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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

**FORM S-1**

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**Skyline Medical Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**3842**  
(Primary Standard Industrial  
Classification Code Number)

**33-1007393**  
(I.R.S. Employer  
Identification Number)

**2915 Commers Drive, Suite 900**  
**Eagan, Minnesota 55121**  
**(651) 389-4800**  
(Address, including zip code, and telephone number,  
including area code, of registrant's principal executive offices)

**Bob Myers, Chief Financial Officer**  
**2915 Commers Drive, Suite 900**  
**Eagan, Minnesota 55121**  
**(651) 389-4800**  
(Name, address, including zip code, and telephone number,  
including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company

**CALCULATION OF REGISTRATION FEE**

<b>Title of Each Class of Securities to be Registered</b>	<b>Amount to be Registered</b>	<b>Proposed Maximum Per Share Offering Price</b>	<b>Proposed Maximum Aggregate Offering Price (1)</b>	<b>Amount of Registration Fee (1)(2)</b>
Shares of Common Stock, par value \$0.01 per share (3)	1,925,000	\$ 3.185	\$ 6,140,750	\$ 711.72
Series D Warrants (4)	385,000	-	-	-
Shares of Common Stock underlying the Series D Warrants (5)	385,000	\$ 3.185	\$ 1,228,150	\$ 142.35
Underwriter's Unit Purchase Option		-	-	-
Shares of Common Stock underlying the Underwriter's Unit Purchase Option (4)	96,250	\$ 3.185	\$ 307,037.5	\$ 35.59
Series D Warrants underlying Underwriter's Unit Purchase Option (4)	19,250	-	-	-
Shares of Common Stock underlying Series D Warrants underlying Underwriter's Unit Purchase Option	19,250	\$ 3.185	\$ 61,407.5	\$ 7.2
<b>Total Registration Fee</b>			<b>\$ 7,737,345</b>	<b>\$ 896.86</b>

- (1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").
- (2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price of the securities registered hereunder to be sold by the registrant.
- (3) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(c) under the Securities Act based on an average of the high and low reported sales prices of the registrant's common stock, as reported on The Nasdaq Capital Market on December 2, 2016, of \$3.37 and \$3.00.
- (4) No registration fee required pursuant to Rule 457(g) under the Securities Act.
- (5) There will be issued a warrant to purchase 0.2 shares of common stock for every one share offered.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer of sale is not permitted.

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION

DATED DECEMBER 9, 2016



**1,925,000 Units, Each Unit Consisting of One Share of Common Stock and 0.2 of a Series D Warrant**

**385,000 Shares of Common Stock Underlying the Series D Warrants**

We are offering 1,925,000 shares of our common stock, par value \$0.01 per share, and Series D Warrants to purchase up to an aggregate of 385,000 shares of our common stock, par value \$0.01 per share, pursuant to this prospectus. The common stock and Series D Warrants will be sold in units (the "Units"), with each unit consisting of one share of common stock and 0.2 of a Series D Warrant, with each whole Series D Warrant purchasing one share of our common stock at an exercise price of \$ \_\_\_ per whole share. Each unit will be sold at a purchase price of \$ \_\_\_. Units will not be issued or certificated. The shares of common stock and Series D Warrants are immediately separable and will be issued separately.

Our common stock is listed on The NASDAQ Capital Market under the symbol "SKLN." The last reported per share price for our common stock was \$3.11, as quoted on The NASDAQ Capital Market on December 2, 2016. There is no established public trading market for the offered Series D Warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series D Warrants on any national securities exchange.

**INVESTING IN THE UNITS AND THE UNDERLYING SECURITIES INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE \_\_\_ OF THIS PROSPECTUS FOR A DISCUSSION OF INFORMATION THAT SHOULD BE CONSIDERED IN CONNECTION WITH AN INVESTMENT IN THE UNITS AND THE UNDERLYING SECURITIES.**

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

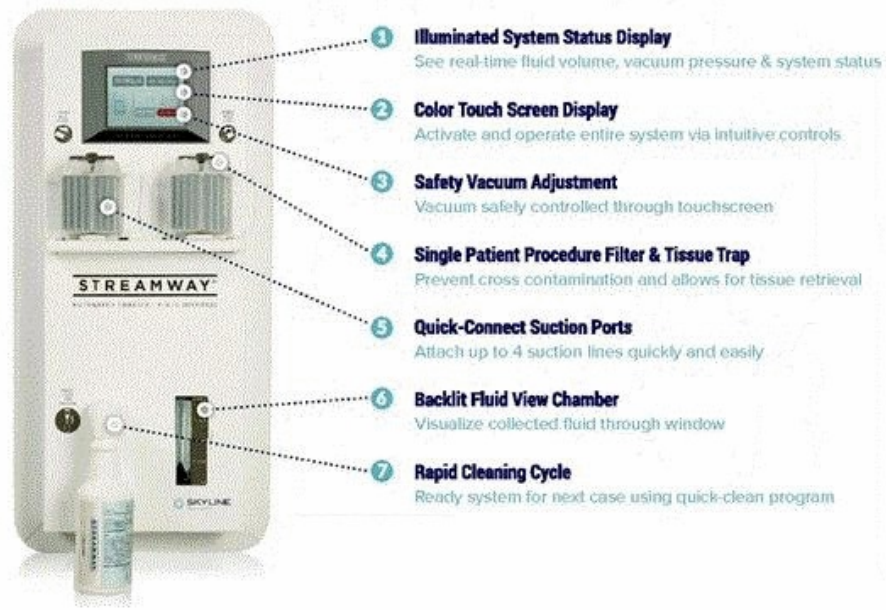
	Per Unit (1)	Total
Public offering price	\$	\$
Underwriting commissions (2)	\$	\$
Offering proceeds to us, before expenses	\$	\$

- (1) The public offering price and underwriting discount correspond to an assumed public offering price per share of common stock of \$ \_\_\_ and an assumed public offering price per warrant of \$0.01.
- (2) The underwriters will receive compensation in addition to the underwriting discount. See "Underwriting" beginning on page \_\_\_ of this prospectus for a description of compensation payable to the underwriters.

We expect to deliver the shares of common stock and warrants to investors on or about \_\_\_\_\_, 2016.

**Dawson James Securities, Inc.**

The date of this prospectus is \_\_\_\_\_, 2016



Skyline Medical Inc. STREAMWAY® System Fluid Management System

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You should rely only on the information contained in this prospectus or in any free writing prospectus that we may specifically authorize to be delivered or made available to you. We have not, and the underwriters have not, authorized anyone to provide you with any information other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus may only be used where it is legal to offer and sell our securities. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

## PROSPECTUS SUMMARY

*This summary contains basic information about us and this offering. You should read the entire prospectus carefully, especially the risks of investing in our common stock discussed under "Risk Factors." Some of the statements contained in this prospectus, including statements under this summary and "Risk Factors" are forward-looking statements and may involve a number of risks and uncertainties. We note that our actual results and future events may differ significantly based upon a number of factors. You should not put undue reliance on the forward-looking statements in this document, which speak only as of the date on the cover of this prospectus.*

*References to "we," "our," "us," the "Company," or "Skyline" refer to Skyline Medical Inc., a Delaware corporation.*

### **Business Overview**

Skyline Medical Inc. is a medical device company that develops and manufactures The STREAMWAY® System, a safe, environmentally conscious, innovative and cost-effective solution for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. Skyline owns patent rights to its product, has previously received 510(k) approval from the FDA, and distributes these products to hospitals, surgical centers, and other medical facilities where bodily and irrigation fluids produced during surgical procedures must be contained, measured, documented, and disposed. Skyline's products minimize the exposure potential to the healthcare workers who handle such fluids. Skyline's goal is to create products that dramatically reduce staff exposure without significant changes to established operative procedures, historically a major stumbling block to innovation and product introduction. In addition to simplifying the handling of these fluids, Skyline believes its technologies provide cost savings to facilities over the aggregate costs incurred today using the traditional canister method of collection, neutralization, and disposal. Skyline currently sells its products through an experienced in-house sales force and independent distributors located throughout the United States. Skyline also intends to seek the necessary approvals to distribute its products in Europe, Asia, Latin America, Canada, and other areas outside of the U.S.

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

Skyline's virtually hands free direct-to-drain technology will (a) significantly reduce the risk of healthcare workers' 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 infectious fluids, and (d) enhance the surgical team's ability to collect data to accurately assess the patient's status during and after procedures.

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 that no surgical procedure will ever have to be interrupted to change canisters. It is wall-mounted and does not take up any valuable operating room space. The FMS can replace the manual process of collecting fluids in canisters and transporting and dumping the fluids in sinks outside of the operating room a process 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.

### **Market — Infectious and Bio-hazardous Waste Management**

Due to the potential for ill effects to healthcare workers from exposure to infectious/bio-hazardous materials Federal and State regulatory agencies have issued mandatory guidelines for the control of such materials, and in particular, bloodborne pathogens. The presence of infectious materials is most prevalent in the surgical suite and post-operative care units where often, large amounts of bodily fluids, including blood, bodily and irrigation fluids are continuously removed from the patient during the surgical procedure. Surgical teams and post-operative care personnel may be exposed to these potentially serious hazards during the procedure via direct contact of blood materials or more indirectly via splash and spray. According to the Occupational Safety and Health Administration ("OSHA"), workers in many different occupations are at risk of exposure to bloodborne pathogens, including Hepatitis B and C, and HIV/AIDS. First aid team members, housekeeping personnel, nurses and other healthcare providers are examples of workers who may be at risk of exposure.

According to the American Hospital Association's (AHA) Hospital Statistics, 2013 edition, America's hospitals performed 86 million surgeries. This number does not include the many procedures performed at surgery centers across the country. The majority of these procedures produce potentially infectious materials that must be disposed with the lowest possible risk of cross-contamination to healthcare workers. Current standards of care allow for these fluids to be retained in canisters, located in the operating room where they can be monitored throughout the surgical procedure. Once the procedure is complete, these canisters and their contents are disposed using a variety of methods, all of which include manual handling and result in a heightened risk to healthcare workers for exposure to their contents.

There are currently approximately 40,000 operating rooms and surgical centers in the U.S. (AHA, *Hospital Statistics*, 2008). The hospital market has typically been somewhat independent of the U.S. economy; therefore, we believe that our targeted market is not cyclical, and the demand for our products will not be heavily dependent on the state of the economy. We benefit by having our products address both the procedure market of nearly 51.6 million inpatient procedures (CDC, National Hospital Discharge Survey: 2010 table) as well as the hospital operating room market (approximately 40,000 operating rooms).

We expect the hospital surgery market to continue to increase due to population growth, the aging of the population, expansion of surgical procedures to new areas, for example, use of the endoscope, which requires more fluid management, and new medical technology. With recent emphasis on increasing healthcare coverage, including several state mandates for universal or near-universal coverage, health-care construction has become one of the fastest growing institutional construction categories.

### ***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 that 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, healthcare personnel must dispose of the fluids. This is typically done by manually transporting the fluids from the operating room to a waste station and directly pouring the material into a sink that drains to the sanitary sewer where it is subsequently treated by the local waste management facility, a process that exposes the healthcare worker to the most risk for direct contact or splash exposure. Once emptied these canisters are placed in large, red pigmented, trash bags and disposed of as infectious waste — a process commonly referred to as “red-bagging.”

Alternatively, the canisters may be opened in the operating room and a gel-forming powder is poured into the canister, rendering the material gelatinous. These gelled canisters are then red-bagged in their entirety and removed to a bio-hazardous/infectious holding area for disposal. In larger facilities the canisters, whether pre-treated with gel or not, are often removed to large carts and transported to a separate special handling area where they are processed and prepared for disposal. Material that has been red-bagged is disposed of separately, and more expensively, from other medical and non-medical waste by companies specializing in that method of disposal.

Although all of these protection and disposal techniques are helpful, they represent a piecemeal approach to the problem and fall short of providing adequate protection for the surgical team and other workers exposed to infectious waste. A major spill of fluid from a canister, whether by direct contact as a result of leakage or breakage, splash associated with the opening of the canister lid to add gel, while pouring liquid contents into a hopper, or during the disposal process, is cause for concern of acute exposure to human blood components — one of the most serious risks any 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, HIV, HPV, and other infectious agents. Given the current legal liability environment, the hospital, unable to identify at-risk patients due to concerns over patient rights and confidentiality, must treat every exposure incident as a potentially infectious incident and treat the exposed employee according to a specific protocol that is both costly to the facility and stressful to the affected employee and his or her co-workers. In cases of possible exposure to communicable disease, the employee could be placed on paid administrative leave, frequently involving worker's compensation, and additional workers must be assigned to cover the affected employee's responsibilities. The facility bears the cost of both the loss of the affected worker and the replacement healthcare worker in addition to any ongoing health screening and testing of the affected worker to confirm if any disease has been contracted from the exposure incident. 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.



## Products

**The STREAMWAY Fluid Management System (“FMS”)** — The STREAMWAY Automated Surgical Fluid Waste Management System suctions surgical waste fluid from the patient using standard surgical tubing. The surgical waste fluid passes through our proprietary disposable filters and into the STREAMWAY 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.

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. 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.

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 Disposables** — The Skyline disposables are a critical component of our business model. The disposables consists of a proprietary, pre-measured amount of cleaning solution in a plastic bottle that attaches to the FMS. The disposables also includes an in-line filter with single or multiple suction ports. The proprietary cleaning solution placed in the specially designed holder is attached and recommended to be used following each surgical procedure. Due to the nature of the fluids and particles removed during surgical procedures, the FMS is recommended to be cleaned following each use. The disposables have the “razor blade business model” characteristic with an ongoing stream of revenue for every FMS unit installed, and revenues from the sale of the disposables are expected to be significantly higher over time than the revenues from the sales of the unit. Our disposable, bifurcated filter is designed specifically for use only on our FMS. The filter is used only once per procedure followed by immediate disposal. Our operation instructions and warranty require that a Skyline filter is used for every procedure. We have exclusive distribution rights to the disposable fluid and facilitate the use of only our fluid for cleaning following procedures by incorporating a special adapter to connect the fluid to the connector on the FMS system. We will also tie the fluid usage, which we will keep track of with the FMS software, to the product warranty.

**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 promote 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.*
- *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.*
- *Utilize existing medical products and independent distributors to achieve the desired market penetration.*
- *Continue to utilize operating room consultants, builders and architects as referrals to hospitals and day surgery centers.*

Our strategy may also include:

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

## Technology and Competition

### *Fluid Management for Surgical Procedures*

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

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

- *Direct Disposal Through the Sanitary Sewer.* In virtually all municipalities, the disposal of liquid blood may be done directly to the sanitary sewer where it is treated by the local waste management facility. This practice is approved and recommended by the EPA. In most cases these municipalities specifically request that disposed bio-materials not be treated with any known anti-bacterial agents such as 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 in the bio-hazardous/infectious waste generated by the hospital (red-bagged).
- *Conversion to Gel for Red-Bag Disposal.* In many hospital systems the handling of this liquid waste has become a liability issue due to worker exposure incidents and in some cases has even been a point of contention during nurse contract negotiations. The healthcare 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 the manual disposal process:

- 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 \$0.30 per pound.
- The canister filled with gelled fluid must be disposed; it cannot be cleaned and re-sterilized for future use.

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

### *Current Competition, Technology, and Costs*

*Single Use Canisters* — In the U.S., glass reusable containers are infrequently used as their high initial cost, frequent breakage and costs of reprocessing are typically more costly than single use high impact plastic canisters, even when disposal is factored in. Each single use 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. We believe our competitive advantage, however, is our unlimited capacity, eliminating the need for any high volume cases to be interrupted for canister changeover.

*Solidifying Gel Powder* — One significant drawback of the solidifying gels is that they increase the weight of the materials being sent to the landfill by a factor of five to seven times, resulting in a significant cost increase to the hospitals that elect to use the products. The FMS eliminates the need for solidifying gel, providing savings in both gel powder usage and associated landfill costs.

*Sterilization and Landfill Disposal* — Current disposal methods include the removal of the contaminated canisters (with or without the solidifying gel) to designated biohazardous/infectious waste sites. Previously many hospitals used incineration as the primary means of disposal, but environmental concerns at the international, domestic and local level have resulted in a systematic decrease in incineration worldwide as a viable method for disposing of blood, organs or materials saturated with bodily fluids. When landfill disposal is used, canisters are included in the general red-bag disposal and, when gel is used, comprise a significant weight factor. Where hopper disposal is still in use, most of the contents of the red-bag consist only of outer packaging of supplies used in surgery and small amounts of absorbent materials impregnated with blood and other waste fluid. These, incidentally, are retained and measured at the end of the procedure to provide a more accurate assessment of fluid loss or retention. Once at the landfill site, the red-bagged material is often steam-sterilized with the remaining waste being ground up and interred into a specially segregated waste dumpsite.

*Handling Costs* — Once the surgical team has finished the procedures, and a blood loss estimate is calculated, the liquid waste (with or without solidifying gels) is removed from the operating room and either disposed of down the sanitary sewer or transported to an infectious waste area of the hospital for later removal. The FMS would significantly reduce the labor costs associated with the disposal of fluid or handling of contaminated canisters, as the liquid waste is automatically emptied into the sanitary sewer after measurements are obtained. We 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 waste 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 body 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, but an internal study at a large healthcare facility in Minneapolis, Minnesota, revealed that the average nursing team spends twenty minutes pre-operatively and intra-operatively setting up, monitoring fluid levels and changing canisters as needed and twenty minutes post-operatively readying blood loss estimates or disposing of canisters. Estimates for the other new technologies reviewed have noted few cost savings to nursing labor.

