Base Salary earned through the Date of Termination (paid on or before the time required by law but in no event more than thirty (30) days after the Date of Termination); (ii) if the Date of Termination occurs following the end of a given calendar year, but prior to payment of the Annual Bonus with respect to such year, the Annual Bonus payable for such prior calendar year (paid in accordance with Section 2(c) (i)); (iii) if applicable under Section 2(c)(i), the Pro-Rata Bonus for the year during which the Date of Termination occurs (paid at the time the Company pays bonuses with respect to such year); (iv) unpaid expense reimbursements (subject to, and in accordance with, Sections 2(d), 2(f) and 2(i) of this Agreement) and, if applicable under Section 2(h), unused vacation that accrued through the Date of Termination (paid on or before the time required by law but in no event more than thirty (30) days after the Date of Termination); and (v) any vested benefits the Executive may have under any Executive Benefit Plan or other employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such benefit plans (collectively, the "Accrued Benefits").

Termination by the Company Without Cause or by the Executive with Good Reason. During the Term, if Mr. Kornberg's employment is terminated by the Company without Cause as provided in Section 3(d) or Mr. Kornberg terminates his employment for Good Reason as provided in Section 3(e), then the Company shall pay Mr. Kornberg his Accrued Benefits (as provided in Section 4(a) above). In addition, subject to Mr. Kornberg signing a full and final release of all releasable claims in favor of the Company and related persons and entities in a reasonable form and manner reasonably satisfactory to the Company (the "Release") and the expiration of the applicable revocation period for the Release:

a. the Company shall pay Mr. Komberg an amount equal to two (2) times the sum of (x) the Executive's Base Salary; and (y) the Executive's Target Annual Bonus (i.e., one hundred percent (100%) of the Target Annual Bonus amount as if employed for the full year and all applicable performance metrics had been fully achieved) (the "Severance Amount"). The Severance Amount shall be paid in a cash lump sum payment within sixty (60) days after the Date of Termination; provided, however, that if the sixty (60) day period begins in one calendar year and ends in a second calendar year, the lump sum payment of the Severance Amount shall be paid in the second calendar year (but prior to the end of the sixty (60) day period). Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulations Section 1.409A-2(b)(2);

- b. effective upon the Date of Termination, all stock options and other stock-based awards (including, without limitation, all such awards/grants under Sections 2(b)(ii) and 2(c)(ii)) held by Mr. Komberg and all yet unvested portions thereof shall immediately and fully accelerate and vest and become exercisable or nonforfeitable as of the Date of Termination (to the extent that the Release is not effective as of the Date of Termination, the Company shall take all necessary corporate action to ensure that no such stock-based awards terminate or are forfeited by Mr. Komberg from the Date of Termination until the date such accelerated vesting and/or exercisability becomes effective);
- c. if the Annual Grant had not been made with respect to the year in which the Date of Termination occurs, the Company shall grant to Mr. Komberg on the Date of Termination such number of shares of common stock with an aggregate fair market value on the Date of Termination equal to two hundred percent (200%) of Mr. Komberg's Base Salary (which grant shall be fully vested on the Date of Termination); and
- d. the Company shall provide Mr. Komberg (and, as applicable, his spouse and eligible dependents) with continued medical (health, dental, and vision), life insurance (as provided in Section 2(g) above) and disability benefits, at the Company's expense, to the same extent in which the Executive participated prior to the Date of Termination for a period of eighteen (18) months following the Date of Termination; provided, however, if the Company cannot provide, for any reason, Mr. Komberg or his dependents with the opportunity to participate in the benefits to be provided pursuant to this paragraph (at the Company's expense), the Company shall pay to Mr. Komberg a single sum cash payment, payable within sixty (60) days following the date the Company cannot provide such benefits, in an amount equal to the fair market value of the benefits to be provided pursuant to this paragraph plus an amount necessary to "gross-up" Mr. Komberg with respect to any Federal, state or local taxation due on such single sum cash payment. If Mr. Komberg (and his spouse and dependents, as applicable) was/were covered by Mr. Komberg's own health insurance premiums for which Mr. Komberg was being reimbursed pursuant to Section 2(t) above, then the Company shall pay to Mr. Komberg a single sum cash payment, payable within sixty (60) days following the Date of Termination, equal to the total amount of the monthly premiums for such insurance coverage for a period of eighteen (18) months.

Change in Control Payment. The provisions of this set forth certain terms of an agreement reached between Mr. Komberg and the Company regarding Mr. Komberg's rights and obligations upon the occurrence of a Change in Control of the Company. These provisions are intended to assure and encourage in advance Mr. Komberg's continued attention and dedication to his assigned duties and his objectivity during the pendency and/or after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4 regarding severance pay and benefits upon a termination of employment by the Company without Cause as provided in Section 3(d), if such termination of employment occurs in connection with or within eighteen (18) months after the occurrence of the first event constituting a Change in Control. These provisions shall terminate and be of no further force or effect beginning eighteen (18) months after the occurrence of a Change in Control if Mr. Komberg remains employed with the Company through and at such time.

Change in Control. In the event of a Change in Control (as defined below):

- a. notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all stock options and other stock-based awards held by Mr. Komberg (including, without limitation, all such awards/grants under Sections 2(b)(ii) and 2(c) (ii)) and all yet unvested portions thereof shall immediately and fully accelerate and vest and become fully exercisable or nonforfeitable as of immediately prior to the closing or occurrence (as applicable) of the event constituting the Change in Control; and
- b. if, in connection with or within eighteen (18) months after a Change in Control, Mr. Komberg's employment is terminated by the Company without Cause as provided in Section 3(d) or Mr. Komberg terminates his employment for any reason, then the Company shall pay Mr. Komberg his Accrued Benefits (as provided in Section 4(a) above). In addition, subject to the signing of the Release by the Executive and the expiration of the applicable revocation period for the Release:
  - (A) the Company shall pay Mr. Komberg a lump sum in cash in an amount equal to three (3) times the sum of (A) Mr. Komberg's current Base Salary (or the Executive's Base Salary in effect immediately prior to the Change in Control, if higher); and (B) Mr. Komberg's Target Annual Bonus (or Mr. Komberg's Target Annual Bonus in effect immediately prior to the Change in Control, if higher). Such payment shall be paid within sixty (60) days after the Date of Termination; provided, however, that if the sixty (60) day period begins in one calendar year and ends in a second calendar year, such payment shall be paid in the second calendar year (but prior to the end of the sixty (60) day period);
  - (B) to the extent not covered by and accelerated pursuant to Section 5(a)(i) above, effective upon the Date of Termination all stock options and other stock-based awards (including, without limitation, all such awards/grants under Sections 2(b)(ii) and 2(c)(ii)) held by Mr. Komberg and all yet unvested portions thereof shall immediately and fully accelerate and vest and become exercisable or nonforfeitable as of the Date of Termination (to the extent that the Release is not effective as of the Date of Termination, the Company shall take all necessary corporate action to ensure that no such stock-based awards terminate or are forfeited by Mr. Komberg from the Date of Termination until the date such accelerated vesting and/or exercisability becomes effective);

- (C) if the Annual Grant had not been made with respect to the year in which the Date of Termination occurs, the Company shall grant to Mr. Komberg on the Date of Termination such number of shares of common stock with an aggregate fair market value on the Date of Termination equal to two hundred percent (200%) of Mr. Komberg's Base Salary (which grant shall be fully vested on the Date of Termination); and
- (D) the Company shall provide Mr. Komberg (and, as applicable, his spouse and eligible dependents) with continued medical (health, dental, and vision), life insurance (as provided in Section 2(g) above) and disability benefits, at the Company's expense, to the same extent in which Mr. Komberg participated prior to the Date of Termination for a period of eighteen (18) months following the Date of Termination; provided, however, if the Company cannot provide, for any reason, Mr. Komberg or his dependents with the opportunity to participate in the benefits to be provided pursuant to this paragraph (at the Company's expense), the Company shall pay to Mr. Komberg a single sum cash payment, payable within sixty (60) days following the date the Company cannot provide such to "gross-up" Mr. Komberg with respect to any Federal, state or local taxation due on such single sum cash payment. If Mr. Komberg (and his spouse and dependents, as applicable) was/were covered by Mr. Komberg's own health insurance premiums for which Mr. Komberg was being reimbursed pursuant to Section 2(f) above, then the Company shall pay to Mr. Komberg a single sum cash payment, payable within sixty (60) days following the Date of Termination, equal to the total amount of the monthly premiums for such insurance coverage for a period of eighteen (18) months.

# (E) Gross-Up Payment.

- (i) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that the amount of any compensation, payment or distribution by the Company to or for the benefit of Mr. Komberg, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Internal Revenue Code of 1986, as amended (the "Code") and the applicable regulations thereunder (the "Severance Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, or any interest or penalties are incurred by Mr. Komberg with respect to such excise tax (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), then Mr. Komberg shall be entitled to receive an additional payment or payments (collectively, the "Gross-Up Payment") such that the net amount retained by Mr. Komberg, after deduction of any Excise Tax on the Severance Payments, any Federal, state, and local income tax, employment tax and Excise Tax upon the payment provided by this Section, and any interest and/or penalties assessed with respect to such Excise Tax, shall be equal to the Severance Payments.
- Subject to the provisions of Section 5(b)(iii) below, all determinations required to be made under this Section 5(b) (ii), including whether a Gross-Up Payment is required and the amount of such Gross-Up Payment, shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and Mr. Kornberg within fifteen (15) business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or Mr. Kornberg. For purposes of determining the amount of the Gross-Up Payment, Mr. Komberg shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the Gross-Up Payment is to be made, and state and local income taxes at the highest marginal rates of individual taxation in the state and locality of Mr. Kornberg's residence on the Date of Termination, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes. The Gross-Up Payment, if any, as determined pursuant to this Section 5(b)(ii), shall be paid to the relevant tax authorities as withholding taxes on behalf of Mr. Komberg at such time or times when each Excise Tax payment is due. Any determination by the Accounting Firm shall be binding upon the Company and Mr. Komberg. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments which will not have been made by the Company should have been made (an "Underpayment"). In the event that the Company exhausts its remedies pursuant to Section 5(b)(iii) below and Mr. Kornberg thereafter is required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred, consistent with the calculations required to be made hereunder, and any such Underpayment, and any interest and penalties imposed on the Underpayment and required to be paid by Mr. Kornberg in connection with the proceedings described in Section 5(b)(iii) below, shall be promptly paid by the Company to the relevant tax authorities as withholding taxes on behalf of Mr. Kornberg.

- (i i i) Mr. Komberg shall notify the Company in writing of any claim by the Internal Revenue Service that, if successful, would require the payment by the Company of the Gross-up Payment. Such notification shall be given as soon as practicable but no later than ten (10) business days after Mr. Komberg knows of such claim and shall apprise the Company of the nature of such claim and the date on which such claim is requested to be paid. Mr. Komberg shall not pay such claim prior to the expiration of the thirty (30) day period following the date on which he gives such notice to the Company (or such shorter period ending on the date that any payment of taxes with respect to such claim is due). If the Company notifies Mr. Komberg in writing prior to the expiration of such period that it desires to contest such claim, provided that the Company has set aside adequate reserves to cover the Underpayment and any interest and penalties thereon that may accrue, the Executive shall:
  - (A) give the Company any information reasonably requested by the Company relating to such claim;
- (B) take such action in connection with contesting such claim as the Company shall reasonably request in writing from time to time, including, without limitation, accepting legal representation with respect to such claim by an attorney selected by the Company;
  - (C) cooperate with the Company in good faith in order to effectively contest such claim; and
- (D) permit the Company to participate in any proceedings relating to such claim; <u>provided</u>, however, that the Company shall bear and pay directly all costs and expenses (including additional interest and penalties) incurred in connection with such contest and shall indemnify and hold Mr. Komberg harmless, on an after-tax basis, for any Excise Tax or income tax, including interest and penalties with respect thereto, imposed as a result of such representation and payment of costs and expenses.
- (iv) If, after a Gross-Up Payment by the Company on behalf of Mr. Komberg pursuant to this Section 5(b), Mr. Komberg becomes entitled to receive any refund with respect to such claim, Mr. Komberg shall (subject to the Company's complying with the requirements of Section 5(b)(iii)) promptly pay to the Company the amount of such refund (together with any interest paid or credited thereon after taxes applicable thereto).

