

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2015.

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

COMMISSION FILE NUMBER: 001-36790

SKYLINE MEDICAL INC.

(Exact name of registrant as specified in its charter)

Delaware  
(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, including area code): (651) 389-4800

Securities registered pursuant to Section 12(b) of the Act:

Common Stock par value \$0.01 per share

NASDAQ Capital Market

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: \$5,873,239 as of June 30, 2015, based upon 1,894,594 shares at \$3.10 per share as reported on OTCQB.

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

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

(APPLICABLE ONLY TO CORPORATE REGISTRANTS)

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the last practicable date: As of March 16, 2016, the registrant had 49,894,145 shares of common stock, par value \$.01 per share outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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## PART I

### ITEM 1. BUSINESS.

#### Overview

We are a medical device company manufacturing an environmentally conscientious system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. We own patent rights to our products, which consist of the STREAMWAY®FMS and distribute our products to medical facilities where bodily and irrigation fluids produced during surgical procedures must be contained, measured, documented, and disposed. Our products minimize the exposure potential to the healthcare workers who handle such fluids. Our goal is to create products that dramatically reduce staff exposure without significant changes to established operative procedures, historically a major stumbling block to innovation and product introduction. In addition to simplifying the handling of these fluids, we believe our technologies provide cost savings to facilities over the aggregate costs incurred today using the traditional canister method of collection, neutralization, and disposal. We sell our products through an experienced in-house sales force. The Company has one regional manager currently on staff. We also intend to utilize independent distributors in the United States and Europe, initially, and eventually to other areas of the world.

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 with 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 can 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. Pursuant to an Agreement and Plan of Merger 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. On August 31, 2015, the Company completed a successful offering and concurrent uplisting to The NASDAQ Capital Market. 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](http://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***

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

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

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

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

According to the American Hospital Association’s (AHA) Hospital Statistics, 2013 edition, America’s hospitals performed approximately 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. A Frost & Sullivan research report from April 24, 2006 estimates that 60 million suction canisters are sold each year and the estimated market value of canisters is upwards of \$120 million.

A study by the Lewin Group, prepared for the Health Industry Group Purchasing Association in April 2007, reports that infectious fluid waste accounts for more than 75% of U.S. hospitals biohazard disposal costs. The study also includes findings from a bulletin published by the University of Minnesota’s Technical Assistance Program. “A vacuum system that uses reusable canisters or empties directly into the sanitary sewer can help a facility cut its infectious waste volume, and save money on labor, disposal and canister purchase costs.” The Minnesota’s Technical Assistance Program bulletin also estimated that, in a typical hospital, “. . . \$75,000 would be saved annually in suction canister purchase, management and disposal cost if a canister-free vacuum system was installed.”

We expect the hospital surgery market to continue to increase due to population growth, the aging of the population, expansion of surgical procedures to new areas, for example, use of the endoscope, which requires more fluid management, and new medical technology.

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).

### ***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 of safely disposing of infectious fluids 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 healthcare 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, Hepatitis B and C, HIV/AIDS, 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. Canisters are the most prevalent means of collecting and disposing of infectious fluids in hospitals today. Traditional, non-powered canisters and related suction and fluid disposable products are exempt and do not require FDA clearance.

We believe that our virtually hands free direct-to-drain technology will (a) significantly reduce the risk of healthcare worker exposure to these infectious fluids by replacing canisters, (b) further reduce the risk of worker exposure when compared to powered canister technology that requires transport to and from the operating room, (c) reduce the cost per procedure for handling these fluids, and (d) enhance the surgical team’s ability to collect data to accurately assess the patient’s status during and after procedures.

In addition to the traditional canister method of waste fluid disposal, several new powered medical devices have been developed which address some of the deficiencies described above. MD Technologies, Inc., Domocho Medical Systems, Inc. (Zimmer), and Stryker Instruments have all developed systems that provide for disposal into the sanitary sewer without pouring the infectious fluids directly through a hopper disposal or using expensive gel powders and most are sold with 510(k) concurrence from the FDA. Most of these competing products continue to utilize some variant on the existing canister technology, and while not directly addressing the canister, most have been successful in eliminating the need for expensive gel and its associated handling and disposal costs. Our existing competitors that already have products on the market have a clear competitive advantage over us in terms of brand recognition and market exposure. In addition, the aforementioned companies have extensive marketing and development budgets that could overpower an early stage company like ours. We believe that Stryker Instruments has the dominant market share position.

## **Products**

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

The STREAMWAY FMS 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 FMS. The STREAMWAY FMS 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.

The STREAMWAY FMS is unique to our 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. The manual process, involving canisters, requires that the operating room personnel open the canisters that contain waste fluid, often several liters, at the end of the surgical procedure and either add a solidifying agent or empty the canisters in the hospital drain system. Some facilities require that used canisters be cleaned by staff and reused. It is during these procedures that there is increased potential for contact with the waste fluid through splashing or spills. The FMS eliminates the use of canisters and these cleaning and disposal steps by collecting the waste fluid in the internal collection chamber and automatically disposing of the fluid with no handling by personnel. Each procedure requires the use of a disposable filter. At the end of each procedure, a proprietary cleaning fluid is attached to the FMS and an automatic cleaning cycle ensues, making the FMS ready for the next procedure. The cleaning fluid bottle is attached to the port on the FMS device. The cleaning fluid bottle and its contents are not contaminated and are used to clean the internal fluid pathway in the FMS device to which personnel have no exposure. During the cleaning cycle, the cleaning fluid is pulled from the bottle into the FMS, and then disposed in the same manner as the waste fluid from the surgical case. At the end of the cleaning cycle, the bottle is discarded. The filter and any suction tubing used during the procedure must be disposed of in the same manner as suction tubing used with the canister system. Handling of this tubing does present the potential for personnel exposure but that potential is minimal.

We believe our product provides substantial cost savings and improvements in safety in facilities that still use manual processes. In cases where healthcare organizations re-use canisters, the FMS cleaning process eliminates the need for cleaning of canisters for re-use. The FMS reduces the safety issues facing operating room nurses, the cost of the handling process, and the amount of infectious waste generated when the traditional method of disposing of canisters is used. The FMS is fully automated, does not require transport to and from the operating room and eliminates any canister that requires emptying. We believe 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.

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. 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**

<b>Feature</b>	<b>Skyline Medical Inc.</b>	<b>Stryker Instruments</b>	<b>DeRoyal</b>	<b>Dornoch Medical Systems, Inc. (Zimmer)</b>	<b>MD Technologies, Inc.</b>
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
<b>Installation Requirements :</b>					
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.

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 us, is used for the automated cleaning cycle at the conclusion of each procedure and prepares the STREAMWAY FMS 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 FMS 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 our cleaning fluid, and only our cleaning fluid, must be used with the STREAMWAY FMS following each surgical case. The warranty is voided if any other solution is used.
- **Procedure Filters.** One or two filters, depending on the type of procedure, will be used for every surgical procedure. The filter has been developed by us, is proprietary to the STREAMWAY FMS and is only sold by us. The filter is a two port, bifurcated, disposable filter that contains a tissue trap that allows staff to capture a tissue sample and send to pathology if needed. The filters are disposed of after each procedure. The cleaning fluid and filter are expected to be a substantial revenue generator for the life of the STREAMWAY FMS.
- **Ease of Use.** The FMS simply connects to the existing suction tubing from the operative field (causing no change to the current operative methods). Pressing the START button on the FMS touch screen 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.
- **Competitive Pricing.** 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 \$261,000 in 2015 and \$394,000 in 2014 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 their 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 is again switched back to the first container to collect fluid while the second container is drained, and so on. Even though the switching of 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 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 single or multiple suction ports. The proprietary cleaning solution placed in the specially designed holder is attached and recommended to be used following each surgical procedure. Due to the nature of the fluids and particles removed during surgical procedures, the FMS is recommended to be cleaned following each use. Utilizing the available vacuum of the wall system, the proprietary cleaning fluid is drawn into the FMS to provide a highly effective cleaning process that breaks up bio-film at the cellular level. Proper cleaning is required for steady, dependable and repeated FMS performance and for maintenance of the warranty of the FMS.

Our 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 our 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, if we are able to sell a substantial number of FMS units. 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 have been 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 are exploring entering into an arrangement with one or more provider's to provide installation services.

### **Corporate Strategy**

Our strategy is focused on 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 healthcare 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. We believe 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 strategies may also include:

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

### **Technology and Competition**

#### ***Fluid Management for Surgical Procedures***

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

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

- *Direct Disposal Through the Sanitary Sewer.* In virtually all municipalities, the disposal of liquid blood may be done directly to the sanitary sewer where it is treated by the local waste management facility. This practice is approved and recommended by the EPA. In most cases these municipalities specifically request that disposed bio-materials not be treated with any known anti-bacterial agents such as glutaldehyde, as these agents not only neutralize potentially infectious agents but also work to defeat the bacterial agents employed by the waste treatment facilities themselves. Disposal through this method is fraught with potential exposure to the service workers, putting them at risk for direct contact with these potentially infectious agents through spillage of the contents or via splash when the liquid is poured into a hopper – a specially designated sink for the disposal of infectious fluids. Once the infectious fluids are disposed of into the hopper, the empty canister is sent to central processing for re-sterilization (glass and certain plastics) or for disposal with 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 healthcare 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., Cardinal Health, Inc., Domoch 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. 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 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. It is clear that solidifying gels, while not providing complete freedom from exposure to healthcare workers do 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 solidifying gels.

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.

### *Handling Costs*

Once the surgical team has finished the procedure, 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 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 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 healthcare 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, our management team estimates 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 four new product entries within the infectious material control field. Stryker Instruments introduced the "Neptune™" system, offering a combination of bio-aerosol and fluid management in a portable two-piece system; Waterstone Medical (now DeRoyal) introduced the "Aqua Box™" stationary system for fluid disposal; Cardinal Health introduced the Orwell Fluid Collection and Disposal System; and Dornoch Medical Systems, Inc. (Zimmer) introduced the "Red Away™" 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 our products do. 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 and independent distributors covering the vast majority of major U.S. markets. Currently we have one regional manager selling, and demoing the FMS for prospective customers and distributors, as well as, supporting our current customer base for disposable resupply. We are close to signing contracts with various hospital purchasing groups and signed on independent distributors. 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 will be to introduce the FMS as a standalone device capable of effectively removing infectious waste and disposing of it automatically while providing accurate measurement of fluids removed, and also limiting exposure of the surgical team and healthcare support staff.

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

Our distributors may have installation and service capability, or we will contract those functions with an independent service/maintenance company. We have hired both distributors and service companies regarding these installation requirements. We have established extensive training and standards for the service and installation of the FMS to ensure consistency and dependability in the field. Users of the system require a minimal amount of training to operate the FMS. The instructions for use and the installation guide are 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.

### ***Promotion***

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

We supplement our sales efforts with a promotional mix that include a number of printed materials, video support and a website. We believe our greatest challenge lies in reaching and educating the 1.6 million medical personnel who are exposed daily to fluid waste in the operating room or in other healthcare settings (OSHA, CPL 2-2.44C). These efforts 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 have partnered with the Association for Radiologic & Imaging Nursing ("ARIN") and will be presenting in their April 2016 annual educational conference in Vancouver, British Columbia. 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. 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 will continue to be used with our system and should not be considered in the return on investment equation. Our cleaning solution's bottle is completely recyclable, and the 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. Once the canister has touched blood, it is considered "red bag" biohazard waste, whereas the cleaning fluid bottle used in the FMS 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 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 a leased facility. We have the capability to manufacture, test, house, ship and receive from our warehouse. We contracted 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, is 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. 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 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 FMS is valid and enables us to continue to market and sell our product domestically.

A new standard; IEC 60601-1 3<sup>rd</sup> 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 December 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 us as we did not sell internationally.

The U.S. FDA compliance date to meet the new standard was December 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 Kornberg	42	President, Chief Executive Officer, and Interim Chairman of the Board
David O. Johnson	63	Chief Operating Officer
Bob Myers	61	Chief Financial Officer
Thomas J. McGoldrick	74	Director
Andrew P. Reding	46	Director
Richard L. Taney	59	Director

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

There are no family relationships among our directors and executive officers. Our executive officers are appointed by our Board of Directors and serve at the Board's discretion. Mr. Kornberg was appointed Interim Chairman of the Board on August 21, 2013.

## Business Experience

**Josh Kornberg, President, Chief Executive Officer and Interim Chairman of the Board.** Effective July 22, 2012, Mr. 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 significant 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. We believe Mr. Kornberg's experience as CEO of our Company, familiarity with our business, and extensive experience in the financial industry provide valuable insight on our Board.

**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.** Effective July 1, 2012, Mr. Myers was appointed as the Chief Financial Officer of the Company. Mr. Myers 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 past ten years has been a financial contractor represented 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. We believe Mr. McGoldrick's experience as CEO of a public company and extensive experience in the medical device industry provide valuable insight on our Board.

**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. We believe Mr. Reding's strong experience in sales and marketing of capital equipment to hospital operating rooms provides unique insight into the industry we serve and makes him a valued member of the Board.