The FMS would save nursing time as compared to the manual process of collecting and disposing of surgical waste. Set-up is as easy as attaching the suction tube to the inflow port of the FMS. Post-operative clean-up requires approximately five minutes, the time required to dispose of the suction tubing and disposable filter to the red-bag, calculate the patient’s blood loss, attach the bottle of cleaning solution to the inlet port of the unit, initiate the cleaning cycle, and dispose of the emptied cleaning solution. The steps that our product avoids, which are typically involved with the manual disposal process include, canister setup, interpretation of an analog read out for calculating fluid, canister management during the case (i.e. swapping out full canisters), and then temporarily storing, transferring, dumping, and properly disposing of the canisters.

#### **Marketing and Sales Distribution**

We sell the FMS and procedure disposables through various methods that may include a direct sales force, independent distributors and manufacturer’s representatives 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 have signed on independent distributors. Our targeted customer base includes nursing administration, operating room managers, CFOs, CEOs, risk management, and infection control.

*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 will include a number of printed materials, video support and a website. We believe our greatest challenge lies in reaching and educating the 1.6 million medical personnel who are exposed daily to fluid waste in the operating room or in other healthcare settings (OSHA, CPL 2-2.44C). These efforts will require utilizing single page selling pieces, video educational pieces for technical education, use of scientific journal articles and a webpage featuring product information, educational materials, and training sites.

**Pricing** — We believe prices for the FMS and its disposable procedure kit reflect a substantial cost savings to hospitals and surgical centers 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. Our cleaning solution's bottle is recyclable, and the anticipated selling price of the fluid is built into our cost analysis. In contrast, an operation using traditional disposal methods will often produce multiple canisters destined for biohazard processing. Biohazard disposal costs are estimated by *Outpatient Surgery Magazine* to be 5 times more per pound to dispose of than regular waste (*Outpatient Surgery Magazine*, April 2007). Once the canister has touched blood, it is considered "red bag" biohazard waste, whereas the cleaning fluid bottle used in the FMS can be recycled or disposed with the rest of the facility's plastics.

The FMS lists for \$24,900 per system (one per operating room — installation extra) and \$24 per unit retail for the proprietary disposables: one filter and one bottle of cleaning solution 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.

#### **Ability to Continue as a Going Concern**

We have suffered recurring losses from operations and have a stockholders' deficit. Although we have been able to fund our current working capital requirements, principally through debt and equity financing, there is no assurance that we will be able to do so in the future. These factors raise substantial doubt about our ability to continue as a going concern. As a result of the above factors, our independent registered public accounting firm has indicated in their audit opinion, contained in our financial statements included in this prospectus that they have serious doubts about our ability to continue as a going concern. See "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Plan of Financing; Going Concern Qualification."

#### **Recent Developments**

On August 30, 2016, the Company entered into a letter of intent to form a joint venture with Electronic On-Ramp, Inc. ("EOR"). EOR's partner contracts with government agencies are expected to provide the Company with access to bid on procurement contracts for up to \$550 million or more in federal funds budgeted for health, security, life safety systems support, humanitarian assistance and disaster preparedness.

At a special meeting of stockholders held on September 15, 2016, the Company's stockholders (i) approved an amendment to the Company's certificate of incorporation to increase the number of authorized shares of common stock from 100,000,000 to 200,000,000 and (ii) approved an amendment to the Company's certificate of incorporation to effect a reverse stock split of the outstanding shares of its common stock within certain limits. On September 16, 2016, the Company filed a Certificate of Amendment to its Certificate of Incorporation to effect the increase in the authorized capital stock. On October 26, 2016, the Company filed a Certificate of Amendment to its Certificate of Incorporation to effect a reverse stock split of the outstanding shares of its common stock at a ratio of one-for-twenty-five (1:25), and a proportionate decrease of the authorized common stock from 200,000,000 shares to 8,000,000 shares. The reverse stock split took effect at 5:00 p.m. New York time on October 27, 2016, and the Company's common stock commenced trading on a post-split basis on October 28, 2016. The Company's board of directors has determined that the Company may require additional authorized shares for anticipated equity financings, future equity offerings, strategic acquisition opportunities, the continued issuance of equity awards under our stock incentive plan to recruit and retain key employees, and for other proper corporate purposes. As a result, the board of directors plans to call another special meeting of stockholders in the near future to vote on a proposal to increase the number of authorized shares of common stock under the Company's certificate of incorporation.

On September 20, 2016, the Company entered into a partnership and exclusive reseller agreement with GLG Pharma ("GLG"). Under the terms of the agreement, GLG intends to develop rapid diagnostic tests that utilize fluid and tissue collected by the STREAMWAY System during procedures. The Company will issue an aggregate of 400,000 shares common stock to GLG in four separate tranches of 100,000 shares of common stock in each tranche. The shares reserved in each tranche will be released after the achievement of certain development milestones designated in the agreement. In addition, the Company will pay a royalty to GLG on the sale of individual tests. Also, on November 1, 2016, the Company announced that it agreed to grant GLG exclusive rights to market and distribute the STREAMWAY System in the U.K. On November 2, 2016, the Company announced that it agreed to grant GLG the same rights in Poland and certain other countries in Central Europe.

In order to maintain our listing on The NASDAQ Capital Market, our common stock must sustain a minimum shareholders' equity of \$2.5 million and a minimum bid price of at least \$1.00 per share. We must also satisfy the other requirements for continued listing on The NASDAQ Capital Market. On October 11, 2016, the Company received a letter from the Listing Qualifications Department (the "Staff") of The NASDAQ Stock Market LLC ("Nasdaq"), indicating that the Staff had determined to delist the Company's securities from The Nasdaq Capital Market due to the Company's continued non-compliance with the minimum bid price requirement as of October 10, 2016, unless the Company timely requests a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company timely requested a hearing before the Panel, which request stayed any delisting or suspension action by the Staff pending the issuance of the Panel's decision and the expiration of any extension granted by the Panel. At the hearing, the Company intends to present its plan to address compliance with the minimum bid price requirement as well as the minimum stockholders' equity requirement and to request the continued listing of its securities on The Nasdaq Capital Market, pursuant to an extension if necessary. The Company believes it has satisfied the minimum bid price requirement. Therefore, the focus of the hearing before the Panel will be to address the minimum shareholders' equity requirement. There can be no assurance that the Panel will determine to continue the Company's listing or that the Company will be able to demonstrate compliance with the applicable listing criteria within the period of time that may be granted by the Panel.

Effective October 27, 2016, the board of directors of the Company appointed J. Melville ("Mel") Engle and Timothy A. Krochuk to serve as directors of the company. These appointments increase the number of directors to five.

Effective November 21, 2016, the Company received a Medical Device Establishment License to sell the STREAMWAY System and related disposables in Canada. The Company is negotiating with several distributors and expects to come to terms in the next few weeks covering approximately 1,500 hospitals in all 13 provinces of Canada.

On November 25, 2016 the Company completed a registered direct offering of common stock and warrants. In connection with the registered direct offering, the Company entered into Common Stock Purchase Agreements (the "Purchase Agreements") with three institutional investors pursuant to which the Company sold an aggregate of 756,999 shares of common stock, par value \$0.01 per share, and warrants (the "Series C Warrants") to purchase up to an aggregate of 756,999 shares of our common stock, par value \$0.01 per share. The common stock and Series C Warrants were sold in units, with each unit consisting of one share of common stock and a Series C Warrant to purchase one share of our common stock at an exercise price of \$4.46 per share. Each unit was sold at a purchase price of \$2.62. Units were not issued or certificated. The shares of common stock and Series C Warrants were immediately separable and were issued separately. The sales of the units were completed on November 28, 2016. The net proceeds to the Company from the registered direct offering, after deducting placement agent fees and estimated offering expenses, were approximately \$1.74 million. The units were offered and sold in the registered direct offering pursuant to the Company's "shelf" registration statement (File No. 333-213766), which was declared effective by the United States Securities and Exchange Commission (the "SEC") on October 4, 2016. Dawson James Securities, Inc. served as the sole placement agent in connection with the registered direct offering. The Company issued a unit purchase option to the placement agent, pursuant to which the Company granted the placement agent 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 37,850 units) at an exercise price equal to 125% of the public offering price of the Units in the offering, or \$3.275 per unit. The unit purchase option will expire on November 25, 2021.

Effective December 1, 2016, the board of directors of the Company appointed Carl Schwartz to serve as the Chief Executive Officer, and appointed Richard Gabriel to serve as a director of the company. Mr. Gabriel's appointment increases the number of directors to six.

## THE OFFERING

Price per Unit	\$ ____ per Unit
Securities offered by us	1,925,000 Units. Each Unit consists of one share of common stock and 0.2 of a Series D Warrant. Under the registration statement of which this prospectus forms a part, we are also registering the shares of common stock issuable upon the exercise of the Series D Warrants.
Common stock offered	1,925,000 shares.
Warrants	An aggregate of 385,000 Series D Warrants to purchase up to an aggregate of 385,000 shares of our common stock will be offered in this offering. The warrants will have a term of five years and will be exercisable at any time on and after the date of issuance at an exercise price of \$ ____ per share. For additional information regarding the warrants, see “Description of Securities We are Offering – Series D Warrants Included in the Units Offered Hereby” below.
Common Stock Outstanding Immediately Before This Offering	4,562,127 shares.
Common Stock Outstanding Immediately After This Offering	6,872,127 shares (assuming exercise of 385,000 Series D Warrants into an aggregate of 385,000 shares of common stock).
Proceeds of offering	We estimate that the net proceeds from the offering, after deducting placement agent fees and estimated offering expenses, will be approximately \$ ____ million.
Use of Proceeds	We intend to use the net proceeds from this offering for working capital and general corporate purposes. See “Use of Proceeds” on page ____ of this prospectus.
Risk factors	An investment in our securities involves a high degree of risk. See the information contained in or incorporated by reference under “Risk Factors” beginning on page ____ of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.
Listing	Our common stock is listed on The NASDAQ Capital Market under the symbol “SKLN.” The last reported per share price for our common stock was \$3.11, as quoted on The NASDAQ Capital Market on December 2, 2016. There is no established public trading market for the offered Series D Warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series D Warrants on any national securities exchange.

## 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 prospectus, including our financial statements and related notes.*

### **Risks Related to Our Business**

***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 had revenues of \$317,000 in the nine months ended September 30, 2016, but we had negative operating cash flows of \$3.7 million in that time period. 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 first quarter 2016 and the remainder of 2015, we paid \$10.2 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. Additionally, we have covered our monthly operating expenses, research and development costs and expanded effort in sales and marketing including the successful search for our newly hired Vice President of Sales. Our cash balance was \$0.6 million as of September 30, 2016, and our accounts payable and accrued expenses were an aggregate \$2.0 million. We expect our monthly negative cash flow to reduce to approximately \$350,000 beginning in June 2016. 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 efforts and maintain adequate inventories.

As of September 30, 2016, 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 our annual report on Form 10-K filed on March 16, 2016, 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 common stock could be delisted from The NASDAQ Capital Market, which delisting could hinder your ability to obtain accurate quotations on the price of our common stock, or dispose of our common stock in the secondary market.***

In order to maintain our listing on The NASDAQ Capital Market, our common stock must sustain a minimum shareholders’ equity of \$2.5 million and a minimum bid price of at least \$1.00 per share. We must also satisfy the other requirements for continued listing on The NASDAQ Capital Market. On October 11, 2016, the Company received a letter from the Listing Qualifications Department (the “Staff”) of The NASDAQ Stock Market LLC (“Nasdaq”), indicating that the Staff had determined to delist the Company’s securities from The Nasdaq Capital Market due to the Company’s continued non-compliance with the minimum bid price requirement as of October 10, 2016, unless the Company timely requests a hearing before the Nasdaq Hearings Panel (the “Panel”). The Company timely requested a hearing before the Panel, which request stayed any delisting or suspension action by the Staff pending the issuance of the Panel’s decision and the expiration of any extension granted by the Panel. At the hearing, the Company intends to present its plan to address compliance with the minimum bid price requirement as well as the minimum stockholders’ equity requirement and to request the continued listing of its securities on The Nasdaq Capital Market, pursuant to an extension if necessary. The Company believes it has satisfied the minimum bid price requirement. Therefore, the focus of the hearing before the Panel will be to address the minimum shareholders’ equity requirement. There can be no assurance that the Panel will determine to continue the Company’s listing or that the Company will be able to demonstrate compliance with the applicable listing criteria within the period of time that may be granted by the Panel.

In the event our common stock is delisted from The NASDAQ Capital Market and we are also unable to maintain listing on another alternate exchange, trading in our common stock could thereafter be conducted in FINRA's OTC Bulletin Board or in the over-the-counter markets in the so-called pink sheets. In such event, the liquidity of our common stock would likely be impaired, not only in the number of shares which could be bought and sold, but also through delays in the timing of the transactions, and there would likely be a reduction in our coverage by security analysts and the news media, thereby resulting in lower prices for our common stock than might otherwise prevail.

***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 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, there is no assurance that there will not be supply interruptions or delays.***

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: Carl Schwartz, our Chief Executive Officer, David O. Johnson, our Chief Operating Officer, and Bob Myers, our Chief Financial Officer. We have entered into employment agreements with the Chief Operating Officer and the Chief Financial Officer 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.

## **Risks Related to Our Securities**

### ***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; you must rely on stock appreciation for any return on your investment.***

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. As a result, you must rely on stock appreciation and a liquid trading market for any return on your investment in our common stock.

### ***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, 79,246 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 our 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.

***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.

***Management will have broad discretion over the use of the net proceeds from the sale of shares by us and may apply the net proceeds in ways that do not improve our operating results or increase the value of your investment.***

Our management will have broad discretion in the application of the net proceeds from the sale of shares by us and could spend the net proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business and cause the price of our common stock to decline.

***You may experience future dilution as a result of future equity offerings.***

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, including investors who purchase shares of common stock in this offering. The price per share at which we sell additional shares of our common stock or securities convertible into common stock in future transactions may be higher or lower than the price per share in this offering.

***Investors who exercise their Series D Warrants into common stock will incur immediate dilution in the net tangible book value per share of the common stock issuable upon conversion.***

Upon exercise of Series D Warrants, you will experience immediate and substantial dilution because the per share exercise price of the Series D Warrants of \$ \_\_\_\_\_ will be higher than the net tangible book value per share of the outstanding common stock immediately after this offering. As of September 30, 2016, our tangible net book value per share was \$(2.57).

***Our Board of Directors' ability to issue "blank check" preferred stock and any anti-takeover provisions we adopt may depress the value of our common stock.***

Our certificate of incorporation authorizes 20,000,000 shares of "blank check" preferred stock, of which 19,920,754 remain available for issuance. Our Board of Directors has the power to issue any or all of the shares of such 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 the approval of our common stockholders, subject to certain limitations on this power under the listing requirements of The NASDAQ Capital Market and the laws of the state of Delaware. The authority of our Board of Directors to issue "blank check" preferred stock, along with any future anti- takeover measures we may adopt, may, in certain circumstances, delay, deter or prevent takeover attempts and other changes in control of us not approved by our Board of Directors. As a result, our stockholders may lose opportunities to dispose of their shares of our common stock at favorable prices generally available in takeover attempts or that may be available under a merger proposal and the market price of our common stock and the voting and other rights of our stockholders may also be affected.

***Holders of our Series D Warrants will have no rights as a common stockholder until such holders exercise their Series D Warrants and acquire our common stock.***

Until holders of our Series D Warrants acquire shares of our common stock upon exercise, such holders will have no rights with respect to shares of our common stock underlying such Series D Warrants. Upon exercise of the Series D Warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the conversion or exercise date.

***There is no public market for the Series D Warrants being offered by us in this offering.***

There is no established public trading market for the Series D Warrants being offered in this offering, and a public market may never develop. In addition, we do not intend to apply to list the Series D Warrants on any national securities exchange or other nationally recognized trading system, including the NASDAQ Capital Market. Without an active market, the liquidity of the Series D Warrants will be limited.

***The Series D Warrants included in this offering may not have any value.***

Each Series D Warrant has an initial exercise price of \$ per share of common stock and will expire five years from the date of issuance. In the event our common stock price does not exceed the exercise price of the Series D Warrant during the period when the Series D Warrant are exercisable, the Series D Warrant will not have any value.

***Significant holders or beneficial holders of our common stock may not be permitted to exercise Series D Warrants that they hold.***

The warrant agreement governing the Series D Warrant being offered hereby will prohibit a holder from exercising its warrants if doing so would result in such holder (together with such holder's affiliates and any other persons acting as a group together with such holder or any of such holder's affiliates) beneficially owning more than 9.99% of our common stock. Furthermore, during any period in which a holder beneficially owns less than 5% of our common stock, the warrant agreement will limit the ability of such holder to exercise its Series D Warrant if doing so would result in such holder (together with such holder's affiliates and any other persons acting as a group together with such holder or any of such holder's affiliates) beneficially owning more than 4.99% of our common stock. As a result, you may not be able to exercise your Series D Warrant for shares of our common stock at a time when it would be financially beneficial for you to do so. In such circumstance you could seek to sell your Series D Warrant to realize value, but you may be unable to do so.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements made in this prospectus are “forward-looking statements” that indicate certain risks and uncertainties related to the Company, many of which are beyond the Company’s control. The Company’s actual results could differ materially and adversely from those anticipated in such forward-looking statements as a result of certain factors, including those set forth below and elsewhere in this report. Important factors that may cause actual results to differ from projections include:

- Inability to raise sufficient additional capital to operate our business;
- Unexpected costs and operating deficits, and lower than expected sales and revenues, if any;
- Adverse economic conditions;
- Adverse results of any legal proceedings;
- The volatility of our operating results and financial condition;
- Inability to attract or retain qualified senior management personnel, including sales and marketing personnel;
- The potential delisting of our common stock from The Nasdaq Capital Market; 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 under the caption “Risk Factors”. 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.