<u>Definitions</u>. For purposes of this Section 5, the following terms shall have the following meanings:

"Change in Control" shall mean any of the following:

- (i) there is consummated a merger, consolidation, statutory exchange or reorganization, unless securities representing more than fifty percent (50%) of the total combined voting power of the outstanding voting securities of the successor corporation are immediately thereafter beneficially owned directly or indirectly and in substantially the same proportion, by the persons who beneficially owned the Company's outstanding voting securities immediately prior to such transaction;
- (ii) any transaction or series of related transactions pursuant to which any person or any group of persons comprising a "group" within the meaning of Rule 13d-5(b)(1) under the Securities Exchange Act of 1934, as amended (other than the Company or a person that, prior to such transaction or series of related transactions, directly or indirectly controls, is controlled by or is under common control with the Company) becomes directly or indirectly the beneficial owner (within the meaning of Rule 13d-3 of the Securities Exchange Act of 1934, as amended) of securities possessing (or convertible into or exercisable for securities possessing) thirty percent (30%) or more of the total combined voting power of the securities (determined by the power to vote with respect to the elections of Board members) outstanding immediately after the consummation of such transaction or series of related transactions, whether such transaction involves a direct issuance from the Company or the acquisition of outstanding securities held by one or more of the Company's shareholders;

- (iii) there is consummated a sale, lease, exclusive license, or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license, or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by shareholders of the Company in substantially the same proportions as their ownership of the Company immediately prior to such sale, lease, license, or other disposition; or
- (iv) individuals who, on the Effective Date, are members of the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new director was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new director shall, for purposes of sentence, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (ii) solely as the result of (A) the acquisition of additional securities by Dr. Samuel Herschkowitz, Joshua Komberg or their affiliates; or (B) a repurchase or other acquisition of securities by the Company which, by reducing the number of shares of voting securities outstanding, increases the proportionate number of voting securities beneficially owned by any person to thirty percent (30%) or more of the combined voting power of all of the then outstanding voting securities; provided, however, that if any person referred to in this clause (B) shall thereafter become the beneficial owner of any additional shares of voting securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns thirty percent (30%) or more of the combined voting power of all of the then outstanding voting securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (ii).

Employment Agreements with Chief Operating Officer and Chief Financial Officer.

On August 13, 2012, the Company entered into employment agreements with David O. Johnson, who has served as Chief Operating Officer since July 1, 2012, and Bob Myers, who has served as Chief Financial Officer since July 1, 2012 (Messrs. Johnson and Myers are referred to as the "executives"). Under the agreements the employment of each of these individuals with the Company is at will.

The annualized base salaries of Messrs. Johnson and Myers were \$150,000 and \$125,000, respectively for their first year employed. Effective July 1, 2013 the annualized base salaries of Messrs. Johnson and Myers were \$180,000 and \$150,000, respectively. Effective in March 2014 Mr. Myers annualized base salary was increased to \$165,000. Such base salaries may be adjusted by the Company but may not be reduced except in connection with a reduction imposed on substantially all employees as part of a general reduction. The executives will also each be eligible to receive an annual incentive bonus for each calendar year at the end of which he remains employed by the Company, subject to the attainment of certain objectives. The executives have a minimum bonus guarantee of twenty percent (20%) of their annualized salary. Messrs. Johnson and Myers each had received ten year stock options to purchase 13,334 shares of common stock at \$6.00 per share with each option vested immediately with respect to 9,334 shares and with the remaining 4,000 shares to vest 18 months after the date of grant. The executives received bonuses for 2012 equal to one hundred percent (100%) of their annualized salary; fifty percent (50%) in cash and fifty percent (50%) in options to purchase 12,659 and 10,549 shares of common stock, respectively, at \$5.93 per share, with each option vesting immediately. Also, in 2013 the 4,000 unvested shares for Messrs. Johnson and Myers were accelerated to immediate vesting.

If the Company terminates the executive's employment without cause or if the executive terminates his employment for "good reason," he shall be entitled to receive from Company severance pay in an amount equal to (a) before the first anniversary of the date of the agreement, three months of base salary, or (b) on or after the first anniversary of the date of the agreement, twelve months of base salary, in either case less applicable taxes and withholdings. In that event, he will receive a bonus payment on a pro-rata basis through the date of termination and any accrued, unused vacation pay. The severance pay, bonus payment, and other consideration are conditioned upon executive's execution of a full and final release of liability. "Cause" is defined to mean the executive engages in willful misconduct or fails to follow the reasonable and lawful instructions of the Board, if such conduct is not cured within 30 days after notice; the executive embezzles or misappropriates assets of Company or any of its subsidiaries; the executive's violation of his obligations in the agreement, if such conduct is not cured within 30 days after notice; breach of any agreement between the executive and the Company or to which Company and the executive are parties, or a breach of his fiduciary responsibility to the Company; commission by of fraud or other willful conduct that adversely affects the business or reputation of Company; or, Company has a reasonable belief the executive engaged in some form of harassment or other improper conduct prohibited by Company policy or the law. "Good reason" is defined as (i) a material diminution in Employee's position, duties, base salary, and responsibilities; or (ii) Company's notice to Employee that his or her position will be relocated to an office which is greater than 100 miles from Employee's prior office location. In all cases of Good Reason, Employee must have given notice to Company that an alleged Good Reason event has occurred and the circumstances must remain uncorrected by Compan

During each executive's employment with the Company and for twelve months thereafter, regardless of the reason for the termination, he will not engage in a competing business, as defined in the agreement and will not solicit any person to leave employment with the Company or solicit clients or prospective clients of the Company with whom he worked, solicited, marketed, or obtained confidential information about during his employment with the Company, regarding services or products that are competitive with any of the Company's services or products.

#### Potential Payments Upon Termination or Change of Control

Most of our stock option agreements provide for an acceleration of vesting in the event of a change in control as defined in the 2012 Stock Incentive Plan. Also, see "Employment Contracts" below.

Most of our stock option agreements provide for an acceleration of vesting in the event of a change in control as defined in the agreements and in the 2012 Stock Incentive Plan. Additionally, the restricted stock agreements that were awarded to management and directors in 2013 also provide for an acceleration of vesting in the event there is a change in control as defined in the 2012 Plan. Also, see "Employment Contracts" above.

#### **Director Compensation**

Effective in 2013 the Board instituted a quarterly and an annual stock options award program for all the directors under which they will be awarded options to purchase \$5,000 worth of shares of common stock, par value \$0.01 per quarter at an exercise price determined by the close on the last day of the quarter. Additionally, the directors that serve on a committee will receive options to purchase \$10,000 worth of shares of common stock, par value \$0.01 annually, per committee served, at an exercise price determined by the close on the last day of the year.

# **Director Compensation Table for Fiscal 2014**

The following table summarizes the compensation paid to each non-employee director in the fiscal year ended December 31, 2014:

	Fees P	aid or	C	Option	
	Earned	in Cash Stock Av	wards A	wards	Total
Thomas McGoldrick	\$	- \$	- \$	22,161(1) \$	22,161
Ricardo Koenigsberger	\$	- \$	- \$	22,161(2) \$	22,161
Andrew Reding	\$	- \$	- \$	18,468(3) \$	18,468
Frank Mancuso, Jr.	\$	- \$	- \$	18,468(4) \$	18,468
Dr. Arnon Dreyfuss	\$	- \$	- \$	14,797(5) \$	14,797

- (1) Mr. McGoldrick was awarded options to purchase 3,068 shares of common stock both for serving on the Board and for participating on the Audit and Corporate Governance Committees.
- (2) Mr. Koenigsberger was awarded options to purchase 3,068 shares of common stock both for serving on the Board and for participating on the Audit and Corporate Governance Committees.
- (3) Mr. Reding was awarded options to purchase 2,624 shares of common stock both for serving on the Board and for participating on the Audit Committee.
- (4) Mr. Mancuso was awarded options to purchase 2,624 shares of common stock both for serving on the Board and for participating on the Compensation Committee.
- (5) Dr. Dreyfuss was awarded options to purchase 1,855 shares of common stock both for serving on the Board and for participating on the Compensation Committee. Dr. Dreyfuss resigned as a director effective October 1, 2014.

# **Equity Compensation Plan Information**

The following table presents the equity compensation plan information as of December 31, 2014:

	Number of securities to be issued upon exercise of outstanding restricted stock, warrants and options (a)	Weighted- average exercise price of outstanding options, warrants (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)
Equity compensation plans approved by			
security holders (1)	515,268	\$ 7.63	869,410
Equity compensation plans not approved by security holders	-	\$ -	-

(1) Consists of outstanding options under the 2008 Equity Incentive Plan and the 2012 Stock Incentive Plan. The remaining share authorization under the 2008 Equity Incentive Plan was rolled over to the current 2012 Stock Incentive Plan.

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

The following table sets forth as of December 31, 2014 certain information regarding beneficial ownership of our common stock by:

- Each person know to us to beneficially own 5% or more of our common stock;
- Each executive officer who in this Annual Report Form 10-K are collectively referred to as the "Named Executive Officers;"
- Each of our directors; and
- All of our executive officers (as that term is defined under the rules and regulations of the SEC) and directors as a group.

We have determined beneficial ownership in accordance with Rule 13d-3 under the Exchange Act. Beneficial ownership generally means having sole or shared voting or investment power with respect to securities. Unless otherwise indicated in the footnotes to the table, each shareholder named in the table has sole voting and investment power with respect to the shares of common stock set forth opposite the shareholder's name. We have based our calculation of the percentage of beneficial ownership on 3,092,766 shares of the Company's common stock outstanding on December 31, 2014. Unless otherwise noted below, the address for each person or entity listed in the table is c/o Skyline Medical Inc., 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121.

