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

Amendment No. 1

to

# 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.  $\Box$ 

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.  $\Box$ 

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.  $\Box$ 

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  $\square$ Non-accelerated filer  $\square$  Accelerated filer □ Smaller reporting company ☑

# CALCULATION OF REGISTRATION FEE

			Proposed		Proposed		
		N	<b>Iaximum Per</b>		Maximum		Amount of
	Amount to	S	hare Offering		Aggregate	Re	gistration Fee
Title of Each Class of Securities to be Registered	be Registered		Price	Offering Price (1)			(1)(2)
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
Total Registration Fee (6)				\$	7,368,900	\$	854.07

(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.

(6) The total registration fee of \$854.07 was paid previously.

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 JANUARY 10, 2017



# 1,750,000 Units, Each Unit Consisting of One Share of Common Stock and 0.2 of a Series D Warrant

350,000 Shares of Common Stock Underlying the Series D Warrants

We are offering 1,750,000 shares of our common stock, par value \$0.01 per share, and Series D Warrants to purchase up to an aggregate of 350,000 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 \$2.66, as quoted on The NASDAQ Capital Market on January 5, 2017. 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 15 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.

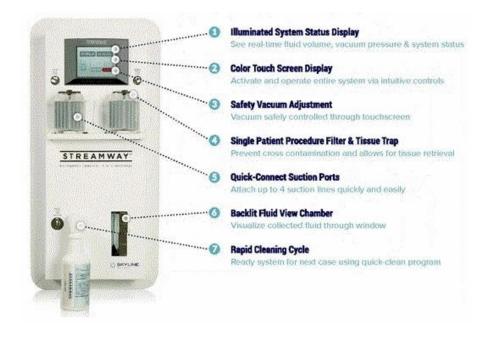
(2) The underwriter will receive compensation in addition to the underwriting discount. See "Underwriting" beginning on page 71 of this prospectus for a description of compensation payable to the underwriter.

We expect to deliver the shares of common stock and warrants to investors on or about \_\_\_\_\_\_, 2017. We have granted to the underwriters a 45-day option to purchase (i) up to 175,000 additional shares of common stock at the public offering price per unit less the price per warrant included in the unit and less the underwriting discount or (ii) additional warrants to purchase up to 35,000 additional shares of common stock at a purchase price of \$0.01 per warrant to cover over-allotments, if any. If the underwriter exercises the option in full, the total underwriting discounts and commissions payable by us will be \$ and the total proceeds to us, before expenses, will be \$

# **Dawson James Securities, Inc.**

The date of this prospectus is

,2017



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 underwriter has 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 underwriter is 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 underwriter has 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 bloodbome 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 glutalderhyde, as these agents not only neutralize potentially infectious agents but also work to defeat the bacterial agents employed by the waste treatment facilities themselves. Disposal through this method is fraught with potential exposure to the service workers, putting them at risk for direct contact with these potentially infectious agents through spillage of the contents or via splash when the liquid is poured into a hopper a specially designated sink for the disposal of infectious fluids. Once the infectious fluids are disposed of into the hopper, the empty canister is sent to central processing for resterilization (glass and certain plastics) or for disposal in the bio-hazardous/infectious waste generated by the hospital (red-bagged).
- Conversion to Gel for Red-Bag Disposal. In many hospital systems the handling of this liquid waste has become a liability issue due to worker exposure incidents and in some cases has even been a point of contention during nurse contract negotiations. 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.



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.

Effective December 29, 2016, the Nasdaq Hearings Panel granted the Company's request for continued listing on NASDAQ pursuant to an extension through April 11, 2017 to evidence compliance with the \$2.5 million stockholders' equity requirement. There can be no assurance that the Company will be able to demonstrate compliance with the applicable listing criteria within this period of time.

# THE OFFERING

Price per Unit	\$ per Unit
Securities offered by us	1,750,000 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. We have granted to the underwriters a 45-day option to purchase (i) up to 175,000 additional shares of common stock at the public offering price per unit less the price per warrant included in the unit and less the underwriting discount or (ii) additional warrants to purchase up to 35,000 additional shares of common stock at a purchase price of \$0.01 per warrant to cover over-allotments, if any.
Common stock offered	1,750,000 shares.
Warrants	An aggregate of 350,000 Series D Warrants to purchase up to an aggregate of 350,000 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	4,564,428 shares.
Common Stock Outstanding Immediately After This Offering	6,664,428 shares (assuming exercise of 350,000 Series D Warrants into an aggregate of 350,000 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 24 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 15 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 \$2.66, as quoted on The NASDAQ Capital Market on January 5, 2017. 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.
Unloss we indicate otherwise all information in this ru	respectus assumes no everyise by the underwriter of its option to purchase up to an additional 175,000

Unless we indicate otherwise all information in this prospectus assumes no exercise by the underwriter of its option to purchase up to an additional 175,000 shares of common stock or warrants to purchase 35,000 shares of common stock to cover over-allotments, if any.

# **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.

The Company is in the process of working toward compliance with the continued listing standards of The Nasdaq Capital 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, among other requirements for continued listing on The Nasdaq Capital Market. The Company was recently granted an extension through April 11, 2017 to evidence compliance with the \$2.5 million stockholders' equity requirement. There can be no assurance that the Company will be able to demonstrate compliance with the applicable listing criteria within this period of time.



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 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'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 is 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 1,750,000 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. If the underwriter exercises the option to purchase an additional 175,000 Units in full, the total proceeds to us, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately \$\_\_\_ million.

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 2-4weeks, 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 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 Komberg resigned as the Chief Executive Officer and President and an employee of the Company. In connection with Mr. Komberg'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. Komberg 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. Komberg 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 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



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.