#### USE OF PROCEEDS

Assuming we complete the sale of \_\_\_\_\_ Units offered hereby at a public offering price of \$\_\_\_\_\_ per Unit, we estimate that the net proceeds from this offering will be approximately \$\_\_ million after deducting the underwriting discount and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering for working capital and general corporate purposes.



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing elsewhere in this prospectus. Our discussion includes forward-looking statements based upon current expectations that involve risks and uncertainties, such as our plans, objectives, expectations, and intentions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of a number of factors, including those set forth under the "Special Note Regarding Forward-Looking Statements," "Business," and "Risk Factors" sections in this prospectus.*

### Overview

We were incorporated in Minnesota in April 2002 under the name BioDrain Medical, Inc. Effective August 6, 2013, the Company changed its name to Skyline Medical Inc. Pursuant to an Agreement and Plan of Merger dated effective December 16, 2013, the Company merged with and into a Delaware corporation with the same name that was its wholly-owned subsidiary, with such Delaware corporation as the surviving corporation of the merger. We are a development stage company manufacturing an environmentally conscientious system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. Since our inception in 2002, we have invested significant resources into product development. We believe that our success depends upon converting the traditional process of collecting and disposing of infectious fluids from the operating rooms of medical facilities to our wall-mounted Fluid Management System ("FMS") and use of our proprietary cleaning fluid and filter kit.

We currently have one regional sales manager to sell the STREAMWAY FMS, and have recently hired a new Vice President of Sales to build our sales and marketing infrastructure. 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. In 2016, we signed a contract with a large independent distributor covering Georgia and South Carolina. We also signed a reseller agreement granting Munro Enterprises LLC certain exclusive rights to market and distribute the STREAMWAY FMS to the U.S. federal government including U.S. Department of Veterans Affairs, U.S. Department of Defense and U.S. Health and Human Services facilities, among others. Munro Enterprises LLC is an Economically-Disadvantaged, Woman-Owned Small Business.

Since inception, we have been unprofitable. We incurred net losses of approximately \$1.1 million and \$5.8 million for the three and nine months ended September 30, 2016, and \$1.1 million and \$2.5 million for the three months and nine months ended September 30, 2015, respectively. As of September 30, 2016 and September 30, 2015, we had an accumulated deficit of approximately \$46.3 million and \$38.2 million, respectively. We received approval from the FDA in April 2009 to commence sales and marketing activities of the STREAMWAY FMS 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 sold ninety-six STREAMWAY FMS 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 products (cleaning fluid and filters) 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. 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. In August 2015, we completed a public unit offering for \$13,555,003, after deducting underwriting discounts, commissions and expenses. 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.

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 Three and Nine Month Periods Ended September 30, 2016 with Periods Ended September 30, 2015***

On October 27, 2016, the Company effected a 1-for-25 reverse stock split of its common stock. All share information in the financial statements for fiscal years 2016 and 2015 reflect the impact of the reverse stock split.

*Revenue.* The Company recognized \$135,000 of revenue in the three months ended September 30, 2016 compared to \$86,000 in revenue in the three months ended September 30, 2015. The Company recognized \$317,000 of revenue in the nine months ended September 30, 2016 compared to \$471,000 in revenue in the nine months ended September 30, 2015. There have been two sales of the STREAMWAY unit in 2016, both in the third quarter. Our sales efforts were curtailed in late 2015 and early 2016 due to our concentrated efforts on customer management. We have hired a Vice President of Sales who has implemented a nine point program focusing on gaining market presence and brand awareness. The Vice President of Sales is rebuilding the infrastructure of our sales team and we expect a positive impact on future sales.

*Cost of sales.* Cost of sales was \$26,000 in the three months ended September 30, 2016 and \$20,000 in the three months ended September 30, 2015. Cost of sales was \$149,000 in the nine months ended September 30, 2016 and \$199,000 in the nine months ended September 30, 2015. The gross profit margin was approximately 53% in the nine months ended September 30, 2016 compared to 58% in the nine months ended September 30, 2015. We expect our margins to increase over the next several quarters as our manufacturing production becomes more consistent, and as increased sales allow us to achieve volume purchasing discounts on both equipment components and our cleaning solution. Over the next several quarters, we expect increases in revenues to exceed increases in costs related to increasing manufacturing and sales capabilities.

*General and Administrative expense.* General and administrative expense primarily consists of management salaries, professional fees, consulting fees, travel expense, administrative fees and general office expenses.

General and Administrative (G&A) expenses decreased by \$128,000 from the three months ended September 30, 2016 compared to September 30, 2015. G&A expenses increased by \$3,095,000 from the nine months ended September 30, 2016 compared to September 30, 2015. For the three month period ending September 30, 2016 payroll, bonuses, payroll taxes, benefits, travel and automobile leases decreased by \$133,000 due to the CEO resignation and zero dollar compensation for the current Executive Chairman; license fees and payroll tax penalty and interest were also reduced by \$38,000. Another reduction resulted from zero expenses for convertible notes in 2016 versus \$475,000 in such expenses in 2015. Investor relations, stock based compensation and investor's stock compensation were offsets that increased by \$319,000. A further offset was a \$220,000 increase in legal expenses in 2016 as a result of large credits issued in 2015. The nine month increase was affected by severance pay increasing \$1,018,000 due to the negotiated settlement with the former CEO. Investors stock compensation and investor relations increased by \$1,689,000 due to the new investment banker and the exercise of cashless warrants as a result of the separation of the Units in February 2016. Legal fees increased by \$723,000 in 2016 due to the Unit Exchange Offer, the Exchange Offer, negotiations with our former CEO and as a result of large credits issued in the third quarter of 2015. Recruiting fees increased by \$107,000 due to hiring the new Vice President of Sales. Offsets include: convertible note expense reductions for \$475,000, stock based compensation of \$116,000, tax and penalties of \$143,000 and payroll expenses of \$191,000.

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

Operations expense increased by \$90,000 in the three months ended September 30, 2016 compared to the three months ended September 30, 2015. The three month increase was due to increased salaries of \$24,000 for new engineer and quality control positions; additional consulting expenses of \$52,000 to assist in our STREAMWAY software upgrades; employee stock options to retain employees with a value of \$47,000 to stock based compensation, and by \$21,000 for research and development. Offsets were from decreases to bonuses in 2016 of \$43,000 and to reduced miscellaneous expenses of \$13,000. Operations expense increased by \$553,000 in the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015. The nine month increase was due to \$94,000 in increased salaries, taxes and benefits for the two new positions mentioned above; \$206,000 in bonuses as a result of the 2015 reversal of bonus accruals as waived by officers and the additional bonus in 2016 resulting from options exercised; employee stock options to retain employees with a value of \$47,000 to stock based compensation; \$66,000 in consulting expenses for the STREAMWAY software upgrades and \$123,000 for research and development expenses.

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

Sales and marketing expenses increased by \$71,000 in the three months ended September 30, 2016 compared to the three months ended September 30, 2015. The three month increase was due to \$71,000 in bonuses negated in the 2015 quarter (there were no bonuses in 2016); \$15,000 in value for employee options recorded to stock based compensation; \$23,000 in increased commissions; \$7,000 in increased travel expenses with the addition of the Vice President of Sales to our staff and enhanced sales programs; and \$18,000 for increased advertising and trade show participation. Partially offsetting the increases were reduced salaries of \$64,000 due to the reduction of our sales staff in 2015. Sales expense decreased by \$91,000 in the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015. The nine month decrease was due to \$207,000 reduction in salaries, payroll taxes and benefits; \$9,000 in commissions; and \$20,000 in reduced stock based compensation all due to a reduced sales staff in 2016. These increases were partially offset due to \$68,000 in increased advertising and trade show participation, \$45,000 in increased consulting expenses as we seek to increase our government sales, \$7,000 in increased travel due to the addition of our Vice President of Sales and the enhanced sales programs instituted, and \$15,000 as result of reversed bonuses in 2015.

*Interest expense.* Interest decreased by \$52,000 in the three months ended September 30, 2016 compared to the three months ended September 30, 2015, and by \$395,000 in the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015, as there was no outstanding debt during this period.

#### ***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 Nine Month Periods Ended September 30, 2016 and 2015***

Net cash used in operating activities was \$3,704,000 for the nine months ended September 30, 2016 compared with net cash used of \$4,637,000 for the 2015 period. The \$933,000 decrease in cash used in operating activities was primarily due to the issuance of common stock in cashless warrant exchanges and equity instruments issued for consulting as a result of hiring an investment banking firm and as a result of large payments to accounts payable and accrued expenses in 2015 after the public offering. There was an offset due to the increased net loss of 3,266,000.

Cash flows used in investing activities was \$604,000 for the nine months ended September 30, 2016 and \$23,800 for the nine months ended September 30, 2015. The Company invested in marketable securities. There was a moderate increase to purchases in fixed assets and minimal fees related to patents.

Net cash provided by financing activities was \$86,000 for the nine months ended September 30, 2016 compared to net cash provided of \$12,378,000 for the nine months ended September 30, 2015. The Chief Operating Officer and the Chief Financial Officer exercised options in 2016, and there was a public offering in 2015 that resulted in \$13 million net brought into the Company.

#### ***Cash Flows for the Years Ended December 31, 2015 and 2014***

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.

#### ***Capital Resources***

We had a cash balance of \$634,000 as of September 30, 2016. Since our inception, we have incurred significant losses. As of September 30, 2016, we had an accumulated deficit of approximately \$46,300,000.

From inception to September 30, 2016, our operations have been funded through a bank loan and private convertible debt of approximately \$5,685,000 and equity investments totaling approximately \$22,325,000.

In November 2016, we received \$1.7 million in net proceeds of a registered directed offering of common stock and Series C Warrants.

In the first nine months of 2016, we recognized \$317,000 in revenues. Our product sales since the end of the third quarter have resulted in approximately \$110,000 in revenues.

#### ***Payment Obligations Under Separation Agreement With Former CEO***

Effective May 5, 2016, Joshua Kornberg resigned as the Chief Executive Officer and President and an employee of the Company. In connection with Mr. Kornberg's resignation, the Company and Mr. Kornberg entered into a separation agreement on June 13, 2016 (the "Separation Agreement"). Pursuant to the Separation Agreement, on July 15, 2016, the Company was required to pay Mr. Kornberg: (a) \$15,443.20 less any required tax withholdings in a lump sum on July 15, 2016; and (b) \$75,000 less any required tax withholdings on July 15, 2016. The Company is required to pay Mr. Kornberg an additional \$75,000 less any required tax withholdings payable in 6 monthly installments of \$12,500, due on the first regular payday of each month, starting on August 15, 2016; and (d) an additional \$450,000 less any required tax withholdings payable in 11 monthly installments of \$40,909, due on the first regular payday of each month, starting on February 15, 2017. The Company issued to Mr. Kornberg a restricted stock award (the "Award") under the Company's stock incentive plan consisting of 20,000 shares. The Award vested on July 15, 2016. The value of the Award for purposes of the Separation Agreement (the "Award Value") is \$90,350.61, based on a ten day volume-weighted average closing sale price per share of the Company's common stock. Mr. Kornberg agreed that the withholding taxes in connection with the Award will be offset against cash payments otherwise due to him in four monthly installments. In addition, the Company agreed to, at its option, either (a) pay Mr. Kornberg \$309,649.39 (the "Additional Cash Amount"), equal to the difference between \$400,000 and the Award Value, payable in equal monthly installments of \$40,909, due on the first regular payday of each month, starting on January 15, 2018, less any required tax withholding, or (b) issue to Mr. Kornberg shares of common stock of the Company (the "Additional Shares") on January 15, 2018 with an aggregate fair market equal to the Additional Cash Amount, based on a ten day volume-weighted average closing sale price per share. Under the Separation Agreement, all of Mr. Kornberg's outstanding stock options and outstanding restricted stock prior to the date of the Separation Agreement were canceled, consisting of options to purchase 22,085 shares and 2,667 shares of restricted stock. The Separation Agreement included a waiver and release of claims by Mr. Kornberg. He will also continue to be bound by the terms of any restrictive covenant agreements he had with the Company.

The foregoing summary of the Separation Agreement does not purport to be complete and is qualified in its entirety by reference to the Separation Agreement, a copy of which was filed on June 17, 2016 as an exhibit to our Current Report on Form 8-K.

***Plan of Financing; Going Concern Qualification***

Since our inception, we have incurred significant losses, and our accumulated deficit was approximately \$46.3 million as of September 30, 2016. 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 fiscal 2016.

We had revenues of \$317,000 in 2016, but we had negative operating cash flows of \$3.7 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 first quarter of 2016 and the remainder of 2015, we paid \$10.2 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. Additionally, we have covered our monthly operating expenses, research and development costs and expanded effort in sales and marketing including the successful search for our newly hired Vice President of Sales. Our cash balance was \$0.6 million as of September 30, 2016, and our accounts payable and accrued expenses were an aggregate \$2.0 million. In November 2016, we reviewed \$1.7 million in net proceeds of a registered directed offering of common stock and Series C Warrants. We have reduced our monthly negative cash flow to approximately \$350,000 beginning in June 2016. 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 efforts and maintain adequate inventories.

As of September 30, 2016, 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 our 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 21,350 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.

#### *2015 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 75,800 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 twenty-fifth 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 \$123.75 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.

Holder 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 \$10.75 per share (as adjusted for the 1-for-25 reverse stock split on October 27, 2016 and subject to appropriate adjustment in the event of other 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 \$123.75 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 \$108.115, and the closing bid price of Common Stock as of March 11, 2016, was \$4.50. Therefore, an exercise on that date would have resulted in the issuance of 0.40 shares of Common Stock for each Series A Warrant. Approximately 3,390,935 Series A Warrants had been exercised in cashless exercises as of March 11, 2016, resulting in the issuance of 1,362,146 shares of Common Stock. A significant number of Series A Warrants were exchanged for Series B Warrants in a registered exchange offer in April 2016. See “Exchange Offer For Series A Warrants” below.

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 was terminated in May 2016 in exchange for 135,995 shares of common stock.

*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. 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.

#### *Exchange Offer for Series A Warrants*

On March 25, 2016, the Company commenced a registered exchange offer (the "Exchange Offer") to exchange Series B Warrants (the "Series B Warrants") to purchase shares of our common stock (the "Warrant Shares"), for up to an aggregate of 3,157,186 outstanding Series A Warrants (the "Series A Warrants"). On March 31, 2016, each Series A Warrant could be exercised on a cashless basis for 0.40 shares of common stock.

For each outstanding Series A Warrant tendered by holders, we offered to issue 10.2 Series B Warrants, which are subject to cashless exercise at a fixed rate of one share of common stock per Series B Warrant (subject to further adjustment for stock splits, etc.).

The Exchange Offer expired at midnight, Eastern time, on April 21, 2016. 1,770,556 Series A Warrants were tendered by holders. On April 25, 2016, the Company delivered 18,059,671 Series B Warrants exercisable into an aggregate of 722,387 shares of common stock pursuant to the terms of the Exchange Offer.

#### *Additional Exercise of Warrants; Outstanding Warrants*

Between March 31, 2016 and September 30, 2016, 1,251,510 Series A Warrants were exercised in cashless exercises, resulting in the issuance of 20,121 shares of common stock, and 7,025,718 Series B Warrants were exercised in cashless exercises, resulting in the issuance of 281,029 shares of common stock. As of September 30, 2016, 35,084 Series A Warrants were outstanding, which could be exercised for 1,404 shares of common stock. As of September 30, 2016, 2,317,027 Series B Warrants were outstanding, which could be exercised for 96,282 shares of common stock.

#### **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” included in this prospectus.

**Inflation**

We do not believe that inflation has had a material impact on our business and operating results during the periods presented.

**Off-Balance Sheet Transactions**

We have not engaged in any off-balance sheet activities as defined in Item 303(a)(4) of Regulation S-K.

## 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 aseptic 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 prospectus.

## 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., Dornoch Medical Systems, Inc. (Zimmer), and Stryker Instruments have all developed systems that provide for disposal into the sanitary sewer without pouring the infectious fluids directly through a hopper disposal or using expensive gel powders and most are sold with 510(k) concurrence from the FDA. 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 \$24,900 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 Disposables**

The disposables are an integral, critical component of the FMS and our total value proposition to the customer. They consist of a proprietary, pre-measured amount of cleaning solution in a plastic bottle that attaches to the FMS and 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 disposables 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 providers 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., Dornoch Medical Systems, Inc. (now Zimmer) and Stryker Instruments have all developed systems that provide disposal into the sanitary sewer without pouring the infectious fluids directly through a hopper disposal or using expensive gel powders. All of these newer products are currently sold with 510(k) exempt concurrence from the FDA. Most of these competing products incorporate an internal collection canister with finite capacity, and while not directly eliminating the need to transport a device to and from the surgical room, we believe most have been successful in eliminating the need for expensive gel and its associated handling and disposal costs.