Name of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
Officers and Directors		
Officers with Directors		
Josh Komberg (5)(6)	1,119,890	32.88%
David Johnson <sup>(2)</sup>	30,227	0.97%
Bob Myers <sup>(3)</sup>	27,493	0.88%
Ricardo Koenigsberger <sup>(4)</sup>	4,513	0.15%
Thomas J. McGoldrick <sup>(4)</sup>	6,093	0.20%
Andrew Reding <sup>(7)</sup>	4,888	0.16%
Frank Mancuso <sup>(7)</sup>	6,908	0.22%
All directors and executive officers as a group (7 persons)	1,200,012	38.76%
5% Security Holders		
Sam Herschkowitz (5) (6)	1,436,304	46.39%
SOK Partners	805,982	25.99%
APA, SOK, Sam Herschkowitz, Josh Komberg	1,750,211	51.39%
Carl Schwartz (8)	164,469	5.21%

- 1. Under Rule 13d-3, a beneficial owner of a security includes any person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares: (i) voting power, which includes the power to vote, or to direct the voting of shares; and (ii) investment power, which includes the power to dispose or direct the disposition of shares. Certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire the shares (for example, upon exercise of an option) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares outstanding is deemed to include the amount of shares beneficially owned by such person (and only such person) by reason of these acquisition rights. As a result, the percentage of outstanding shares of any person as shown in this table does not necessarily reflect the person's actual ownership or voting power with respect to the number of shares of common stock actually outstanding.
- 2. Includes (i) option to purchase 13,334 shares of common stock at a price of \$6.00 per share (ii) option to purchase 12,659 shares of common stock at a price of \$5.93 per share and (iii) option to purchase 4,045 shares of common stock at a price of \$17.25 per share that may be exercised within 60 days of February 10, 2015.
- 3. Includes (i) option to purchase 13,334 shares of common stock at a price of \$6.00 per share (ii) option to purchase 10,549 shares of common stock at a price of \$5.93 per share and (iii) option to purchase 3,479 shares of common stock at a price of \$17.25 per share that may be exercised within 60 days of February 10, 2015.
- 4. Includes (i) option to purchase 210 shares of common stock at a price of \$23.85 per share (ii) option to purchase 1,235 shares of common stock at a price of \$20.25 (iii) option to purchase 1,334 shares of common stock at a price of \$11.25 (iv) option to purchase 606 shares of common stock at a price of \$8.25, and (v) option to purchase 769 shares of common stock at a price of \$6.50 per share that may be exercised within 60 days of February 10, 2015.
- 5. Includes (i) options to purchase 306,476 shares common stock that may be exercised within the next 60 days, (ii) 788,808 shares owned directly by SOK Partners, (iii) warrants to purchase 1,261 shares of common stock at a price of \$24.38 per share, respectively, and (iv) 1,282 shares of common stock issuable upon conversion of 250 shares of Series A Convertible Preferred Stock, par value, \$0.01, stated value \$100.00. Mr. Kornberg and Dr. Samuel Herschkowitz are the managing partners of SOK Partners.
- Includes 788,808 shares owned directly by SOK Partners. Joshua Komberg and Dr. Samuel Herschkowitz are the managing partners of SOK Partners.
- 7. Includes (i) option to purchase 210 shares of common stock at a price of \$23.85 per share (ii) option to purchase 741 shares of common stock at a price of \$20.25 (iii) option to purchase 889 shares of common stock at a price of \$11.25 (iv) option to purchase 606 shares of common stock at a price of \$8.25, and (v) option to purchase 769 shares of common stock at a price of \$6.50 per share that may be exercised within 60 days of February 10, 2015.
- 8. Includes 106,310 shares of common stock. Includes an option to purchase 1,778 shares of common stock at \$11.25 and a warrant to purchase 56,381 shares of common stock at \$11.25.

# **Changes in Control**

We are not aware of any arrangements, including any pledge by any person of our stock, the operation of which may at a subsequent date result in a change of control of the Company.

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

The Audit Committee has the responsibility to review and approve all transactions to which a related party and the Company may be a party prior to their implementation, to assess whether such transactions meet applicable legal requirements. Rick Koenigsberger, a director, is a holder of membership units of SOK Partners.

# Agreements with Former Directors

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 3,704 shares at \$6.75 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 was 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 400 shares at \$11.25 per share in June 30, 2012 as compensation for service as Chairman. Mr. Gadbaw and Mr. Morawetz have both resigned from the Board in the third quarter of 2013. Both Mr. Gadbaw and Mr. Morawetz received 667 shares of common stock each at \$24.38 per share; 267 of these shares were for compensation from serving as Board members and the remaining 400 shares were issued to satisfy previous contractual agreements.

#### Convertible Note Issuances to Dr. Samuel Herschkowitz and SOK Partners, LLC

On September 11, 2013, both the Herschkowitz Note and the SOK Note (each as defined below in this Note 9) were converted in full by the holders thereof at \$1.05 per share. The principal and interest balance of the Herschkowitz Note of \$314,484 was converted into 299,509 shares of common stock. The principal and interest balance of the SOK Note of \$680,444 was converted into 648,050 shares of common stock. The collateral that secured these notes was released back to the Company.

The remaining disclosure of this Note 9 provides historical information regarding the Herschkowitz Note, the SOK Note and certain other convertible note issuances.

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"), and an investment partnership. Josh Komberg, 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.

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 \$4.88 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 \$4.88 per share. In March 2012, the Company issued the first equity bonus to SOK Partners, consisting of 61,539 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 61,539 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. The principal balance of the SOK Note was \$357,282 as of December 31, 2012.

As long as any amount payable under the SOK 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 20,623 shares of common stock. An additional 100,000 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 described below, relating to the defaults under the Herschkowitz Note and other matters.

As long as any amount payable under the Herschkowitz Note remained outstanding, Dr. Herschkowitz or his designee was entitled to appoint a special advisor to the Company's Board of Directors, to be appointed as a member of the Board upon request. Pursuant to this authority, Josh Komberg was appointed to the Board on March 9, 2012. In addition, pursuant to this authority, Ricardo Koenigsberger was appointed to the Board on June 25, 2012.

Pursuant to a letter dated April 20, 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.

In addition, the Company and Atlantic Partners Alliance LLC ("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 213,334 shares of common stock to parties other than APA and its affiliates, resulting in significant dilution.

Effective August 15, 2012, the Company entered into a letter agreement with Dr. Herschkowitz, APA and SOK (the "Forbearance Agreement"). 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 353,334 shares of common stock to Dr. Herschkowitz and SOK and adjusted the conversion price of the Herschkowitz Note and the SOK Note, respectively, to \$1.05 per share from \$4.88 per share, to satisfy the Company's obligations to adjust for dilution under the March 14, 2012 letter agreement; (iii) Dr. Herschkowitz and SOK agreed to extend the maturity of the Herschkowitz Note and the SOK Note, respectively, 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.

In the Forbearance Agreement, Dr. Herschkowitz agreed 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 agreed 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 under the Herschkowitz Note: (a) that does not constitute an existing default and (b) occurs and accrues after the effective date of the letter agreement.

Dr. Herschkowitz and the Company acknowledged that 100,000 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.

Under the Forbearance Agreement, the Herschkowitz Note and the SOK Note were amended as follows: (i) the due dates of the notes were 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 consideration of the extension additional milestone fees were revised as described below. Pursuant to a Forbearance and Settlement Agreement with these parties dated August 15, 2012, as subsequently amended, the due date of these notes were extended to August 31, 2013.

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 176,667 shares to Dr. Herschkowitz, (ii) issued 176,667 shares to SOK, and (iii) the conversion price of the Herschkowitz Note and the SOK Note, respectively was changed to \$1.05 per share from \$4.88 per share.

In the event that the Company consummated 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 would have been required to 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 was also required to reimburse Dr. Herschkowitz at his actual out-of-pocket cost for reasonable expenses incurred in connection with the shell transactions, with a maximum limit of \$10,000 for such expenses.

In connection with the extension of the due date for the Herschkowitz Note and the SOK Note on March 6, 2013, the milestone fees were revised. The following fees were payable to Dr. Herschkowitz in the event that the Company consummates the following series of transactions on or prior to December 31, 2013: (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. In May 2013 Dr. Herschkowitz received \$75,000 after the Company surpassed raising \$1 million. On January 6, 2014 a side-letter to the forbearance agreement was signed between Dr. Herschkowitz and the Company. Skyline agreed that the private offering for its Series A Convertible Preferred Stock, plus any future offering of any class of its preferred stock, shall be considered a NASDAQ underwriting for purposes of Section 8(e) of the Forbearance Agreement. As such Dr. Herschkowitz received \$200,000 or 3% of the gross proceeds of any such offering per the terms of Section 8(e) of the Forbearance Agreement. In addition, any listing of the Company's shares on the New York Stock Exchange shall qualify as a NASDAQ underwriting under the Forbearance Agreement. For the avoidance of doubt, the payment in the aggregate for all offerings qualifying as a NASDAQ underwriting shall under no circumstances be less than \$200,000 or greater than \$1,000,000. Section 8(e) of the Forbearance Agreement will apply to any transactions consummated by Skyline on or before June 30, 2014.

As a result of the transactions under the Forbearance Agreement and other investments, Dr. Herschkowitz, SOK and their affiliates currently own shares of common stock and securities representing beneficial ownership of approximately 57% of the Company's outstanding common stock, giving such parties significant control over election of the Board of Directors and other matters.

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 20,833 shares of common stock in consideration of placement of the notes. These 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. Such notes were converted in April 2013 into 13,889 shares of common stock at \$7.50 per share.

In December 2013 the Company received an additional \$300,000 in debt financing from SOK Partners under a non-convertible grid note due February 28, 2014, with 10% interest based on a 365 day year. Dr. Herschkowitz received 10% of the gross proceeds in advance, and the Company received \$250,000 in three tranches in December 2013. In January 2014, the Company received an additional \$20,000 from SOK Partners completing the grid note maximum. Should the company default on the note the interest rate will increase to 20% interest based on a 365 day year. In February 2014, the Company wired \$305,589.04 to SOK Partners in complete payment of the grid note, including interest.

In connection with the sale of the Preferred Shares on February 4, 2014, Josh Komberg, our CEO, was one of the Purchasers. Mr. Komberg purchased 19,231 Preferred Shares for a purchase price of \$25,000 and received warrants to purchase 52 shares of common stock.

Finally, SOK invested in the July 2014 offering of convertible notes and warrants. In November 2014, the convertible noteholders agreed to convert certain balances of the convertible notes in connection with this offering, in consideration of the agreement to issue certain additional shares. See "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Historical Financing — 2014 Sales of Convertible Notes and Warrants."

# ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

In connection with the audit of the fiscal 2014 financial statements, the Company entered into an engagement agreement with Olsen Thielen & Co., Ltd., which sets forth the terms by which Olsen Thielen & Co., Ltd. will perform audit services for the Company.

The following table represents aggregate fees billed to the Company for the fiscal years ended December 31, 2014 and December 31, 2013, by Olsen Thielen & Co., Ltd., the Company's principal accountant. All fees described below were approved by the Audit Committee.

	2014	2013
Audit Fees (1)	\$ 75,750	\$ 91,205
Audit-Related Fees (2)	-	-
Tax Fees (3)	10,851	7,119
All Other Fees (4)	11,400	-
	\$ 98,001	\$ 98,324

- (1) Audit Fees were principally for services rendered for the audit and/or review of our consolidated financial statements. Also, includes fees for services rendered in connection with the filing of registration statements and other documents with the SEC, the issuance of accountant consents and comfort letters and assistance in responding to SEC comment letters.
- (2) There were no audit-related fees in 2014 and 2013.
- (3) Tax Fees consist of fees billed in the indicated year for professional services performed by Olsen Thielen & Co., Ltd. with respect to tax compliance and tax advice.
- (4) All Other Fees consist of fees billed in the indicated year for other permissible work performed by Olsen Thielen & Co., Ltd. that is not included within the above category descriptions.