**Richard Taney, Director.** Mr. Taney is the President and Chief Executive Officer of PalliaTech, Inc., a New York-based palliative care company that produces, manufactures, dispenses, and tests cannabinoid medicines. Prior to joining PalliaTech, Mr. Taney was President and Chief Executive Officer of Delcath Systems, Inc. (NASDAQ: DCTH), a medical technology company. Mr. Taney served as Chairman of the Board of Directors of MGT Capital Investments, Inc. (NYSE MKT: MGT), a medical technology company engaged in the development and commercialization of computer aided detection applications that analyze CT scans. Mr. Taney is also the founding member of T2 Capital Management, LLC, an investment management company, and a founding partner of Sandpiper Capital Partners, an investment partnership. Prior to establishing his money management and advisory ventures, Mr. Taney spent 20 years advising, institutional and high net worth clients at Salomon Brothers, Goldman Sachs, Merrill Lynch and Banc of America Securities. Mr. Taney holds a Bachelor of Arts degree from Tufts University and a JD from Temple University School of Law. We believe Mr. Taney's experience as CEO of a public company and extensive experience in the medical device and financial industries provide valuable insight on our Board.

#### **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 finance operating expenses and fulfill our business plan. Such financing will be dilutive. 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 2016. We had revenues of \$654,000 in 2015, but we had negative operating cash flows of \$7.5 million. In August 2015, we received proceeds of \$13.5 million (net of commissions but before payment of expenses) as a result of our public offering. During the remainder of 2015, we paid \$5.8 million in cash to cover accrued debts and obligations, most of which were required to be paid upon completion of the offering or were considered past due. Our cash balance was \$4.9 million as of December 31, 2015, and our accounts payable and accrued expenses were an aggregate \$1.5 million. We are currently incurring negative operating cash flows of approximately \$275,000 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.

As of December 31, 2015, the Company had no debt. We will require additional funding to finance operating expenses and to invest in our sales organization and new product development and to enter the international marketplace. We will attempt to raise these funds through equity or debt financing, alternative offerings or other means. If we are successful in securing adequate funding we plan to make significant capital or equipment investments, and we will also continue to make human resource additions over the next 12 months. Such additional financing will be dilutive to existing stockholders, and there is no assurance that such financing will be available upon acceptable terms. If such financing or adequate funds from operations are not available, we will be forced to limit our business activities, which will have a material adverse effect on our results of operations and financial condition.

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 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 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 as to whether we will be able to:

- 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., with non-provisional patents 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 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. 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 \$94 million and we estimate the total cost of using surgical canisters is a greater than \$94 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. Our competitors include Cardinal Health, Inc., a medical manufacturer and distributor, and Stryker Instruments, a wholly owned subsidiary of Stryker Corporation, which has a leading position in our market. Both of these competitors are substantially larger than our company and are better capitalized than we are.

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 business is subject to intense governmental regulation and scrutiny, both in the U.S. and abroad.***

The production, marketing, and research and development of our product is subject to extensive regulation and review by the 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.

***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 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.

***If demand for our product is unexpectedly high, we may be unable to produce the product in sufficiently high quantity to meet demands.***

We are currently manufacturing the STREAMWAY FMS, following GMP compliance regulations of the FDA, at our own facility and anticipate the capability of producing the STREAMWAY FMS in sufficient quantities for future near term sales. We have contracted with a manufacturing company that can manufacture products at higher volumes. However, if demand for our product is unexpectedly high, there is no assurance that we or our manufacturing partners will be able to produce the product in sufficiently high quantity to satisfy demands. Any supply interruptions or inadequate supply would have a material adverse effect on our results of operations.

***We are dependent on a few key executive officers for our success. 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 Komberg, our President, Chief Executive Officer and Interim Chairman of the Board, David O. 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.

***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.

***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 common stock. The numbers of institutions or persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or nonexistent. This situation may be attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume. 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 common stock will develop or be sustained.

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

Our certificate 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 stockholders 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 stockholders from bringing suit against a director for breach of fiduciary duty and may reduce the likelihood of derivative litigation brought by stockholders on our behalf against a director. In addition, our certificate of incorporation and bylaws may provide for mandatory indemnification of directors and officers to the fullest extent permitted by governing state law.

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

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

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.

***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 stockholders may be eligible to sell some or all of their shares of common stock pursuant to Rule 144, promulgated under the Securities Act subject to certain limitations. In general, pursuant to Rule 144 as in effect as of the date of this registration statement, a stockholder (or stockholders 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 addition, there is no assurance that the price of our common stock will not be volatile. 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.

***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 20 million shares of preferred stock. Of this amount, 18,950 shares have been designated as Series B 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 of Directors 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.

***Future sales and issuances of our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.***

We also expect that significant additional capital will be needed in the future to continue our planned operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. In addition, in the past, we have issued warrants to acquire shares of common stock. To the extent these warrants are ultimately exercised, you will sustain further dilution.

***Future sales of our common stock in the public market may cause our stock price to decline and impair our ability to raise future capital through the sale of our equity securities.***

There are a substantial number of shares of or common stock held by stockholders who owned shares of our capital stock prior to this offering that may be able to sell in the public market upon expiration of the 90-day lock-up agreements they signed in connection with the Company's public offering which was consummated in August 2015. Sales by such stockholders of a substantial number of shares could significantly reduce the market price of our common stock.

***The Series A Warrants contain a cashless exercise feature with the potential for a higher dilutive issuance of Common Stock, which could adversely affect the value of the Common Stock.***

The Series A Warrants, described in Note 3 to the Financial Statements included in this report under "Stockholders' Deficit, Stock Options and Warrants," can be exercised starting February 2016. The Series A Warrants contain a cashless exercise feature that provides for the issuance of a number of shares of our common stock that increases as the trading market price of our common stock decreases, subject to a floor price of \$0.43. Approximately 3,390,935 Series A Warrants have been exercised in cashless exercises as of March 11, 2016, resulting in the issuance of 34,053,653 shares of common stock. If all of the remaining 4,189,105 Series A Warrants that were issued as part of the Units sold in the Offering and part of the Units issued on August 31, 2015 were exercised pursuant to a cashless exercise and the closing bid price of our common stock as of the two trading days prior to the time of such exercise was \$0.43 per share or less and the Black Scholes Value were \$4.3246 (the Black Scholes Value as of March 11, 2016), then a total of approximately 76,184,359 shares of our common stock would be issued to the holders of such Series A Warrants. The potential for such dilutive exercise of the Series A Warrants may depress the price of our common stock regardless of the Company's business performance, and could encourage short selling by market participants, especially if the trading price of our common stock begins to decrease.

***From our inception, through December 2013, our shares and other securities were issued in violation of the preemptive rights of existing stockholders, which could result in claims against us.***

In 2013, it was brought to the attention of our management and Board of Directors that the Company was subject to preemptive rights under Minnesota corporate law, because the articles of incorporation did not "opt out" and deny them. Prior to our reincorporation in Delaware in December 2013 the Company issued shares of common stock and other equity securities on numerous occasions to raise capital and for other purposes and, to our knowledge; we never complied with the Minnesota preemptive rights statute in connection with such issuances. Starting in December 2013, stockholders no longer had preemptive rights. In connection with issuances of securities prior to that time, we may be still subject to the claims of previous and current stockholders based on violations of their preemptive rights; the risk and magnitude of these claims are uncertain. If there are any future claims, we intend to vigorously defend against such claims; however, there can be no assurance that the Company would not be liable for damages or other remedies that might have a material adverse effect on the Company's financial condition or results of operations.

#### **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.**

Not applicable.

#### **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 is listed on The NASDAQ Capital Market under the symbol "SKLN". Prior to August 31, 2015, our common stock was quoted by the OTCQB under the symbol "SKLN.QB." The following table sets forth the high and low bid information for our common stock for each quarter within our last two fiscal years as reported by The NASDAQ Capital Market or the OTCQB, as applicable. The bid prices reflect inter-dealer quotations, do not include retail markups, markdowns, or commissions, and do not necessarily reflect actual transactions. These prices reflect the 1:75 reverse stock split of our outstanding shares effected on October 24, 2014, as well as rounding.

#### Common Stock

Quarter Ended	High Bid	Low Bid
December 31, 2015	\$ 6.76	\$ 2.31
September 30, 2015	\$ 5.78	\$ 2.75
June 30, 2015	\$ 7.15	\$ 2.00
March 31, 2015	\$ 7.00	\$ 2.00
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

#### Units

Our Units commenced trading on August 26, 2015. The Units separated on February 29, 2016 into shares of common stock, Series B Preferred Stock and Series A Warrants, and the Units are no longer listed. The following table sets forth the high and low bid prices for the Existing Units for each quarter subsequent to August 26, 2015 as reported by The NASDAQ Capital Market.

Quarter Ended	High Bid	Low Bid
December 31, 2015	\$ 8.95	\$ 6.17
September 30, 2015 (commencing August 26, 2015)	\$ 10.00	\$ 7.00

As of March 11, 2016, the closing bid price for shares of our common stock was \$0.18 per share. The Series B Preferred Stock and Series A Warrants are not traded on any security markets.

#### Holders

As of March 11, 2016, there were approximately 145 stockholders of record of our Common Stock and 2 holders of record of the Series B Preferred Stock and 2 holders of record of Series A Warrants.

#### 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.

#### 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:

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 \$0.75.

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 \$4.88 per share to receive 134 shares of the Company’s common stock.

In October a warrant holder exercised at a reduced rate of \$9.38 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 \$0.75.

In January 2014 a vendor received 2,000 shares of common stock at \$20.63 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.

In February 2014, we raised \$2,055,000 in gross proceeds from a private placement of Series A Convertible Preferred Stock, par value \$0.01 (the “Series A Preferred Shares”) pursuant to a Securities Purchase Agreement with certain investors (the “Purchasers”) who purchased 20,550 Series A Preferred Shares, and warrants (the “Warrants”) to acquire an aggregate of approximately 21,538 shares of Common Stock. The Series A Preferred Shares were initially convertible into shares of Common Stock at an initial conversion price of \$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 was required to issue additional Warrants to purchase additional shares of Common Stock, equal to 30% of the shares of Common Stock which the Series A Preferred Shares each Purchaser purchased are convertible into. As of August 4, 2014, the Company issued additional warrants to purchase 61,452 shares to the Purchasers in connection with this provision. See (Note 3 to the 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 4,445 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 March 2014 one warrant holder opted for a cashless warrant exercise resulting in issuing 299 shares of common stock pursuant to the warrant instruction for cashless exercise.

In March 2014 the Company issued preferred dividends pursuant to the PPM agreement. The preferred shares were converted into common stock resulting in the issuance of 971 shares of common stock.

In March 2014 a warrant holder exercised a combined cashless and cash warrant exercise. The cashless exercise resulted in issuing 3,334 shares of common stock pursuant to the warrant instruction for exercise. The cash exercise resulted in the issuance of 4,445 shares of common stock at an exercise price of \$11.25 per share.

In April 2014, SOK transferred 20,000 shares of common stock, par value \$0.01, to six stockholders. Two of these stockholders, Frank Mancuso Jr. and Amon Dreyfuss are former directors of the Company who served on the Board at the time of these transfers. Mr. Mancuso received 3,334 shares and Dr. Dreyfuss received 6,667 shares.

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.

On June 30, 2014, the Company issued dividends to the holders of Series A Preferred Shares in the form of common stock per a stipulated \$19.50 per share. As a result 1,560 shares of common stock were issued to the Preferred Holders.

On July 23, 2014, the Company entered into Securities Purchase Agreements with certain investors, including SOK, an affiliate of the Company, pursuant to which the Company agreed to offer and sell an aggregate of \$733,173.60 in principal amount of senior convertible notes, in addition to warrants to purchase shares of the Company's common stock.

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.

On July 31, 2014, the Company pursuant to a securities purchase agreement dated July 31, 2014 between the Company and the purchaser named therein, offered and sold convertible notes and warrants for an aggregate of \$122,195.60 in principal amount of senior convertible notes, in addition to warrants to purchase shares, of the Company's common stock.

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.

On August 8, 2014 the Company, pursuant to a securities purchase agreement dated August 8, 2014 between the Company and the purchaser named therein, offered and sold an aggregate of \$305,489.00 in principal amount of senior convertible notes, in addition to warrants to purchase shares of the Company's common stock.

On August 12, 2014, the Company pursuant to a securities purchase agreement dated August 12, 2014 between the Company and the purchaser named therein, offered and sold an aggregate of \$122,195.60 in principal amount of senior convertible notes, in addition to warrants to purchase shares of the Company's common stock.

On September 4, 2014, the Company, pursuant to a securities purchase agreement dated September 4, 2014 between the Company and the purchaser named therein, offered and sold an aggregate of \$30,548.90 in principal amount of senior convertible notes, in addition to warrants to purchase shares of the Company's common stock.