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

We believe that Stryker Instruments has the dominant market share position. 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, and 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 have 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, anesthesiologists, 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 \$24,900 per system (one per operating room – installation extra) and \$24 per unit retail for the proprietary disposables 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 2nd 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 3rd Edition Medical Device Safety Testing was adopted by the International Organization of Standards in 2005 and had a compliance date of June 2012 for OUS and 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 2nd 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 3rd 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 2nd 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 2nd 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 10 employees, eight of whom are full-time, and two who are part-time.

#### **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.

## MARKET PRICE OF AND DIVIDENDS ON THE COMPANY'S COMMON EQUITY AND RELATED STOCKHOLDER MATERIALS

### 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 1:25 reverse stock split of our outstanding shares which became effective for trading at the open of the market on October 28, 2016, as well as rounding.

#### Common Stock

Quarter Ended	High Bid	Low Bid
December 31, 2016 (through December 2, 2016)	\$ 6.05	\$ 1.52
September 30, 2016	\$ 6.75	\$ 2.00
June 30, 2016	\$ 7.25	\$ 2.53
March 31, 2016	\$ 96.50	\$ 4.13
December 31, 2015	\$ 169.00	\$ 57.75
September 30, 2015	\$ 144.50	\$ 68.75
June 30, 2015	\$ 178.75	\$ 50.00
March 31, 2015	\$ 175.00	\$ 50.00
December 31, 2014	\$ 272.00	\$ 81.25
September 30, 2014	\$ 450.00	\$ 131.25
June 30, 2014	\$ 356.25	\$ 198.75
March 31, 2014	\$ 543.75	\$ 328.25

As of December 2, 2016, the closing sale price for shares of our common stock was \$3.11 per share. The Series B Preferred Stock and Series B Warrants are not traded on any security markets.

### Holders

As of December 1, 2016, there were approximately 142 stockholders of record of our Common Stock and 11 holders of record of the Series B Preferred Stock, 1 holders of record of Series A Warrants and 9 holders of record of our Series B 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.

## MANAGEMENT

Our directors and executive officers, their ages, their respective offices and positions, and their respective dates of election or appointment are as follows:

Name	Age	Position	Date of Election or Appointment
Thomas J. McGoldrick	74	Director	2005
Andrew P. Reding	45	Director	2006
Carl Schwartz	75	Chief Executive Officer and Director	December 1, 2016 March 23, 2016 December 1, 2016
Timothy A. Krochuk	47	Director	October 27, 2016
J. Melville Engle	66	Director	October 27, 2016
Richard L. Gabriel	68	Director	December 1, 2016
David O. Johnson	64	Chief Operating Officer	July 1, 2012
Bob Myers	61	Chief Financial Officer	July 1, 2012

### Business Experience Descriptions

Set forth below is a summary of our executive officers' and directors' business experience for the past five years. Other than as described below, the experience and background of each of the directors, as summarized below, were significant factors in their previously being nominated as directors of the Company.

**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.

**Carl Schwartz, Chief Executive Officer and Director.** Mr. Schwartz was the owner manager of dental groups in Burton, Michigan and Grand Blanc, Michigan. Dr. Schwartz previously served on the Board of Delta Dental Corporation of Michigan, was a member of the Michigan Advisory Board for Liberty Mutual Insurance and was a member of the Board of Trustees of the Museum of Contemporary Art in Florida. He became a director on March 23, 2016 and served as Executive Chairman from October 11, 2016 to December 1, 2016. On December 1, 2016 he was appointed Chief Executive Officer.

**J. Melville Engle, Director.** Mr. Engle was appointed to the Board of Directors on October 27, 2016. Mr. Engle has worked in the healthcare industry for the past three decades. Since 2012 he has served as President and Chief Executive Officer of Engle Strategic Solutions, a consulting company focused on CEO development and coaching, senior management consulting, corporate problemsolving and strategic and operational planning. He is Chairman of the Board of Windgap Medical, Inc., a start-up medical device firm focused on unique drug delivery applications, and has held executive positions at prominent companies including Chairman and Chief Executive Officer at ThermoGenesis Corp., Regional Head/Director, North America at Merck Generics, President and Chief Executive Officer of Dey, L.P. and Senior Vice President, U.S. Sales at Allergan. In addition to ThermoGenesis, he has served on the Board of Directors of several public companies, including Oxygen Biotherapeutics and Anika Therapeutics. Mr. Engle holds a BS in Accounting from the University of Colorado Boulder and a MBA in Finance from the University of Southern California. He has served as a Trustee of the Queen of the Valley Medical Center Foundation, and a Board Member of the Napa Valley Community Foundation and the Napa College Foundation all in Napa, Calif., and as Vice Chair of the Thunderbird Global Council at the Thunderbird School of Global Management in Glendale, Ariz.

**Timothy A. Krochuk, Director.** Mr. Krochuk was appointed to the Board of Directors on October 27, 2016 and is a co-founder and Managing Director of GRT Capital Partners, LLC, an investment adviser based in Boston, and is a Portfolio Manager and Managing Partner for the GRT BioEdge Ventures Fund, a fund focused on equity investments in privately held, emerging healthcare and biopharmaceutical companies. Prior to starting GRT Capital Partners in 2001, Mr. Krochuk became the youngest diversified portfolio manager in the history of Fidelity and was responsible for the development, programming and implementation of investment models used by mutual funds with more than \$20 billion in assets under management. He currently serves as Chief Executive Officer of CHP Clean Energy, a full-service provider of biogas powered combined heat and power systems for wastewater treatment facilities with anaerobic digesters, which he founded in 2009. He also serves on the Board of Directors of Windgap Medical and Flatirons Bank. Mr. Krochuk holds an AB in Economics from Harvard College, a Chartered Financial Analyst designation, an Executive Masters Professional Director Certification from the American College of Corporate Directors and is an active member of the Board of the Massachusetts General Hospital President's Council.

**Richard L. Gabriel, Director.** Mr. Gabriel has more than 40 years of relevant healthcare experience, including two decades of executive leadership and as a director and a consultant to development-stage companies. In addition serving as chief operating officer of GLG Pharma since 2009, from 2003 until 2009 Mr. Gabriel was chief executive officer of DNAPrint Genomics and DNAPrint Pharmaceuticals. He is currently a director of Windgap Medical, a Massachusetts-based medical device company that is developing a compact and easy to use epinephrine autoinjector for the treatment of anaphylaxis. Mr. Gabriel holds an MBA from Suffolk University in Boston, and a BS in Chemistry from Ohio Dominican College in Columbus.

**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.



## **Family Relationships**

There are no family relationships among our directors and executive officers.

## **Audit Committee of the Board; Audit Committee Financial Expert**

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. Reding and Mr. Krochuk. Mr. McGoldrick has a strong and vast financial history specializing in the medical device industry. He qualifies as a financial expert and meets independence within the meaning of NASDAQ's listing standards. Each Audit Committee member is a non-employee director of the Board. The Board of Directors reviews the NASDAQ listing standards definition of independence for Audit Committee members on an annual basis and has determined that all current members of our Audit Committee are independent (as independence is currently defined in Rule 5605(a)(2) of the NASDAQ listing standards). The Audit Committee met four times in fiscal 2014 and four times in fiscal 2015.

## **Director Independence**

Under NASDAQ listing standards, a majority of the members of a listed company's Board of Directors must qualify as "independent," as affirmatively determined by the board of directors. The Board of Directors consults with our counsel to ensure that the Board of Directors' determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of the NASDAQ, as in effect from time to time.

Consistent with these considerations, after review of all relevant transactions or relationships between each director, or any of his or her family members, and the Company, its senior management, and its independent registered public accounting firm, the Board of Directors has affirmatively determined that the following directors and nominees are independent directors within the meaning of the NASDAQ listing standards: Messrs. McGoldrick, Reding, Krochuk, Engle and Schwartz. In making this determination, the Board of Directors found that none of these directors and nominees had a material or other disqualifying relationship with the Company.

## **Compensation Committee**

The Compensation Committee of the Board of Directors currently consists of two directors, Mr. McGoldrick, as the chairperson, and Mr. Engle. Both members of the Compensation Committee were appointed by the Board of Directors, and such committee consists 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. Engle. 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 are 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.

### **Structure and Meetings**

The chairperson of the Committee presides at each meeting and, in consultation with the other members of the Committee, sets the frequency and length of each meeting and the agenda of items to be addressed at each meeting. The chairperson of the Committee ensures that the agenda for each meeting is circulated to each Committee member in advance of the meeting. The Committee reports its actions and recommendations to the Board.

### **Goals and Responsibilities**

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, will 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 Certificate 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.

### **Committee Resources**

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.

## EXECUTIVE COMPENSATION

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, former CEO and 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) Effective May 5, 2016, Mr. Kornberg resigned as the Chief Executive Officer and President and an employee of the Company. In connection with Mr. Kornberg’s resignation, the Company and Mr. Kornberg entered into a separation agreement on June 13, 2016 (the “Separation Agreement”). See “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Payment Obligations Under Separation Agreement With Former CEO.” In 2014 Mr. Kornberg also received options to purchase 88 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 8,366 shares of common stock at \$65.75 per share. Mr. Kornberg also received options to purchase 253 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 685 shares of common stock at \$65.75 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 628 shares of common stock at \$65.75 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:

	<b>Grant Date</b>	<b>Number of Securities Underlying Options Exercisable</b>	<b>Number of Securities Underlying Options Unexercisable</b>	<b>Option Exercise Price</b>	<b>Option Expiration Date</b>
Joshua Komberg (1)	8/13/2012	3,200		\$ 150.00	8/13/2022
	3/14/2013	7,680		\$ 140.75	3/14/2023
	9/30/2013	9		\$ 596.25	9/30/2018
	12/31/2013	10		\$ 506.25	12/31/2018
	3/6/2014	1,305		\$ 431.25	3/6/2024
	3/31/2014	15		\$ 347.00	3/31/2024
	6/30/2014	18		\$ 281.25	6/30/2024
	9/30/2014	25		\$ 206.25	9/30/2024
	12/31/2014	31		\$ 162.50	12/31/2024
	3/31/2015	58		\$ 86.25	3/31/2025
	6/30/2015	65		\$ 77.50	6/30/2025
	9/30/2015	63		\$ 80.25	9/30/2025
	10/21/2015	8,366		\$ 65.75	10/21/2025
12/31/2015	69		\$ 73.50	12/31/2025	
David O. Johnson	8/13/2012	534		\$ 150.00	8/13/2022
	3/18/2013	507		\$ 148.25	3/18/2023
	3/6/2014	167		\$ 431.25	3/6/2024
	10/21/2015	685		\$ 65.75	10/21/2025
Bob Myers	8/13/2012	534		\$ 150.00	8/13/2022
	3/18/2013	422		\$ 148.25	3/18/2023
	3/6/2014	140		\$ 431.25	3/6/2024
	10/21/2015	628		\$ 65.75	10/21/2025

(1) Does not reflect an award of 2,667 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 2015

*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 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. See also "Employment Contracts" above.

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. See also "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 (1)	\$ 36,759
Ricardo Koenigsberger	\$ -	\$ -	\$ 7,340 (2)	\$ 7,340
Andrew Reding	\$ -	\$ -	\$ 29,402 (3)	\$ 29,402
Frank Mancuso, Jr.	\$ -	\$ -	\$ 29,402 (4)	\$ 29,402

- (1) Mr. McGoldrick was awarded options to purchase 661 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 123 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 525 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 525 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:

	<b>Number of securities to be issued upon exercise of outstanding restricted stock, warrants and options (a)</b>	<b>Weighted- average exercise price of outstanding options, warrants (b)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (C)</b>
Equity compensation plans approved by security holders (1)	850,385	\$ 133.25	21,372
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.



## CERTAIN RELATIONSHIPS AND 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.

In connection with the sale of the Series A Preferred Shares on February 4, 2014, Joshua Kornberg, our former 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 significant 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 — 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 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.

One of the Company’s directors, Richard L. Gabriel, is the Chief Operating Officer and serves as a director of GL Pharma (“GLG”). Another Company director, Tim Krochuk, is on the supervisory board for GLG. In September 20, 2016, the Company entered into a partnership and exclusive reseller agreement with GLG. Under the terms of the agreement, GLG intends to develop rapid diagnostic tests that utilize fluid and tissue collected by the STREAMWAY System during procedures. The Company will issue an aggregate of 400,000 shares common stock to GLG in four separate tranches of 100,000 shares of common stock in each tranche. The shares reserved in each tranche will be released after the achievement of certain development milestones designated in the agreement. In addition, the Company will pay a royalty to GLG on the sale of individual tests. Also, on November 1, 2016, the Company announced that it agreed to grant GLG exclusive rights to market and distribute the STREAMWAY System in the U.K. On November 2, 2016, the Company announced that it agreed to grant GLG the same rights in Poland and certain other countries in Central Europe.

**SECURITY OWNERSHIP OF  
CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth as of December 1, 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 registration statement 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 4,562,127 shares of the Company’s common stock outstanding on November 30, 2016. 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.

<b>Name of Beneficial Owner</b>	<b>Amount and Nature of Beneficial Ownership(1)</b>	<b>Percent of Class</b>
<b>Officers and Directors</b>		
Carl Schwartz <sup>(2)</sup>	72,148	1.58%
David Johnson <sup>(3)</sup>	5,656	0.12%
Bob Myers <sup>(4)</sup>	5,429	0.12%
Thomas J. McGoldrick <sup>(5)</sup>	4,627	0.10%
Andrew Reding <sup>(6)</sup>	4,443	0.10%
Timothy A. Krochuk	0	0%
J. Melville Engle	0	0%
Richard L. Gabriel <sup>(7)</sup>	400,000	8.77%
Joshua Komberg <sup>(8)</sup>	10,828	0.24%
Kodiak Capital Group, LLC <sup>(9)</sup> 260 Newport Center Drive, Newport Beach, CA 92660	252,333	6.61%
Nations Advisory Partners, Ltd. <sup>(9)</sup> 4900 State Line Rd, Suite 410, Leawood, KS 66206	252,333	6.61%
River North Equity, LLC <sup>(9)</sup> 501 N. Clinton St., Unit 603, Chicago, IL 60654	252,333	6.61%
<b>All directors and executive officers as a group (8 persons)</b>	<b>492,303</b>	<b>10.79%</b>

- (1) Under Rule 13d-3, a beneficial owner of a security includes any person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares: (i) voting power, which includes the power to vote, or to direct the voting of shares; and (ii) investment power, which includes the power to dispose or direct the disposition of shares. Certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire the shares (for example, upon exercise of an option) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares outstanding is deemed to include the amount of shares beneficially owned by such person (and only such person) by reason of these acquisition rights. As a result, the percentage of outstanding shares of any person as shown in this table does not necessarily reflect the person's actual ownership or voting power with respect to the number of shares of common stock actually outstanding.
- (2) Includes (i) 64,728 shares owned directly, (ii) 36,111 shares of Series B Convertible Preferred Stock, (iii) 2,255 shares issuable upon exercise of warrants held by Dr. Schwartz that are exercisable within 60 days of December 2, 2016, and (iv) 3,721 shares issuable upon exercise of options held by Dr. Schwartz that are exercisable within 60 days of December 2, 2016.
- (3) Includes options to purchase 4,780 shares that are exercisable within 60 days of December 2, 2016.
- (4) Includes options to purchase 4,668 shares that are exercisable within 60 days of December 2, 2016.
- (5) Includes options to purchase 4,563 shares that are exercisable within 60 days of December 2, 2016.
- (6) Includes options to purchase 4,390 shares that are exercisable within 60 days of December 2, 2016.
- (7) Includes 400,000 shares which may be released to GLG Pharma, LLC ("GLG") pending satisfaction of certain performance criteria. Richard L. Gabriel is an executive officer of GLG and has shared voting control over the shares. GLG has agreed to vote its shares in accordance with recommendations of the Company's board of directors.
- (8) Mr. Kornberg is a former executive officer and director of the Company. The beneficial ownership indicated includes the shares beneficially owned by Mr. Kornberg to the best knowledge of the Company. Includes (i) 10,535 shares owned directly, (ii) 41 shares issuable upon exercise of warrants held by Mr. Kornberg that are exercisable within 60 days of December 2, 2016 and (iii) 252 shares issuable upon exercise of warrants held by SOK Partners, of which Mr. Kornberg is believed to be a managing partner, and are exercisable within 60 days of December 2, 2016.
- (9) Based upon a Schedule 13G filed by the Reporting Person on December 7, 2016.

## DESCRIPTION OF SECURITIES

*The following information describes our capital stock and provisions of our certificate of incorporation and our bylaws. This description is only a summary. You should also refer to our certificate of incorporation and bylaws, each as amended, that have been incorporated by reference or filed with the SEC as exhibits to the registration statement on Form S-1 of which this prospectus forms a part.*

### General

We are authorized to issue 8,000,000 shares of common stock, par value \$0.01 per share, and 20,000,000 shares of preferred stock.

In this offering, we are offering up to 1,925,000 shares of common stock and an aggregate of 385,000 Series D Warrants to purchase an aggregate of 385,000 shares of common stock. The common stock and Series D Warrants to purchase 0.2 shares of common stock will be sold as Units.