# PART IV

# ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

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

# (1) Financial Statements

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

- Report of Independent Registered Public Accounting Firm dated April 30, 2015;
- Balance Sheets as of December 31, 2014 and December 31, 2013;
- Statements of Operations for the Years Ended December 31, 2014 and December 31, 2013;
- Statements of Stockholders' Deficit from December 31, 2012 to December 31, 2014;
- Statements of Cash Flows for the Years Ended December 31, 2014 and December 31, 2013;
- 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: April 30, 2015 Skyline 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 Komberg Joshua Komberg	President, Chief Executive Officer and Interim Chairman of the Board (principal executive officer)	April 30, 2015
/s/ Bob Myers Bob Myers	Chief Financial Officer (principal financial officer)	April 30, 2015
/s/ Andrew P. Reding Andrew P. Reding	Director	April 30, 2015
/s/ Ricardo Koenigsberger Ricardo Koenigsberger	Director	April 30, 2015
/s/ Thomas J. McGoldrick Thomas J. McGoldrick	Director	April 30, 2015
/s/ Frank Mancuso, Jr. Frank Mancuso, Jr.	Director	April 30, 2015

# EXHIBIT INDEX SKYLINE MEDICAL INC. FORM 10-K

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated December 16, 2013, between Skyline Medical Inc., a Minnesota corporation, and the registrant (1)
3.1	Certificate of Incorporation (1)
3.2	Certificate of Amendment to Certificate of Incorporation filed with the Delaware Secretary of State on October 20, 2014 (19)
3.3	Bylaws (1)
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (2)
4.1	Form of Warrant (2)
4.2	Form of Warrant (7)
4.3	Form of Warrant (11)
4.4	Form of Warrant (15)
4.5	Form of Warrant (16)
4.6	Amended and Restated 2012 Stock Incentive Plan (3)**
10.1	Form of Securities Purchase Agreement, dated as of February 4, 2014, by and among the Company and certain Purchasers (2)
10.2	Settlement Agreement and Mutual General Release dated September 18, 2013, entered into by and among Kevin Davidson, Skyline Medical Inc., Atlantic Partners Alliance, LLC, SOK Partners, LLC, Joshua Komberg and Dr. Samuel Herschkowitz (4)
10.3	Amended and Restated Executive Employment Agreement with Joshua Komberg, signed on June 17, 2013 and effective March 14, 2013 (6)**
10.4	BioDrain Medical, Inc., 2012 Stock Incentive Plan Restricted Stock Award Agreement with Joshua Komberg, signed on June 17, 2013 and effective March 14, 2013 (6)**
10.5	Form of Convertible Promissory Note (7)
10.6	Promissory Note in the Principal amount of \$100,000 in favor of Brookline Group, LLC, dated as of March 8, 2013 (9)
10.7	Form of Securities Purchase Agreement (11)
10.8	Office Lease Agreement between the registrant and Roseville Properties Management Company, as agent for Lexington Business Park, LLC (12)
10.9	Form of Non-Qualified Stock Option Agreement under the 2012 Stock Incentive Plan (13)**
10.10	Employment Agreement with Josh Kornberg dated August 13, 2012 (13)**
10.11	Non-Qualified Stock Option Agreement with Josh Kornberg dated August 13, 2012 (13)**
10.12	Employment Agreement with Robert Myers dated August 11, 2012 (13)**
10.13	Employment Agreement with David Johnson dated August 13, 2012 (13)**
10.14	Separation Agreement with Kevin Davidson effective October 11, 2012 (13)**
10.15	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and BioDrain Medical, Inc. (14)
10.16	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and BioDrain Medical, Inc. (14)
10.17	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and BioDrain Medical, Inc. (14)
10.18	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and BioDrain Medical, Inc. (14)

10.19	Amended Lease with Roseville Properties Management Company, Inc. dated January 28, 2013 (14)
10.20	Form of Convertible Promissory Note (15)
10.21	Forbearance and Settlement Agreement among the registrant, Dr. Samuel Herschkowitz and SOK Partners, LLC dated August 15, 2012 (13)
10.22	Form of Securities Purchase Agreement (16)
10.23	Convertible Note Purchase Agreement between the Company and SOK Partners, LLC dated March 28, 2012, including the form of Convertible Promissory Grid Note (18)
10.24	Amended and Restated Note Purchase Agreement between the Company and Dr. Samuel Herschkowitz dated as of December 20, 2011, including the form of Convertible Promissory Note (issued in the amount of \$240,000) (18)
10.25	Letter Agreement, dated August 22, 2013, among Dr. Samuel Herschkowitz, SOK Partners, LLC and Skyline Medical Inc. (5)
10.26	Letter Agreement, dated April 25, 2013, among Dr. Samuel Herschkowitz, SOK Partners, LLC and BioDrain Medical, Inc. (8)
10.27	Letter Agreement, dated March 6, 2013, among Dr. Samuel Herschkowitz, SOK Partners, LLC and BioDrain Medical, Inc. (10)
14.1	Code of Ethics (17)
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
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

<sup>\*</sup>Filed herewith.

- (1) Filed on December 19, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (2) Filed on February 5, 2014 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (3) Filed on August 27, 2013 as an exhibit to our Proxy Statement on Schedule 14A and incorporated herein by reference.
- (4) Filed on November 14, 2013 as an exhibit to our Quarterly Report on Form 10-Q and incorporated herein by reference.
- (5) Filed on August 28, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (6) Filed on June 18, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (7) Filed on June 12, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (8) Filed on May 1, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (9) Filed on March 14, 2013 as an exhibit to our Current report on Form 8-K and incorporated herein by reference.
- (10) Filed on March 12, 2013 as an exhibit to our Current Report on Form 8-K (by incorporation by reference from the Schedule 13D/A filed by Dr. Herschkowitz and other parties on March 8, 2013) and incorporated herein by reference.
- (11) Filed on February 26, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (12) Filed on November 12, 2008 as an exhibit to our Registration Statement on Form S-1 and incorporated herein by reference.

<sup>\*\*</sup>Compensatory Plan or arrangement required to be filed pursuant to Item 15(b) of Form 10-K.

- (13) Filed on October 18, 2012 as an exhibit to our Registration Statement on Form S-1 and incorporated herein by reference.
- (14) Filed on January 31, 2013 as an exhibit to our Registration Statement on Form S-1 (except for Exhibit 10.19, by incorporation by reference from the Schedule 13D/A filed by Dr. Herschkowitz and other parties on November 8, 2012) 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.
- (16) Filed on June 21, 2012 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (17) Filed on April 16, 2012 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference.
- (18) Filed on April 3, 2012 as an exhibit to our Current report on Form 8-K and incorporated herein by reference.
- (19) Filed on October 24, 2014 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, 2014 and December 31, 2013 are included on the following pages:

# INDEX TO FINANCIAL STATEMENTS

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Financial Statements:	
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Statements of Operations	F-3
Statements of Stockholders' Deficit	F-4
Statements of Cash Flows	F-5
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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and stockholders of Skyline Medical Inc.

We have audited the accompanying balance sheets of Skyline Medical Inc. as of December 31, 2014 and 2013 and the related statements of operations, stockholders' deficit and cash flows for the years then ended. Skyline 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 also 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 Skyline Medical Inc. as of December 31, 2014 and 2013, and the results of its operations and its cash flows for the years then ended, 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 April 30, 2015

# SKYLINE MEDICAL INC. BALANCE SHEETS

	D	December 31, 2014		ecember 31, 2013
ASSETS				,
Current Assets:				
Cash	\$	16,384	\$	101,953
Accounts Receivable		57,549		97,245
Inventories		367,367		122,175
Prepaid Expense and other assets		190,015		60,588
Total Current Assets		631,315		381,961
Fixed Assets, net		196,479		158,110
Intangibles, net		73,183		53,355
Total Assets	\$	900,977	\$	593,426
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current Liabilities:				
Accounts Payable		2,194,518		1,062,108
Accrued Expenses		3,066,379		2,057,957
Short-term notes payable net of discounts of \$194,097 and \$0 (See Note 4)		937,424		280,000
Deferred Revenue		5,000		69,000
Total Current Liabilities		6,203,321		3,469,065
Accrued Expenses		213,883		331,216
Liability for equity-linked financial instruments (See Note 8)		_		11,599
Total Liabilities	\$	6,417,204	\$	3,811,880
Commitments and Contingencies	<u> </u>	-	Ė	-
Stockholders' Deficit:				
Series A Convertible Preferred Stock, \$.01 par value, \$100 Stated Value, 10,000,000 authorized, 20,550 outstanding		206		-
Common Stock, \$.01 par value, 10,666,667 authorized, 3,092,766 and 2,932,501 outstanding		30,927		29,325
Additional paid-in capital		30,093,745		25,449,636
Deficit accumulated during development stage		(35,641,105)		(28,697,415)
Total Stockholders' Deficit		(5,516,227)		(3,218,454)
Total Liabilities and Stockholders' Deficit	\$	900,977	\$	593,426

See Notes to Financial Statements

# SKYLINE MEDICAL INC. STATEMENTS OF OPERATIONS

Year Ended December 31,

	2014	2013
Revenue	\$ 951,559	\$ 468,125
Cost of goods sold	 385,323	 189,707
Gross margin	566,236	278,418
General and administrative expense	4,882,549	7,530,037
Operations expense	972,830	1,096,969
Sales and marketing expense	1,178,305	578,793
Interest expense	377,719	636,503
Loss (gain) on valuation of equity-linked financial instruments	 (11,599)	(157,580)
Total Expense	7,399,804	9,684,722
Net loss available to common shareholders	\$ (6,833,568)	\$ (9,406,304)
Loss per common share - basic and diluted	\$ (2.29)	\$ (4.64)
Weighted average shares used in computation - basic and diluted	2,990,471	2,026,115

See Notes to Financial Statements

# SKYLINE MEDICAL INC. STATEMENTS OF STOCKHOLDERS' DEFICIT FOR THE YEARS ENDED DECEMBER 31, 2014 and 2013

•	$\Gamma_{\Lambda}$	m	mn	n	St	oc	b	

		Commo	n St	ock						
	Preferred Stock	Shares		Amount		id-in ipital		Deficit		Total
Balance at 12/31/2012	-	1,389,963	\$	13,900		5,974,008	\$	(19,291,111)	\$	(3,303,203)
Shares issued to debtors as compensation at \$11.25 per share		3,869		39		43,482				43,521
Shares issued under PPM to five investors at \$5.25 per share		95,238		952		499,048				500,000
Shares issued to an escrow account underlying a debt agreement		13,333		133		9,867				10,000
Shares issued to debtors as compensation at \$11.25 per share		3,071		31		34,519				34,550
Shares issued to an institutional investor at \$5.25 per share		95,238		952		499,048				500,000
Value of shares per an agreement with a former officer		-		-		40,480				40,480
Shares issued to consultant as compensation at \$5.03 per share		3,333		33		16,717				16,750
Value of Equity instruments issued with debt		3,333		-		392,556				392,556
Shares issued to former consultant exercising options at \$.75						2,2,000				3,2,550
per share		2,667		27		1,973				2,000
Shares issued to former CEO exercising options at \$.01 per						2 200				2 222
share. Shares issued upon conversion of four notes payable at		4,444		44		3,289				3,333
\$11.25 per share		13,888		139		156,104				156,243
Shares issued for interest to the four notes payable at \$11.25		,				,				,
per share		993		10		11,160				11,170
Shares issued for cashless exercise of warrants at \$9.00 per		2 704		37		2.741				2 779
share Shares issued for cashless exercise of warrants at \$12.00 per		3,704		37		2,741				2,778
share		2,178		22		1,611				1,633
Shares issued for cashless exercise of warrants at \$11.25 per										
share		8,436		84		6,243				6,327
Shares issued for cashless exercise of warrants at \$15.00 per share		3,491		35		2,583				2,618
Shares issued to 24 warrant holders exercised at a reduced		3,471		33		2,505				2,010
price for \$7.50 per share		139,265		1,393		,043,097				1,044,490
Shares issued to 4 PPM investors converting notes at \$9.00 per										
share Shares issued to 10 PPM investors converting notes at \$13.50		35,167		352		316,152				316,504
per share		72,072		721		1,019,479				1,020,200
Shares issued to consultant as compensation at \$28.50 per		, _, , , _		,		,,,,,,,,,				-,,
share		2,000		20		56,980				57,000
Shares issued for two note conversions at \$1.05 per share		947,551		9,476		985,452				994,928
Shares issued for warrant exercise at \$11.25 per share Shares issued for a cashless exercise of warrants at \$7.50 per		14,286		143		160,572				160,715
share		40,325		403		29,841				30,244
Shares issued to an investor for a cashless exercise of warrants		,				,				ĺ
at \$12.75 per share		2,724		27		2,017				2,044
Shares issued for a cashless exercise of warrants at \$5.63 per share		7,263		73		5,374				5,447
Shares issued to former Board Directors as compensation at		7,203		73		3,374				3,447
\$24.38 per share		1,333		13		99,987				100,000
Reduced warrant exercise compensation expense		-		-	2	2,140,946				2,140,946
Options issued as part of employee bonus		-		-		147,500				147,500
Shares issued to one investor for cashless warrant exercised at \$9.00 per share		3,704		37		2,741				2,778
Shares issued for cashless warrant exercise at \$9.75 per share		2,130		21		1,576				1,597
Shares issued for interest on two note conversions at \$13.50										
per share		546		5		7,360				7,365
Shares issued in settlement with a former noteholder at \$20.25 per share		5,040		50		102,010				102,060
Shares issued for a stock option exercise at \$4.88 per share		133		1		649				650
Shares issued to one warrant holder executed at a reduced		100		•		0.0				050
price of \$9.38 per share		13,333		133		124,867				125,000
Shares issued for option exercise at \$5.25 per share		227		2		1,188				1,190
Shares issued for cashless warrant exercise at \$5.63 per share Vesting expense		1,556		16		1,151				1,167 1,505,270
Net loss		-		-		-		(9,406,304)		(9,406,304)
Balance at 12/31/13		2,932,501		29,325	25	449,636	_	(28,697,415)		(3,218,454)
Shares issued for cashless warrant exercise at \$15.00 per share		1,728	_	17		1,279	_	(20,007,110)	_	1,296
Shares issued for option exercise at \$1.25 per share		4,336		43		5,387				5,430
Shares issued at \$20.63 per share as Investor Relations										ĺ
compensation		2,000		20		41,230				41,250
Shares issued for an antion exercise at \$12.75 per share		3,323 267		33		2,460				2,493 1,400
Shares issued for an option exercise at \$5.25 per share Shares issued for cashless warrant exercise at \$.75 per share		2,174		22		1,397 1,608				1,630
Shares issued for warrant exercise at \$13.50 per share		2,667		27		35,973				36,000
Shares issued at \$18.75 per share as Investor Relations										
compensation		1,333		13		24,987				25,000
Reduction in escrow account per settlement agreement Shares issued for cashless warrant exercise at \$7.50 per share		(4,444) 4,807		(44) 48		(3,289) 3,557				(3,333) 3,605
Shares issued for easiness warrant exercise at \$7.50 per share		7,007		70		3,337				5,005