On September 5, 2014, the Company, pursuant to a securities purchase agreement dated September 5, 2014 between the Company and the purchaser named therein, offered and sold an aggregate of \$488,782.40 in principal amount of senior convertible notes, in addition to warrants to purchase shares of the Company's common stock.

On September 30, 2014, the Company issued dividends to the holders of Series A Preferred Shares 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 the Preferred Holders.

In October 2014, SOK Partners, LLC transferred 138,977 shares of Skyline Medical common stock to Prospect Park Capital Corp. a nonaffiliated company. There is one current director of the Company, Joshua Komberg on the Board of Prospect Park Capital Corp. Mr. Komberg is also President and Chief Executive Officer of the Company. In addition, Frank Mancuso Jr., a former director if the Company, is on the Board of Prospect Park Capital Corp. Mr. Mancuso served on the Company's board at the time of the transfer.

In November 2014, the Company issued warrants to an advisor to purchase 5,557 shares of common stock at \$12.38 per share, subject to adjustment of the exercise price in certain events.

On December 31, 2014, the Company issued dividends to the holders of Series A Preferred Shares 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 the Preferred Holders (in January 2015, the Company issued additional shares as dividends because of a true-up for using \$19.50 as a price per share in September and December instead of \$9.75).

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.

On April 8, 2015, the Company sold a senior convertible note, in an original principal amount of \$125,000 which shall be convertible into a certain amount of shares of Common Stock, in accordance with the terms of the agreement for a purchase price of \$125,000 (representing an approximately 20% original issue discount).

On May 8, 2015, the Company sold a senior convertible note, in an original principal amount of \$150,000 which shall be convertible into a certain amount of shares of Common Stock, in accordance with the terms of the agreement for a purchase price of \$150,000.

On August 31, 2015, the Company consummated the Unit Exchange described in Note 3 under "Unit Exchange", whereby the Company issued a total of 228,343 Units (the "Exchange Units") in exchange for the outstanding Series A Preferred Shares, which were then cancelled. The Exchange Units were exempt from registration under the Securities Act pursuant to Section 3(a)(9) thereof.

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:

- Current negative operating cash flows;
- The terms of any further financing, which may be highly dilutive and may include onerous terms;
- Risk that we will be unable to protect our intellectual property or claims that we are infringing on others' intellectual property;
- Risk that we never become profitable if our product is not accepted by potential customers;
- Inability to attract or retain qualified senior management personnel, including sales and marketing personnel;
- The impact of competition, the obtaining and maintenance of any necessary regulatory clearances applicable to applications of the Company's technology;
- 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;
- The features of the Company's Series A Warrants that include a cashless exercise feature that has the potential to be highly dilutive, and the existence of which may depress the price of our common stock regardless of the Company's business performance; 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 manufacture 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 one regional sales manager to sell the STREAMWAY FMS. In 2014 we signed a contract with an independent distributor covering New York and surrounding areas as well as, three other independent contracting groups handling parts of the Midwest, the Southeast and Oklahoma.

Since inception, we have been unprofitable. We incurred net losses of approximately \$4.8 million and \$6.8 million for the years ended December 31, 2015, and December 31, 2014, respectively. As of December 31, 2015 and December 31, 2014, we had an accumulated deficit of approximately \$40.5 million and \$35.6 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.

In the first quarter of 2014, the Company commenced sales of an updated version of the STREAMWAY FMS, which provides a number of enhancements to the existing product line including a more intuitive and easier to navigate control screen, data storage capabilities, and additional inlet ports on the filters, among other improvements. This updated version utilizes improved technology, including the capability for continuous flow and continuous suctioning, as covered by our provisional patent application filed in 2013 and our non-provisional patent application filed in January 2014. We have sold ninety-four STREAMWAY units to date.

We expect the revenue for STREAMWAY FMS units to increase significantly at such time as the hospitals approve the use of the units for their applications and place orders for billable units. We also expect an increase in trial based 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 – Financing Transaction" below. In 2014, we completed private placements of Series A Preferred Stock and convertible notes raising aggregate gross proceeds of \$3,530,000. In September 2014 we commenced a public offering that was delayed, and we did not complete our public offering until August 2015. During that period of time, due to limited funding and continued operating losses, we curtailed our operations and delayed our expenditures to stay in operation. These factors negatively affected our sales in late 2014 and the full year 2015. Our future cash requirements and the adequacy of available funds depend on our ability to sell our products and the availability of future financing to fulfill our business plans. See "Plan of Financing; Going Concern Qualification" below.

As a company, 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, 2015 with Year Ended December 31, 2014*

*Revenue.* We recorded revenue of \$654,000 in 2015, compared to \$952,000 in 2014. Revenue in 2015 included the sale of twenty STREAMWAY systems and disposable supplies to operate the STREAMWAY. The revenue in 2014 included the sale of forty-four STREAMWAY systems and disposable supplies to operate the STREAMWAY. Our revenues and product sales declined in 2015 due to the delay in our public offering until August 2015, which caused us to curtail our operations and delay our expenditures. These factors negatively impacted sales throughout 2015.

*Cost of sales.* Cost of sales was \$304,000 in 2015 compared to \$385,000 in 2014. The gross profit margin was 54% in 2015 and 60% in 2014. 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 costs through tooling parts and purchasing different components that improved the STREAMWAY Systems while costing less. However, in 2015, our sharp decline in sales negatively impacted our ability to leverage costs and negatively impacted our profit margin. Also, in 2015, margins were negatively affected as we absorbed the cost of replacing fifteen units of the original STREAMWAY generation model with its newer iteration initially 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 \$3,399,000, for 2015 from \$4,883,000 in 2014. The \$1,484,000 decrease in G&A expenses for 2015, compared to 2014, is primarily due to higher expenses for financings and legal proceedings in 2014, as well as our efforts to curtail expenses in 2015. Our legal expenses decreased by \$1.1 million, because in 2015 the majority of our legal expenses were in association with our public offering and were therefore capitalized as appropriate. By comparison, in 2014 legal fees were higher due to our two private placements and certain legal disputes. Other decreases included \$204,000 in salaries and payroll taxes; \$329,000 in miscellaneous expenses in 2014 relating to a legal settlement; \$269,000 related to finders fees associated with fund raising in 2014; \$218,000 in payroll taxes, penalty and interest originally accrued in 2014 but not incurred; \$60,000 in investor relations costs and \$59,000 in recruiting fees. These decreases were partially offset by increases in 2015 that included increased expenses of \$475,000 due to an extension fee for the convertible notes issued in 2015 and 2014; \$216,000 in bonuses; \$79,000 in stock based and investor's stock compensation as a result of employee options issued; and \$52,000 in corporate insurance expenses.

*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 \$847,000 in 2015 compared to \$973,000 in 2014. The \$126,000 decrease in operations expense in 2015 was primarily due to decreases of \$52,000 in salaries and payroll taxes; \$133,000 in research and development expenses as a result of curtailed operations; \$59,000 in consulting; and \$30,000 in reduced shipping expenses. These decreases were partially offset by increases in 2015 that included \$82,000 in bonuses; \$45,000 in miscellaneous expenses for inventory adjustments and obsolescence; and \$28,000 for stock based compensation as a result of employee options issued.

*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 decreased to \$504,000 in 2015 compared to \$1,178,000 in 2014. The \$674,000 decrease is a result of a \$335,000 decrease in salaries, payroll taxes and benefits due to a reduced sales staff; \$99,000 decreased commissions for less sales in 2015; \$158,000 for reduced bonuses; and \$71,000 in travel expenses.

*Interest Expense.* Interest expense increased to \$391,000 in 2015 compared to \$377,000 in 2014. The \$14,000 increase was a result of the convertible notes issued in 2014 and 2015.

*Loss (gain) on valuation of equity-linked financial instruments.* The Company realized a \$0 gain on valuation of equity-linked financial instruments in 2015 compared to a gain of \$12,000 in 2014 resulting in expiration of certain older warrants in 2014.

## Liquidity and Capital Resources

### *Cash Flows for the Year Ended December 31, 2015*

Net cash used in operating activities was \$7,487,000 for 2015, compared with net cash used of \$3,371,000 for 2014. In August 2015, we received proceeds of \$13.5 million (net of commissions but before payment of expenses) as a result of our public offering. During the remainder of 2015, we paid \$5.8 million in cash to cover accrued debts and obligations, most of which were required to be paid upon completion of the offering or were considered past due. These payments included: premium paid plus interest to redeem convertible notes as agreed with the holders to induce the redemption at a rate of 140% of principal: \$616,000; past due payrolls and taxes for employees: \$1,420,000; and past due amounts upon agreed upon legal settlements, including interest and penalties: \$916,000. In addition, the Company decreased payables by paying an aggregate \$3,900,000 in cost of goods to vendors for past due amounts for production of our product and in past due professional fees.

Cash flows used in investing activities was \$61,000 for 2015 and \$121,000 in 2014. Our investment expenses in 2015 were primarily for intangibles associated with our patents.

Net cash provided by financing activities was \$12,388,000 for 2015 compared to net cash provided of \$3,407,000 for 2014. In the second quarter of 2015 the Company received cash for two convertible notes totaling \$250,000. The Company completed a public offering on August 31, 2015 raising a net \$13,555,003. This was partially offset by redeeming the convertible notes issued in 2014 and 2015 with a remaining principal amount of \$933,074 not including accrued interest and redemption premiums.

***Liquidity, Plan of Financing and Going Concern Qualification***

Since our inception, we have incurred significant losses, and our accumulated deficit was approximately \$40.5 million as of December 31, 2015. 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) and a qualified public offering raising a net \$13,555,003, after deducting underwriting discounts, commissions and expenses. We currently have no outstanding bank debt and no secured indebtedness.

We have not achieved profitability and anticipate that we will continue to incur net losses at least through the first two quarters of 2016.

We had revenues of \$654,000 in 2015, but we had negative operating cash flows of \$7.5 million. In August 2015, we received proceeds of \$13.5 million, after deducting underwriting discounts, commissions and expenses, as a result of our public offering. During the remainder of 2015, we paid \$5.8 million in cash to cover accrued debts and obligations, most of which were required to be paid upon completion of the offering or were considered past due. Our cash balance was \$4.9 million as of December 31, 2015, and our accounts payable and accrued expenses were an aggregate \$1.5 million. We are currently incurring negative operating cash flows of approximately \$275,000 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.

As of December 31, 2015, the Company had no debt. We will require additional funding to finance operating expenses and to invest in our sales organization and new product development and to enter the international marketplace. We will attempt to raise these funds through equity or debt financing, alternative offerings or other means. If we are successful in securing adequate funding we plan to make significant capital or equipment investments, and we will also continue to make human resource additions over the next 12 months. Such additional financing will be dilutive to existing stockholders, and there is no assurance that such financing will be available upon acceptable terms. If such financing or adequate funds from operations are not available, we will be forced to limit our business activities, which will have a material adverse effect on our results of operations and financial condition.

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.

### ***Financing Transactions***

We have funded our operations through a combination of debt and equity instruments. We have funded our operations through an early bank loan (since repaid), and a variety of debt and equity offerings.

*Series A Preferred Stock.* On February 4, 2014, we raised \$2,055,000 in gross proceeds from a private placement of Series A Convertible Preferred Stock. The investors purchased 20,550 Preferred Shares, and warrants (the “Warrants”) initially to acquire an aggregate of approximately 21,334 shares of Common Stock. The Warrants were initially exercisable at an exercise price of \$24.38 per share and expire after five years from the Closing Date. In August 2014, because the Common Stock was not listed on the Nasdaq Stock Market, the New York Stock Exchange, or the NYSE MKT within 180 days of the closing date, the Company was required to issue 61,542 additional Warrants. As a result of not reaching certain sales goals by January 2015, the number of shares of Common stock for which such Warrant may be exercised were increased 2.5 times under the terms of the Warrants; these additional Warrants were subsequently canceled in connection with the Unit Exchange described below. The Warrants are exercisable on any day or after the date of issuance, and have a term of five years. However, a holder is prohibited from exercising a Warrant if, as a result of such exercise, the holder, together with its affiliates, would exceed 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 exercise of the Warrants held by the applicable holder, with the percentage subject to increase in certain circumstances.

The Preferred Shares were initially 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, reduced in July 2015 to \$9.75 per share, subject to adjustment for stock splits, reverse stock splits and similar recapitalization events. The Preferred Shares were 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, after the satisfaction in full of the debts of the Company and the payment of any liquidation preference owed to the holders of senior preferred shares, the holders of the Series A Preferred Shares were entitled to 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.

On August 31, 2015, the Company completed the Unit Exchange as described below under “Public Offering of Units – Unit Exchange.” After the Unit Exchange, there were no shares of Series A Preferred Stock outstanding.