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

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

Where:

- Total Shares is the number of shares of Common Stock to be issued upon a Cashless Exercise.
- A is the total number of shares with respect to which the Series A Warrant is then being exercised.
- B is the Black Scholes Value (as defined below).
- C is the closing bid price of the Common Stock as of two trading days prior to the time of such exercise, provided that in no event may "C" be less than \$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 Ii) 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 shares of Common Stock (subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events) on the six month anniversary of the Issuance Date or on the date of an Early Separation. In addition, the Series B Preferred Stock will automatically convert into shares of common stock upon the occurrence of a fundamental transaction, as described in the certificate of designations for the Series B Preferred Stock but including mergers, sales of the company's assets, changes in control and similar transactions. The Series B Preferred Stock is not convertible by the holder of such preferred stock to the extent (and only to the extent) that the holder or any of its affiliates would beneficially own in excess of 4.99% of the common stock of the Company. The Series B Preferred Stock has no voting rights, except for the right to approve certain amendments to the certificate of designations or similar actions. With respect to payment of dividends and distribution of assets upon liquidation or dissolution or winding up of the Company, the Series B Preferred Stock shall rank equal to the common stock of the Company. No sinking fund has been established for the retirement or redemption of the Series B Preferred Stock.

*Unit Exchange.* On February 4, 2014, the Company raised \$2,055,000 in gross proceeds from a private placement of 20,550 shares of Series A Convertible Preferred Stock, par value \$0.01, with a stated value of \$100 per share (the "Series A Preferred Shares") and warrants to purchase shares of the Company's common stock. The Series A Preferred Shares and warrants were sold to investors pursuant to a Securities Purchase Agreement, dated as of February 4, 2014. On August 31, 2015, the Company issued a total of 228,343 Units (the "Exchange Units") in exchange for the outstanding Series A Preferred Stock which were then cancelled pursuant to an agreement with the holders of the Series A Preferred Shares. The warrants that were issued in connection with the issuance of the Series A Preferred Shares remained outstanding; however, the warrant amounts were reduced so that the warrants are exercisable into an aggregate of 84,770 shares of the Company 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 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 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 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**

# 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 ascetic fluid with no evac bottles, suction canisters, transport or risk of exposure. The Company also manufactures and sells two disposable products required for system operation: a bifurcated single procedure filter with tissue trap and a single use bottle of cleaning solution. Both items are used on a single procedure basis and must be discarded after use.

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

Skyline believes that the STREAMWAY FMS is unique to the industry in that it allows for continuous suction to the surgical field and provides unlimited capacity to the user so no surgical procedure will ever have to be interrupted to change canisters. It is wall mounted and takes up no valuable operating room space. The FMS can replace the manual process of collecting fluids in canisters and transporting and dumping in sinks outside of the operating room that is still being used by many hospitals and surgical centers.

Skyline believes its products provide substantial cost savings and improvements in safety in facilities that still use manual processes. In cases where healthcare organizations re-use canisters, the FMS cleaning process eliminates the need for cleaning of canisters for re-use. The FMS reduces the safety issues facing operating room nurses, the cost of the handling process, and the amount of infectious waste generated when the traditional method of disposing of canisters is used. The FMS is fully automated, does not require transport to and from the operating room and eliminates any canister that requires emptying. It is positioned to penetrate its market segment due to its virtually hands free operation, simple design, ease of use, continuous suction, continuous flow, unlimited capacity and efficiency in removal of infectious waste with minimal exposure of operating room personnel to potentially infectious material.

The Company was originally incorporated on April 23, 2002 in Minnesota as BioDrain Medical, Inc. Effective August 6, 2013, the Company changed its name to Skyline Medical Inc. Pursuant to an Agreement and Plan of Merger effective December 16, 2013, the Company merged with and into a Delaware corporation with the same name that was its wholly-owned subsidiary, with such Delaware Corporation as the surviving corporation of the merger. On August 31, 2015, the Company completed a successful offering and concurrent uplisting to The NASDAQ Capital Market. Our address is 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121. Our telephone number is 651-389-4800, and our website address is www.skylinemedical.com. 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 affectious 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 sever 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								
	Skyline Medical	Stryker		Dornoch Medical Systems, Inc.	MD Technologies,			
Feature	Inc.	Instruments	DeRoyal	(Zimmer)	Inc.			
Portable to Bedside vs. Fixed Installation	Fixed	Portable	Fixed	Portable	Fixed			
Uses Canisters	No	Yes	Yes	Yes	No			
Secondary Installed Device Required for Fluid Disposal	No	Yes	Yes	Yes	No			
Numeric Fluid Volume Measurement	Yes	Yes	No	Yes	Optional			
Unlimited Fluid Capacity	Yes	No	No	No	Yes			
Continuous, Uninterrupted Vacuum	Yes	No	No	No	No			
Installation Requirements :								
Water	No	Yes	Yes	Yes	No			
Sewer	Yes	Yes	Yes	Yes	Yes			
Vacuum	Yes	No	No	No	Yes			

The FMS system may be installed on or in the wall during new construction or renovation or installed in a current operating room by connecting the device to the hospital's existing sanitary sewer drain and wall suction systems. With new construction or renovation, the system will be placed in the wall and the incremental costs are minimal, limited to connectors to the hospital drain and suction systems (which systems are already required in an operating room), the construction of a frame to hold the FMS in position, and minimal labor. The fluid collection chamber is internal to the FMS unit and requires no separate installation. Based upon our consultations with several architects, we believe that there is no appreciable incremental expense in planning for the FMS system during construction.

For on-the-wall installation in a current operating room, the location of the FMS may be chosen based on proximity to the existing hospital drain and suction systems. Installation will require access to those systems through the wall and connection to the systems in a manner similar to that for within-the-wall installation. The FMS system is mounted on the wall using a mounting bracket supplied with the system and standard stud or drywall attachments.