Shares issued for cashless warrant exercise at \$5.63 per share		3,112	31	2,302		2,333
Shares issued for cashless warrant exercise at \$12.75 per share		299	3	221		224
Shares issued to 16 shareholders of Series A Convertible						
Preferred Stock Dividends as converted to common shares at						
\$19.50 per share		972	10	18,909	(18,919)	-
Vesting Expense		-	-	705,434	,	705,434
Options issued as part of employee bonus		-	-	694,500		694,500
Shares issued for combined cashless and cash warrant exercise						
@ \$11.25 per share.		7,778	78	52,422		52,500
Issuance of Preferred stock	206	-	-	2,054,795		2,055,001
Shares issued to Investor Relations consultant exercisable at						
\$11.25 per share		2,133	21	23,979		24,000
Shares issued to Investor Relations consultant exercisable at						
\$18.75 per share		1,333	13	24,987		25,000
Shares issued for cashless warrant exercise at \$13.50 per share		3,725	37	2,757		2,794
Shares issued to 16 shareholders of Series A Convertible						
Preferred Stock Dividends as converted to common shares at						
\$19.50 per share		1,561	16	30,384	(30,400)	-
Value of equity instruments issued with debt		-	-	313,175		313,175
Shares issued for cashless warrant exercise at \$9.75 per share		1,410	14	1,044		1,058
Shares issued for a cash warrant exercise at \$5.63 per share		11,111	111	62,389		62,500
Shares issued for an option exercise at \$5.25 per share		333	3	1,747		1,750
Shares issued for a note conversion at \$6.68 per share		3,018	30	19,970		20,000
Shares issued for a note conversion at \$6.68 per share		3,019	30	19,970		20,000
Shares issued for a note conversion at \$5.85 per share		3,435	34	19,966		20,000
Shares issued for a note conversion at \$5.03 per share		3,894	38	19,962		20,000
Shares issued to 16 shareholders of Series A Convertible						
Preferred Stock Dividends as converted to common shares at						
\$19.50 per share		1,561	16	30,385	(30,401)	-
Shares issued for a note conversion at \$5.14 per share		3,894	39	19,961		20,000
Shares issued for a note conversion at \$5.00 per share		3,997	40	19,960		20,000
Shares issued for a note conversion at \$5.26 per share		3,804	38	19,962		20,000
Shares issued for a note conversion at \$5.26 per share		5,706	57	29,943		30,000
Shares issued for a note conversion at \$5.95 per share		5,044	50	29,950		30,000
Shares issued into an escrow account per settlement agreement		13,700	137	-		137
Shares issued for a note conversion at \$5.05 per share		55,568	556	280,060		280,616
Shares issued to 16 shareholders of Series A Convertible						
Preferred Stock Dividends as converted to common shares at						
\$19.50 per share		1,561	16	30,385	(30,402)	(1)
Shares adjusted for rounding per reverse stock split		106	1	1	-	2
Net loss					(6,833,568)	(6,833,568)
Balance at 12/31/2014	\$ 206	3,092,766	\$ 30,927	\$ 30,093,745	\$ (35,641,105)	\$ (5,516,227)

See Notes to Financial Statements

# SKYLINE MEDICAL INC. STATEMENTS OF CASH FLOWS

Year Ended

December 31 2014 2013 Cash flow from operating activities: Net loss (6,833,568)(9,406,305) Adjustments to reconcile net loss to net cash used in operating activities: Depreciation and amortization 63,040 148,761 Vested stock options and warrants 723,367 3,700,070 Equity instruments issued for management and consulting 112,054 239,290 Amortization of debt discount 247,338 413,695 (Gain) loss on valuation of equity-linked instruments (11,599)(157,580)Changes in assets and liabilities: Accounts receivable 39,696 (57,534)Inventories (245,192)23,034 Prepaid expense and other assets (129,427)(33,179)Accounts payable 1,132,410 429,033 Accrued expenses 1,594,468 776,548 Deferred Revenue 69,000 (64,000)Net cash used in operating activities: (3,371,413)(3,855,166)Cash flow from investing activities: Purchase of fixed assets (101,409)(162,761)Purchase of intangibles (19,828)(53,355)Net cash used in investing activities (121,237)(216,116)Cash flow from financing activities: Proceeds from long-term and convertible debt 1,500,000 1,822,718 Principal payments on debt (305,000)Issuance of preferred stock 2,055,000 Issuance of common stock 157,081 2,337,378 Net cash provided by (used in) financing activities 3,407,081 4,160,096 Net increase (decrease) in cash (85,569)88,814 Cash at beginning of period 101.953 13.139 Cash at end of period 16.384 101.953 Non cash transactions: Conversion of debt to accrued liabilities 415,775 Common stock issued for accrued interest/bonus 402,669 694,500 Common stock issued to satisfy debt 2,318,568 480,616 Stock/warrant issued to satisfy accounts payable/Liabilities 100,521

See Notes to Financial Statements

## NOTE 1 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### Nature of Operations and Continuance of Operations

Skyline Medical Inc. (the "Company") was incorporated under the laws of the State of Minnesota in 2002. Effective August 6, 2013, the Company changed its name to Skyline Medical Inc. As of December 31, 2014, the registrant had 3,092,766 shares of common stock, par value \$.01 per share, outstanding, adjusted for a 1-for-75 reverse stock split effective October 24, 2014. In this Report, all numbers of shares and per share amounts, as appropriate, have been stated to reflect the reverse stock split. Pursuant to an Agreement and Plan of Merger dated effective December 16, 2013, the Company merged with and into a Delaware corporation with the same name that was its wholly-owned subsidiary, with such Delaware Corporation as the surviving corporation of the merger. 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 and filters 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. In September 2014, we filed a registration statement with the SEC in connection with a proposed public offering of common stock and warrants. We continue to pursue this public offering, with the intention of listing our common stock on NASDAQ, and we intend to update the registration statement as soon as possible following the filing of this report. We also are seeking additional financing through one or more private placements of securities.

Since inception to December 31, 2014, the Company raised approximately \$9,168,000 in equity, inclusive of \$2,055,000 from a private placement of Series A Convertible Preferred Stock, and \$5,435,000 in debt financing. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources."

#### **Recent Accounting Developments**

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, Revenue from Contracts with Customers and created a new topic in the FASB Accounting Standards Codification ("ASC"), Topic 606. The new standard provides a single comprehensive revenue recognition framework for all entities and supersedes nearly all existing U.S. GAAP revenue recognition guidance, including industry-specific guidance. The core principle of the revenue model is that an entity should recognize revenue in a manner that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is designed to create greater comparability for financial statement users across industries and also requires enhanced disclosures. The amendments are effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early application is not permitted. We are currently evaluating the impact this guidance may have on our financial statements and related disclosures.

In June 2014, the FASB issued ASU 2014-10, *Development Stage Entities* (Topic 915): Elimination of Certain Financial Reporting Requirements. ASU 2014-10 eliminates the distinction of a development stage entity and certain related disclosure requirements, including the elimination of inception-to-date information on the statements of operations, cash flows and stockholders' equity. The amendments in ASU 2014-10 will be effective prospectively for annual reporting periods beginning after December 15, 2014, and interim periods within those annual periods, however early adoption is permitted. The Company evaluated and adopted ASU 2014-10 during the year 2014.

In June 2014, the FASB issued ASU 2014-12, "Compensation - Stock Compensation" providing explicit guidance on how to account for share-based payments granted to employees in which the terms of the award provide that a performance target that affects vesting could be achieved after the requisite service period. The amendments in this Update are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. We are currently evaluating the impact this guidance may have on our financial statements.

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

## Valuation of Intangible Assets

We review identifiable intangible assets for impairment in accordance with ASC 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. The Company wrote off the entire original STREAMWAY FMS product patent of \$140,588 in June 2013. The balance represented intellectual property in the form of patents for our original STREAMWAY FMS product. The Company's enhanced STREAMWAY FMS product has a new patent pending.

## **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. Advertising expenses were \$19,394 in 2014, and there were no advertising expenses in 2013.

#### Research and Development

Research and development costs are charged to operations as incurred. Research and development costs were approximately \$394,000 and \$235,000 for 2014 and 2013, 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.

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 Skyline 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, 2014	December 31, 2013
Finished goods	\$ 88,362	\$ 56,818
Raw materials	237,556	18,603
Work-In-Process	41,449	46,754
Total	\$ 367,367	\$ 122,175

## **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 - 7
Leasehold improvements	5
Manufacturing Tooling	3 - 7
Demo Equipment	3

The Company's investment in Fixed Assets consists of the following:

	De	cember 31, 2014	Dec	cember 31, 2013
Computers and office equipment	\$	123,708	\$	61,505
Leasehold Improvements		23,874		23,614
Manufacturing Tooling		97,288		89,900
Demo Equipment		30,576		
Total		275,446		175,019
Less: Accumulated Depreciation		78,967		16,909
Total Fixed Assets, Net	\$	196,479	\$	158,110

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.

## **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 2011 remain open to examination by federal and state tax authorities.

#### **Patents and Intellectual Property**

On January 25th, 2014 the Company filed a non-provisional PCT Application No. PCT/US2014/013081 claiming priority from the U.S. Provisional Patent Application, number 61756763 which was filed one year earlier on January 25th, 2013. The Patent Cooperation Treaty ("PCT") allows an applicant to file a single patent application to seek patent protection for an invention simultaneously in each of the 148 countries of the PCT, including the United States. By filing this single "international" patent application through the PCT, it is easier and more cost effective than filing separate applications directly with each national or regional patent office in which patent protection is desired.