### ***2014 and 2015 Sales of Convertible Notes and Warrants.***

From July through September 2014, we issued approximately \$1.8 million original principal amount (subsequently reduced to approximately \$1.6 million aggregate principal amount in accordance with their terms) of convertible promissory notes (the “2014 Convertible Notes”) and warrants exercisable for shares of our common stock for an aggregate purchase price of \$1,475,000 in private placements. Of this amount, we issued to SOK Partners, LLC, an affiliate of the Company, \$122,196 original principal amount of the 2014 Convertible Notes and warrants exercisable for 5,431 shares of our common stock for an aggregate purchase price of \$100,000. In April and May 2015, we issued and sold to a private investor additional Convertible Notes in an aggregate original principal amount of \$275,000 for an aggregate purchase price of \$250,000, containing terms substantially similar to the 2014 Convertible Notes (the “2015 Convertible Notes”) and, together with the 2014 Convertible Notes, the “Convertible Notes”). No warrants were issued with the 2015 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 stockholders with respect to any meeting of stockholders for the election of the Company’s directors or any other matter, or to exercise any rights whatsoever as our stockholders. If, however, the Company decides to declare a dividend or make distributions of its assets, the holders will be entitled to such distribution to the same extent that the holder’s would have participated therein if the holder had held the number of shares of Common Stock acquirable upon complete exercise of the Warrants. At any time in connection with certain events relating to a change of control, the Company or the successor entity (as the case may be) may be required to purchase the Warrants from the holder in an amount equal to the Black Scholes Value (as defined in the Warrants).

In August of 2014, as a result of the Company filing a resale registration statement and the SEC declaring it effective within certain time periods, (1) the outstanding principal amount of the 2014 Convertible 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 related Warrants was reduced from 80,106 shares of Common Stock to 71,257 shares of Common Stock (without any cash payment by the Company). In connection with this reduction, the principal amount of the Convertible Note issued to SOK Partners, LLC was reduced to \$108,695 and the number of related warrants was reduced to 4,831 shares.

On August 31, 2015, in connection with the Offering, as described below, pursuant to an agreement with the holders of the Convertible Notes, the Company redeemed the remaining \$933,074 aggregate principal amount of Convertible Notes plus interest and a 40% redeemable premium, for a total payment of \$1,548,792. Of this amount, approximately \$167,031 was paid to its affiliates in redemption of their Convertible Notes. Each holder of the Convertible Notes agreed to the foregoing terms and entered into an Amendment to Senior Convertible Notes and Agreement with the Company. As of September 30, 2015, none of the Convertible Notes were outstanding.

### ***Public Offering of Units***

On August 31, 2015 (the “Issuance Date”), the Company completed a public offering (the “Offering”) of 1,666,667 Units (the “Units”) as described below. The public offering price in the Offering was \$9.00 per Unit, and the purchase price for the underwriter of the Offering (the “Underwriter”) was \$8.28 per Unit, resulting in an underwriting discount and commission of \$0.72 (or 8.00%) per Unit and total net proceeds to the Company before expenses of \$13.8 million. The Company had granted the Underwriter an option for a period of 45 days to purchase up to an additional 250,000 Units solely to cover over-allotments. The Underwriter chose not to purchase any additional Units under the over-allotment option. The Company paid to the Underwriter a non-accountable expense allowance equal to 1% of the gross proceeds of the Offering and agreed to reimburse expenses incurred by the Underwriter up to \$70,000. On August

31, 2015, as a result of the consummation of the Offering and the issuance of the 228,343 Exchange Units in the Unit Exchange described below, the Company issued a total of 1,895,010 Units, comprised of a total of aggregate of 1,895,010 shares of Common Stock, 1,895,010 shares of Series B Preferred Stock and 7,580,040 Series A Warrants.

Each Unit consisted of one share of common stock, par value \$0.01 per share (the “Common Stock”), one share of Series B Convertible Preferred Stock (“Series B Preferred Stock”) and four Series A Warrants. The shares of Common Stock, the shares of Series B Preferred Stock and the Series A Warrants that comprise the Units automatically separated on February 29, 2016.

*Series A Warrants.* The Series A Warrants separated from the Series B Convertible Preferred Stock and the Common Stock included within the Units as described above and are currently exercisable. The Series A Warrants will terminate on August 31, 2020. Each Series A Warrant is exercisable into one share of Common Stock at an initial cash exercise price of \$4.95 per share. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the Common Stock and the exercise price.

Holders may exercise Series A Warrants by paying the exercise price in cash or, in lieu of payment of the exercise price in cash, by electing to receive a number of shares of Common Stock equal to the Black Scholes Value (as defined below) based upon the number of shares the holder elects to exercise. The number of shares of Common Stock to be delivered will be determined according to the following formula, referred to as the “Cashless Exercise.”

Total Shares =  $(A \times B) / C$

Where:

- Total Shares is the number of shares of Common Stock to be issued upon a Cashless Exercise.
- A is the total number of shares with respect to which the Series A Warrant is then being exercised.
- B is the Black Scholes Value (as defined below).
- C is the closing bid price of the Common Stock as of two trading days prior to the time of such exercise, provided that in no event may “C” be less than \$0.43 per share (subject to appropriate adjustment in the event of stock dividends, stock splits or similar events affecting the Common Stock).

As defined in the Series A Warrants, “Black Scholes Value” means the Black Scholes value of an option for one share of Common Stock at the date of the applicable Cashless Exercise, as such Black Scholes Value is determined, calculated using the Black Scholes Option Pricing Model obtained from the “OV” function on Bloomberg utilizing (i) an underlying price per share equal to 55% of the Unit price, or \$4.95 per share, (ii) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the remaining term of the Series A Warrant as of the applicable Cashless Exercise, (iii) a strike price equal to the exercise price in effect at the time of the applicable Cashless Exercise, (iv) an expected volatility equal to 135% and (v) a remaining term of such option equal to five years (regardless of the actual remaining term of the Series A Warrant). In the event that the Black Scholes Pricing Model from the “OV” function on Bloomberg is unavailable, the Company will calculate the Black Scholes Value in good faith, which calculation shall be definitive.

The Black Scholes Value (as defined above) as of March 11, 2016 was \$4.3246, and the closing bid price of Common Stock as of March 11, 2016, was \$0.18. Therefore, an exercise on that date would have resulted in the issuance of 10.06 shares of Common Stock for each Series A Warrant. Approximately 3,390,935 Series A Warrants have been exercised in cashless exercises as of March 11, 2016, resulting in the issuance of 34,053,653 shares of Common Stock. If all of the remaining 4,189,105 Series A Warrants that were issued as part of the Units sold in the Offering and part of the Units issued on August 31, 2015 were exercised pursuant to a cashless exercise and the closing bid price of our common stock as of the two trading days prior to the time of such exercise was \$0.43 per share or less and the Black Scholes Value were \$4.3246 (the Black Scholes Value as of March 11, 2016), then a total of approximately 76,184,359 shares of our common stock would be issued to the holders of such Series A Warrants. The potential for such dilutive exercise of the Series A Warrants may depress the price of our common stock regardless of the Company’s business performance, and could encourage short selling by market participants, especially if the trading price of our common stock begins to decrease.

The Series A Warrants will not be exercisable or exchangeable by the holder of such warrants to the extent (and only to the extent) that the holder or any of its affiliates would beneficially own in excess of 4.99% of the common stock of the Company, determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and the regulations promulgated thereunder.

In addition to (but not duplicative of) the adjustments to the exercise price and the number of shares of Common Stock issuable upon exercise of the Series A Warrants in the event of stock dividends, stock splits, reorganizations or similar events, the Series A Warrants provide for certain adjustments if the Company, at any time prior to the three year anniversary of the Issuance Date, (1) declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to all or substantially all of the holders of shares of Common Stock at any time after the Issuance Date, or (2) grants, issues or sells any options, convertible securities or rights to purchase stock, warrants, securities or other property pro rata to all or substantially all of the record holders of any class of shares of Common Stock. Further, if at any time a Series A Warrant is outstanding, the Company consummates any fundamental transaction, as described in the Series A Warrants and generally including any consolidation or merger into another corporation, or the sale of all or substantially all of our assets, or other transaction in which the Common Stock is converted into or exchanged for other securities or other consideration, the holder of any Series A Warrants will thereafter receive, the securities or other consideration to which a holder or the number of shares of Common Stock then deliverable upon the exercise or exchange of such Series A Warrants would have been entitled upon such consolidation or merger or other transaction.

*Unit Purchase Option.* The Company, in connection with the Offering, entered into a Unit Purchase Option Agreement, dated as of August 31, 2015 (the "Unit Purchase Option"), pursuant to which the Company granted the Underwriter the right to purchase from the Company up to a number of Units equal to 5% of the Units sold in the Offering (or up to 83,333 Units) at an exercise price equal to 125% of the public offering price of the Units in the Offering, or \$11.25 per Unit. The Unit Purchase Option expires on August 25, 2018.

*Series B Preferred Stock.* Each share of Series B Preferred Stock is convertible into one shares of Common Stock (subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events) on the six month anniversary of the Issuance Date or on the date of an Early Separation. In addition, the Series B Preferred Stock will automatically convert into shares of common stock upon the occurrence of a fundamental transaction, as described in the certificate of designations for the Series B Preferred Stock but including mergers, sales of the company's assets, changes in control and similar transactions. The Series B Preferred Stock is not convertible by the holder of such preferred stock to the extent (and only to the extent) that the holder or any of its affiliates would beneficially own in excess of 4.99% of the common stock of the Company. The Series B Preferred Stock has no voting rights, except for the right to approve certain amendments to the certificate of designations or similar actions. With respect to payment of dividends and distribution of assets upon liquidation or dissolution or winding up of the Company, the Series B Preferred Stock shall rank equal to the common stock of the Company. No sinking fund has been established for the retirement or redemption of the Series B Preferred Stock.

*Unit Exchange.* On February 4, 2014, the Company raised \$2,055,000 in gross proceeds from a private placement of 20,550 shares of Series A Convertible Preferred Stock, par value \$0.01, with a stated value of \$100 per share (the "Series A Preferred Shares") and warrants to purchase shares of the Company's common stock. The Series A Preferred Shares and warrants were sold to investors pursuant to a Securities Purchase Agreement, dated as of February 4, 2014. On August 31, 2015, the Company issued a total of 228,343 Units (the "Exchange Units") in exchange for the outstanding Series A Preferred Stock which were then cancelled pursuant to an agreement with the holders of the Series A Preferred Shares. The warrants that were issued in connection with the issuance of the Series A Preferred Shares remained outstanding; however, the warrant amounts were reduced so that the warrants are exercisable into an aggregate of 84,770 shares of the Company's common stock. The Exchange Units were exempt from registration under Section 3(a)(9) of the Securities Act. On August 31, 2015, the Company filed a termination certificate with the Delaware Secretary of State. Following that date there were no shares of Series A Preferred Stock outstanding, and the previously authorized shares of Series A Preferred Stock resumed the status of authorized but unissued and undesignated shares of preferred stock of the Company.

*Redemption of Convertible Notes.* In connection with the closing of the Offering, \$933,074 aggregate principal amount of Convertible Notes plus interest and a 40% redeemable premium were redeemed for total payments of \$1,548,792. See Note 4. Of this amount, approximately \$167,031 was paid to its affiliates in redemption of their Convertible Notes.

#### *Exchange Offer for Units*

In January 2016 we commenced a registered offer (the "Exchange Offer") to exchange, on a one-for-one basis, new units in exchange for the 1,895,010 outstanding units (the "Units") that were issued in the Offering and the Unit Exchange. Each new unit, if issued, would have consisted of shares of common stock and certain warrants to purchase common stock. On March 2, 2016, we announced the termination of the Exchange Offer. None of the Units were accepted for exchange in the Exchange Offer.

#### **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-22 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, 2015.

##### **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, 2015 based on the criteria in “Internal Control - Integrated Framework (2013)” 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, 2015.

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 four 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 stockholder. To submit a candidate for consideration for nomination, stockholders 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.

<b>Name</b>	<b>Age</b>	<b>Position</b>
<b>Directors:</b>		
Joshua Komberg	42	President, Chief Executive Officer and Interim Chairman of the Board of Directors
Richard L. Taney (1) (2)	59	Director
Thomas J. McGoldrick (1) (2) (3)	74	Director
Andrew P. Reding (1) (3)	46	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. McGoldrick, as the chairperson, Mr. Taney 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 2015.

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

The Board has determined that Mr. McGoldrick 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. McGoldrick, Mr. Taney 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, 2015, as filed with the Securities and Exchange Commission.

Thomas McGoldrick, Chair  
Andrew P. Reding  
Richard L. Taney

#### **Compensation Committee**

The Compensation Committee of the Board of Directors currently consists of two directors, Mr. McGoldrick, as the chairperson, and Mr. Taney. 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 2015, 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. Taney. 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. Reding. 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 stockholders' meeting;
- Reviews candidates for Board membership, if any, recommended by the Company's stockholders;
- 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 Certification 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.

## Section 16(a) Beneficial Ownership Reporting Compliance

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, 2015 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, 2015: Ricardo Koenigsberger, 1 late report covering 1 transaction; Joshua Kornberg, 4 late reports covering 5 transactions; Frank Mancuso Jr., 2 late reports covering 2 transactions; Thomas J. McGoldrick, 2 late reports covering 2 transactions; Andrew P. Reding, 2 late reports covering 2 transactions; and SOK Partners LLC, 1 late report covering 1 transaction.