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:

- <u>Minimal Human Interaction</u>. 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.
- <u>Procedure Filters.</u> 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.
- <u>Sales Channel Partners</u>. The FMS is sold to end-users through a combination of independent stocking distributors, manufacturer's representatives, and direct sales personnel. We intend for all personnel involved in direct contact with the end-user will have extensive training and will be approved by Skyline. We plan to maintain exclusive agreements between Skyline and the sales channel partners outlining stocking expectations, sales objectives, target accounts and the like. Contractual agreements with the sales channel partners will be reviewed on an annual basis and expect that such agreements will contain provisions allowing them to be terminated at any time by Skyline based on certain specified conditions.

• <u>Competitive Pricing</u>. The list sales price to a hospital or surgery center is \$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 nonprovisional 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 first container to collect fluid while the second container becomes full, the vacuum between containers is automated in certain MD Technology models, the automated switching is still believed to result in brief interruptions or reductions in suction during the surgical procedure.

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

In general, the Patents are directed to a system and method for collecting waste fluid from a surgical procedure while ensuring there is no interruption of suction during the surgical procedure and no limit on the volume of waste fluid which can be collected. More particularly, the Patents claim a system and method in which waste fluid is suctioned or drawn into holding tanks connected to a vacuum source which maintains a constant negative pressure in the holding tanks. When the waste fluid collected in the holding tanks reaches a predetermined level, the waste fluid is measured and pumped from the holding tanks while maintaining the negative pressure. Therefore, because the negative pressure is maintained in the holding tanks, waste fluid will continue to be drawn into the holding tanks while the waste fluid is being pumped from the holding tanks. Thus, there is no limit to the volume of waste fluid which can be collected, and the 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, premeasured 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 manufactures 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, 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.
- o Providing a leasing program and/or "pay per use" program as alternatives to purchasing.
- o Providing service contracts to establish an additional revenue stream.
- 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 glutalderhyde, as these agents not only neutralize potentially infectious agents but also work to defeat the bacterial agents employed by the waste treatment facilities themselves. Disposal through this method is fraught with potential exposure to the service workers, putting them at risk for direct contact with these potentially infectious agents through spillage of the contents or via splash when the liquid is poured into a hopper – a specially designated sink for the disposal of infectious fluids. Once the infectious fluids are disposed of into the hopper, the empty canister is sent to central processing for resterilization (glass and certain plastics) or for disposal 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 "NeptuneTM" system, offering a combination of bio-aerosol and fluid management in a portable two-piece system; Waterstone Medical (now DeRoyal) introduced the "Aqua BoxTM" stationary system for fluid disposal; Cardinal Health introduced the Orwell Fluid Collection and Disposal System; and Dornoch Medical Systems, Inc. (Zimmer) introduced the "Red AwayTM" stationary system for fluid collection and disposal. All companies, regardless of size, have their own accessory kits.

We differentiate from these competitors since we are completely direct-to-drain and have the most automatic, hands-free process of any of the systems currently on the market. Each of our competitors, with the exception of MD Technologies, Inc., has some significant manual handling involved in the process. For instance, some competing products require transport of the mobile unit to a docking port and then emptying of the fluid, while others require that the canister be manually transported to a more efficient dumping station. Regardless, most of our competitors require more human interaction with the fluid than 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, anesthetists, imaging, anesthesiologists, human resources, legal, administration and housekeeping.

The major focus of our marketing efforts will be to introduce the FMS as a standalone device capable of effectively removing infectious waste and disposing of it automatically while providing accurate measurement of fluids removed, and also limiting exposure of the surgical team and healthcare support staff.

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

Our distributors may have installation and service capability, or we will contract those functions with an independent service/maintenance company. We have hired both distributors and service companies regarding these installation requirements. We have established extensive training and standards for the service and installation of the FMS to ensure consistency and dependability in the field. Users of the system require a minimal amount of training to operate the FMS. The instructions for use and the installation guide are included with every system along with a quick start guide, a troubleshooting manual and an on-board PLC controlling an intuitive touch screen with step by step instruction and safety features.

We have structured our pricing and relationships with distributors and/or service companies to ensure that these entities receive at least a typical industry level compensation for their activities.

#### Promotion

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

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

We support our sales organization by attending major scientific meetings where large numbers of potential users are in attendance. The theme of our trade show booths focus on education, the awareness of the hazards of infectious waste fluids and the Company's innovative solution to the problem. We have focused our efforts initially on the Association of Operating Room Nurses ("AORN") meetings, where the largest concentration of potential buyers and influencers are in attendance and the Radiological Society of North America Scientific Assembly and Annual Meeting. We have partnered with the Association for Radiologic & Imaging Nursing ("ARIN") and will be presenting in their April 2016 annual educational conference in Vancouver, British Columbia. We feature information on protection of the healthcare worker on our website as well as links to other relevant sites. We have invested in limited journal advertising for targeted audiences that have been fully identified. The initial thrust focuses on features of the product and ways of contacting the Company via the webpage or directly through postage paid cards or direct contact. Additionally, we will create a press release distribution to clinician-oriented periodicals for inclusion in their new product development columns. These periodicals will provide the reader with an overview of the FMS and will direct readers to pursue more information by direct contact with us by accessing our webpage.



## Pricing

We believe prices for the FMS and its disposable procedure kit reflect a substantial cost savings to hospitals compared to their long-term procedure costs. Our pricing strategy ensures that the customer realizes actual cost savings when using the FMS versus replacing traditional canisters, considering the actual costs of the canisters and associated costs such as biohazard processing labor and added costs of biohazard waste disposal. Suction tubing that is currently used in the operating room will continue to be used with our system and should not be considered in the return on investment equation. Our cleaning solution's bottle is completely recyclable, and the selling price of the fluid is built into our cost analysis. In contrast, an operation using traditional disposal methods will often produce multiple canisters destined for biohazard processing. Once the canister has touched blood, it is considered "red bag" biohazard waste, whereas the cleaning fluid bottle used in the FMS can be recycled or disposed with the rest of the facility's plastics.