Our PCT patent application is for the new model of the surgical fluid waste management system. We obtained a favorable International Search Report from the PCT searching authority indicating that the claims in our PCT application are patentable (i.e., novel and non-obvious) over the cited prior art. A feature claimed in the PCT application is the ability to maintain continuous suction to the surgical field while measuring, recording and evacuating fluid to the facilities sewer drainage system. This provides for continuous operation of the STREAMWAY System unit in suctioning waste fluids, which means that suction is not interrupted during a surgical operation, for example, to empty a fluid collection container or otherwise dispose of the collected fluid.

The Company holds the following granted patents in the United States and a pending application in the United States on its earlier models: US7469727, US8123731 and U.S. Publication No. US20090216205 (collectively, the "Patents"). These Patents will begin to expire on August 8, 2023.

#### NOTE 2 – DEVELOPMENT STAGE OPERATIONS

The Company was formed April 23, 2002. Since inception through December 31, 2014, 3,092,766 shares of common stock have been issued between par value and \$125.25. Operations since incorporation have primarily been devoted to raising capital, obtaining financing, development of the Company's product, administrative services, customer acceptance and sales and marketing strategies.

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

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.

On February 4, 2014, (the "Closing Date") we raised \$2,055,000 in gross proceeds from a private placement of Series A Convertible Preferred Stock, par value \$0.01 (the "Preferred Shares") pursuant to a Securities Purchase Agreement with certain investors (the Purchasers") purchased 20,550 Preferred Shares, and warrants (the "Warrants") to acquire an aggregate of approximately 21,334 shares of Common Stock. The Preferred Shares are convertible into shares of Common Stock at an initial conversion price of \$19.50 per share of Common Stock. The Warrants are exercisable at an exercise price of \$24.38 per share and expire five years from the Closing Date. If the Common Stock is not listed on the NASDAQ Stock Market, the New York Stock Exchange, or the NYSE MKT within 180 days of the Closing, the Company was required to issue additional Warrants to purchase additional shares of Common Stock, equal to 30% of the shares of Common Stock which the Preferred Shares each Purchaser purchased are convertible into. As of August 4, 2014, the Company issued additional warrants to purchase 61,539 shares to the Purchasers in connection with this provision.

The Securities Purchase Agreement requires the Company to register the resale of the shares of Common Stock underlying the Preferred Shares (the "Underlying Shares") and the Common Stock underlying the Warrants (the "Warrant Shares"). On September 9, 2014, a resale registration statement covering the Underlying Shares, the Warrant Shares and certain other securities (the "Resale Registration Statement") was declared effective.

The Preferred Shares are convertible at the option of the holder into the number of shares of Common Stock determined by dividing the stated value of the Preferred Shares being converted by the conversion price of \$19.50, subject to adjustment for stock splits, reverse stock splits and similar recapitalization events. If the Company issues additional shares of Common Stock, other than certain stock that is excluded under the terms of the Securities Purchase Agreement, in one or more capital raising transactions with an aggregate purchase price of at least \$100,000 for a price less than the then existing conversion price for the Preferred Shares (the "New Issuance Price"), then the then existing conversion price shall be reduced to the New Issuance Price, provided, however, that under no circumstances shall the New Issuance Price be less than \$9.75 or reduced to a price level that would be in breach of the listing rules of any stock exchange or that would have material adverse effect on the Company's ability to list its Common Stock on a stock exchange, including but not limited to the change of accounting treatment of the Preferred Stock. In July 2014, in connection with the issuance of certain convertible notes, the conversion price of the Preferred Stock was adjusted to \$9.75 per share. Further, the Company has agreed to additional shares of Common Stock to holders of the Preferred Stock in certain circumstances, as described in the following paragraph. The Preferred Shares contain certain limitations on conversion so that the holder will not own more than 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon conversion of Preferred Shares held by the applicable holder, with the percentage subject to increase in certain circumstances. The Preferred Shares are eligible to vote with the Common Stock on an as-converted basis, but only to the extent that the Preferred Shares are eligible for conversion without exceeding the Beneficial Ownership Limitation. The Preferred Shares are entitled to receive dividends on a pari passu basis with the Common Stock, when, and if declared. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary (a "Liquidation"), after the satisfaction in full of the debts of the Company and the payment of any liquidation preference owed to the holders of shares of Common Stock ranking prior to the Preferred Shares upon liquidation, the holders of the Preferred Shares shall receive, prior and in preference to the holders of any junior securities, an amount equal to \$2,055,000 times 1.2, plus all declared but unpaid dividends.

In July 2014, in connection with the offering of convertible notes and warrants and in connection with the waiver of certain rights, the Company agreed to issue additional shares of Common Stock to the Preferred Stockholders (the "Additional Shares") (A) automatically upon the closing of a Qualified Public Offering (as defined in the Certificate of Designation), to the extent that (i) the Qualified Public Offering closes within six (6) months of the first closing of the convertible notes offering ("Qualified Public Offering Deadline") and (ii) 70% of the public offering price per share of the Common Stock in the Qualified Public Offering (the "QPO Discount Price") is less than the Conversion Price floor contained in Section 7(e)(i) of the Certificate of Designation (the "Conversion Price Floor"), or (B) if a Qualified Public Offering has not been consummated by the Qualified Public Offering Deadline, upon the Preferred Stockholders' conversion of their shares of Preferred Stock to the extent that 70% of the volume weighted average price of the Common Stock on the principal Trading Market (as defined in the Certificate of Designation) of the Common Stock during the ten Trading Days (as defined in the Certificate of Designation) immediately preceding the Qualified Public Offering Deadline (the "Non-QPO Discount Price") is less than the Conversion Price Floor.

The Warrants are exercisable on any day on or after the date of issuance, have an exercise price of \$24.38 per share, subject to adjustment, and a term of five years from the date they are first exercisable. However, a holder will be prohibited from exercising a Warrant if, as a result of such exercise, the holder, together with its affiliates, would exceed the Beneficial Ownership Limitation as described above for the Preferred Shares. If any Warrant has not been fully exercised prior to the first anniversary of the Closing and if during such period the Company has not installed or received firm purchase orders (accepted by the Company) for at least 500 STREAMWAY ® Automated Surgical Fluid Disposal Systems, then, the number of shares of Common Stock for which such Warrant may be exercised shall be increased 2.5 times.

In addition, in July, August and September 2014, the Company issued 71,257 warrants to investors in convertible notes as further described below.

# 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.

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 33,333 shares of common stock assuming a conversion rate of \$9.00 per share and five year warrants to purchase up to an aggregate of 33,333 shares of the corporation's common stock at an exercise price of \$11.25 per share. The value of the notes are being treated as a debt discount with an aggregate discount of \$77,644, and amortized as an additional interest expense over the twelve month term of the notes. In addition, we issued to the placement agent for these sales five year warrants to purchase an aggregate of 2,667 shares of common stock at an exercise price of \$9.00 per share.

In January and March 2013, in connection with a separate and new private placement offering we issued 95,238 shares of common stock at \$5.25 per share and warrants to purchase 95,238 shares of common stock at \$11.25 per share to 5 investors in return for their \$500,000 investment in the Company.

On March 15, 2013 the Company completed the private sale of 95,239 shares of the Company's common stock, par value \$.01 per share, at \$5.25 per share for an aggregate purchase price of \$500,000, warrants to purchase 95,239 shares of common stock at an exercise price of \$6.00 per share, and warrants to purchase 47,619 shares of common stock at an exercise price of \$11.25 per share.

In April 2013, the Company issued 2,667 shares of common stock, par value \$.01 per share, to a former consultant exercising options; the Company issued 4,444 shares of common stock, par value \$.01 per share, at \$0.75 per share to the former CEO exercising options.

In May 2013, the Company converted four (4) notes totaling \$156,243, plus \$11,169 in interest; issued in November 2012, the noteholders received 14,881 shares of common stock, par value \$.01, at \$7.50 per share. One of the noteholders was Dr. Samuel Herschkowitz who received 4,762 shares.

In May and June 2013 in connection with a private placement offering we issued 8% convertible one year promissory notes in an aggregate principal amount of \$1,000,000 convertible into 80,000 shares of common stock assuming a conversion rate of \$13.50 per share and five year warrants to purchase up to an aggregate of 61,481 shares of the corporation's common stock at an exercise price of \$14.85 per share. The value of the notes net of discount was \$275,640 in 2013; due in May and June 2014. In addition, we issued to the placement agent for these sales five year warrants to purchase an aggregate of 5,926 shares of common stock at an exercise price of \$13.50 per share.

In August and September 2013 the Company entered into agreements with holders of certain of its outstanding warrants to purchase the Company's common stock to amend the exercise price of the warrant to \$7.50 per share in connection with the agreement of each such holder to exercise the warrants in full. Prior to the amendments, the exercise prices of such warrants ranged from \$11.25 to \$34.50 per share. Twenty-four warrants were exercised with a reduced exercise price, and nineteen warrants were exercised pursuant to a net exercise provision. Together such warrant exercises resulted in aggregate cash proceeds of \$1,044,490 to the Company, and the issuance of an aggregate 139,265 shares of common stock through the reduced warrant exercise and 87,117 shares which were issued pursuant to a net exercise provision.

In October 2013 the Company entered into agreements with a holder of certain of its outstanding warrants to purchase the Company's common stock to amend the exercise price of the warrant to \$9.38 per share in connection with the agreement of the holder to exercise the warrants in full. Prior to the amendments, the exercise price of such warrants was \$18.75 per share. Two warrants were exercised with a reduced exercise price. Together the warrant exercises resulted in aggregate cash proceeds of \$125,000 to the Company, and the issuance of an aggregate 13,333 shares of common stock.

For grants of stock options and warrants in 2013 the Company used a 0.78% to 2.04% risk-free interest rate, 0% dividend rate, 59% or 66% volatility and estimated terms of 5 or 10 years. Value computed using these assumptions ranged from \$1.43 to \$18.34 per share.

In January 2014 the Company issued 4,336 shares of common stock to the former CEO at \$1.25 per share upon his exercising options.

In January through March 2014, 9 warrant holders exercised warrants through a cashless exercise for a total of 15,442 shares of common stock.

In January and February 2014 the Company issued warrants to purchase 21,538 shares pursuant to a February 4, 2014 private placement whereby the Company issued 20,550 shares of Series A Convertible Preferred Stock raising gross proceeds of \$2,055,000. The warrants are at an exercise price of \$24.38.

In February 2014 the Company issued a warrant to purchase 1,482 shares of common stock at an exercise price of \$20.25 to a major shareholder Dr. Samuel Herschkowitz. The warrant is in consideration for a bridge loan extended in December 2013 that has been paid in February 2014.

On March 31, 2014, the Company issued dividends to the Purchasers of the Preferred Shares as described above. The dividends are at an annual rate of 6% of the stated value of the Preferred Shares paid on a quarterly basis in the form of common stock per a stipulated \$19.50 per share. As a result 970 shares of common stock were issued to 16 holders of Preferred Shares.

In March 2014, the Company issued 4,444 shares of common stock to a warrant holder for a partial cash exercise at \$11.25 per share; issued 3,333 shares to the holder via the cashless exercise of the remainder of the warrant.

In June 2014, the Company issued 3,725 shares of common stock to a warrant holder exercising cashless warrants.

On June 30, 2014, the Company issued dividends to the Purchasers of the Preferred Shares as described above. The dividends are at an annual rate of 6% of the stated value of the Preferred Shares paid on a quarterly basis in the form of common stock per a stipulated \$19.50 per share. As a result 1,561 shares of common stock were issued to 16 holders of Preferred Shares.

On June 30, 2014, the Company issued a warrant to purchase 5,431 shares of common stock at an exercise price of \$12.38 to SOK Partners, LLC, in consideration for a bridge loan in the form of convertible notes. On September 9, 2014 the Resale Registration Statement went into effect. The convertible note agreement provided an immediate approximately 11% reduction to the warrant agreement. Therefore, the warrant has been adjusted to purchase 4,831 shares of common stock at an exercise price of \$12.38 to SOK Partners, LLC in consideration for a bridge loan.