## 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 2015 and 2014

The following table provides information regarding the compensation earned during the fiscal years ended December 31, 2015 and December 31, 2014 by each of the Named Executive Officers:

Name and Principal Position	Year	(5) Salary	Bonus	Stock Awards	(1) Option Awards	(6) All Other Compensation	Total Compensation
Joshua Kornberg, CEO, President <sup>(2)</sup>	2015	\$ 326,162	\$ 562,941	\$ -	\$ 417,628	\$ 27,000	\$ 1,333,731
	2014	\$ 275,000	\$ -	\$ -	\$ 428,708	\$ 33,000	\$ 736,708
David O. Johnson, COO <sup>(3)</sup>	2015	\$ 180,926	\$ 178,000	\$ -	\$ 32,969	\$ -	\$ 391,895
	2014	\$ 180,000	\$ -	\$ -	\$ 52,910	\$ -	\$ 232,910
Bob Myers, CFO <sup>(4)</sup>	2015	\$ 174,550	\$ 130,750	\$ -	\$ 30,222	\$ -	\$ 335,522
	2014	\$ 165,000	\$ -	\$ -	\$ 44,087	\$ -	\$ 209,087

- (1) Represents the actual compensation cost recognized during 2015 and 2014 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 report.
- (2) In 2014 Mr. Kornberg also received options to purchase 2,179 shares of common stock as fees for serving on the Board of Directors. Mr. Kornberg's minimum bonus for 2015 was 75% of his base salary or \$206,250. During 2015 he also received \$356,691 in additional bonuses, in recognition of bonus amounts from prior years that were waived. In 2015 also received bonus options to purchase 209,126 shares of common stock at \$2.63 per share. Mr. Kornberg also received options to purchase 6,321 shares of common stock as fees for serving on the Board of Directors.
- (3) Mr. Johnson's minimum bonus for 2015 was 20% of his base salary, or \$36,000. During 2015 he received \$117,000 in income from additional bonuses in recognition of bonus amounts from prior years that were waived and \$25,000 in an unwaived previous year's bonus. In 2015 he also received bonus options to purchase 17,111 shares of common stock at \$2.63 per share.
- (4) Mr. Myers's minimum bonus for 2015 was 20% of his base salary, or \$33,000. During 2015 he received \$97,000 in income from additional bonuses in recognition of bonus amounts from prior years that were waived. During 2015 he also received bonus options to purchase 15,685 shares of common stock at \$2.63 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 premiums for Canadian health insurance for 2015 and 2014.

## Outstanding Equity Awards at Fiscal Year-end for Fiscal 2015

The following table sets forth certain information regarding outstanding equity awards held by the named executive officers as of December 31, 2015:

	Grant Date	Number of Securities Underlying Options Exercisable	Number of Securities Underlying Options Unexercisable	Option Exercise Price	Option Expiration Date
Joshua Komberg (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
	3/31/2015	1,449		\$ 3.45	3/31/2025
	6/30/2015	1,613		\$ 3.10	6/30/2025
	9/30/2015	1,558		\$ 3.21	9/30/2025
10/21/2015	209,126		\$ 2.63	10/21/2025	
12/31/2015	1,701		\$ 2.94	12/31/2025	
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
	10/21/2015	17,111		\$ 2.63	10/21/2025
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
	10/21/2015	15,685		\$ 2.63	10/21/2025

- (1) 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 stockholder 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 stockholder value creation and alignment of executive interests with those of stockholders, 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 stockholders' interests by providing an incentive to achieve corporate goals and increase stockholder 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. Kornberg 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 Kornberg, 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. Kornberg'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. Kornberg in his current capacity with our Company. The compensation package for Mr. Kornberg 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 stockholder value.

Incentive Compensation. In connection with his employment during the Term, Mr. Kornberg 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. Kornberg 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 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 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 earn and be entitled to payment of an Annual Bonus in respect of a given calendar year, Mr. Kornberg 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. Kornberg (or his estate, if applicable) shall receive a pro-rata portion of the Target Annual Bonus (calculated as if all applicable performance metrics had been attained at 100% and based on the 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 for Good Reason (as defined below); or (iii) termination due to the Executive's death or Disability (as defined below).

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 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. Kornberg's employment with the Company is terminated for any reason, the Company shall pay or provide to Mr. Kornberg (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 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) of the Employment Contract); (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 the Employment Contract) and, if applicable under Section 2(h) of the Employment Contract, unused vacation that accrued through the Date of Termination (paid on or before the time required by law but in no event more than 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) of the Employment Contract 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) of the Employment Contract). 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. Kornberg 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.*, 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 60 days after the Date of Termination; provided, however, that if the 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 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. Kornberg 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. Kornberg 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. Kornberg 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 200% of Mr. Kornberg's Base Salary (which grant shall be fully vested on the Date of Termination); and
- d. the Company shall provide Mr. Kornberg (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 18 months following the Date of Termination; provided, however, if the Company cannot provide, for any reason, Mr. Kornberg 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. Kornberg a single sum cash payment, payable within 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. Kornberg with respect to any Federal, state or local taxation due on such single sum cash payment. If Mr. Kornberg (and his spouse and dependents, as applicable) was/were covered by Mr. Kornberg's own health insurance premiums for which Mr. Kornberg was being reimbursed pursuant to Section 2(t) above, then the Company shall pay to Mr. Kornberg a single sum cash payment, payable within 60 days following the Date of Termination, equal to the total amount of the monthly premiums for such insurance coverage for a period of 18 months.

Change in Control Payment. The provisions of this set forth certain terms of an agreement reached between Mr. Kornberg and the Company regarding Mr. Kornberg'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. Kornberg'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 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 18 months after the occurrence of a Change in Control if Mr. Kornberg 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. Kornberg (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. Kornberg's employment is terminated by the Company without Cause as provided in Section 3(d) or Mr. Kornberg terminates his employment for any reason, then the Company shall pay Mr. Kornberg 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 60 days after the Date of Termination; provided, however, that if the 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 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 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 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 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(f) above, then the Company shall pay to Mr. Komberg a single sum cash payment, payable within 60 days following the Date of Termination, equal to the total amount of the monthly premiums for such insurance coverage for a period of 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.

(ii) 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. Komberg within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or Mr. Komberg. 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. Komberg'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. Komberg 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. Komberg 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. Komberg.

(iii) Mr. Kornberg 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 10 business days after Mr. Kornberg 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. Kornberg shall not pay such claim prior to the expiration of the 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. Kornberg 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; provided, 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. Kornberg 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. Kornberg pursuant to this Section 5(b), Mr. Kornberg becomes entitled to receive any refund with respect to such claim, Mr. Kornberg 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).

Definitions. 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 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) 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 stockholders;

(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 50% of the combined voting power of the voting securities of which are owned by stockholders 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 Kornberg 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 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 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 20% of their annualized salary.

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 Company after the expiration of 30 days after receipt by Company of such notice.

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 2015

The following table summarizes the compensation paid to each non-employee director in the fiscal year ended December 31, 2015:

	Fees Paid or Earned in Cash	Stock Awards	Option Awards	Total
Thomas McGoldrick	\$ -	\$ -	\$ 36,759 <sup>(1)</sup>	\$ 36,759
Ricardo Koenigsberger	\$ -	\$ -	\$ 7,340 <sup>(2)</sup>	\$ 7,340
Andrew Reding	\$ -	\$ -	\$ 29,402 <sup>(3)</sup>	\$ 29,402
Frank Mancuso, Jr.	\$ -	\$ -	\$ 29,402 <sup>(4)</sup>	\$ 29,402

- (1) Mr. McGoldrick was awarded options to purchase 16,525 shares of common stock both for serving on the Board and for participating on the Audit, Compensation and Corporate Governance Committees.
- (2) Mr. Koenigsberger was awarded options to purchase 3,062 shares of common stock both for serving on the Board and for participating on the Audit and Corporate Governance Committees. Mr. Koenigsberger resigned as a Director effective June 5, 2015.
- (3) Mr. Reding was awarded options to purchase 13,124 shares of common stock both for serving on the Board and for participating on the Audit and Corporate Governance Committees.
- (4) Mr. Mancuso was awarded options to purchase 13,124 shares of common stock both for serving on the Board and for participating on the Audit and Compensation Committees. Mr. Mancuso resigned as a Director effective January 13, 2016.

### Equity Compensation Plan Information

The following table presents the equity compensation plan information as of December 31, 2015:

	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) (c)
Equity compensation plans approved by security holders (1)	850,385	\$ 5.33	534,293
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 March 11, 2016 certain information regarding beneficial ownership of our common stock by:

- Each person known 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 stockholder named in the table has sole voting and investment power with respect to the shares of common stock set forth opposite the stockholder's name. We have based our calculation of the percentage of beneficial ownership on 39,498,125 shares of the Company's common stock outstanding on December 31, 2015. 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
<b>Officers and Directors</b>		
Josh Kornberg <sup>(2)</sup>	1,995,506	5.0%
David Johnson <sup>(3)</sup>	47,338	0.1%
Bob Myers <sup>(4)</sup>	43,178	0.1%
Thomas J. McGoldrick <sup>(5)</sup>	22,619	*%
Andrew Reding <sup>(6)</sup>	18,013	*%
Richard Taney <sup>(10)</sup>	26,666	*%
<b>All directors and executive officers as a group (6 persons)</b>	<b>2,153,321</b>	<b>5.5%</b>
<b>5% Security Holders</b>		
Sam Herschkowitz <sup>(9)</sup>	1,995,506	5.1%
SOK Partners <sup>(8)</sup>	1,995,506	5.1%
APA, SOK, Sam Herschkowitz, Josh Kornberg	1,995,506	5.0%
APA <sup>(7)</sup>	1,995,506	5.0%

\* Under 0.1%

- 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.
- Includes (i) 4,183 shares owned directly, (ii) 519,433 shares issuable upon exercise of options that are exercisable within 60 days of March 11, 2016, (iii) 1,025 shares issuable upon exercise of warrants, (iv) 821,023 shares owned directly by SOK Partners, (v) 10,862 shares issuable upon conversion of a convertible note held by SOK Partners, (vi) 6,312 shares issuable upon exercise of warrants held by SOK Partners, (vii) 630,322 shares owned directly by APA, and (viii) 15,041 shares held directly by Dr. Herschkowitz. Mr. Kornberg and Dr. Samuel Herschkowitz are the managing partners of SOK Partners and APA. Upon the consummation of the Unit Offering, 250 shares of Series A Convertible Preferred Stock held by Mr. Kornberg were exchanged for 2,778 Exchange Units.
- Includes options to purchase 47,147 shares that are exercisable within 60 days of March 11, 2016.
- Includes options to purchase 43,045 shares that are exercisable within 60 days of March 11, 2016.
- Includes options to purchase 9,133 shares that are exercisable within 60 days of March 11, 2016.
- Includes options to purchase 8,195 shares that are exercisable within 60 days of March 11, 2016.
- Includes (i) 630,322 shares owned directly, (ii) 821,023 shares owned directly by SOK Partners, (iii) 10,962 shares issuable upon conversion of a convertible note held by SOK Partners, (iv) 6,312 shares issuable upon exercise of warrants held by SOK Partners, (v) 4,183 shares held directly by Mr. Kornberg, and (vi) 15,041 shares held directly by Dr. Herschkowitz. Mr. Kornberg and Dr. Samuel Herschkowitz are the managing partners of SOK Partners and APA. Upon the consummation of the Unit Offering, 250 shares of Series A Convertible Preferred Stock held by Mr. Kornberg were exchanged for 2,778 Exchange Units.

8. Includes (i) 821,023 shares owned directly, (ii) 10,862 shares issuable upon conversion of a convertible note, (iii) 6,312 shares issuable upon exercise of warrants held by SOK Partners, (iv) 15,041 shares held directly by Dr. Herschkowitz, (v) 4,183 shares held directly by Mr. Komberg, (vi) 519,433 shares issuable upon exercise of options held by Mr. Komberg that are exercisable within 60 days of March 11, 2016, (vii) 1,025 shares issuable upon exercise of warrants held by Mr. Komberg, and (viii) 630,322 shares owned directly by APA. Mr. Komberg and Dr. Samuel Herschkowitz are the managing partners of SOK Partners and APA. Upon the consummation of the Unit Offering, 250 shares of Series A Convertible Preferred Stock held by Mr. Komberg were exchanged for 2,778 Exchange Units.
9. Includes (i) 15,041 shares owned directly, (ii) 821,023 shares owned directly by SOK Partners, (iii) 10,862 shares issuable upon conversion of a convertible note held by SOK Partners, (iv) 6,312 shares issuable upon exercise of warrants held by SOK Partners, (v) 4,183 shares held directly by Mr. Komberg, (vi) 519,433 shares issuable upon exercise of options held by Mr. Komberg that are exercisable within 60 days of March 11, 2016, (vii) 1,025 shares issuable upon exercise of warrants held by Mr. Komberg, and (viii) 630,322 shares owned directly by APA. Mr. Komberg and Dr. Samuel Herschkowitz are the managing partners of SOK Partners and APA. Upon consummation of the Unit Offering, 250 shares of Series A Convertible Preferred Stock held by Mr. Komberg were exchanged for 2,778 Exchange Units.
10. Includes (i) 13,333 shares owned directly, (ii) 13,333 shares issuable upon exercise of warrants that are exercisable within 60 days of March 11, 2016.