The FMS lists for \$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	\$ 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	\$ 	\$	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 January 5, 2017, the closing sale price for shares of our common stock was \$2.66 per share. The Series B Preferred Stock and Series B Warrants are not traded on any security markets.

#### Holders

As of December 30, 2016, there were approximately 141 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	62	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 problem solving 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. Krochuk, as the chairperson, Mr. Reding and Mr. Engle. Mr. Krochuk has a strong and vast financial history specializing as an investment advisor. 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 and Engle. 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. Engle, as the chairperson, and Mr. McGoldrick. 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. Engle and Mr. McGoldrick. 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. Krochuk, 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 2016 and 2015

The following table provides information regarding the compensation earned during the fiscal years ended December 31, 2016 and December 31, 2015 by each of the named executive officers:

Name and Principal Position	Year	 (5) Salary	 Bonus	<u></u>	Stock Awards	 (1) Option Awards	<u> </u>	(6) All Other compensation	C	Total ompensation
Joshua Kornberg, former CEO and President <sup>(2)</sup>	2016	\$ 121,284		\$	90,351		\$	,	\$	364,135
	2015	\$ 326,162	\$ 562,941	\$	-	\$ 417,628	\$	27,000	\$	1,333,731
Carl Schwartz, CEO <sup>(7)</sup>	2016	\$ 0	\$ -	\$	-	\$ 14,766	\$	-	\$	14,766
David O. Johnson, COO <sup>(3)</sup>	2016	\$ 149,053	\$ 72,000	\$	97,950	\$ 10,920	\$	-	\$	329,923
	2015	\$ 180,926	\$ 178,000	\$	-	\$ 32,969	\$	-	\$	391,895
Bob Myers, CFO <sup>(4)</sup>	2016	\$ 131,234	\$ 66,000	\$	90,938	\$ 10,920	\$	-	\$	299,092
	2015	\$ 174,550	\$ 130,750	\$	-	\$ 30,222	\$	-	\$	335,522

 Represents the actual compensation cost recognized during 2016 and 2015 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. Komberg resigned as the Chief Executive Officer and President and an employee of the Company. In connection with Mr. Komberg's resignation, the Company and Mr. Komberg 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 2015 Mr. Komberg also received options to purchase 253 shares of common stock as fees for serving on the Board of Directors. Mr. Komberg'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. In 2016, Mr. Komberg received \$18,685 as part of his salary that was paid through his settlement contract. The restricted stock award for \$90,351 was part of his severance settlement. All of Mr. Komberg's options to purchase stock were cancelled as part of his settlement contract.

- (3) Mr. Johnson's minimum bonus for 2016 was 20% of his base salary, or \$36,000. During 2016 he received \$36,000 in income from additional bonuses in recognition of bonus amounts from the prior year. In 2016 he also received bonus options to purchase 3,574 shares of common stock at \$4.20 per share. In 2016, Mr. Johnson exercised stock options valued at \$97,950.
- (4) Mr. Myers's minimum bonus for 2016 was 20% of his base salary, or \$33,000. During 2016 he received \$33,000 in income from additional bonuses in recognition of bonus amounts from the prior year. During 2016 he also received bonus options to purchase 3,574 shares of common stock at \$4.20 per share. In 2016, Mr. Myers exercised stock options valued at \$90,938.
- (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 \$137,500 in severance and \$15,000 in medical reimbursement.
- (7) Dr. Schwartz 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. Dr. Schwartz did not receive a salary, bonus or other payment during 2016. Dr. Schwartz received options to purchase 4,920 shares of common stock as fees for serving on the Board of Directors. Dr. Schwartz also received options to purchase 7,143 shares of common stock in 2016 as fees for serving on the Medical Advisory Committee.

# 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, 2016:

Grant Date	Number of Securities Underlying Options Exercisable	Number of Securities Underlying Options Unexercisable	Option	Exercise Price	Option Expiration Date
3/31/2016	588		\$	4.25	3/31/2026
6/30/2016	1,334		\$	3.75	6/30/2026
9/30/2016	1,212		\$	4.13	9/30/2026
12/31/2016	1,786		\$	2.80	12/31/2026
12/31/2016	7,143		\$	2.80	12/31/2026
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
9/16/2016	3,574		\$	4.20	9/16/2026
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
9/16/2016	3,574		\$	4.20	9/16/2026
	3/31/2016 6/30/2016 9/30/2016 12/31/2016 12/31/2016 8/13/2012 3/18/2013 3/6/2014 9/16/2016 8/13/2012 3/18/2013 3/6/2014	Securities Underlying Options           Grant Date         Exercisable           3/31/2016         588           6/30/2016         1,334           9/30/2016         1,212           12/31/2016         1,786           12/31/2016         7,143           8/13/2012         534           3/18/2013         507           3/6/2014         167           9/16/2016         3,574           8/13/2012         534           3/18/2013         422           3/6/2014         140	Securities Underlying Options         Securities Underlying Options           Grant Date         Exercisable         Underlying Options           3/31/2016         588           6/30/2016         1,334           9/30/2016         1,212           12/31/2016         1,786           12/31/2016         7,143           8/13/2012         534           3/18/2013         507           3/6/2014         167           9/16/2016         3,574           8/13/2012         534           3/18/2013         422           3/6/2014         140	$\begin{array}{c c c c c c c c c c c c c c c c c c c $	$\begin{array}{c c c c c c c c c c c c c c c c c c c $

# **Executive Compensation Components for Fiscal 2016**

*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. Komberg received \$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; breach of any agreement between 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 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 30days 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 2016**