### Units

We are offering Units, each Unit consisting of one share of common stock and 0.2 of a Series D Warrant. Each whole Series D Warrant is exercisable for one share of common stock at an initial cash exercise price of \$ \_\_\_ per whole share. The Series D Warrants will expire on the fifth anniversary of the date of issuance.

Units will not be issued or certificated. The shares of common stock and Series D Warrants are immediately separable and will be issued separately.

### Common Stock Included in the Units Offered Hereby

As of December 1, 2016, we had 4,562,127 shares of common stock issued and outstanding and held by approximately 142 stockholders of record.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders, provided that no proxy shall be voted if executed more than three years prior to the date of the stockholders' meeting except if such proxy provides for a longer period. Holders of our common stock do not have cumulative voting rights.

The holders of common stock are entitled to receive ratably any dividends that may be declared from time to time by our board of directors out of funds legally available for that purpose. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities. The common stock has no preemptive or conversion rights or other subscription rights and there are no redemption provisions applicable to our common stock. All outstanding shares of common stock are fully paid and non-assessable, and the shares of common stock offered in this Exchange Offer will be fully paid and not liable for further call or assessment.

Except for directors, who are elected by receiving the highest number of affirmative votes of the shares entitled to be voted for them, or as otherwise required by Delaware law, and subject to the rights of the holders of preferred stock then outstanding (if any), all stockholder action is taken by the vote of a majority of the issued and outstanding shares of common stock present at a meeting of stockholders at which a quorum consisting of a majority of the issued and outstanding shares of common stock is present in person or proxy. In the absence of a quorum for the transaction of business, any meeting may be adjourned from time to time. The stockholders present at a duly called or held meeting may continue to do business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum. Our Chairman of the Board or, in his absence, any other director designated from time to time by the board of directors, shall preside at all meetings of stockholders.

### *Series D Warrants Included in the Units Offered Hereby*

In connection with this offering, we will issue as part of the Units 385,000 Series D Warrants to purchase an aggregate of 385,000 shares of our common stock. The Series D Warrants will separate from the shares of common stock included within the Unit immediately and be exercisable at any time on or after the date of issuance. The Series D Warrants will terminate on the fifth anniversary of the date of issuance and have an initial cash exercise price of \$ \_\_\_ per whole 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 our common stock and the exercise price.

The shares of common stock issuable on exercise of the Series D Warrants are duly authorized and will be, when issued, delivered and paid for in accordance with the Series D Warrants, validly issued and fully paid and non-assessable. We will authorize and reserve at least that number of shares of common stock equal to the number of shares of common stock issuable upon exercise of all outstanding Series D Warrants.

The Series D 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 outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share.

If, at any time a Series D Warrant is outstanding, we consummate any fundamental transaction, as described in the Series D 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 our common stock is converted into or exchanged for other securities or other consideration, the holder of any Series D Warrants will have the right to receive, for each share of common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, at the option of the holder, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock for which the Series D Warrant is exercisable immediately prior to such fundamental transaction.

The Series D Warrants will be issued in physical form under a warrant agreement between each investor and us.

### **THE HOLDER OF A SERIES D WARRANT WILL NOT POSSESS ANY RIGHTS AS A STOCKHOLDER UNDER THAT SERIES D WARRANT UNTIL THE HOLDER EXERCISES THE SERIES D WARRANT.**

You should review a copy of the form of warrant, which is included as an exhibit to the registration statement of which this prospectus forms a part.

There is no established public trading market for our Series D Warrants, and we do not expect a market to develop. We do not intend to apply to list Series D Warrants on any securities exchange. Without an active market, the liquidity of the Series D Warrants will be limited.

### **Anti-Takeover Provisions**

#### **Delaware Law**

We are subject to Section 203 of the Delaware General Corporation Law. This provision generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date the stockholder became an interested stockholder, unless:

- prior to such date, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual meeting or special meeting of stockholders and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an “interested stockholder” as any entity or person beneficially owning 15% or more of the outstanding voting stock of a corporation, or an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of a corporation at any time within three years prior to the time of determination of interested stockholder status; and any entity or person affiliated with or controlling or controlled by such entity or person.

These statutory provisions could delay or frustrate the removal of incumbent directors or a change in control of our company. They could also discourage, impede, or prevent a merger, tender offer, or proxy contest, even if such event would be favorable to the interests of stockholders. In addition, note that while Delaware law permits companies to opt out of its business combination statute, our Certificate of Incorporation does not include this opt-out provision.

#### ***Certificate of Incorporation and Bylaws***

Our current Certificate of Incorporation authorizes the issuance of “blank check” preferred stock that could be issued by our Board of Directors to defend against a takeover attempt. See “Preferred Stock” above.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Corporate Stock Transfer, Inc.

#### **Listing**

The shares of our common stock are listed on The NASDAQ Capital Market under the symbol “SKLN.” On December 2, 2016, the last reported sale price per share for our common stock as reported by The NASDAQ Capital Market was \$3.11.

## UNDERWRITING

We have entered into an underwriting agreement with Dawson James Securities, Inc. with respect to the Units being offered. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriter, and the underwriter has agreed to purchase from us on a firm commitment basis, the number of Units set forth opposite its name in the table below.

Underwriter	Number of Units
Dawson James Securities, Inc.	
Total	

The underwriting agreement provides that the obligations of the underwriter are subject to certain conditions precedent and that the underwriter has agreed to purchase all of the Units sold under the underwriting agreement if any of the Units are purchased.

The underwriter proposes to offer to the public the Units purchased pursuant to the underwriting agreement at the public offering price per Unit on the cover page of this prospectus supplement. The underwriter may offer some of the Units to other securities dealers at such price less a concession of \$ per Unit. The underwriter may also allow, and such dealers may reallocate, a concession not in excess of \$ per Unit to other dealers. After the Units are released for sale to the public, the underwriter may change the offering price and other selling terms at various times.

The factors considered in determining the public offering price included the recent market price of our common stock, the general condition of the securities market at the time of this offering, the history of, and the prospects for, the industry in which we compete, our past and present operations and our prospects for future revenues.

Dawson James Securities, Inc., its officers and its registered representatives may participate in this offering on the same terms and conditions as the investors participating in this offering.

### Discounts, Commissions and Expenses

The following table shows the per share and warrant and total underwriting discounts and commissions we will pay in connection with the sale of the common stock and warrants.

	Per Unit	Total
Public offering price (1)	\$	\$
Underwriting discounts and commissions paid by us	\$	\$

(1) The public offering price and underwriting discount correspond to an assumed public offering price per share of common stock of \$ \_\_\_\_ and an assumed public offering price per warrant of \$0.01.

We have also agreed to reimburse the underwriter for its expenses in connection with this offering, up to \$50,000, and have agreed to reimburse the underwriter for its reasonable "blue sky" fees and expenses, up to \$25,000. We estimate the total expenses of this offering which will be payable by us, excluding the underwriting discount, will be approximately \$[ ]. After deducting the underwriting discount and our estimated offering expenses, we expect the net proceeds from this offering to be approximately \$[ ].

We have agreed to issue to the underwriter or its designees a unit purchase option to purchase up to 5% of the Units sold in this offering. The underwriter's unit purchase option will be exercisable at any time and from time to time, in whole or in part, during the period commencing six months following the consummation of this offering, and ending five years from the date of this prospectus, at a price per share equal to 125% of the public offering price per Unit in this offering. The underwriter's unit purchase option provide for a cashless exercise provision, piggyback registration rights and customary anti-dilution provisions (for stock dividends and splits and recapitalizations) consistent with FINRA Rule 5110. The underwriter's unit purchase option and the underlying securities are deemed compensation by FINRA, and are therefore subject to FINRA Rule 5110(g)(1). In accordance with FINRA Rule 5110(g)(1), neither the underwriter's unit purchase option nor any securities issued upon exercise of the underwriter's unit purchase option may be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of the offering pursuant to which the underwriter's unit purchase option are being issued, except the transfer of any security: (i) by operation of law or by reason of reorganization of our company; (ii) to any FINRA member firm participating in this offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction described above for the remainder of the time period; (iii) if the aggregate amount of our securities held by either an underwriter or a related person do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period. The underwriter's unit purchase option and the securities underlying the underwriter's unit purchase option are being registered pursuant to this prospectus supplement.

## **Indemnification**

We have agreed to indemnify the underwriter and certain other persons against certain liabilities relating to or arising out of the underwriter's activities under the underwriting agreement. We have also agreed to contribute to payments that the underwriter may be required to make in respect of such liabilities.

## **Price Stabilization, Short Positions and Penalty Bids**

*Stabilization.* In connection with this offering, the underwriters may engage in stabilizing transactions, syndicate covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase common stock so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.
- Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. If the underwriters sell more shares than set forth herein and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.
- Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the common stock originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

## **Electronic Distribution**

This prospectus may be made available in electronic format on Internet sites or through other online services maintained by the underwriter or its affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. Other than this prospectus in electronic format, any information on the underwriter's or its affiliates' websites and any information contained in any other website maintained by the underwriter or any affiliate of the underwriter is not part of this prospectus or the registration statement of which this prospectus form a part, has not been approved and/or endorsed by us or the underwriter and should not be relied upon by investors.



## Other

The underwriter or its affiliates may engage in transactions with, and may perform, from time to time, investment banking and advisory services for us in the ordinary course of their business and for which they would receive customary fees and expenses. In addition, in the ordinary course of their business activities, the underwriter and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for its own account and for the accounts of its customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriter and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

On November 25, 2016, we entered into purchase agreements with three institutional investors pursuant to which we sold an aggregate of 756,999 shares of common stock and warrants to purchase up to an aggregate of 756,999 shares of our common stock. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase one share of our common stock at an exercise price of \$4.46 per share. Each unit was sold at a purchase price of \$2.62. Dawson James Securities, Inc. served as placement agent for such offering. In connection with the foregoing offering, we issued to the placement agent a unit purchase option to purchase from us up to 37,850 units at an exercise price equal to 125% of the public offering price of the units in the offering, or \$3.275 per unit, and we paid the placement agent a cash fee equal to 8% of the aggregate purchase price of the securities sold. In addition, we agreed to reimburse the placement agent for its expenses in connection with the offering, up to \$60,000, and agreed to reimburse the placement agent for its reasonable “blue sky” fees and expenses, of \$15,000.

## LEGAL MATTERS

Maslon LLP, Minneapolis, Minnesota is representing us in connection with this offering. Certain legal matters in connection with this offering will be passed upon for the underwriters by Schiff Hardin LLP, Washington, DC.

## EXPERTS

Our financial statements for the fiscal years ended December 31, 2015 and December 31, 2014 were audited by our independent auditors, Olsen Thielen & Co., Ltd., certified public accountants registered with the Public Company Accounting Oversight Board.

We have included our financial statements in this prospectus in reliance on the reports of the above-named independent auditors, given upon their authority as experts in accounting and auditing.

#### **WHERE YOU CAN FIND MORE INFORMATION**

We are subject to the reporting requirements of the Exchange Act. Reports filed with the SEC pursuant to the Exchange Act, including proxy statements, annual and quarterly reports, and other reports filed by the Company can be inspected and copied at the public reference facilities maintained by the SEC at the Headquarters Office, 100 F. Street N.E., Room 1580, Washington, D.C. 20549. The reader may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The reader can request copies of these documents upon payment of a duplicating fee by writing to the SEC. Our filings are also available on the SEC's internet site at <http://www.sec.gov>. and the Company's website at [www.skylinemedical.com](http://www.skylinemedical.com).

SKYLINE MEDICAL INC.

The audited financial statements for the periods ended December 31, 2015 and December 31, 2014 and the unaudited financial statements for the three and nine month periods ended September 30, 2016 and September 30, 2015 are included on the following pages:

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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, 4,000,000 authorized, 208,259 and 123,711 outstanding	2,080	1,237
Additional paid-in capital	44,584,118	30,123,435
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	\$ (4,790,530)	\$ (6,833,568)
Loss per common share - basic and diluted	\$ (30.86)	\$ (57.13)
Weighted average shares used in computation - basic and diluted	155,233	119,619

See Notes to Financial Statements



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

	Common Stock		Paid- in Capital	Deficit	Total	
	Preferred Stock	Shares				Amount
Balance at 12/31/13	\$ -	117,300	\$ 1,173	\$ 25,477,788	\$ (28,697,415)	\$ (3,218,454)
Shares issued for cashless warrant exercise at \$375.00 per share		69	1	1,295		1,296
Shares issued for option exercise at \$31.25 per share		173	2	5,428		5,430
Shares issued at \$515.75 per share as Investor Relations compensation		80	1	41,249		41,250
Shares issued for cashless warrant exercise at \$318.75 per share		133	1	2,492		2,493
Shares issued for an option exercise at \$131.25 per share		11	0	1,400		1,400
Shares issued for cashless warrant exercise at \$18.75 per share		87	1	1,629		1,630
Shares issued for warrant exercise at \$337.50 per share		107	1	35,999		36,000
Shares issued at \$468.75 per share as Investor Relations compensation		53	1	24,999		25,000
Reduction in escrow account per settlement agreement		(178)	(2)	(3,331)		(3,333)
Shares issued for cashless warrant exercise at \$187.50 per share		192	2	3,603		3,605
Shares issued for cashless warrant exercise at \$140.75 per share		124	1	2,332		2,333
Shares issued for cashless warrant exercise at \$318.75 per share		12	0	224		224
Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$487.50 per share		39	0	18,919	(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 @ \$281.25 per share.		311	3	52,497		52,500
Issuance of Preferred stock	206		-	2,054,795		2,055,001
Shares issued to Investor Relations consultant exercisable at \$281.25 per share		85	1	23,999		24,000
Shares issued to Investor Relations consultant exercisable at \$468.75 per share		53	1	24,999		25,000
Shares issued for cashless warrant exercise at \$337.50 per share		149	1	2,793		2,794
Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$487.50 per share		62	1	30,399	(30,400)	-
Value of equity instruments issued with debt			-	313,175		313,175
Shares issued for cashless warrant exercise at \$243.75 per share		56	1	1,057		1,058
Shares issued for a cash warrant exercise at \$140.75 per share		444	4	62,496		62,500
Shares issued for an option exercise at \$131.25 per share		13	0	1,750		1,750
Shares issued for a note conversion at \$167.00 per share		121	1	19,999		20,000
Shares issued for a note conversion at \$167.00 per share		121	1	19,999		20,000
Shares issued for a note conversion at \$146.25 per share		137	1	19,999		20,000
Shares issued for a note conversion at \$125.75 per share		156	2	19,998		20,000
Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$487.50 per share		62	1	30,400	(30,401)	-
Shares issued for a note conversion at \$128.50 per share		156	2	19,998		20,000
Shares issued for a note conversion at \$125.00 per share		160	2	19,998		20,000
Shares issued for a note conversion at \$131.50 per share		152	2	19,998		20,000
Shares issued for a note conversion at \$131.50 per share		228	2	29,998		30,000
Shares issued for a note conversion at \$148.75 per share		202	2	29,998		30,000
Shares issued into an escrow account per settlement agreement		548	5	132		137
Shares issued for a note conversion at \$126.25 per share		2,223	22	280,594		280,616
Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$487.50 per share		62	1	30,400	(30,402)	(1)
Shares adjusted for rounding per reverse stock split		8	0	3		3
Net loss			-	-	(6,833,568)	(6,833,568)
Balance at 12/31/2014	\$ 206	123,711	\$ 1,237	\$ 30,123,435	\$ (35,641,105)	\$ (5,516,227)
Shares issued to 16 shareholders of Series A Convertible Preferred Stock Adjustment as converted to common shares at \$243.75 per share		125	1	(1)		-
Reduction in escrow account per settlement agreement		(356)	(4)	(6,663)		(6,667)
Shares issued for a note conversion at \$72.50 per share		138	1	9,999		10,000
Shares issued for a note conversion at \$74.00 per share		270	3	19,997		20,000
Shares issued for a note conversion at \$72.75 per share		413	4	29,996		30,000
Shares issued for a note conversion at \$69.25 per share		484	5	33,473		33,478
Shares issued for a note conversion at \$56.25 per share		622	6	34,994		35,000
Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$243.75 per share		125	1	30,399	(30,401)	(1)
Shares issued for a note conversion at \$50.00 per share		1,400	14	69,986		70,000
Shares issued for a note conversion at \$56.82 per share		3,520	35	199,965		200,000
Shares issued for a note conversion at \$50.45 per share		595	6	29,994		30,000
Shares issued for a note conversion at \$48.10 per share		520	5	24,995		25,000
Shares issued for a note conversion at \$46.45 per share		646	6	29,994		30,000
Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$243.75 per share		125	1	30,401	(30,401)	1
Vesting Expense			-	871,877		871,877
Shares issued in public offering; net	16,667	66,667	667	13,043,546		13,060,880
Preferred stock conversion	2,077	9,134	91	(2,168)		(0)
Series A warrant exercise		120	1	9,899		9,900
Net loss			-	-	(4,790,530)	(4,790,530)
Balance @ 12/31/2015	\$ 18,950	208,259	\$ 2,080	\$ 44,584,118	\$ (40,492,437)	\$ 4,112,711

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 208,259 shares of common stock, par value \$.01 per share, outstanding, adjusted for a 1-for-75 reverse stock split effective October 24, 2014, and then a 1-for-25 reverse stock split effective October 27, 2016. In this Report, all numbers of shares and per share amounts, as appropriate, have been stated to reflect the both reverse stock splits. 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	283,677	275,446
Less: Accumulated Depreciation	144,079	78,967
Total Fixed Assets, Net	\$ 139,598	\$ 196,479

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, 208,259 shares of common stock have been issued between par value and \$3,131.25. 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 75,800 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.”