### 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.

In connection with the sale of the Series A Preferred Shares on February 4, 2014, Joshua Komberg, our President, Chief Executive Officer and Interim Chairman of the Board, was one of the purchasers. Mr. Komberg purchased 19,231 Series A Preferred Shares for a purchase price of \$25,000 and received warrants to purchase 52 shares of common stock.

SOK Partners, LLC (“SOK”), a 10% stockholder with Mr. Komberg and Dr. Samuel Herschkowitz as managing partners, 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 the public offering of the Units, 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.” In connection with the Unit Offering in August 2015, all such convertible notes were redeemed at a redemption price of 140% of the principal amount thereof, plus accrued and unpaid interest. The Company paid approximately \$163,000 to SOK in redemption of its convertible note. In addition, Ricardo Koenigsberger, a former director who resigned on June 5, 2015, is a holder of membership units of SOK Partners.

In connection with the Unit Exchange that was consummated on August 31, 2015, 250 shares of Series A Convertible Stock held by Mr. Komberg were exchanged for 2,778 Exchange Units.

### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

In connection with the audit of the fiscal 2015 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, 2015 and December 31, 2014, by Olsen Thielen & Co., Ltd., the Company’s principal accountant. All fees described below were approved by the Audit Committee.

	2015	2014
Audit Fees (1)	\$ 129,209	\$ 75,750
Audit-Related Fees (2)	-	-
Tax Fees (3)	8,779	10,851
All Other Fees (4)	-	11,400
	\$ 137,988	\$ 98,001

- (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.
- (2) There were no audit-related fees in 2015 and 2014.
- (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.
- (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 March 16, 2016;
- Balance Sheets as of December 31, 2015 and December 31, 2014;
- Statements of Operations for the Years Ended December 31, 2015 and December 31, 2014;
- Statements of Stockholders' Equity (Deficit) from December 31, 2013 to December 31, 2015;
- Statements of Cash Flows for the Years Ended December 31, 2015 and December 31, 2014;
- Notes to Financial Statements.

#### (2) Financial Statement Schedules

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

#### (3) Exhibits

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

## SIGNATURES

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

Dated: March 16, 2016

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	
<u>/s/ Joshua Kornberg</u> Joshua Kornberg	President, Chief Executive Officer and Interim Chairman of the Board (principal executive officer)	March 16, 2016
<u>/s/ Bob Myers</u> Bob Myers	Chief Financial Officer (principal financial officer)	March 16, 2016
<u>/s/ Andrew P. Reding</u> Andrew P. Reding	Director	March 16, 2016
<u>/s/ Thomas J. McGoldrick</u> Thomas J. McGoldrick	Director	March 16, 2016
<u>/s/ Richard L. Taney</u> Richard L. Taney	Director	March 16, 2016

EXHIBIT INDEX  
SKYLINE MEDICAL INC.  
FORM 10-K

<b>Exhibit Number</b>	<b>Description</b>
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	Certificate of Amendment to Certificate of Incorporation regarding increase in share capital, filed with the Delaware Secretary of State on July 24, 2015 (20)
3.4	Bylaws (21)
3.5	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (22)
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)**
4.7	Form of Senior Convertible Note (23)
4.8	Form of Warrant issued to investors of Convertible Notes (23)
4.9	Form of Registration Rights Agreement (23)
4.10	Form Waiver and Consent of, and Notice to, Holder of Preferred Stock of the registrant (23)
4.11	Form of Series A Warrant Agency Agreement by and between Skyline Medical Inc. and Corporate Stock Transfer, Inc. and Form of Warrant Certificate (24)
4.12	Form of Series A Warrant Certificate (included as part of Exhibit 4.11) (24)
4.13	Form of Unit Purchase Option issued in connection with offering of Units (25)
4.14	Form of Exchange Agreement with Holders of Series A Preferred Stock (26)
4.15	Form of Amendment to Senior Convertible Notes and Agreement by and Between Skyline Medical Inc. and Senior Convertible Notes (26)
4.16	Form of specimen certificate evidencing shares of Series B Convertible Preferred Stock (25)
4.17	Form of Unit Agreement (including form of Unit Certificate) (24)

- 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 Kornberg and Dr. Samuel Herschkowitz (4)
- 10.3 Amended and Restated Executive Employment Agreement with Joshua Kornberg, 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 Kornberg, 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)

- 10.28 Form of Securities Purchase Agreement with investors in Convertible Notes (23)
- 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

\*Filed herewith.

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

- (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.
- (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.
- (20) Filed on June 30, 2015 as an appendix to our Information Statement on Schedule 14C and incorporated herein by reference.
- (21) Filed on January 27, 2016 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (22) Filed on August 20, 2015 as an exhibit to our Registration Statement on Form S-1 (File No. 333-198962) and incorporated herein by reference.
- (23) Filed on July 24, 2014 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (24) Filed on August 20, 2015 as an exhibit to our Registration Statement on Form S-1 (File No. 333-198962) and incorporated herein by reference.
- (25) Filed on August 10, 2015 as an exhibit to our Registration Statement on Form S-1 (File No. 333-198962) and incorporated herein by reference.
- (26) Filed on July 24, 2015 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, 2015 and December 31, 2014 are included on the following pages:

**INDEX TO FINANCIAL STATEMENTS**

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Financial Statements:	
<a href="#">Report of Independent Registered Public Accounting Firm</a>	<a href="#">F-1</a>
<a href="#">Balance Sheets</a>	<a href="#">F-2</a>
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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, 2015 and 2014 and the related statements of operations, stockholders' equity (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 audit 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, 2015 and 2014, 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  
March 16, 2016

SKYLINE MEDICAL INC.  
BALANCE SHEETS

	December 31, 2015	December 31, 2014
<b>ASSETS</b>		
Current Assets:		
Cash	\$ 4,856,232	\$ 16,384
Accounts Receivable	38,283	57,549
Inventories	231,740	367,367
Prepaid Expense and other assets	271,579	190,015
Total Current Assets	<u>5,397,834</u>	<u>631,315</u>
Fixed Assets, net	139,598	196,479
Intangibles, net	94,987	73,183
Total Assets	<u>\$ 5,632,419</u>	<u>\$ 900,977</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current Liabilities:		
Accounts Payable	650,413	2,194,518
Accrued Expenses	864,295	3,066,379
Short-term notes payable net of discounts of \$0 and \$194,097 (See Note 4)	-	937,424
Deferred Revenue	5,000	5,000
Total Current Liabilities	<u>1,519,708</u>	<u>6,203,321</u>
Accrued Expenses	-	213,883
Liability for equity-linked financial instruments (See Note 8)	-	-
Total Liabilities	<u>\$ 1,519,708</u>	<u>\$ 6,417,204</u>
Commitments and Contingencies	-	-
Stockholders' Equity (Deficit):		
Series A Convertible Preferred Stock, \$.01 par value, \$100 Stated Value, 10,000,000 authorized, 0 and 20,550 outstanding	-	206
Series B Convertible Preferred Stock, \$.01 par value, 10,000,000 authorized, 1,895,010 and 0 outstanding	18,950	-
Common Stock, \$.01 par value, 100,000,000 authorized, 5,206,428 and 3,092,766 outstanding	52,063	30,927
Additional paid-in capital	44,534,135	30,093,745
Accumulated deficit	(40,492,437)	(35,641,105)
Total Stockholders' Equity (Deficit)	<u>4,112,711</u>	<u>(5,516,227)</u>
Total Liabilities and Stockholders' Equity (Deficit)	<u>\$ 5,632,419</u>	<u>\$ 900,977</u>

See Notes to Financial Statements

**SKYLINE MEDICAL INC.  
STATEMENTS OF OPERATIONS**

	<b>Year Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
Revenue	\$ 654,354	\$ 951,559
Cost of goods sold	303,982	385,323
Gross margin	350,372	566,236
General and administrative expense	3,399,339	4,882,549
Operations expense	846,687	972,830
Sales and marketing expense	503,989	1,178,305
Interest expense	390,887	377,719
Loss (gain) on valuation of equity-linked financial instruments	-	(11,599)
Total Expense	5,140,902	7,399,804
Net loss available to common shareholders	<u>\$ (4,790,530)</u>	<u>\$ (6,833,568)</u>
Loss per common share - basic and diluted	\$ (1.23)	\$ (2.29)
Weighted average shares used in computation - basic and diluted	3,880,828	2,990,471

See Notes to Financial Statements

**SKYLINE MEDICAL INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
**FOR THE YEARS ENDED**  
**DECEMBER 31, 2015 and 2014**

	Common Stock					Total
	Preferred Stock	Shares	Amount	Paid-in Capital	Deficit	
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		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 compensation		2,000	20	41,230		41,250
Shares issued for cashless warrant exercise at \$12.75 per share		3,323	33	2,460		2,493
Shares issued for an option exercise at \$5.25 per share		267	3	1,397		1,400
Shares issued for cashless warrant exercise at \$.75 per share		2,174	22	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		(4,444)	(44)	(3,289)		(3,333)
Shares issued for cashless warrant exercise at \$7.50 per share		4,807	48	3,557		3,605
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)
Shares adjusted for rounding per reverse stock split	106	1	1	2
Net loss		-	-	(6,833,568)
Balance at 12/31/2014	\$ 206	3,092,766	\$ 30,927	\$ 30,093,745
Shares issued to 16 shareholders of Series A Convertible Preferred Stock Adjustment as converted to common shares at \$9.75 per share	3,122	31	(31)	-
Reduction in escrow account per settlement agreement	(8,889)	(89)	(6,578)	(6,667)
Shares issued for a note conversion at \$2.90 per share	3,447	34	9,966	10,000
Shares issued for a note conversion at \$2.96 per share	6,762	68	19,932	20,000
Shares issued for a note conversion at \$2.91 per share	10,313	103	29,897	30,000
Shares issued for a note conversion at \$2.77 per share	12,098	120	33,358	33,478
Shares issued for a note conversion at \$2.25 per share	15,552	156	34,844	35,000
Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$9.75 per share	3,121	31	30,369	(30,401)
Shares issued for a note conversion at \$2.00 per share	20,000	200	39,800	40,000
Shares issued for a note conversion at \$2.27283 per share	87,997	880	199,120	200,000
Shares issued for a note conversion at \$2.0179 per share	14,867	149	29,851	30,000
Shares issued for a note conversion at \$2.00 per share	15,000	150	29,850	30,000
Shares issued for a note conversion at \$1.92417 per share	12,993	130	24,870	25,000
Shares issued for a note conversion at \$1.8578 per share	16,148	162	29,838	30,000
Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$9.75 per share	3,121	31	30,371	(30,401)
Vesting Expense		-	871,877	871,877
Shares issued in public offering; net	16,667	1,666,667	16,667	13,027,546
Preferred stock conversion	2,077	228,343	2,283	(4,360)
Series A warrant exercise	3,000	30	9,870	9,900
Net loss		-	-	(4,790,530)
Balance @ 12/31/2015	\$ 18,950	5,206,428	\$ 52,063	\$ 44,534,135

See Notes to Financial Statements

**SKYLINE MEDICAL INC.  
STATEMENTS OF CASH FLOWS**

	Year Ended December 31,	
	2015	2014
Cash flow from operating activities:		
Net loss	(4,790,530)	(6,833,568)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	78,566	63,040
Vested stock options and warrants	871,877	723,367
Equity instruments issued for management and consulting	(6,667)	112,054
Amortization of debt discount	219,097	247,338
Penalty on debt provision	10,031	-
Loss on Sales of Equipment	17,076	-
(Gain) loss on valuation of equity-linked instruments	-	(11,599)
Changes in assets and liabilities:		
Accounts receivable	19,266	39,696
Inventories	135,627	(245,192)
Prepaid expense and other assets	(81,564)	(129,427)
Accounts payable	(1,544,105)	1,132,410
Accrued expenses	(2,415,967)	1,594,468
Deferred Revenue	-	(64,000)
Net cash used in operating activities:	(7,487,293)	(3,371,413)
Cash flow from investing activities:		
Purchase of fixed assets	(32,470)	(101,409)
Purchase of intangibles	(28,095)	(19,828)
Net cash used in investing activities	(60,565)	(121,237)
Cash flow from financing activities:		
Proceeds from long-term and convertible debt	250,000	1,500,000
Principal payments on debt	(933,074)	(305,000)
Net proceeds from issuance of preferred stock	18,950	2,055,000
Net proceeds from issuance of common stock	13,051,830	157,081
Net cash provided by financing activities	12,387,706	3,407,081
Net increase (decrease) in cash	4,839,848	(85,569)
Cash at beginning of period	16,384	101,953
Cash at end of period	4,856,232	16,384
Non cash transactions:		
Common stock issued for accrued interest/bonus	-	694,500
Common stock issued to satisfy debt	483,478	480,616

See Notes to Financial Statements

**SKYLINE MEDICAL INC.**  
**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, 2015, the registrant had 5,206,428 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 had a stockholders' deficit until August 31, 2015 whereupon the Company closed its public offering of units of common stock, Series B Convertible Preferred Stock and Series A Warrants (the "Units"). There remains though, substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Since inception to December 31, 2015, the Company raised approximately \$22,732,961 in equity, inclusive of \$2,055,000 from a private placement of Series A Convertible Preferred Stock, \$13,555,003 from the public offering of Units and \$5,685,000 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 2014-12, *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.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The new standard requires management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The standard is effective for public entities for annual and interim periods beginning after December 15, 2016, with early adoption permitted. We are currently evaluating the impact this guidance may have on our financial statements.