The following table summarizes the compensation paid to each non-employee director in the fiscal year ended December 31, 2016:

	s Paid or ed in Cash	Stock Awards	Option Awards	Total
Thomas McGoldrick	\$ -	\$ -	\$ 36,742 (1) \$	36,742
Richard Taney	\$ -	\$ -	\$ 1,823 (2) \$	1,823
Andrew Reding	\$ -	\$ -	\$ 29,360 (3) \$	29,360
Richard Gabriel	\$ -	\$ -	\$ 3,692 (4) \$	3,692
Tim Krochuk	\$ -	\$ -	\$ 3,692 (5) \$	3,692
J. Melvin Engle	\$ -	\$ -	\$ 3,692 (6) \$	3,692
Carl Schwartz	\$ -	\$ -	\$ 12,771(7) \$	12,771

 Mr. McGoldrick was awarded options to purchase 12,500 shares of common stock both for serving on the Board and for participating on the Audit, Compensation and Corporate Governance Committees.

- (2) Mr. Taney was awarded options to purchase 588 shares of common stock for serving on the Board. Mr. Taney resigned as a Director effective March 18, 2016.
- (3) Mr. Reding was awarded options to purchase 8,929 shares of common stock both for serving on the Board and for participating on the Audit and Corporate Governance Committees.
- (4) Mr. Gabriel was awarded options to purchase 1,786 shares of common stock for serving on the Board.
- (5) Mr. Krochuk was awarded options to purchase 1,786 shares of common stock for serving on the Board.
- (6) Mr. Engle was awarded options to purchase 1,786 shares of common stock for serving on the Board.
- (7) Dr. Schwartz was awarded options to purchase 4,920 shares of common stock for serving on the Board.

# **Equity Compensation Plan Information**

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

	Number of securities to be issued upon exercise of outstanding restricted stock, warrants and options (a)	Weighted- average exercise price of outstanding options, warrants (b)	plans (excluding securities reflected in
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 Komberg, our former President, Chief Executive Officer and Interim Chairman of the Board, was one of the purchasers. Mr. Komberg purchased 19,231 Series A Preferred Shares for a purchase price of \$25,000 and received warrants to purchase 52 shares of common stock.

SOK Partners, LLC ("SOK"), a significant 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 — 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. Komberg 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 4,564,428 shares of the Company's common stock outstanding on December 31, 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.

Name of Beneficial Owner	Amount and Nature of Beneficial Ownership(1)	Percent of Class
Officers and Directors		
Carl Schwartz <sup>(2)</sup>	81,077	1.77%
David Johnson <sup>(3)</sup>	5,656	0.12%
Bob Myers <sup>(4)</sup>	5,429	0.12%
Thomas J. McGoldrick <sup>(5)</sup>	17,127	0.37%
Andrew Reding <sup>(6)</sup>	13,372	0.29%
Timothy A. Krochuk <sup>(10)</sup>	1,786	0%
J. Melville Engle <sup>(11)</sup>	1,786	0%
Richard L. Gabriel <sup>(7)</sup>	401,786	8.80%
Joshua Kornberg <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%
All directors and executive officers as a group (8 persons)	528,019	11.57%

- (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 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 31, 2016, and (iv) 12,650 shares issuable upon exercise of options held by Dr. Schwartz that are exercisable within 60 days of December 31, 2016.
- (3) Includes options to purchase 4,780 shares that are exercisable within 60 days of December 31, 2016.
- (4) Includes options to purchase 4,668 shares that are exercisable within 60 days of December 31, 2016.
- (5) Includes options to purchase 17,063 shares that are exercisable within 60 days of December 31, 2016.
- (6) Includes options to purchase 13,319 shares that are exercisable within 60 days of December 31, 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. Includes options to purchase 1,786 shares that are exercisable within 60 days of December 31, 2016.
- (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.
- (10) Includes options to purchase 1,786 shares that are exercisable within 60 days of December 31, 2016.
- (11) Includes options to purchase 1,786 shares that are exercisable within 60 days of December 31, 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 1,750,000 shares of common stock and an aggregate of 350,000 Series D Warrants to purchase an aggregate of 350,000 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 31, 2016, we had 4,564,428 shares of common stock issued and outstanding and held by approximately 141 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 present at a meeting 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 350,000 Series D Warrants to purchase an aggregate of 350,000 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 warrants may also be exercised on a cashless basis in the event that no effective registration statement or prospectus is available at the time of exercise. In this case, the number of shares issuable upon exercise of a warrant will be calculated pursuant to a formula based on the volume weighted average price of the stock, as described in the warrant. The exercise price and number of shares of common stock insuable 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 book-entry form under a warrant agency agreement between Corporate Stock Transfer, Inc. as warrant agent, and us, and shall initially be represented by one or more book-entry certificates deposited with Cede & Co.

# 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 January 5, 2017, the last reported sale price per share for our common stock as reported by The NASDAQ Capital Market was \$2.66.



# 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. However, the underwriter is not required to take or pay for the Units covered by the underwriter's over-allotment option described below.

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 reallow, 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.

#### **Over-allotment Option**

We have granted to the underwriters a 45-day option to purchase (i) up to 175,000 additional shares of common stock at the public offering price per unit less the price per warrant included in the unit and less the underwriting discount or (ii) additional warrants to purchase up to 35,000 additional shares of common stock at a purchase price of \$0.01 per warrant to cover over-allotments, if any. The over-allotment option may be used to purchase common stock, warrants or any combination thereof, as determined by the underwriters, but such purchases cannot exceed an aggregate of 10% of the number of shares of common stock and warrants underlying the Units sold in the primary offering.

#### **Discounts, Commissions and Expenses**

The following table shows the underwriting discounts and commissions payable to the underwriter by us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriter's over-allotment option to purchase additional Units.