Total Shares = (A x 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 \$10.75 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 \$108.115, and the closing bid price of Common Stock as of March 11, 2016, was \$4.50. Therefore, an exercise on that date would have resulted in the issuance of 0.40 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 1,362,147 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 \$10.75 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 1,685,229 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 3,391 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 174 shares of common stock to the former CEO at \$31.25 per share upon his exercising options.

In January through March 2014, 9 warrant holders exercised warrants through a cashless exercise for a total of 618 shares of common stock.

In January and February 2014 the Company issued warrants to purchase 862 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 \$609.50.

In February 2014 the Company issued a warrant to purchase 60 shares of common stock at an exercise price of \$506.25 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 \$487.50 per share. As a result 39 shares of common stock were issued to 16 holders of Preferred Shares.

In March 2014, the Company issued 178 shares of common stock to a warrant holder for a partial cash exercise at \$281.25 per share; issued 134 shares to the holder via the cashless exercise of the remainder of the warrant.

In June 2014, the Company issued 149 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 \$487.50 per share. As a result 63 shares of common stock were issued to 16 holders of Preferred Shares.

On June 30, 2014, the Company issued a warrant to purchase 218 shares of common stock at an exercise price of \$309.50 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 194 shares of common stock at an exercise price of \$309.50 to SOK Partners, LLC in consideration for a bridge loan.

In July 2014, the Company issued warrants to purchase 1,160 shares of common stock at an exercise price of \$309.50 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 2,462 of common stock at an exercise price of \$609.50 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 1,498 shares of common stock at an exercise price of \$309.50 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 \$487.50 per share. As a result 63 shares of common stock were issued to 16 holders of Preferred Shares.

In November 2014, the Company issued 548 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 \$487.50 per share. As a result 63 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 \$80.02 to \$347.99 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 \$487.50 per share, but should have been calculated at \$243.75 per share. As a result 125 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 \$243.75 per share. As a result 125 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 \$243.75 per share. As a result 125 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 \$6.88 to \$139.24 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	15,430	\$ 168.75	18,477	\$ 262.50
Issued	3,028	203.00	6,455	95.25
Expired	(316)	589.50	(3,275)	338.50
Exercised	(198)	44.00	(1,629)	209.50
Outstanding at December 31, 2014	17,944	\$ 187.75	20,028	\$ 198.75
Issued	14,171	69.00	303,269	123.75
Cancelled	(766)	293.25	(79)	283.50
Exercised	-	-	(120)	123.75
Outstanding at December 31, 2015	31,349	\$ 133.25	323,098	\$ 128.50

At December 31, 2015, 31,229 stock options are fully vested and currently exercisable with a weighted average exercise price of \$132.25 and a weighted average remaining term of 8.17 years. There are 323,098 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>		
\$18.75	293	5.52
\$65.75	10,019	9.81
\$73.50	1,225	10.01
\$77.50	2,387	9.50
\$80.25	250	9.76
\$86.25	289	9.25
\$121.88	6	7.20
\$131.25	82	6.69
\$140.63	7,679	7.21
\$148.13	929	7.22
\$150.00	4,959	6.63
\$162.50	153	9.01
\$206.25	145	8.76
\$248.44	120	7.54
\$262.50	130	7.54
\$281.25	546	7.09
\$318.75	3	7.36
\$346.88	87	8.25
\$431.25	1,610	8.19
\$468.75	134	8.15
\$506.25	198	8.01
\$543.75	54	7.77
\$596.25	51	7.75
<b>Total</b>	<b>31,349</b>	
<b>Warrants:</b>		
\$123.75	303,081	4.67
\$150.00	4,114	2.20
\$225.00	107	2.07
\$243.75	2,529	3.59
\$281.25	8,152	2.02
\$309.38	2,850	3.61
\$309.50	222	3.85
\$337.50	178	2.47
\$371.25	944	2.41
\$506.25	59	3.13
\$609.38	861	3.10
<b>Total</b>	<b>323,098</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 4,000,000 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	467	18.75
2012	5,041	131.25 – 150.00
2013	9,310	121.88 – 596.25
2014	2,361	162.50 – 468.75
2015	14,170	65.75 – 86.25
Total	31,349	\$ 18.75 – 596.25

##### Warrants:

Year	Shares	Price
2012	2,792	281.25 – 375.00
2013	10,703	150.00 – 371.25
2014	6,455	309.38 – 609.38
2015	303,148	123.75
Total	323,098	\$123.75 – 609.38

#### 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 218 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 2,851 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:

	<b>Year Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Numerator:</b>		
Net loss available in basic and diluted calculation	\$ (4,790,530)	\$ (6,833,568)
<b>Denominator:</b>		
Weighted average common shares outstanding-basic	155,234	119,619
Effect of dilutive stock options, warrants and preferred stock (1)	-	-
Weighted average common shares outstanding-diluted	<u>155,234</u>	<u>119,619</u>
Loss per common share-basic and diluted	<u>\$ (30.86)</u>	<u>\$ (57.13)</u>

(1) The number of shares underlying options and warrants outstanding as of December 31, 2015 and December 31, 2014 are 354,447 and 37,972, respectively. The number of shares underlying the preferred stock as of December 31, 2015 is 75,921. 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	\$ —	\$ —

#### 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 \$862.50 per share, a stock price of \$656.25, 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 \$937.50 to \$412.50 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	\$93.75 to \$937.50
Exercise price	\$18.75 to \$609.50
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 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 3 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 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. Komberg 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)

**SKYLINE MEDICAL INC.**  
**CONDENSED BALANCE SHEETS**  
(Unaudited)

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
<b>Current Assets:</b>		
Cash and Cash Equivalents	\$ 634,478	\$ 4,856,232
Marketable Securities (Note 11)	576,888	-
Accounts Receivable	45,017	38,283
Inventories	289,249	231,740
Prepaid Expense and other assets	163,188	271,579
<b>Total Current Assets</b>	<b>1,708,820</b>	<b>5,397,834</b>
<b>Fixed Assets, net</b>		
Fixed Assets, net	110,910	139,598
Intangibles, net	97,335	94,987
<b>Total Assets</b>	<b>\$ 1,917,065</b>	<b>\$ 5,632,419</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities:</b>		
Accounts Payable	\$ 648,061	\$ 650,413
Accrued Expenses	820,114	864,295
Deferred Revenue	5,000	5,000
<b>Total Current Liabilities</b>	<b>1,473,175</b>	<b>1,519,708</b>
Accrued Expenses	432,376	-
<b>Total Liabilities</b>	<b>1,905,551</b>	<b>1,519,708</b>
<b>Commitments and Contingencies</b>		
	-	-
<b>Stockholders' Equity:</b>		
Series B Convertible Preferred Stock, \$.01 par value, 20,000,000 authorized, 79,246 and 1,895,010 outstanding	792	18,950
Common Stock, \$.01 par value, 8,000,000 authorized, 3,404,860 and 208,259 outstanding	34,048	2,080
Additional paid-in capital	46,257,774	44,584,118
Accumulated Deficit	(46,285,679)	(40,492,437)
Accumulated Other Comprehensive Income	4,579	-
<b>Total Stockholders' Equity</b>	<b>11,514</b>	<b>4,112,711</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 1,917,065</b>	<b>\$ 5,632,419</b>

See Notes to Condensed Financial Statements

**SKYLINE MEDICAL INC.**  
**CONDENSED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE INCOME**  
(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Revenue	\$ 134,605	\$ 85,792	\$ 316,931	\$ 471,078
Cost of goods sold	26,481	19,773	149,130	199,307
Gross Margin	108,124	66,019	167,801	271,771
General and administrative expense	733,074	861,098	4,684,130	1,589,522
Operations expense	292,856	202,799	928,062	375,429
Sales and marketing expense	137,784	66,720	348,848	439,703
Interest expense	3	51,804	3	394,641
Total expense	<u>1,163,717</u>	<u>1,182,421</u>	<u>5,961,043</u>	<u>2,799,295</u>
Net loss available to common shareholders	(1,055,593)	(1,116,402)	(5,793,242)	(2,527,524)
<b>Other comprehensive income</b>				
Unrealized gain (loss) from marketable securities	<u>(1,299)</u>	<u>-</u>	<u>4,579</u>	<u>-</u>
Comprehensive loss	<u>\$ (1,056,892)</u>	<u>\$ (1,116,402)</u>	<u>\$ (5,788,663)</u>	<u>\$ (2,527,524)</u>
Loss per common share - basic and diluted	\$ (0.32)	\$ (7.09)	\$ (2.57)	\$ (18.39)
Weighted average shares used in computation - basic and diluted	3,320,139	157,445	2,250,315	137,428

See Notes to Condensed Financial Statements

**SKYLINE MEDICAL INC.**  
**STATEMENT OF STOCKHOLDERS' EQUITY**  
**(UNAUDITED)**

	Preferred Stock	Shares	Amount	Paid-in Capital	Deficit	Other Comprehensive Income	Total
Balance at 12/31/2014	\$ 206	123,711	\$ 1,237	\$ 30,123,435	\$ (35,641,105)		\$ (5,516,227)
Shares issued to 16 shareholders of Series A Convertible Preferred Stock Adjustment as converted to common shares at \$243.75 per share		125	1	(1)			-
Reduction in escrow account per settlement agreement		(356)	(4)	(6,663)			(6,667)
Shares issued for a note conversion at \$72.50 per share		138	1	9,999			10,000
Shares issued for a note conversion at \$74.00 per share		270	3	19,997			20,000
Shares issued for a note conversion at \$72.75 per share		413	4	29,996			30,000
Shares issued for a note conversion at \$69.25 per share		484	5	33,473			33,478
Shares issued for a note conversion at \$56.25 per share		622	6	34,994			35,000
Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$243.75 per share		125	1	30,399	(30,401)		(1)
Shares issued for a note conversion at \$50.00 per share		1,400	14	69,986			70,000
Shares issued for a note conversion at \$56.82 per share		3,520	35	199,965			200,000
Shares issued for a note conversion at \$50.45 per share		595	6	29,994			30,000
Shares issued for a note conversion at \$48.10 per share		520	5	24,995			25,000
Shares issued for a note conversion at \$46.45 per share		646	6	29,994			30,000
Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$243.75 per share		125	1	30,401	(30,401)		1
Vesting Expense			-	871,877			871,877
Shares issued in public offering; net	16,667	66,667	667	13,043,546			13,060,880
Preferred stock conversion	2,077	9,134	91	(2,168)			(0)
Series A warrant exercise		120	1	9,899			9,900
Net loss			-	-	(4,790,530)		(4,790,530)
Balance @ 12/31/2015	<u>\$ 18,950</u>	<u>208,259</u>	<u>\$ 2,080</u>	<u>\$ 44,584,118</u>	<u>\$ (40,492,437)</u>		<u>\$ 4,112,711</u>
Shares issued for two options exercised at \$65.75 per share		1,312	13	86,240			86,253
Shares issued for preferred stock conversion into common stock per the break-up of the Unit from the 2015 public offering	(18,158)	66,396	664	17,494			(0)
Shares issued for cashless Series A warrant exercises per the break-up of the Unit from the 2015 public offering		2,318,663	23,187	556,479			579,666
Shares issued for cashless Series B warrant exercises per the tender offer exchange		628,237	6,282	150,777			157,059
Shares issued at \$3.75 per share, to an investment banker per contractual agreement		135,995	1,360	508,620			509,980
Shares issued at \$4.50 per share to former CEO per severance agreement		20,000	200	90,151			90,351
Vesting Expense			-	147,158			147,158
Unrealized gain from marketable securities						4,579	4,579
Shares issued at \$4.50 per share to investor relations consultant		26,000	260	116,740			117,000
Corrections due to rounding for reverse split		(2)	2	(3)			(1)
Net loss					(5,793,242)		(5,793,242)
Balance @ 9/30/2016	<u>\$ 792</u>	<u>3,404,860</u>	<u>\$ 34,048</u>	<u>\$ 46,257,774</u>	<u>\$ (46,285,679)</u>	<u>\$ 4,579</u>	<u>\$ 11,514</u>

See Notes to Condensed Financial Statements

**SKYLINE MEDICAL INC.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
(Unaudited)

	Nine Months Ended September 30,	
	2016	2015
Cash flow from operating activities:		
Net loss	\$ (5,793,242)	\$ (2,527,524)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	62,427	57,512
Vested stock options and warrants	147,158	320,334
Equity instruments issued for management and consulting	717,331	(6,667)
Issuance of common stock in cashless warrant exchange	736,724	-
Amortization of debt discount	-	219,097
Penalty on debt provision	-	10,031
Loss on Sales of Equipment	(2,387)	16,917
Gain from sale of marketable securities	(2,309)	-
Changes in assets and liabilities:		
Accounts receivable	(6,734)	43,353
Inventories	(57,509)	130,477
Prepaid expense and other assets	108,391	(23,208)
Accounts payable	(2,352)	(1,056,006)
Accrued expenses	388,195	(1,845,850)
Deferred Revenue	-	24,180
Net cash used in operating activities:	\$ (3,704,307)	\$ (4,637,354)
Cash flow from investing activities:		
Purchase of marketable securities	(850,000)	-
Proceeds from sale of marketable securities	280,000	-
Purchase of certificates of deposit	(1,000,000)	-
Redemption of certificates of deposit	1,000,000	-
Purchase of fixed assets	(25,127)	-
Purchase of intangibles	(8,573)	(23,739)
Net cash used in investing activities:	\$ (603,700)	\$ (23,739)
Cash flow from financing activities:		
Proceeds from long-term and convertible debt	-	250,000
Principal payments on debt	-	(933,074)
Issuance of preferred stock	-	18,950
Issuance of common stock	86,253	13,041,930
Net cash provided by financing activities:	\$ 86,253	\$ 12,377,806
Net increase in cash and cash equivalents	(4,221,754)	7,716,713
Cash and cash equivalents at beginning of period	4,856,232	16,384
Cash and cash equivalents at end of period	\$ 634,478	\$ 7,733,097
Non cash transactions:		
Common stock issued for accrued interest/bonus	-	-
Common stock issued to satisfy debt	-	483,478

See Notes to Condensed Financial Statements

**SKYLINE MEDICAL INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**(Amounts presented at and for the three and nine months ended September, 2016 and September, 2015 are unaudited)**

**NOTE 1 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Nature of Operations and Continuance of Operations**

On October 27, 2016, the Company effected a 1-for-25 reverse stock split of its common stock. All share information in the financial statements for fiscal years 2016 and 2015 reflect the impact of the reverse stock split.

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 September 30, 2016, the registrant had 3,404,860 shares of common stock, par value \$.01 per share, outstanding. 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 September 30, 2016, the Company raised approximately \$22,325,091 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 and related disclosures.

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 and related disclosures.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). The standard changes how entities measure certain equity investments and present changes in the fair value of financial liabilities measured under the fair value option that are attributable to their own credit. Under the new guidance, entities will be required to measure equity investments that do not result in consolidation and are not accounted for under the equity method at fair value and recognize any changes in fair value in net income unless the investments qualify for the new practicability exception. The standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company does not believe that the adoption of this guidance will have a material impact on the Company's consolidated financial statements and disclosures.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)" ("ASU 2016-02"), which requires lessees to put most leases on their balance sheets but recognize the expenses on their income statements in a manner similar to current practice. The standard states that a lessee would recognize a lease liability for the obligation to make lease payments and a right-to-use asset for the right to use the underlying asset for the lease term. The standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2018. Early adoption is permitted. We are currently evaluating the timing of our adoption and the impact that the updated standard will have on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting" ("ASU 2016-09"). ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2016. Early adoption is permitted. We are currently evaluating the timing of our adoption and the impact that the updated standard will have on our consolidated financial statements.

During August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, to address diversity in how certain cash receipts and cash payments are presented and classified in the statements of cash flows. The amendments are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The amendments should be applied using a retrospective transition method to each period presented. If retrospective application is impractical for some of the issues addressed by the update, the amendments for those issues would be applied prospectively as of the earliest date practicable. Early adoption is permitted, including adoption in an interim period. The Company does not expect the adoption of ASU 2016-15 to have a material impact on its consolidated 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 \$10,343 and \$57,004 in the three and nine months ended September 30, 2016 and were \$500 and \$1,917 in the three and nine months ended September 30, 2015.

#### **Research and Development**

Research and development costs are charged to operations as incurred. Research and development expenses were \$79,936 and \$302,330 in the three and nine months ended September 30, 2016 and were \$58,792 and \$179,739 in the three and nine months ended September 30, 2015.

## 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 filters and fluids. 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 or filters may be returned. Additionally, since the Company buys the STREAMWAY FMS units, cleaning solution and filters from "turnkey" suppliers, the Company would have the right to replacements from the suppliers if this situation should occur.

## Cash Equivalents

The Company considers all highly liquid debt instruments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents are stated at cost, which approximate fair value.

## Certificates of Deposit

Short-term interest bearing investments are those with maturities of less than one year but greater than three months when purchased. Certificates with maturity dates beyond one year are classified as noncurrent assets. These investments are readily convertible to cash and are stated at cost plus accrued interest, which approximates fair value.