In July 2014, the Company issued warrants to purchase 28,986 shares of common stock at an exercise price of \$12.38 to two lenders in consideration for a bridge loan in the form of convertible notes. The shares above reflect approximately an 11% reduction resulting from the Resale Registration Statement that went effective September 9, 2014.

In August 2014, the Company issued warrants to purchase 61,539 of common stock at an exercise price of \$24.38 to the Purchasers of the Preferred Shares. The Securities Purchase Agreement with the Preferred Shareholders stipulated that if the Company was not listed on either the NASDAQ Stock Market, the New York Stock Exchange or the NYSE MKT within 180 days of closing the agreement then warrants to purchase the above additional shares would be issued in aggregate to the Preferred Shareholders.

In August and September 2014, the Company issued warrants to purchase 37,440 shares of common stock at an exercise price of \$12.38 to four lenders in consideration for a bridge loan in the form of convertible notes. The shares above reflect the approximate 11% reduction resulting from the Resale Registration Statement that went effective September 9, 2014.

On September 30, 2014, the Company issued dividends to the Purchasers of the Preferred Shares as described above. The dividends are at an annual rate of 6% of the stated value of the Preferred Shares paid on a quarterly basis in the form of common stock per a stipulated \$19.50 per share. As a result 1,561 shares of common stock were issued to 16 holders of Preferred Shares.

In November 2014, the Company issued 13,700 shares of common stock, par value \$0.01, in escrow for debt settlement.

On December 31, 2014, the Company issued dividends to the Purchasers of the Preferred Shares as described above. The dividends are at an annual rate of 6% of the stated value of the Preferred Shares paid on a quarterly basis in the form of common stock per a stipulated \$19.50 per share. As a result 1,559 shares of common stock were issued to 16 holders of Preferred Shares.

For grants of stock options and warrants in 2014 the Company used a 1.44% to 2.75% risk-free interest rate, 0% dividend rate, 59% or 66% volatility and estimated terms of 5 or 10 years. Value computed using these assumptions ranged from \$3.2006 to \$13.9195 per share.

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

	Stock Options		Warrants			
	Number of Shares		Average Exercise Price	Number of Shares		Average Exercise Price
Outstanding at December 31, 2012	168,856	\$	6.75	468,431	\$	9.75
Issued	239,816		6.75	343,196		9.00
Expired	(15,467)		18.00	(111,025)		13.50
Exercised	(7,472)		0.75	(238,682)		8.25
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Outstanding at December 31, 2013	385,733	\$	6.75	461,920	\$	10.50
Issued	75,683		8.12	161,375		3.81
Expired	(7,879)		23.58	(81,851)		13.54
Exercised	(4,936)		1.76	(40,722)		8.38
Outstanding at December 31, 2014	448,601	\$	7.51	500,722	\$	7.95

At December 31, 2014, 429,930 stock options are fully vested and currently exercisable with a weighted average exercise price of \$7.19 and a weighted average remaining term of 7.94 years. There are 500,722 warrants that are fully vested and exercisable. Stock-based compensation recognized in 2014 and 2013 was \$723,367 and \$3,700,070, respectively. The Company has \$198,220 of unrecognized compensation expense related to non-vested stock options that are expected to be recognized over the next 16 months.

The following summarizes the status of options and warrants outstanding at December 31, 2014:

		Range of Exercise Prices	Shares	Weighted Average Remaining Life
Options:				
\$	0.75		7,333	6.52
\$	4.875		134	8.20
\$	5.25		2,031	7.62
\$	5.625		192,000	8.21
\$	5.925		23,206	8.22
\$	6.00		123,998	7.63
\$	6.50		3,845	10.00
\$	6.60		5,332	7.07
\$	8.25		3,636	9.76
\$	9.9375		3,019	8.54
\$	10.50		3,238	8.54
\$	11.25		13,666	8.08
\$	12.75		10,069	9.29
\$	13.875		2,160	9.25
\$	15.00		3,334	9.22
\$	17.25		40,261	9.19
\$	18.75		3,335	9.15
\$	20.25		4,940	9.01
\$	21.75		1,336	8.77
\$	23.85		1,260	8.75
\$	24.75		334	8.73
\$	25.6125		134	8.49
Total			448,601	
Warrants	•			
\$	0.75		400	0.94
\$	6.00		102,857	3.20
\$	9.00		2,666	3.07
\$	11.25		204,200	3.02
\$	12.375		71,257	4.61
\$	12.373		5,557	4.85
\$	13.50		4,444	3.47
\$	14.85		23,612	3.41
\$ \$	15.00		1,168	0.09
\$	20.25		1,108	4.13
\$ \$	24.375		83,080	4.13
Total	47.373			7.40
Total			500,722	

Stock options and warrants expire on various dates from January 2015 to December 2024.

The shareholders approved an increase in authorized shares to 1,066,067 shares in an annual shareholder meeting held on June 22, 2010 and approved an increase in authorized shares to 2,666,667 shares in a special shareholder meeting held on September 7, 2011.

The shareholders approved an increase in authorized shares to 4,000,000 shares in a special shareholder meeting held on January 15, 2013.

The shareholders approved an amendment of the Company's 2012 Stock Incentive Plan to increase the reserve of shares authorized for issuance to 666,667 shares and to increase the threshold of limitation on certain grants to 266,667 shares on April 15, 2013.

An increase from 4,000,000 to 10,666,667 authorized shares, and an amendment of the Company's 2012 Stock Incentive Plan to increase the reserve of shares authorized for issuance to 1,333,334 shares was approved at the September 10, 2013 annual meeting.

# Stock Options and Warrants Granted by the Company

The following table is the listing of stock options and warrants as of December 31, 2014 by year of grant:

Year	Shares	Price
2011	11,666	.75
2012	126,029	5.25 - 6.00
2013	238,556	4.875 - 25.613
2014	72,350	6.50 - 18.75
Total	448,601	\$ .75 – 25.613

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Year	Shares	Price
2010	400	.75
2012	71,368	11.25 - 15.00
2013	267,579	6.00 - 14.85
2014	161,375	12.375 - 24.375
Total	500,722	\$ .75 – 24.375

#### NOTE 4 - SHORT-TERM NOTES PAYABLE

On July 23, 2014, the Company entered into a Securities Purchase Agreement (the "SOK Securities Purchase Agreement") with SOK Partners, LLC, an affiliate of the Company ("SOK"), pursuant to which the Company agreed to issue and sell (i) a senior convertible note, in an original principal amount of \$122,196 (the "SOK Note"), which SOK Note shall be convertible into a certain amount of shares (the "SOK Conversion Shares") of Common Stock, in accordance with the terms of the SOK Note, and (ii) a warrant (the "SOK Warrant") to initially acquire up to 5,431 additional shares of Common Stock (the "SOK Warrant Shares," and collectively with the SOK Note, the SOK Warrant and the SOK Conversion Shares, the "SOK Securities") for an aggregate purchase price of \$100,000 (with the reduced principal amount as described below representing an approximately 8.7% original issue discount) (the "SOK Convertible Notes Offering"). Upon effectiveness of the Resale Registration Statement (as defined below) on September 9, 2014, the principal amount of the note was reduced to \$108,696 and the number of warrants was reduced to 4.831 shares.

Also, on July 23, 2014, the Company entered into a Securities Purchase Agreement with 31 Group, LLC (an affiliate of Aegis Capital Corp., the underwriter for the Company's pending public offering) pursuant to which the Company agreed to issue and sell (i) a senior convertible note, in an original principal amount of \$610,978 (subsequently reduced to \$543,478) (the "31 Group Note"), which shall be convertible into a certain amount of shares of Common Stock, in accordance with the terms of the 31 Group Note, (ii) a warrant (the "31 Group Warrant") to initially acquire up to 27,155 additional shares of Common Stock (subsequently reduced to 24,155 shares) (the "31 Group Conversion Shares," and collectively with the 31 Group Note, the 31 Group Warrant and the 31 Conversion Shares, the "31 Group Securities") for an aggregate purchase price of \$500,000 (representing an approximately 8.7% original issue discount) (the "31 Group Convertible Notes Offering").

On July 31, 2014, August 8, 2014, August 12, 2014, September 4, 2014 and September 5, 2014, the Company entered into Securities Purchase Agreements (collectively, the "Affiliate Securities Purchase Agreements") with certain affiliates of the Company and certain persons with whom the Company was required to have a pre-existing relationship (the "Affiliates") pursuant to which the Company agreed to issue and sell (i) senior convertible notes, in an original aggregate principal amount of \$1,069,222 (subsequently reduced to \$951,086) (the "Affiliate Notes"), which Affiliate Notes shall be convertible into a certain amount of shares (the "Affiliate Conversion Shares") of the Company's Common Stock in accordance with the terms of the Affiliate Notes, and (ii) warrants (the "Affiliate Warrants") to initially acquire up to 48,879 additional shares of Common Stock (subsequently reduced to 42,271 shares) (the "Affiliate Warrant Shares," and collectively with the Affiliate Notes, the Affiliate Warrants and the Affiliate Conversion Shares, the "Affiliate Securities") for an aggregate purchase price of \$875,000 (representing an approximately 8.7% original issue discount) (the "Affiliate Convertible Notes Offering").

The SOK Note, 31 Group Note and the Affiliate Notes mature on July 23, 2015 (subject to extension as provided in the Notes) and, in addition to the original issue discount, accrue interest at a rate of 12.0% per annum. The Notes are convertible at any time after issuance, in whole or in part, at the Investor's or SOK's option, as the case may be, into shares of Common Stock, at a conversion price equal to the lesser of (i) the product of (x) the arithmetic average of the lowest three volume weighted average prices of the Common Stock during the ten consecutive trading days ending and including the trading day immediately preceding the applicable conversion date and (y) 72.5% (or if an event of default has occurred and is continuing, 70%), and (ii) \$11.25 (as adjusted for stock splits, stock dividends, recapitalizations or similar events).

On September 30, 2014, the SOK Note, 31 Group Note and the Affiliate Notes had a combined amortization of \$250,494. At the same point in time the SOK Note, the 31 Group Note and the Affiliate Notes had a combined original issue discount of \$103,088. Additionally, as of September 30, 2014, the 31 Group, LLC converted \$40,000 of their note. One of the affiliate investors also converted \$40,000 of their note by September 30, 2014.

In October 2014, the 31 Group LLC converted \$40,000 of their note, and one of the affiliate investors converted \$80,000 of their note.

On November 18, 2014, one of the other affiliate investors converted their entire note totaling \$280,615.81.

On December 31, 2014, the SOK Note, 31 Group Note and the Affiliates Note had a combined amortization of \$137,470. At the same point in time the SOK Note, the 31 Group Note and the Affiliates Note had a combined original issue discount of \$56,627.

#### NOTE 5 - LOSS PER SHARE

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

	Year Ended December 31,		
	2014		2013
Numerator:	 		
Net loss available in basic and diluted calculation	\$ (6,833,568)	\$	(9,406,304)
Denominator:			
Weighted average common shares outstanding-basic	2,990,471		2,026,115
Effect of dilutive stock options and warrants (1)	-		-
Weighted average common shares outstanding-diluted	 2,990,471		2,026,115
Loss per common share-basic and diluted	\$ (2.29)	\$	(4.64)

(1) The number of shares underlying options and warrants outstanding as of December 31, 2014 and December 31, 2013 are 949,323 and 847,777, 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 6- INCOME TAXES

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

There is no income tax provision in the accompanying 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.

During September 2013, the Company experienced an "ownership change" as defined in Section 382 of the Internal Revenue Code which could potentially limit the ability to utilize the Company's net operating losses (NOLs). The general limitation rules allow the Company to utilize its NOLs subject to an annual limitation that is determined by multiplying the federal long-term tax-exempt rate by the Company's value immediately before the ownership change.