	Per Unit	Total Without Exercise of Over-Allotment Option	Total With Exercise of Over-Allotment Option
Public offering price (1)	\$	\$	\$
Underwriting discounts Payable by us	\$	\$	\$
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.

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  $\_$ .



# 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 underwriter may engage in stabilizing transactions, over-allotment 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.
- Over-allotment involves sales by the underwriter of securities in excess of the number of securities the underwriter is obligated to purchase, which
  creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the
  number of securities over-allotted by the underwriter is not greater than the number of securities that they may purchase in the over-allotment option.
  In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option.
  In a naked short position by either exercising their over-allotment option and/or purchasing securities in the open market.
- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriter will consider, among other things, the price of securities available for purchase in the open market as compared to the price at which it may purchase such securities through the overallotment option. If the underwriter sells more securities than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing 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 underwriter 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.

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## 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:

## INDEX TO FINANCIAL STATEMENTS

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Balance Sheets	<u>F-2</u>
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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. Our audits included consideration of 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	1	December 31, 2014
ASSETS				
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		5,397,834		631,315
Fixed Assets, net		139,598		196,479
Intangibles, net		94,987		73,183
Total Assets	\$	5,632,419	\$	900,977
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)				
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		1,519,708		6,203,321
Accrued Expenses		-		213,883
Liability for equity-linked financial instruments (See Note 8)		-		-
Total Liabilities	\$	1.519,708	\$	6,417,204
Commitments and Contingencies	<u>.</u>	-	. <u>.</u>	-
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		- 200
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)		4,112,711	_	(5,516,227)
Total Liabilities and Stockholders' Equity (Deficit)	\$	5,632,419	\$	900,977
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See Notes to Financial Statements

# SKYLINE MEDICAL INC. STATEMENTS OF OPERATIONS

	Yea	Year Ended December 31,			
	2015	;	2014		
Revenue	\$ 6	\$54,354	951,559		
Cost of goods sold	3	03,982	385,323		
Gross margin	3	50,372	566,236		
General and administrative expense	3,3	99,339	4,882,549		
Operations expense	8	46,687	972,830		
Sales and marketing expense	5	03,989	1,178,305		
Interest expense	3	90,887	377,719		
Loss (gain) on valuation of equity-linked financial instruments			(11,599)		
Total Expense	5,1	40,902	7,399,804		
Net loss available to common shareholders	\$ (4,7	90,530) \$	(6,833,568)		
Loss per common share - basic and diluted	\$	(30.86) \$	(57.13)		
Weighted average shares used in computation - basic and diluted	1	55,233	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							
	Pref	ferred			Paid-	Paid-		
		ock	Shares	Amount	in Capital	Deficit	Total	
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 Shares issued at \$515.75 per share as Investor Relations compensation			173 80	2	5,428 41,249		5,430 41,250	
Shares issued at \$315.75 per share as investor relations compensation 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 Reduction in escrow account per settlement agreement			53 (178)	1	24,999		25,000	
Shares issued for cashless warrant exercise at \$187.50 per share			192	(2)	(3,331) 3,603		(3,333) 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 Options issued as part of employee bonus				-	705,434 694,500		705,434 694,500	
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 Shares issued for cashless warrant exercise at \$337.50 per share			53	1	24,999		25,000	
Shares issued for cashess warrant exercise at \$537.50 per share Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as			149	1	2,793		2,794	
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			13 121	0	1,750 19,999		1,750 20,000	
Shares issued for a note conversion at \$167.00 per share 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			121	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			156 160	2 2	19,998		20,000	
Shares issued for a note conversion at \$125.00 per share Shares issued for a note conversion at \$131.50 per share			152	2	19,998 19,998		20,000 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	30,400	(30,402)	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) 138	(4) 1	(6,663) 9,999		(6,667) 10,000	
Shares issued for a note conversion at \$72.50 per share Shares issued for a note conversion at \$74.00 per share			270	3	19,999		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			105		20.200	(20, 401)		
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 Shares issued for a note conversion at \$56.82 per share			1,400 3,520	14 35	69,986 199,965		70,000 200,000	
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 Shares issued in public offering; net	14	6,667	66 667	667	871,877 13,043,546		871,877 13,060,880	
Preferred stock conversion		0,007 2,077	66,667 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	8,950	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

20152014Cash flow from operating activities:(4,790,530)Net loss(4,790,530)Adjustments to reconcile net loss to net cash used in operating activities:Depreciation and amortization78,566Vested stock options and warrants871,877Equity instruments issued for management and consulting(6,667)112,
Net loss(4,790,530)(6,833,Adjustments to reconcile net loss to net cash used in operating activities:78,56663,Depreciation and amortization78,56663,Vested stock options and warrants871,877723,
Adjustments to reconcile net loss to net cash used in operating activities:Depreciation and amortization78,566Vested stock options and warrants871,877723,
Depreciation and amortization78,56663,Vested stock options and warrants871,877723,
Vested stock options and warrants 871,877 723,
Equity instruments issued for management and consulting (6,667) 112,
Amortization of debt discount219,097247,
Penalty on debt provision 10,031
Loss on Sales of Equipment 17,076
(Gain) loss on valuation of equity-linked instruments - (11,
Changes in assets and liabilities:
Accounts receivable 19,266 39,
Inventories 135,627 (245,
Prepaid expense and other assets (81,564) (129,
Accounts payable (1,544,105) 1,132,
Accrued expenses (2,415,967) 1,594,
Deferred Revenue (64,
Net cash used in operating activities: (7,487,293) (3,371,
Cash flow from investing activities:
Purchase of fixed assets (32,470) (101,
Purchase of intangibles (28,095) (19,
Net cash used in investing activities(60,565)(121,
Carle Arm from from the activities
Cash flow from financing activities:250,0001,500,Proceeds from long-term and convertible debt250,0001,500,
Principal payments on debt (933,074) (305,
Net proceeds from issuance of preferred stock 18,950 2,055,
Net proceeds from issuance of prefered stock 13,051,830 157.
Net cash provided by financing activities12,387,7063,407,
Net increase (decrease) in cash 4,839,848 (85,
Cash at beginning of period 16,384 101,
Cash at end of period 4,856,232 16,
Non cash transactions:
Common stock issued for accrued interest/bonus694,
Common stock issued to satisfy debt 483,478 480,