## Investment Securities

Readily marketable investments in debt and equity securities are classified as available-for-sale and are reported at fair value with unrealized gains and losses recorded in other comprehensive income. Unrealized gains are charged to earnings when an incline in fair value above the cost basis is determined to be other-than-temporary. Realized gains and losses on dispositions are based on the net proceeds and the adjusted book value of the securities sold, using the specific identification method.

## Fair Value Measurements

Under generally accepted accounting principles as outlined in the Financial Accounting Standards Board's *Accounting Standards Certification* (ASC) 820, fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The accounting standards ASC 820 establishes a three-level fair value hierarchy that prioritizes information used in developing assumptions when pricing an asset or liability as follows:

Level 1 – Observable inputs such as quoted prices in active markets;

Level 2 – Inputs other than quoted prices in active markets, that are observable either directly or indirectly; and

Level 3 – Unobservable inputs where there is little or no market data, which requires the reporting entity to develop its own assumptions.

The Company uses observable market data, when available, in making fair value measurements. Fair value measurements are classified according to the lowest level input that is significant to the valuation.

The fair value of the Company's investment securities were determined based on Level 1 inputs.

### 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:

	September 30, 2016	December 31, 2015
Finished goods	\$ 72,540	\$ 30,237
Raw materials	157,044	162,623
Work-In-Process	59,665	38,880
Total	<u>\$ 289,249</u>	<u>\$ 231,740</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:

	September 30, 2016	December 31, 2015
Computers and office equipment	\$ 164,319	\$ 153,553
Leasehold improvements	25,635	23,874
Manufacturing tooling	101,104	97,288
Demo Equipment	17,702	8,962
Total	<u>308,760</u>	<u>283,677</u>
Less: Accumulated depreciation	197,850	144,079
Total Fixed Assets, Net	<u>\$ 110,910</u>	<u>\$ 139,598</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. Amortization expense was \$2,515 and \$6,225 in the three and nine months ended September 30, 2016, and was \$1,632 and \$4,520 in the three and nine months ended September 30, 2015. 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 has a credit risk concentration as a result of depositing \$454,369 of funds in excess of insurance limits in a single bank.

### **Product Warranty Costs**

In the three and nine months ending September 30, 2016 the incurred approximately \$2,102 and \$33,083 in current warranty costs and incurred \$12,084 and \$39,688 in warranty costs for the three and nine months ending September 30, 2015.

### **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 the three and nine months ending September 30, 2016 and for 2015 in entirety were located at or derived from operations in the United States. There were no revenue from sales outside of the United States. The Company has recently attained its ISO 13485 certification and is applying to sell our products in Canada.

### **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.

### **Subsequent Events**

The Company filed a Certificate of Amendment effecting a 1:25 reverse stock split (the "Reverse Stock Split" with the Secretary of State of the State of Delaware, which became effective under Delaware law at 5:00 p.m. New York time on October 27, 2016. The Company's common stock opened for trading on October 28, 2016 on a post-split basis. At the effective time (the "Effective Time") of the Reverse Stock Split, the issued and outstanding Common Stock of the Company was combined on a 1-for-25 basis such that every twenty-five shares of Common Stock outstanding immediately prior to the Effective Time was combined into one share of Common Stock. The share combination was effected through the exchange and replacement of certificates representing issued and outstanding shares of Common Stock as of the Effective Time, together with immediate book-entry adjustments to the stock register of the Company maintained in accordance with the Delaware General Corporation Law. In the event that the share combination would have resulted in a shareholder being entitled to receive less than a full share of Common Stock, the fractional share that would so result was rounded up to the nearest whole share of Common Stock. The par value of each share of issued and outstanding Common Stock was not affected by the share combination.

### **Interim Financial Statements**

The Company has prepared the unaudited interim financial statements and related unaudited financial information in the footnotes in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. These interim financial statements reflect all adjustments consisting of normal recurring accruals, which, in the opinion of management, are necessary to present fairly the Company's financial position, the results of its operations and its cash flows for the interim periods. These interim financial statements should be read in conjunction with the annual financial statements and the notes thereto contained in the Form 10-K filed with the SEC on March 16, 2016. The nature of the Company's business is such that the results of any interim period may not be indicative of the results to be expected for the entire year.

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

The Company was formed April 23, 2002. Since inception to October 24, 2016, 3,804,860 shares of common stock have been issued between par value and \$3,131.25 (as adjusted for the reverse stock split). Operations since incorporation have been devoted to raising capital, obtaining financing, development of the Company's product, and administrative services, customer acceptance and sales and marketing strategies.

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

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

#### 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 75,800 shares of Common Stock (as adjusted for the reverse stock split), 1,895,010 shares of Series B Preferred Stock and 7,580,040 Series A Warrants, (as adjusted for the reverse stock split).

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 "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 terminate on August 31, 2020. Each Series A Warrant is exercisable into one share of Common Stock at an initial cash exercise price of \$123.75 per share. The Cash exercise price and number of shares of common stock issuable upon cash 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 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 September 30, 2016 was \$108.115, and the closing bid price of Common Stock as of September 30, 2016, was \$4.125. Therefore, an exercise on that date would have resulted in the issuance of 0.40 shares of Common Stock for each Series A Warrant. Approximately 6,141,115 Series A Warrants have been exercised in cashless exercises as of September 30, 2016, resulting in the issuance of 2,318,663 shares of Common Stock. If all of the remaining 35,084 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 \$123.75 per share or less and the Black-Scholes Value were \$108.115 (the Black-Scholes Value as of September 30, 2016), then a total of an additional approximately 564 shares of our common stock would be issued to the holders of such Series A Warrants.

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) or the component securities of such 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 was terminated in May 2016 in exchange for 135,995 shares of common stock.

*Series B Preferred Stock.* Each share of Series B Preferred Stock became convertible into one share of Common Stock (subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events) as of February 29, 2016. 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, shares 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 3,391 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 issued 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.

*Registered Exchange Offer for Warrants.* On March 25, 2016, the Company commenced a registered exchange offer (the "Exchange Offer") to exchange Series B Warrants (the "Series B Warrants") to purchase shares of our common stock, par value \$0.01 per share (the "Warrant Shares"), for up to an aggregate of 3,157,186 outstanding Series A Warrants (the "Series A Warrants"). On March 31, 2016, each Series A Warrant could be exercised on a cashless basis for 0.40 shares of common stock. Each Series B Warrant may be exercised on a cashless basis for one twenty-fifth of one share of common stock (subject to further adjustment for stock splits, etc.). For each outstanding Series A Warrant tendered by holders, we offered to issue 10.2 Series B Warrants. The Exchange Offer expired at midnight, Eastern time, on April 21, 2016. 1,770,556 Series A Warrants were tendered by holders. The Company delivered an aggregate of 18,059,671 Series B Warrants pursuant to the terms of the Exchange Offer. In addition, between March 31, 2016 and July 6, 2016 1,251,510 Series A Warrants were exercised in cashless exercises, resulting in the issuance of 503,034 shares of common stock.

#### *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 174 shares of common stock to the former CEO at \$31.25 per share upon his exercising options.

In January through March 2014, 9 warrant holders exercised warrants through a cashless exercise for a total of 618 shares of common stock.

In January and February 2014 the Company issued warrants to purchase 862 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 \$609.50.

In February 2014 the Company issued a warrant to purchase 60 shares of common stock at an exercise price of \$506.25 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 \$487.50 per share. As a result 39 shares of common stock were issued to 16 holders of Preferred Shares.

In March 2014, the Company issued 178 shares of common stock to a warrant holder for a partial cash exercise at \$281.25 per share; issued 134 shares to the holder via the cashless exercise of the remainder of the warrant.

In June 2014, the Company issued 149 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 \$487.50 per share. As a result 63 shares of common stock were issued to 16 holders of Preferred Shares.

On June 30, 2014, the Company issued a warrant to purchase 218 shares of common stock at an exercise price of \$309.50 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 194 shares of common stock at an exercise price of \$309.50 to SOK Partners, LLC in consideration for a bridge loan.

In July 2014, the Company issued warrants to purchase 1,160 shares of common stock at an exercise price of \$309.50 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 2,462 of common stock at an exercise price of \$609.50 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 1,498 shares of common stock at an exercise price of \$309.50 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 \$487.50 per share. As a result 63 shares of common stock were issued to 16 holders of Preferred Shares.

In November 2014, the Company issued 548 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 \$487.50 per share. As a result 63 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% to 66% volatility and estimated terms of 5 to 10 years. Value computed using these assumptions ranged from \$80.015 to \$347.9864 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 \$487.50 per share, but should have been calculated at \$243.75 per share. As a result 125 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 \$243.75 per share. As a result 125 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 \$243.75 per share. As a result 125 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 \$6.8745 to \$139.2386 per share.

On March 25, 2016, the Company commenced the Exchange Offer which was completed on April 20, 2016, as described above.

On July 1, 2016, the Company issued inducement stock options in accordance with NASDAQ listing rules for 40,000 shares of common stock, par value \$0.01, at \$3.75 per share to the Company's newly hired Vice President of Sales. The options will vest in six equal increments: on the first, second, third, fourth, fifth and sixth quarters of the hiring date anniversary.

On October 4, 2016, the Company issued 400,000 shares of common stock, par value \$0.01, to be held in escrow in connection with the Company's Partnership and Exclusive Reseller Agreement with GLG Pharma, LLC.

For grants of stock options and warrants in 2016 the Company used a 1.46% to 1.78% risk free interest rate, 0% dividend rate, 66% volatility and estimated terms of 10 years. Value computed using these assumptions ranged from \$1.6329 to \$3.7195 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, 2014	17,945	\$ 187.75	20,029	\$ 198.75
Issued	14,171	69.00	303,269	123.75
Expired	(766)	293.25	(79)	283.50
Exercised	-	-	(120)	123.75
Outstanding at December 31, 2015	31,350	\$ 133.23	323,099	\$ 128.40
Issued	100,837	3.329	730,882	1.44
Expired	(22,377)	122.132	-	-
Exercised	(1,312)	65.750	(939,879)	-
Outstanding at September 30, 2016	108,498	\$ 15.652	114,102	\$ 369.06

At September 30, 2016, 64,542 stock options are fully vested and currently exercisable with a weighted average exercise price of \$23.46 and a weighted average remaining term of 9.57 years. All warrants are fully vested and exercisable. Stock-based compensation recognized for the nine months ending September 2016 and September 2015 was \$1,393,862 and \$320,334, respectively. The Company has \$132,675 of unrecognized compensation expense related to non-vested stock options that are expected to be recognized over a period of approximately 18 months.

The following summarizes the status of options and warrants outstanding at September 30, 2016:

	<i>Range of Prices</i>	<i>Shares</i>	<i>Weighted Remaining Life</i>
Options			
\$	2.25	293	9.90
\$	2.42	37,152	9.89
\$	3.75	44,000	9.76
\$	4.125	3,636	10.00
\$	4.1975	7,147	9.97
\$	4.25	3,529	9.50
\$	5.125	3,902	9.94
\$	65.75	342	9.06
\$	73.50	1,157	9.26
\$	77.50	2,323	8.75
\$	80.25	187	9.01
\$	86.25	232	8.50
\$	121.875	5	6.45
\$	131.25	81	5.94
\$	148.125	928	6.47
\$	150.00	1,760	5.88
\$	162.50	123	8.26
\$	206.25	121	8.01
\$	248.4375	121	6.79
\$	262.50	130	6.79
\$	281.25	529	6.30
\$	318.75	3	6.60
\$	346.875	72	7.50
\$	431.25	306	7.44
\$	468.75	133	7.40
\$	506.25	188	7.25
\$	543.75	53	7.02
\$	596.25	42	7.00
		108,498	
Warrants			
\$	93.75	2,255	1.45
\$	123.75	94,084	3.92
\$	150.00	4,114	1.45
\$	225.00	107	1.32
\$	243.75	2,529	2.84
\$	281.25	5,897	1.20
\$	309.375	2,850	2.86
\$	309.50	222	3.10
\$	337.50	178	1.72
\$	371.25	944	1.66
\$	506.25	59	2.38
\$	609.375	862	2.34
		114,102	

Stock options and warrants expire on various dates from June 2017 to September 2026.

On July 24, 2015, an amendment to the Certificate of Incorporation became effective, pursuant to which the authorized common stock was increased to 4,000,000 shares of common stock and the authorized preferred stock was increased to 20,000,000 shares.

Under a Separation Agreement effective June 13, 2016, all of our former CEO Josh Kornberg's 22,085 outstanding stock options were canceled.

On September 16, 2016, an amendment to the Certificate of Incorporation became effective, pursuant to which the authorized common stock was increased to 8,000,000 shares of common stock.

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

The following table is the listing of stock options and warrants as of September 30, 2016 by year of grant:

Stock Options:

Year	Shares	Price	
2011	173	0.00	- 281.25
2012	1,841	131.25	- 150.00
2013	1,612	121.88	- 596.25
2014	969	162.50	- 468.75
2015	4,240	65.75	- 86.25
2016	99,661	2.25	- 5.13
Total	108,498	\$0.00	- 596.25

Warrants:

Year	Shares	Price	
2012	2,792	281.25	
2013	10,703	93.75	- 371.25
2014	6,455	243.75	- 609.38
2015	94,152	0.00	- 243.75
Total	114,102	\$0.00	- 609.38

**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 218 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 2,851 shares.

As of September 30, 2016 \$927,663 aggregate principal amount of Convertible Notes, plus accrued and unpaid interest thereto, have been converted into shares of our common stock and no aggregate principal amount of Convertible Notes remains 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 September 30, 2016, 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:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Numerator:				
Net loss available in basic and diluted calculation	\$ (1,055,593)	\$ (1,116,402)	\$ (5,793,242)	\$ (2,527,524)
Other comprehensive income:				
Unrealized gain (loss) from marketable securities	(1,299)	-	4,579	-
Comprehensive (loss)	(1,056,892)	(1,116,402)	(5,788,663)	(2,527,524)
Denominator:				
Weighted average common shares outstanding-basic	3,320,139	157,445	2,250,315	137,428
Effect of diluted stock options, warrants and preferred stock (1)	-	-	-	-
Weighted average common shares outstanding-basic	3,320,139	157,445	2,250,315	137,428
Loss per common share-basic and diluted	<u>\$ (0.32)</u>	<u>\$ (7.09)</u>	<u>\$ (2.57)</u>	<u>\$ (18.39)</u>

(1) The number of shares underlying options and warrants outstanding as of September 30, 2016 and September 30, 2015 are 222,600 and 343,554 respectively. 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

### Availability and Utilization of Net Operating Losses

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.

During the first quarter of 2016, the Company likely had another ownership change that could further limit the Company’s ability to fully utilize its NOLs however, the determination of the annual limitation has not yet been made.

### Income Taxes

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 2036 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.

At September 30, 2016, the Company had approximately \$29.2 million of gross NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2017, subject to the Section 382 limitations described above. The federal NOLs will expire beginning in 2022 if unused. The Company also had approximately \$15.0 million of gross NOLs to reduce future state taxable income at September 30, 2016, which will expire in years 2022 through 2037 if unused. The Company’s net deferred tax assets, which include the NOLs, are subject to a full valuation allowance. At September 30, 2016, the federal and state valuation allowances were \$10.1 million and \$0.3 million, respectively.

The components of deferred income taxes at September 30, 2016 and December 31, 2015 are as follows:

	September 30, 2016	December 31, 2015
Deferred Tax Asset:		
Net Operating Loss	\$ 10,271,000	\$ 10,338,000
Other	166,000	359,000
Total Deferred Tax Asset	10,437,000	10,697,000
Less Valuation Allowance	10,437,000	10,697,000
Net Deferred Income Taxes	\$ —	\$ —

#### NOTE 7 – RENT OBLIGATION

The Company leases its principal office under a lease that can be cancelled after three years with proper notice per the lease and an amortized schedule of adjustments that will be due to the landlord. The lease extends five years and expires January 2018. In addition to rent, the Company pays real estate taxes and repairs and maintenance on the leased property. Rent expense was \$16,356 and \$50,106 for the three and nine months ended September 30, 2016 and was \$15,900 and \$50,156 for the three and nine months ended September 30, 2015 respectively.

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

2016	\$ 9,500
2017	\$ 39,000
2018	\$ 3,600

#### NOTE 8 – 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.

In connection with the sale of the Series A Preferred Share on February 4, 2014, Josh Kornberg, our former, and then President, CEO and Interim Chairman of the Board, was one of the Purchasers. Mr. Kornberg purchased 770 Preferred Shares for a purchase price of \$25,000 and received warrants to purchase 3 shares of common stock.

SOK Partners, LLC ("SOK"), a large 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 Conditions 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, Rick 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 9 – RETIREMENT SAVINGS PLAN

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 2016 and 2015, we matched 100%, of the employee's contribution up to 4% of their earnings. The employer contribution was \$7,401 and \$28,196 for the three and nine months ending September 30, 2016 and was \$7,021 and \$21,735 for the three and nine months ending September 30, 2015, respectively.



**NOTE 10 – SUPPLEMENTAL CASH FLOW DATA**

There were \$3 in cash payments for interest for the three and nine months ended September 30, 2016 and were \$226,960 and \$237,121 for the three and nine months ended September 30, 2015.