At December 31, 2013, the Company had approximately \$13.0 million of gross NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2015, subject to the Section 382 limitation described above. The federal NOLs will expire beginning in 2022 if unused. The Company also had approximately \$13.6 million of gross NOLs to reduce future state taxable income at December 31, 2013, which will expire in years 2022 through 2033 if unused. The Company's net deferred tax assets, which include the NOLs, are subject to a full valuation allowance. At December 31, 2013, the federal and state valuation allowances were \$6.0 million and \$1.2 million, respectively.

At December 31, 2014, the Company had approximately \$18.7 million of gross NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2015, subject to the Section 382 limitation described above. The federal NOLs will expire beginning in 2022 if unused. The Company also had approximately \$12.4 million of gross NOLs to reduce future state taxable income at December 31, 2014, which will expire in years 2022 through 2034 if unused. The Company's net deferred tax assets, which include the NOLs, are subject to a full valuation allowance. At December 31, 2014, the federal and state valuation allowances were \$8.1 million and \$1.0 million, respectively.

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, 2014 and December 31, 2013 are as follows:

	December 31, 2013	December 31, 2012
Deferred Tax Asset:		
Net Operating Loss	\$ 7,919,000	\$ 3,259,000
Other	1,150,000	59,000
Total Deferred Tax Asset	9,069,000	3,318,000
Less Valuation Allowance	9,069,000	3,318,000
Net Deferred Income Taxes	\$ —	\$ —

#### 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 \$64,753 and \$61,150 for 2014 and 2013, respectively.

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

2015	\$ 37,000
2016	\$ 38,000
2017	\$ 39,000
2018	\$ 3.000

## 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 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 \$34.50 per share, a stock price of \$26.25, 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 \$37.50 to \$16.50 per share in the underlying stock price. The Company realized a slight increase in the liability for existing warrants during the first quarter of 2012. In 2013 there was a significant decrease in the liability primarily due to current expirations and the amount of warrants reaching expiration in the near term. In 2014, all warrants expired and the liability was reduced to zero.

The inputs to the Black-Scholes model during 2009 through 2014 were as follows:

Stock price	\$ 3.75 - \$37.50
Exercise price	\$ .75 - \$24.38
Expected life	2.0 to 6.5 years
Expected volatility	59%
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:

								2012 Gain	Value	2013 Gain	Value	2014 Gain	Value at
January 1,	Initial Value	Annual Gain (Loss)	Value at 12/31/09 20	10 Gain (Loss) Valu	e at 12/31/10 2011 0	jain (Loss)	12/31/2011	(Loss)	at 12/31/2012	(Loss)	at 12/31/2013	(Loss)	12/31/2014
2009													
	\$ 479,910	\$ (390,368)	\$ 870,278 \$	868,772 \$	1,506 \$	(88,290) \$	89,796	\$ (21,856)	\$ 111.652	\$ 100,053	\$ 11.599	\$ 11,599	s -
Warrants		. (,,		,	,	(11)	,	,,,,,		,	,,,,,	, , , , , , ,	
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	714	-	-	-
Warrants is													
used in													
quarter													
ended 12/31/2009		617		12,053	28	(724)	752	415	337	337			
	12,070	617	12,081	12,033	28	(724)	132	413	337	33/	-	-	-
Subtotal Warrants	702,205		1,071,847										
issued in													
quarter													
ended													
3/31/2010	25,553			25,014	539	(5,570)	6,109	3,701	2,408	2,408	-	-	-
Warrants													
issued in													
quarter ended													
6/30/2010	31,332			30,740	592	(6,122)	6,714	6,083	631	631	_	_	_
Warrants	31,032			30,710	3,2	(0,122)	0,711	0,003	031	051			
issued in													
quarter													
ended													
9/30/2010	31,506			20,891	10,615	(44,160)	54,775	1,338	53,437	53,437			
Total	\$ 790,596	\$ (369,642)	\$ 1,071,847 \$	1,145,292 \$	14,946 \$	(151,117) \$	166,063	\$ (3,116)	\$ 169,179	\$ 157,580	\$ 11,599	\$ 11,599	\$ -

## NOTE 9 - RELATED PARTY TRANSACTIONS

The Audit Committee has the responsibility to review and approve all transactions to which a related party and the Company may be a party prior to their implementation, to assess whether such transactions meet applicable legal requirements. Rick Koenigsberger, a director, is a holder of membership units in SOK Partners.

Convertible Note Issuances to Dr. Samuel Herschkowitz and SOK Partners, LLC

On September 11, 2013, both the Herschkowitz Note and the SOK Note (each as defined below in this Note 9) were converted in full by the holders thereof at \$0.014 per share. The principal and interest balance of the Herschkowitz Note of \$314,484 was converted into 299,509 shares of common stock. The principal and interest balance of the SOK Note of \$680,444 was converted into 648,050 shares of common stock. The collateral that secured these notes was released back to the Company.

The remaining disclosure of this Note 9 provides historical information regarding the Herschkowitz Note, the SOK Note and certain other convertible note issuances.

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"), and an investment partnership. Josh Komberg, 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.

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 \$4.88 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 \$4.88 per share. In March 2012, the Company issued the first equity bonus to SOK Partners, consisting of 61,539 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 61,539 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 to \$600,000 less the aggregate advances on the note made prior to the breach. The principal balance of the SOK Note was \$357,282 as of December 31, 2012

As long as any amount payable under the SOK 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 20,623 shares of common stock. An additional 100,000 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 described below, relating to the defaults under the Herschkowitz Note and other matters.

As long as any amount payable under the Herschkowitz Note remains outstanding, Dr. Herschkowitz or his designee is entitled to appoint a special advisor to the Company's Board of Directors, to be appointed as a member upon request. Pursuant to this authority, Josh Komberg was appointed to the Board on March 9, 2012. In addition, pursuant to this authority, Mr. Koenigsberger was appointed to the Board on June 25, 2012.

Pursuant to a letter dated April 12, 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.

In addition, the Company and Atlantic Partners Alliance LLC ("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 had issued in excess of 213,334 shares of common stock to parties other than APA and its affiliates, resulting in significant dilution.

Effective August 15, 2012, the Company entered into a letter agreement with Dr. Herschkowitz, APA and SOK (the "Forbearance Agreement"). 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 353,334 shares of common stock to Dr. Herschkowitz and SOK and adjusted the conversion price of their convertible notes to \$1.05 per share from \$4.88 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.

In the Forbearance Agreement, Dr. Herschkowitz agreed 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 agreed 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 under the Herschkowitz Note: (a) that does not constitute an existing default; and (b) occurs and accrues after the date of the letter agreement.

Dr. Herschkowitz and the Company acknowledged that 100,000 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.

Under the Forbearance Agreement, the Herschkowitz Note and the SOK Note were amended as follows: (i) the due dates of the notes were 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 consideration of the extension additional milestone fees were revised as described below. Pursuant to a Forbearance and Settlement Agreement with these parties dated August 15, 2012, as subsequently amended, the due date of these notes were extended to August 31, 2013.

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 forbear and to extend the due dates of the notes, the Company (i) issued 176,667 shares to Dr. Herschkowitz, (ii) issued 176,667 shares to SOK, and (iii) the conversion price of the Herschkowitz Note and the SOK Note, respectively was changed to \$1.05 per share from \$4.88 per share.

In the event that the Company consummated 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 would have to be required to 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 was also required to reimburse Dr. Herschkowitz at his actual out-of-pocket cost for reasonable expenses incurred in connection with the shell transactions, with a maximum limit of \$10,000 for such expenses.

In connection with the extension of the due date for the Herschkowitz Note and the SOK Note on March 6, 2013, the milestone fees were revised. The following fees were payable to Dr. Herschkowitz in the event that the Company consummates the following series of transactions on or prior to December 31, 2013: (i) financing raising not less than \$1 million, compensation of \$75,000; (ii) a going private transaction, compensation of \$200,000 or greater; 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. In May 2013 Dr. Herschkowitz received \$75,000 after the Company surpassed raising \$1 million.

As a result of the transactions under the Forbearance Agreement and other investments, Dr. Herschkowitz, SOK and their affiliates currently own shares of common stock and securities representing beneficial ownership of more than 57% of the Company's outstanding common stock, giving such parties significant control over election of the Board of Directors and other matters.

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 20,833 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. Such notes were converted in April 2013 in to 13,889 shares of common stock at \$7.50 per share.

In December 2013 the Company received an additional \$300,000 in debt financing from SOK Partners under a non-convertible grid note due February 28, 2014, with 10% interest based on a 365 day year. Dr. Herschkowitz received 10% of the gross proceeds in advance, and the Company received \$250,000 in three tranches in December 2013. In January 2014, the Company received an additional \$20,000 from SOK Partners completing the grid note maximum. Should the company default on the note the interest rate will increase to 20% interest based on a 365 day year. In February 2014, the Company wired \$305,589.04 to SOK Partners in complete payment of the grid note, including interest.

In connection with the sale of the Preferred Shares on February 4, 2014 as described in Note 3, Josh Kornberg, our CEO, was one of the Purchasers. Mr. Kornberg purchased 19,231 Preferred Shares for a purchase price of \$25,000 and received warrants to purchase 52 shares of common stock.

On July 23, 2014, the Company entered into the SOK Securities Purchase Agreement pursuant to which the Company agreed to issue and sell certain securities to SOK, as described in Note 4 of this Report.

## 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 2013, and again in 2014, we matched 100%, of the employee's contribution up to 4.0% of their earnings. The employer contribution was \$37,730 and \$32,790 in 2014 and 2013. There were no discretionary contributions to the plan in 2014 and 2013.

#### NOTE 11 - COMMITMENTS AND CONTINGENCIES

On July 17, 2014, Skyline Medical Inc. (the "Company") and a stockholder entered into a settlement agreement and release (the "Settlement Agreement") with Marshall Ryan ("Ryan") and a company related to Ryan (together, the "Plaintiffs"). The settlement relates to a previously disclosed lawsuit by the Plaintiffs initiated in March 2014. Ryan is an engineer who previously worked with the Company on design of certain of the Company's products. The lawsuit alleged among other things, breach of a 2008 consulting agreement, a 2006 manufacturing agreement and a 2006 supply agreement among the Plaintiffs and the Company, various claims of fraud and negligent misrepresentation, and breach of the duty of good faith and fair dealing.

Under the Settlement Agreement, the parties have agreed that the lawsuit will be dismissed. The Company has agreed to pay Ryan an aggregate of \$500,000 in various cash installments through April 25, 2015, which amount includes \$200,000 in installments that are payable during the remainder of 2014. The Settlement Agreement, among other things, extinguishes any prior claims of Plaintiffs for royalties or other alleged rights to payments under their prior agreements with the Company. Payment of the outstanding balance under the Settlement Agreement will be accelerated if the Company raises \$2 million or more of gross dollars in a single funding round or raises aggregate funding of \$4 million of gross dollars on or before April 10, 2015. If the Company defaults on the required cash payments and fails to cure as provided in the Settlement Agreement, then Ryan will have the option to either sue Skyline to enforce the Settlement Agreement or rescind the Settlement Agreement, including returning all payments previously made thereunder.

The Settlement Agreement also contains mutual releases covering claims other than a breach of the Settlement Agreement. In the Settlement Agreement, Ryan fully, unconditionally and irrevocably affirms and ratifies the Company's rights to Ryan's prior patent assignments, and disclaims any right, title or interest in the Company's Streamway product including any claims to royalties both past and future. In addition, the parties confirmed that the patents related to the Streamway product belong exclusively to Skyline and remain in full force and effect.

## Note 12 - Supplemental Cash Flow Data

Cash payments for interest were \$47,111 and \$57,281 for the fiscal years ended December 31, 2014 and December 31, 2013, respectively.

Schedule II

Valuation and Qualifying Accounts

(None)