In April 2015, the FASB issued ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs*. Debt issuance costs related to a recognized debt liability will be presented on the balance sheet as a direct deduction from the debt liability, similar to the presentation of debt discounts, rather than as an asset. Amortization of these costs will continue to be reported as interest expense. ASU 2015-03 is effective for annual and interim reporting periods beginning after December 15, 2015. Early adoption is permitted. The adoption of this ASU is not expected to have an impact on our financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*, requiring that inventory be measured at the lower of cost and net realizable value. Net realizable value is defined as estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. This ASU is effective within annual periods beginning on or after December 15, 2016, including interim periods within that reporting period. We are currently evaluating the impact this guidance may have on our financial statements.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes (Topic 740)* providing guidance on the balance sheet classification of deferred taxes. The guidance requires that deferred tax assets and liabilities to be classified as noncurrent in the Balance Sheet. The guidance is effective for fiscal years beginning after December 15, 2016 and for interim periods within those fiscal years, with early adoption 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.

### **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 \$8,220 in 2015, and \$19,394 in 2014.

### **Research and Development**

Research and development costs are charged to operations as incurred. Research and development costs were approximately \$261,000 and \$394,000 for 2015 and 2014, 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, 2015	December 31, 2014
Finished goods	\$ 30,237	\$ 88,362
Raw materials	162,623	237,556
Work-In-Process	38,880	41,449
Total	<u>\$ 231,740</u>	<u>\$ 367,367</u>

## 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:

	December 31, 2015	December 31, 2014
Computers and office equipment	\$ 153,553	\$ 123,708
Leasehold Improvements	23,874	23,874
Manufacturing Tooling	97,288	97,288
Demo Equipment	8,962	30,576
Total	<u>283,677</u>	<u>275,446</u>
Less: Accumulated Depreciation	144,079	78,967
Total Fixed Assets, Net	<u>\$ 139,598</u>	<u>\$ 196,479</u>

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 2012 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.

In July 2015, Skyline Medical filed an international (PCT) patent application for its fluid waste collection system and received a favorable determination by the International Searching Authority finding that all of the claims satisfy the requirements for novelty, inventive step and industrial applicability. Skyline anticipates that the favorable International Search Report will result in allowance of its various national applications.

### **Credit Risk**

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash. The Company places its cash with high credit quality financial institutions and, by policy, generally limits the amount of credit exposure to any one financial institution. The Company had a credit risk concentration as a result of depositing \$4,621,764 of funds in excess of insurance limits in a single bank.

### **Product Warranty Costs**

In 2015, the Company incurred approximately \$56,201 in current warranty costs.

### **Segments**

The Company operates in one segment for the sale of its medical device and consumable products. Substantially all of the Company’s assets, revenues, and expenses for 2015 and 2014 were located at or derived from operations in the United States. There were no revenues from sales outside of the United States.

### **Risks and Uncertainties**

The Company is subject to risks common to companies in the medical device industry, including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with regulations of the FDA and other governmental agencies.

### **NOTE 2 – DEVELOPMENT STAGE OPERATIONS**

The Company was formed April 23, 2002. Since inception through December 31, 2015, 5,206,428 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' EQUITY (DEFICIT), STOCK OPTIONS AND WARRANTS

#### Public Offering of Units

On August 31, 2015 (the "Issuance Date"), the Company completed a public offering (the "Offering") of 1,666,667 Units (the "Units") as described below. The public offering price in the Offering was \$9.00 per Unit, and the purchase price for the underwriter of the Offering (the "Underwriter") was \$8.28 per Unit, resulting in an underwriting discount and commission of \$0.72 (or 8.00%) per Unit and total net proceeds to the Company before expenses of \$13.8 million. The Company had granted the Underwriter an option for a period of 45 days to purchase up to an additional 250,000 Units solely to cover over-allotments. The Underwriter chose not to purchase any additional Units under the over-allotment option. The Company paid to the Underwriter a non-accountable expense allowance equal to 1% of the gross proceeds of the Offering and agreed to reimburse expenses incurred by the Underwriter up to \$70,000.

On August 31, 2015, as a result of the communication of the Offering and the issuance of the 228,343 Exchange Units in the Unit Exchange described below, the Company issued a total of 1,895,010 Units, comprised of a total of aggregate of 1,895,010 shares of Common Stock, 1,895,010 shares of Series B Preferred Stock and 7,580,040 Series A Warrants.

Each Unit consisted of one share of common stock, par value \$0.01 per share (the "Common Stock"), one share of Series B Convertible Preferred Stock ("Series B Preferred Stock") and four Series A Warrants. The shares of Common Stock, the shares of Series B Preferred Stock and the Series A Warrants that comprise the Units automatically separated on February 29, 2016.

For a description of the terms of the Series B Convertible Preferred Stock included within the Units, see "Certificate of Designation for Series B Preferred Stock" below. For a description of the terms of the Series A Warrants included within the Units, see "Series A Warrants" below.

*Series A Warrants.* The Series A Warrants separated from the Series B Convertible Preferred Stock and the Common Stock included within the Units as described above and are currently exercisable. The Series A Warrants will terminate on August 31, 2020. Each Series A Warrant is exercisable into one share of Common Stock at an initial cash exercise price of \$4.95 per share. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the Common Stock and the exercise price.

Holders may exercise Series A Warrants by paying the exercise price in cash or, in lieu of payment of the exercise price in cash, by electing to receive a number of shares of Common Stock equal to the Black Scholes Value (as defined below) based upon the number of shares the holder elects to exercise. The number of shares of Common Stock to be delivered will be determined according to the following formula, referred to as the "Cashless Exercise."

$$\text{Total Shares} = (A \times B) / C$$

Where:

- Total Shares is the number of shares of Common Stock to be issued upon a Cashless Exercise.
- A is the total number of shares with respect to which the Series A Warrant is then being exercised.
- B is the Black Scholes Value (as defined below).
- C is the closing bid price of the Common Stock as of two trading days prior to the time of such exercise, provided that in no event may "C" be less than \$0.43 per share (subject to appropriate adjustment in the event of stock dividends, stock splits or similar events affecting the Common Stock).

The Black Scholes Value (as defined above) as of March 11, 2016 was \$4.3246, and the closing bid price of Common Stock as of March 11, 2016, was \$0.18. Therefore, an exercise on that date would have resulted in the issuance of 10.06 shares of Common Stock for each Series A Warrant. Approximately 3,390,935 Series A Warrants have been exercised in cashless exercises as of March 11, 2016, resulting in the issuance of 34,053,653 shares of Common Stock. If all of the remaining 4,189,105 Series A Warrants that were issued as part of the Units sold in the Offering and part of the Units issued on August 31, 2015 were exercised pursuant to a cashless exercise and the closing bid price of our common stock as of the two trading days prior to the time of such exercise was \$0.43 per share or less and the Black Scholes Value were \$4.3246 (the Black Scholes Value as of March 11, 2016), then a total of approximately 76,184,359 shares of our common stock would be issued to the holders of such Series A Warrants. The potential for such dilutive exercise of the Series A Warrants may depress the price of our common stock regardless of the Company's business performance, and could encourage short selling by market participants, especially if the trading price of our common stock begins to decrease.

The Series A Warrants will not be exercisable or exchangeable by the holder of such warrants to the extent (and only to the extent) that the holder or any of its affiliates would beneficially own in excess of 4.99% of the common stock of the Company, determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and the regulations promulgated thereunder.

In addition to (but not duplicative of) the adjustments to the exercise price and the number of shares of Common Stock issuable upon exercise of the Series A Warrants in the event of stock dividends, stock splits, reorganizations or similar events, the Series A Warrants provide for certain adjustments if the Company, at any time prior to the three year anniversary of the Issuance Date, (1) declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to all or substantially all of the holders of shares of Common Stock at any time after the Issuance Date, or (2) grants, issues or sells any options, convertible securities or rights to purchase stock, warrants, securities or other property pro rata to all or substantially all of the record holders of any class of shares of Common Stock. Further, if at any time a Series A Warrant is outstanding, the Company consummates any fundamental transaction, as described in the Series A Warrants and generally including any consolidation or merger into another corporation, or the sale of all or substantially all of our assets, or other transaction in which the Common Stock is converted into or exchanged for other securities or other consideration, the holder of any Series A Warrants will thereafter receive, the securities or other consideration to which a holder or the number of shares of Common Stock then deliverable upon the exercise or exchange of such Series A Warrants would have been entitled upon such consolidation or merger or other transaction.

*Unit Purchase Option.* The Company, in connection with the Offering, entered into a Unit Purchase Option Agreement, dated as of August 31, 2015 (the "Unit Purchase Option"), pursuant to which the Company granted the Underwriter the right to purchase from the Company up to a number of Units equal to 5% of the Units sold in the Offering (or up to 83,333 Units) at an exercise price equal to 125% of the public offering price of the Units in the Offering, or \$11.25 per Unit. The Unit Purchase Option expires on August 25, 2018.

*Series B Preferred Stock.* Each share of Series B Preferred Stock is convertible into one share of Common Stock (subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events) on the six month anniversary of the Issuance Date or on the date of an Early Separation. In addition, the Series B Preferred Stock will automatically convert into shares of common stock upon the occurrence of a fundamental transaction, as described in the certificate of designations for the Series B Preferred Stock but including mergers, sales of the company's assets, changes in control and similar transactions. The Series B Preferred Stock is not convertible by the holder of such preferred stock to the extent (and only to the extent) that the holder or any of its affiliates would beneficially own in excess of 4.99% of the common stock of the Company. The Series B Preferred Stock has no voting rights, except for the right to approve certain amendments to the certificate of designations or similar actions. With respect to payment of dividends and distribution of assets upon liquidation or dissolution or winding up of the Company, the Series B Preferred Stock shall rank equal to the common stock of the Company. No sinking fund has been established for the retirement or redemption of the Series B Preferred Stock.

*Unit Exchange.* On February 4, 2014, the Company raised \$2,055,000 in gross proceeds from a private placement of 20,550 shares of Series A Convertible Preferred Stock, par value \$0.01, with a stated value of \$100 per share (the "Series A Preferred Shares") and warrants to purchase shares of the Company's common stock. The Series A Preferred Shares and warrants were sold to investors pursuant to a Securities Purchase Agreement, dated as of February 4, 2014. On August 31, 2015, the Company issued a total of 228,343 Units (the "Exchange Units") in exchange for the outstanding Series A Preferred Stock which were then cancelled pursuant to an agreement with the holders of the Series A Preferred Shares. The warrants that were issued in connection with the issuance of the Series A Preferred Shares remained outstanding; however, the warrant amounts were reduced so that the warrants are exercisable into an aggregate of 84,770 shares of the Company's common stock. The Exchange Units were exempt from registration under Section 3(a)(9) of the Securities Act. On August 31, 2015, the Company filed a termination certificate with the Delaware Secretary of State. Following that date there were no shares of Series A Preferred Stock outstanding, and the previously authorized shares of Series A Preferred Stock resumed the status of authorized but unissued and undesignated shares of preferred stock of the Company.

*Redemption of Convertible Notes.* In connection with the closing of the Offering, \$933,074 aggregate principal amount of Convertible Notes plus interest and a 40% redeemable premium were redeemed for total payments of \$1,548,792. See Note 4. Of this amount, approximately \$167,031 was paid to its affiliates in redemption of their Convertible Notes.

#### Equity Incentive Plan

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

#### Accounting for share-based payment

The Company has adopted ASC 718- *Compensation-Stock Compensation* ("ASC 718"). Under ASC 718 stock-based employee compensation cost is recognized using the fair value based method for all new awards granted after January 1, 2006 and unvested awards outstanding at January 1, 2006. Compensation costs for unvested stock options and non-vested awards that were outstanding at January 1, 2006, are being recognized over the requisite service period based on the grant-date fair value of those options and awards, using a straight-line method. We elected the modified-prospective method under which prior periods are not retroactively restated.

ASC 718 requires companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model or other acceptable means. The Company uses the Black-Scholes option valuation model which requires the input of significant assumptions including an estimate of the average period of time employees will retain vested stock options before exercising them, the estimated volatility of the Company's common stock price over the expected term, the number of options that will ultimately be forfeited before completing vesting requirements, the expected dividend rate and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognized. The assumptions the Company uses in calculating the fair value of stock-based payment awards represent the Company's best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and the Company uses different assumptions, the Company's equity-based compensation expense could be materially different in the future.