**NOTE 11 – INVESTMENT SECURITIES AND OTHER COMPREHENSIVE INCOME (LOSS)**

The cost and fair values of investment securities available-for-sale at September 30, 2016 were as follows:

Description	September 30, 2016			Fair Value
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	
Mutual Funds	\$ 572,309	\$ 4,579	\$ -	\$ 576,888



**1,925,00 Units, Each Unit Consisting of One Share of Common Stock and One Series D Warrant to Purchase 0.2 Shares of Common Stock  
385,000 Shares of Common Stock Underlying the Series D Warrants**

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**PROSPECTUS**

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**Dawson James Securities, Inc.**

The date of this Prospectus is , 2016

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## PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

#### ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the costs and expenses, payable by the registrant in connection with the sale of common stock being registered. All amounts are estimates except the SEC registration fee, the FINRA filing fee and the NASDAQ initial listing fee.

Securities and Exchange Commission registration fee	\$	711.72
FINRA filing fee	\$	
Printing and engraving expenses	\$	
Blue Sky fees and expenses	\$	
Legal fees and expenses	\$	
Accounting fees and expenses	\$	
Miscellaneous	\$	
Total	\$	<u>711.72</u>

#### ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS

We are a Delaware corporation and certain provisions of the Delaware Statutes and our bylaws provide for indemnification of our officers and directors against liabilities that they may incur in such capacities. A summary of the circumstances in which indemnification is provided is discussed below, but this description is qualified in its entirety by reference to our bylaws and to the statutory provisions.

Section 145 of the Delaware General Corporation Law provides for, under certain circumstances, the indemnification of our officers, directors, employees and agents against liabilities that they may incur in such capacities. A summary of the circumstances in which such indemnification provided for is contained herein, but that description is qualified in its entirety by reference to the relevant Section of the Delaware General Corporation Law.

In general, the statute provides that any director, officer, employee or agent of a corporation may be indemnified against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement, actually and reasonably incurred in a proceeding (including any civil, criminal, administrative or investigative proceeding) to which the individual was a party by reason of such status. Such indemnity may be provided if the indemnified person's actions resulting in the liabilities: (i) were taken in good faith; (ii) were reasonably believed to have been in or not opposed to our best interest; and (iii) with respect to any criminal action, such person had no reasonable cause to believe the actions were unlawful. Unless ordered by a court, indemnification generally may be awarded only after a determination of independent members of the Board of Directors or a committee thereof, by independent legal counsel or by vote of the stockholders that the applicable standard of conduct was met by the individual to be indemnified.

The statutory provisions further provide that to the extent a director, officer, employee or agent is wholly successful on the merits or otherwise in defense of any proceeding to which he was a party, he is entitled to receive indemnification against expenses, including attorneys' fees, actually and reasonably incurred in connection with the proceeding.

Indemnification in connection with a proceeding by or in the right of the Company in which the director, officer, employee or agent is successful is permitted only with respect to expenses, including attorneys' fees actually and reasonably incurred in connection with the defense. In such actions, the person to be indemnified must have acted in good faith, in a manner believed to have been in our best interest and must not have been adjudged liable to us unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability, in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expense which the Court of Chancery or such other court shall deem proper. Indemnification is otherwise prohibited in connection with a proceeding brought on behalf of the Company in which a director is adjudged liable to us, or in connection with any proceeding charging improper personal benefit to the director in which the director is adjudged liable for receipt of an improper personal benefit.

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Delaware law authorizes us to reimburse or pay reasonable expenses incurred by a director, officer, employee or agent in connection with a proceeding in advance of a final disposition of the matter. Such advances of expenses are permitted if the person furnishes to us a written agreement to repay such advances if it is determined that he is not entitled to be indemnified by us.

The statutory section cited above further specifies that any provisions for indemnification of or advances for expenses does not exclude other rights under our certificate of incorporation, corporate bylaws, resolutions of our stockholders or disinterested directors, or otherwise. These indemnification provisions continue for a person who has ceased to be a director, officer, employee or agent of the corporation and inure to the benefit of the heirs, executors and administrators of such persons.

The statutory provision cited above also grants the power to the Company to purchase and maintain insurance policies that protect any director, officer, employee or agent against any liability asserted against or incurred by him in such capacity arising out of his status as such. Such policies may provide for indemnification whether or not the corporation would otherwise have the power to provide for it.

Article 8 of our certificate of incorporation provides that we shall indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law.

We have purchased directors' and officers' liability insurance in order to limit the exposure to liability for indemnification of directors and officers, including liabilities under the Securities Act of 1933.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for our directors, officers, and controlling persons pursuant to the foregoing provisions or otherwise, we have been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

#### **ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES**

The following is a summary of our transactions since January 2013 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 1,334 shares of common stock assuming a conversion rate of \$225.00 per share and five year warrants to purchase up to an aggregate of 1,334 shares of the corporation's common stock at an exercise price of \$281.25 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 107 shares of common stock at an exercise price of \$281.25 per share. All of the notes were converted in September 2013 resulting in 1,407 shares of common stock issued at \$225.00 per share.

In January and March, 2013, in connection with a separate and new private placement offering we issued 3,810 shares of common stock at \$131.25 per share and warrants to purchase 3,810 shares of common stock at \$281.25 per share to 5 investors in return for their \$500,000 investment in the Company.

In January 2013, the Company issued 155 shares of common stock at \$281.25 per share in payment to a vendor for \$43,521.39 including principal and interest.

In February 2013, the Company issued 534 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.

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In February 2013, the Company issued 134 shares of common stock in agreement with an investor relations firm canceling their services.

In March 2013, the Company issued 123 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 3,810 shares of common stock as an equity bonus. Includes a warrant to purchase 3,810 shares of common stock at \$150.00 per share. Includes a warrant to purchase 1,905 shares of common stock at \$281.25 per share. Includes a warrant to purchase 102 shares of common stock at \$150.00 per share. Includes a warrant to purchase 204 shares of common stock at \$150.00 per share.

On April 22, 2013, the Company issued 107 shares of common stock to a former consultant exercising stock options with an exercise price of \$18.75.

On April 25, 2013, the Company issued 178 shares of common stock to the former CEO exercising stock options with an exercise price of \$18.75.

On May 7, 2013, the Company converted the notes issuing 596 aggregate shares of common stock at \$281.25 per share to the note holders. One of the note holder's is Dr. Herschkowitz, a related party, who received 191 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 3,200 shares of common stock assuming a conversion rate of \$337.50 per share and five year warrants to purchase up to an aggregate of 2,460 shares of the corporation's common stock at an exercise price of \$371.25 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 238 shares of common stock at an exercise price of \$337.50 per share. All of the notes were converted in September 2013 resulting in 3,032 shares of common stock issued at \$337.50 per share.

In August and September 2013, some warrant holders opted for a cashless warrant exercise resulting in issuing 3,485 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 675 shares.

In September 2013, the Company offered a limited amount of large warrant holders to exercise at a reduced rate of \$187.50 per share. Twenty-four warrants were exercised for a total of 5,571 shares for \$1,044,490.

In September 2013, the Company issued 80 shares of common stock at \$712.50 per share for consulting to a public relation/investor relations company.

In September 2013, the Company issued 11,981 shares of common stock at \$262.50 per share upon conversion of a secured note, which is no longer outstanding.

In September 2013, the Company issued 25,922 shares of common stock at \$262.50 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 27 shares of common stock each at \$609.38 per share; 11 of these shares were for compensation from serving as Board members and the remaining 16 shares were issued to satisfy previous contractual agreements.

In October 2013, the Company issued to Wisconsin Rural Enterprise Fund, LLC ("WREF") 202 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.

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In October 2013, the Company issued 22 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 \$337.50 per share.

In October 2013, an employee exercised vested options at \$122.00 per share to receive 6 shares of the Company's common stock.

In October a warrant holder exercised at a reduced rate of \$234.50 per share. The warrant was exercised for a total of 534 shares for \$125,000.

In November 2013, a vendor exercised a portion of options received in payment for executive placement. He received 10 shares of common stock at \$131.25 per share.

In December 2013, a warrant holder opted for a cashless warrant exercise resulting in issuing 63 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 70 shares of common stock pursuant to the warrant instruction for cashless exercise.

On January 6, 2014, the Company issued 174 shares of common stock to the former CEO exercising stock options with an exercise price of \$18.75.

In January 2014, a vendor received 80 shares of common stock at \$515.75 per share in payment for public relations services.

In January 2014, a warrant holder opted for a cashless warrant exercise resulting in issuing 133 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 11 shares of common stock at \$131.25 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 862 shares of Common Stock. The Series A Preferred Shares were initially convertible into shares of Common Stock at an initial conversion price of \$487.50 per share of Common Stock, subject to adjustment. The Warrants are exercisable at an exercise price of \$609.50 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 2,459 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 87 shares of common stock pursuant to the warrant instruction for cashless exercise.

In February 2014, a warrant holder exercised his warrant resulting in issuing 107 shares of common stock at an exercise price of \$337.50 per share for \$36,000.

In February 2014, the Company issued 54 shares of common stock at \$468.75 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, 534 shares of common stock held in escrow was canceled and reissued for 356 shares. The shares held in escrow will reduce by 178 shares in February 2015 and then again for the remaining 178 shares in February 2016 as the settlement is paid without default.

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In March 2014, four warrant holders opted for a cashless warrant exercise resulting in issuing 317 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 12 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 39 shares of common stock.

In March 2014, a warrant holder exercised a combined cashless and cash warrant exercise. The cashless exercise resulted in issuing 134 shares of common stock pursuant to the warrant instruction for exercise. The cash exercise resulted in the issuance of 178 shares of common stock at an exercise price of \$281.25 per share.

In April 2014, SOK transferred 800 shares of common stock, par value \$0.01, to six stockholders. Two of these stockholders, Frank Mancuso Jr. and Arnon Dreyfuss are former directors of the Company who served on the Board at the time of these transfers. Mr. Mancuso received 134 shares and Dr. Dreyfuss received 267 shares.

In May 2014, the Company issued 86 shares of common stock at \$281.25 per share to a vendor as part of a contract for investor relations consulting.

In May 2014, the Company issued 54 shares of common stock at \$468.75 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 149 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 \$487.50 per share. As a result 63 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 57 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 445 shares of common stock at an exercise price of \$140.45 per share for \$62,500.

In August 2014, a vendor exercised a portion of options received in payment for executive placement. He received 14 shares of common stock at \$131.25 per share.

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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 \$487.50 per share. As a result 63 shares of common stock were issued to the Preferred Holders.

In October 2014, SOK Partners, LLC transferred 5,560 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 223 shares of common stock at \$309.50 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 \$487.50 per share. As a result, 63 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 \$487.50 as a price per share in September and December instead of \$243.75).

In January 2015, the Company released 548 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.

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On May 26, 2016, the Company issued 135,995 shares of common stock valued at \$3.75 per share to an investment banking firm as compensation for its services in connection with potential acquisitions and capital raises, as well as investment planning.

On July 1, 2016, the Company issued inducement stock options in accordance with NASDAQ listing rules for 40,000 shares of common stock, par value \$0.01, at \$3.75 per share to the Company's newly hired Vice President of Sales. The options will vest in six equal increments: on the first, second, third, fourth, fifth and sixth quarters of the hiring date anniversary. The options were granted outside of the Company's stock incentive plan but are subject to terms and conditions generally consistent with the plan. The issuance of these inducement options were made pursuant to the exemption set forth in Section 4(2) of the Securities Act of 1933, as amended for transactions not involving a public offering, and regulations promulgated thereunder.

On October 4, 2016, the Company issued 400,000 shares of common stock, par value \$0.01, to be held in escrow in connection with the Company's Partnership and Exclusive Reseller Agreement with GLG Pharma, LLC. For this issuance, the Company relied on the exemption from federal registration under Section 4(2) of the Securities Act or 1933 and/or Rule 506 promulgated thereunder, based on the Company's belief that the offer and sale of the shares did not involve a public offering.

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.

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## EXHIBIT INDEX

Exhibit Number	Description
1.1*	Form of Underwriting Agreement
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 regarding reverse stock split, filed with the Delaware Secretary of State on October 20, 2014 (20)
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(18)
3.4	Certificate of Amendment to Certificate of Incorporation Regarding increase in share capital <sup>(23)</sup>
3.5	Certificate of Incorporation for reverse split <sup>(24)</sup>
3.6	Bylaws (19)
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (2)
3.8	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock
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 (21)
4.8	Form of Warrant issued to investors of Convertible Notes (21)
4.9	Form of Registration Rights Agreement (21)
4.10	Form Waiver and Consent of, and Notice to, Holder of Preferred Stock of the registrant (21)
4.11*	Form of Series D Warrant Agency Agreement by and between Skyline Medical Inc. and Corporate Stock Transfer, Inc. and Form of Warrant Certificate
4.12*	Specimen certificate evidencing shares of Common Stock
4.13*	Form of Series D Warrant Certificate (included as part of Exhibit 4.11)
4.14*	Form of Unit Purchase Option to be issued in connection with this offering
4.15	Form of Exchange Agreement with Holders of Series A Preferred Stock (22)
4.16	Form of Amendment to Senior Convertible Notes and Agreement by and Between Skyline Medical Inc. and Senior Convertible Notes (22)
4.17*	Form of specimen certificate evidencing shares of Series B Convertible Preferred Stock
5.1*	Opinion of Maslon LLP
10.1	Form of Securities Purchase Agreement, dated as of February 4, 2014, by and among the registrant 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 the registrant (14)
10.16	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and the registrant (14)
10.17	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and the registrant (14)
10.18	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and the registrant (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 Note (17)
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) (17)
10.25	Letter Agreement, dated August 22, 2013, among Dr. Samuel Herschkowitz, SOK Partners, LLC and the registrant (5)
10.26	Letter Agreement, dated April 25, 2013, among Dr. Samuel Herschkowitz, SOK Partners, LLC and the registrant (8)
10.27	Letter Agreement, dated March 6, 2013, among Dr. Samuel Herschkowitz, SOK Partners, LLC and the registrant (10)
10.28	Form of Securities Purchase Agreement with investors in Convertible Notes (21)
23.1**	Consent of Independent Registered Public Accounting Firm
23.2*	Consent of Maslon LLP (included as part of Exhibit 5.1)
24.1**	Power of Attorney (included as part of the signature pages to this registration statement)
101*	Interactive Data File

\* To be filed by amendment.

\*\* Filed herewith.

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

- (11) Filed on February 26, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
  - (12) Filed on November 12, 2008 as an exhibit to our Registration Statement on Form S-1 and incorporated herein by reference.
  - (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 3, 2012 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
  - (18) Filed on June 30, 2015 as an appendix to our Information Statement on Schedule 14C and incorporated herein by reference.
  - (19) Filed on August 27, 2013 as Appendix C to our Definitive Proxy Statement for the 2013 Annual Meeting and incorporated herein by reference.
  - (20) Filed on October 24, 2014 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
  - (21) Filed on July 24, 2014 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
  - (22) Filed on July 24, 2015 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
  - (23) Filed on September 16, 2016 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
  - (24) Filed on October 27, 2016 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
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## ITEM 17. UNDERTAKINGS

The undersigned registrant hereby undertakes:

- (a) (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
    - (i) to include any prospectus required by section 10(a)(3) of the Securities Act of 1933;
    - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, an increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;
    - (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.
  - (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
  - (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
  - (4) [Intentionally omitted]
  - (5) For the purpose of determining any liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
  - (6) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
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- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
  - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
  - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
  - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (7) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.
- (i) The undersigned Registrant hereby undertakes that it will:
    - (1) for determining any liability under the Securities Act, treat the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant under Rule 424(b)(1), or (4) or 497(h) under the Securities Act as part of this registration statement as of the time the Commission declared it effective.
    - (2) for determining any liability under the Securities Act, treat each post-effective amendment that contains a form of prospectus as a new registration statement for the securities offered in the registration statement, and that offering of the securities at that time as the initial bona fide offering of those securities.
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## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Eagan, on December 9, 2016.

### SKYLINE MEDICAL INC.

/s/ Bob Myers  
Bob Myers  
Chief Financial Officer

Each person whose signature appears below hereby constitutes and appoints Carl Schwartz and Bob Myers, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and any and all additional registration statements pursuant to Rule 462(b) of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Carl Schwartz</u> Carl Schwartz	Chief Executive Officer (principal executive officer), Director	December 3, 2016
<u>/s/ Bob Myers</u> Bob Myers	Chief Financial Officer (principal financial and accounting officer),	December 9, 2016
<u>/s/ Thomas J. McGoldrick</u> Thomas J. McGoldrick	Director	December 9, 2016
<u>/s/ Andrew Reding</u> Andrew Reding	Director	December 6, 2016
<u>/s/ Timothy A. Krochuk</u> Timothy A. Krochuk	Director	December 2, 2016
<u>/s/ J. Melville Engle</u> J. Melville Engle	Director	December 3, 2016
<u>/s/ Richard Gabriel</u> Richard Gabriel	Director	December 9, 2016

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the use in this Registration Statement on Form S-1 of our audit report, dated March 16, 2016, relating to the financial statements of Skyline Medical Inc. appearing in the prospectus which are a part of this Registration Statement. We also consent to the reference to our Firm under caption "Experts" in the Prospectus which is part of this Registration Statement.

/s/ Olsen Thielen & Co., Ltd.

Roseville, Minnesota  
December 9, 2016