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 3 2015	December 31, 2015		,		
Finished goods	\$ 30	237 \$	88,362			
Raw materials	162	623	237,556			
Work-In-Process	38	880	41,449			
Total	\$ 231	740 \$	367,367			

### **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:

	Y	lears	
Computers and office equipment	3	-	7
Leasehold improvements		5	
Manufacturing Tooling	3	-	7
Demo Equipment		3	

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

	De	cember 31, 2015	D	ecember 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 carry forwards 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 =  $(A \times B) / C$ 

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 (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 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 Op	otions	Warra	nts
	-	Average		Average
	Number of Shares	Exercise Price	Number of Shares	Exercise Price
Outstanding at December 31, 2013	15,430 \$	5 168.75	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 \$	5 187.75	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		5 133.25	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:

	a	Weighted Average Remaining
Range of Exercise Prices Options:	Shares	Life
\$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
Total	31,349	
Warrants:		
\$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
Total	323.098	2.10
1.0.111	323,098	

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 - 150.00 121.88 2013 9,310 596.25 2014 2,361 162.50 \_ 468.75 2015 14,170 65.75 86.25 18.75 31,349 \$ 596.25 Total

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

Warrants

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.

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:

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

(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	1	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 Valu	e 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			<u></u>					(1000)		(2000)		()	
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		20.047	1 40 007	1 4 7 4 6 9	1.604	(1.600)	6 0 0 0	6 0 0 0					
6/30/2009 Warrants issued	169,854	20,847	149,007	147,403	1,604	(4,689)	6,293	6,293	-	-	-	-	-
in quarter ended													
9/30/2009	39,743	(738)	40,481	40,419	62	(1,562)	1,624	910	714	714	-		_
Warrants is	57,74.	(750)	40,401	40,417	02	(1,502)	1,024	710	/14	/14			
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	51,552			50,740	392	(0,122)	0,/14	0,085	031	031	-	-	-
in quarter ended													
9/30/2010	31,506	5		20,891	10,615	(44,160)	54,775	1,338	53,437	53,437	-	-	-
Total	\$ 790,596		\$ 1,071,847		· · · · · · · · · · · · · · · · · · ·		\$ 166,063	\$ (3,116)	· · · · · · · · · · · · · · · · · · ·	\$ 157,580	\$ 11,599	\$ 11,599	s -
	\$ 790,590	φ (309,042)	φ 1,071,0 <del>4</del> 7	φ 1,1 <del>4</del> <i>3,292</i>	φ 14,940	φ (151,117)	\$ 100,005	<i>(</i> ,110)	φ 109,179	φ157,580	φ 11,399	φ 11, <i>399</i>	φ -

### NOTE 9 - RELATED PARTY TRANSACTIONS

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

In connection with the sale of the Series A Preferred Shares on February 4, 2014, Joshua Kornberg, our President, Chief Executive Officer and Interim Chairman of the Board, was one of the purchasers. Mr. Kornberg purchased 19,231 Series A Preferred Shares for a purchase price of \$25,000 and received warrants to purchase 3 shares of common stock.

SOK Partners, LLC ("SOK"), a 10% stockholder with Mr. Kornberg and Dr. Samuel Herschkowitz as managing partners, invested in the July 2014 offering of convertible notes and warrants. In November 2014, the convertible noteholders agreed to convert certain balances of the convertible notes in connection with the public offering of the Existing Units, in consideration of the agreement to issue certain additional shares. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – History Financing – 2014 Sales of Convertible Notes and Warrants." In connection with the Unit Offering in August 2015, all such convertible notes were redeemed at a redemption price of 140% of the principal amount thereof, plus accrued and unpaid interest. The Company paid approximately \$163,000 to SOK in redemption of its convertible note. In addition, Ricardo Koenigsberger, a former director who resigned on June 5, 2015, is a holder of membership units of SOK Partners.



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

### NOTE 10 - RETIREMENT SAVINGS PLANS

We have a pre-tax salary reduction/profit-sharing plan under the provisions of Section 401(k) of the Internal Revenue Code, which covers employees meeting certain eligibility requirements. In fiscal 2014, and again in 2015, we matched 100%, of the employee's contribution up to 4.0% of their earnings. The employer contribution was \$39,916 and \$37,730 in 2015 and 2014. There were no discretionary contributions to the plan in 2015 and 2014.

### NOTE 11 – SUPPLEMENTAL CASH FLOW DATA

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

## NOTE 12 – SUBSEQUENT EVENTS

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

### Schedule II

# Valuation and Qualifying Accounts

(None)

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

	Sept	ember 30, 2016	Dece	ember 31, 2015
Current Assets:				
Cash and Cash Equivalents	\$	634,478	\$	4,856,232
Marketable Securities (Note 11)	-	576,888	Ť	-
Accounts Receivable		45,017		38,283
Inventories		289,249		231,740
Prepaid Expense and other assets		163,188		271,579
Total Current Assets		1,708,820		5,397,834
		, , , ,		
Fixed Assets, net		110,910		139,598
Intangibles, net		97,335		94,987
Total Assets	\$	1,917,065	\$	5,632,419
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts Payable	\$	648,061	\$	650,413
Accrued Expenses		820,114		864,295
Deferred Revenue		5,000		5,000
Total Current Liabilities		1,473,175		1,519,708
		· · ·		
Accrued Expenses		432,376		-
Total Liabilities		1,905,551		1,519,708
Commitments and Contingencies		-		-
Stockholders' Equity:				
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		-
Total Stockholders' Equity		11,514		4,112,711
Total Liabilities and Stockholders' Equity	\$	1,917,065	\$	5,632,419