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

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

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

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

The Company determines the grant date fair value of options and warrants using a Black-Scholes option valuation model based upon assumptions regarding risk-free interest rate, expected dividend rate, volatility and estimated term.

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.

In January 2015, the Company issued a dividend adjustment to the Purchasers of the Preferred Shares as described above. Certain previous dividends paid were calculated with an exercise price of \$19.50 per share, but should have been calculated at \$9.75 per share. As a result 3,122 shares of common stock were issued to 16 holders of Preferred Shares.

On March 31, 2015, 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 \$9.75 per share. As a result 3,121 shares of common stock were issued to 16 holders of Preferred Shares.

On June 30, 2015, the Company issued dividends to Purchases 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 \$9.75 per share. As a result 3,121 shares of common stock were issued to 16 holders of Preferred Shares.

For grants of stock options and warrants in 2015 the Company used a 1.63% to 2.35% risk-free interest rate, 0% dividend rate, 59% to 66% volatility and estimated terms of 5 to 10 years. Value computed using these assumptions ranged from \$0.2750 to \$5.5695 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, 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
Issued	354,253	2.76	7,581,722	4.95
Cancelled	(19,136)	11.73	(1,967)	11.34
Exercised	-	-	(3,000)	4.95
Outstanding at December 31, 2015	783,718	\$ 5.33	8,077,477	\$ 5.14

At December 31, 2015, 780,718 stock options are fully vested and currently exercisable with a weighted average exercise price of \$5.29 and a weighted average remaining term of 8.17 years. There are 8,077,477 warrants that are fully vested and exercisable. Stock-based compensation recognized in 2015 and 2014 was \$871,877 and \$723,367, respectively. The Company has \$32,682 of unrecognized compensation expense related to non-vested stock options that are expected to be recognized over the next 2 months.

The following summarizes the status of options and warrants outstanding at December 31, 2015:

<b>Range of Exercise Prices</b>	<b>Shares</b>	<b>Weighted Average Remaining Life</b>
<b>Options:</b>		
\$0.75	7,333	5.52
\$2.63	250,481	9.81
\$2.94	30,614	10.01
\$3.10	59,681	9.50
\$3.21	6,232	9.76
\$3.45	7,245	9.25
\$4.875	134	7.20
\$5.25	2,031	6.69
\$5.625	192,000	7.21
\$5.925	23,206	7.22
\$6.00	123,998	6.63
\$6.50	3,845	9.01
\$8.25	3,636	8.76
\$9.9375	3,019	7.54
\$10.50	3,238	7.54
\$11.25	13,666	7.09
\$12.75	67	7.36
\$13.875	2,160	8.25
\$71.25	40,261	8.19
\$18.75	3,334	8.15
\$20.25	4,940	8.01
\$21.75	1,336	7.77
\$23.85	1,260	7.75
<b>Total</b>	<b>783,718</b>	
<b>Warrants:</b>		
\$4.95	7,577,040	4.67
\$6.00	102,857	2.20
\$9.00	2,666	2.07
\$9.75	63,227	3.59
\$11.25	203,801	2.02
\$12.375	71,257	3.61
\$12.38	5,557	3.85
\$13.50	4,444	2.47
\$14.85	23,612	2.41
\$20.25	1,481	3.13
\$24.375	21,535	3.10
<b>Total</b>	<b>8,077,477</b>	

Stock options and warrants expire on various dates from June 2017 to December 2025.

On July 24, 2015, an amendment to the Certificate of Incorporation became effective, pursuant to which the authorized common stock was increased to 100,000,000 shares of common stock and the authorized preferred stock was increased to 20,000,000 shares.

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

The following table is the listing of stock options and warrants as of December 31, 2015 by year of grant:

Stock Options:

Year	Shares	Price
2011	11,666	.75
2012	126,029	5.25 – 6.00
2013	232,756	4.875 – 23.85
2014	59,013	6.50 – 18.75
2015	354,253	2.63 – 3.45
Total	783,718	\$ .75 – 23.85

Warrants:

Year	Shares	Price
2012	69,801	11.25 – 15.00
2013	267,579	6.00 – 14.85
2014	161,375	12.375 – 24.375
2015	7,578,722	4.95
Total	8,077,477	\$ 4.95 – 24.375

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

From July through September 2014, we entered into a series of securities purchase agreements pursuant to which we issued approximately \$1.8 million original principal amount (subsequently reduced to approximately \$1.6 million aggregate principal amount in accordance with their terms) of convertible promissory notes (the “2014 Convertible Notes”) and warrants exercisable for shares of our common stock for an aggregate purchase price of \$1,475,000. Of this amount, we issued to SOK Partners, LLC, an affiliate of the Company, \$122,196 original principal amount of the 2014 Convertible Notes and warrants exercisable for 5,431 shares of our common stock for an aggregate purchase price of \$100,000. In April and May 2015, we issued and sold to a private investor additional Convertible Notes in an aggregate original principal amount of \$275,000 for an aggregate purchase price of \$250,000, containing terms substantially similar to the 2014 Convertible Notes (the “2015 Convertible Notes” and, together with the 2014 Convertible Notes, the “Convertible Notes”). No warrants were issued with the 2015 Convertible Notes.

Under a provision in the existing agreements, upon effectiveness of a resale registration statement covering certain shares, on September 9, 2014, the principal amount of the notes was reduced by 11%, to \$1,603,260 and the number of Warrants was reduced by 11%, to 71,257 shares.

As of June 30, 2015, \$927,663 aggregate principal amount of Convertible Notes, plus accrued and unpaid interest thereto, have been converted into shares of our common stock and \$933,073 aggregate principal amount of Convertible Notes remained outstanding.

In connection with the Offering, the holders of the Convertible Notes agreed to not exercise their right to convert the Convertible Notes into shares of the Company’s common stock, in exchange for the Company’s agreement to redeem all of the outstanding Convertible Notes promptly following the consummation of the Offering at a redemption price equal to 140% of the principal amount, plus accrued and unpaid interest to the redemption date. On August 31, 2015, the closing date of the offering, the Company redeemed the remaining \$933,074 aggregate principal amount of Convertible Notes plus interest and a 40% redeemable premium, for a total payment of \$1,548,792. Of this amount, approximately \$167,031 was paid to its affiliates in redemption of their Convertible Notes. Each holder of the Convertible Notes agreed to the foregoing terms and entered into an Amendment to Senior Convertible Notes and Agreement with the Company. As of December 31, 2015 none of the Convertible Notes were outstanding.

## 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,	
	2015	2014
Numerator:		
Net loss available in basic and diluted calculation	\$ (4,790,530)	\$ (6,833,568)
Denominator:		
Weighted average common shares outstanding-basic	3,880,828	2,990,471
Effect of dilutive stock options, warrants and preferred stock (1)	-	-
Weighted average common shares outstanding-diluted	<u>3,880,828</u>	<u>2,990,471</u>
Loss per common share-basic and diluted	<u>\$ (1.23)</u>	<u>\$ (2.29)</u>

(1) The number of shares underlying options and warrants outstanding as of December 31, 2015 and December 31, 2014 are 8,861,195 and 949,323, respectively. The number of shares underlying the preferred stock as of December 31, 2015 is 1,898,010. The effect of the shares that would be issued upon exercise of such options, warrants and preferred stock 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, 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.

At December 31, 2015, the Company had approximately \$ 24.7 million of gross NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2016, subject to the Section 382 limitation described above. The federal NOLs will expire beginning in 2022 if unused. The Company also had approximately \$ 13.4 million of gross NOLs to reduce future state taxable income at December 31, 2015, which will expire in years 2022 through 2035 if unused. The Company's net deferred tax assets, which include the NOLs are subject to a full valuation allowance. At December 31, 2015, the federal and state valuation allowances were \$ 9.6 million and \$1.1 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, 2015 and December 31, 2014 are as follows:

	December 31, 2015	December 31, 2014
Deferred Tax Asset:		
Net Operating Loss	\$ 10,338,000	\$ 7,919,000
Other	359,000	1,150,000
Total Deferred Tax Asset	10,697,000	9,069,000
Less Valuation Allowance	10,697,000	9,069,000
Net Deferred Income Taxes	<u>\$ —</u>	<u>\$ —</u>

## 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 \$66,345 and \$64,753 for 2015 and 2014, respectively.

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

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	to	\$37.50
Exercise price	\$.75	to	\$24.38
Expected life (years)	2.0	to	6.5
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:

	Initial Value	Annual Gain (Loss)	Value at 12/31/09	2010 Gain (Loss)	Value at 12/31/10	2011 Gain (Loss)	Value at 12/31/2011	2012 Gain (Loss)	Value at 12/31/2012	2013 Gain (Loss)	Value at 12/31/2013	2014 Gain (Loss)	Value at 12/31/2014
January 1, 2009 adoption	\$ 479,910	\$ (390,368)	\$ 870,278	\$ 868,772	\$ 1,506	\$ (88,290)	\$ 89,796	\$ (21,856)	\$ 111,652	\$100,053	\$ 11,599	\$ 11,599	\$ -
Warrants issued in quarter ended 6/30/2009	169,854	20,847	149,007	147,403	1,604	(4,689)	6,293	6,293	-	-	-	-	-
Warrants issued in quarter ended 9/30/2009	39,743	(738)	40,481	40,419	62	(1,562)	1,624	910	714	714	-	-	-
Warrants is used in quarter ended 12/31/2009	12,698	617	12,081	12,053	28	(724)	752	415	337	337	-	-	-
Subtotal	702,205		1,071,847										
Warrants 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 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.

In connection with the sale of the Series A Preferred Shares on February 4, 2014, Joshua Kornberg, our President, Chief Executive Officer and Interim Chairman of the Board, was one of the purchasers. Mr. Kornberg purchased 19,231 Series A Preferred Shares for a purchase price of \$25,000 and received warrants to purchase 52 shares of common stock.

SOK Partners, LLC (“SOK”), a 10% stockholder with Mr. Kornberg and Dr. Samuel Herschkowitz as managing partners, 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 the public offering of the Existing Units, 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 – History Financing – 2014 Sales of Convertible Notes and Warrants.” In connection with the Unit Offering in August 2015, all such convertible notes were redeemed at a redemption price of 140% of the principal amount thereof, plus accrued and unpaid interest. The Company paid approximately \$163,000 to SOK in redemption of its convertible note. In addition, Ricardo Koenigsberger, a former director who resigned on June 5, 2015, is a holder of membership units of SOK Partners.

In connection with the Unit Exchange that was consummated on August 31, 2015, 250 shares of Series A Convertible Stock held by Mr. Kornberg were exchanged for 2,778 Exchange Units.

#### **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 2014, and again in 2015, we matched 100% of the employee’s contribution up to 4.0% of their earnings. The employer contribution was \$39,916 and \$37,730 in 2015 and 2014. There were no discretionary contributions to the plan in 2015 and 2014.

**NOTE 11 – SUPPLEMENTAL CASH FLOW DATA**

Cash payments for interest were \$246,620 and \$47,111 for the fiscal years ended December 31, 2015 and December 31, 2014, respectively.

**NOTE 12 – SUBSEQUENT EVENTS**

In January 2016 we commenced a registered offer (the “Exchange Offer”) to exchange, on a one-for-one basis, new units (the “New Units”) in exchange for the 1,895,010 outstanding units (the “Existing Units”) that were issued in the Offering and the Unit Exchange. Each New Unit, if issued, would have consisted of shares of common stock and certain warrants to purchase common stock. On March 2, 2016, we announced the termination of the Exchange Offer. None of the Existing Units were accepted for exchange in the Exchange Offer.

**Schedule II**

**Valuation and Qualifying Accounts**

(None)

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the following Registration Statements of our report, dated March 16, 2016, which expresses an unqualified opinion and includes an explanatory paragraph relating to the Company's ability to continue as a going concern, appearing in this Annual Report on Form 10-K of Skyline Medical Inc. for the year ended December 31, 2015.

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

Olsen Thielen & Co., Ltd.

St. Paul, Minnesota  
March 16, 2016

## CERTIFICATION

I, Joshua Komberg, certify that:

1. I have reviewed this annual report on Form 10-K of Skyline Medical Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15-d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2016

/s/ Joshua Komberg

Joshua Komberg  
Chief Executive Officer (Principal Executive Officer)

## CERTIFICATION

I, Bob Myers, certify that:

1. I have reviewed this annual report on Form 10-K of Skyline Medical Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15-d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2016

/s/ Bob Myers

Bob Myers

Chief Financial Officer (Principal Financial Officer)

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

In connection with the Annual Report on Form 10-K of Skyline Medical Inc. (the "Company") for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joshua Kornberg, Chief Executive Officer, and I, Bob Myers, Chief Financial Officer, of the Company, certify, pursuant to § 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1350, that to our knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 16, 2016

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

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