See Notes to Condensed Financial Statements

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

	Three Months Ended September 30,				Nine Months Ended September 30			
		2016	2015		2016	2015		
Revenue	\$	134,605	\$ 85,7	92 \$	316,931	\$ 47	1,078	
Cost of goods sold		26,481	19,7	73	149,130	19	9,307	
Gross Margin		108,124	66,0	19	167,801	27	1,771	
General and administrative expense		733,074	861,0	98	4,684,130	1,58	9,522	
Operations expense		292,856	202,7	99	928,062	37	5,429	
Sales and marketing expense		137,784	66,7	20	348,848	43	9,703	
Interest expense		3	51,8	04	3	39	4,641	
Total expense		1,163,717	1,182,4	21	5,961,043	2,79	9,295	
Net loss available to common shareholders		(1,055,593)	(1,116,4	02)	(5,793,242)	(2,52	7,524)	
Other comprehensive income								
Unrealized gain (loss) from marketable securities		(1,299)			4,579		-	
Comprehensive loss	\$	(1,056,892)	\$ (1,116,4	02) \$	(5,788,663)	\$ (2,52	7,524)	
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	157,4	45	2,250,315	13	7,428	

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			· · · · · · · · · · · · · · · · · · ·				<u> </u>
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
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	\$ 792	3,404,860	\$ 34,048	\$46,257,774	\$ (46,285,679)	\$ 4,579	\$ 11,514

See Notes to Condensed Financial Statements

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

	Nine Months H September 3	
	 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:	(( 72.4)	10.050
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 as 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	\$ 289,249	\$ 231,740		

#### **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	D	ecember 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	 308,760		283,677
Less: Accumulated depreciation	197,850		144,079
Total Fixed Assets, Net	\$ 110,910	\$	139,598

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."

# 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 Expired Exercised	14,171 (766)		69.00 293.25	303,269 (79) (120)		123.75 283.50 123.75	
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:

	Range of Prices	Shares	Weighted Remaining Life
Options			
\$	2.25	293	9.90
\$	2.42	37,152	9.89
\$	3.75	44,000	9.76
\$ 0	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 80.25	2,323 187	8.75
	80.25	232	9.01 8.50
\$ \$	121.875	5	6.45
\$ \$	121.875 131.25	81	5.94
\$ \$	148.125	928	6.47
\$ \$	148.125	1,760	5.88
\$	162.50	123	8.26
\$ \$	206.25	125	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

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.

114,102

# 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:



	Three Months Ended September 30,			Nine Months Ended Septem			eptember 30,	
		2016		2015 2016			2015	
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	\$	(0.32)	\$	(7.09)	\$	(2.57)	\$	(18.39)

(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:

	S	September 30, 2016	. <u> </u>	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 2017	9,500
	\$ 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. 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 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. Komberg 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:

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



1,750,000 Units, Each Unit Consisting of One Share of Common Stock and One Series D Warrant to Purchase 0.2 Shares of Common Stock

350,000 Shares of Common Stock Underlying the Series D Warrants

PROSPECTUS

Dawson James Securities, Inc.

The date of this Prospectus is , 2017

#### 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	\$ 854.07
FINRA filing fee	\$ 1,660.60
Printing and engraving expenses	\$ 10,000.00
Legal fees and expenses	\$ 50,000.00
Accounting fees and expenses	\$ 5,000.00
Total	\$ 67,514.67

#### **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.

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.

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.

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 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.

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.

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.

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.

# 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 Series D Warrant Certificate
4.12	Specimen certificate evidencing shares of Common Stock (25)
4.13*	Form of Series D Warrant Certificate (included as part of Exhibit 4.11)
4.14	Form of Exchange Agreement with Holders of Series A Preferred Stock (22)
4.15	Form of Amendment to Senior Convertible Notes and Agreement by and Between Skyline Medical Inc. and Senior Convertible Notes (22)
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 Komberg 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 Komberg dated August 13, 2012 (13)
10.11	Non-Qualified Stock Option Agreement with Josh Komberg 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 Grid 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

101\* Interactive Data File

# \* 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.
- (25) Filed on July 20, 2015 as an exhibit to our Registration Statement on Form S-1 (File No. 333-198962) and incorporated herein by reference.

## **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 to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration stateme
  - (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:

- (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.

# SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Amendment No. 1 to Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Eagan, on January 10, 2017.

# SKYLINE MEDICAL INC.

/s/ Bob Myers Bob Myers Chief Financial Officer

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 1 to Registration Statement has been signed below by the following persons in the capacities and on the dates indicated:

<u>Signature</u>	Title	Date
* Carl Schwartz	Chief Executive Officer (principal executive officer), Director	January 10, 2017
/s/ Bob Myers Bob Myers	Chief Financial Officer (principal financial and accounting officer),	January 10, 2017
* Thomas J. McGoldrick	Director	January 10, 2017
* Andrew Reding	Director	January 10, 2017
* Timothy A. Krochuk	Director	January 10, 2017
* J. Melville Engle	Director	January 10, 2017
* Richard Gabriel	Director	January 10, 2017

\*By: /s/ Bob Myers Bob Myers, Attorney-in-fact

# UNDERWRITING AGREEMENT

between

# SKYLINE MEDICAL INC.

and

DAWSON JAMES SECURITIES, INC., as Representative of the Several Underwriters

# SKYLINE MEDICAL INC.

#### **UNDERWRITING AGREEMENT**

January [•], 2017

Dawson James Securities, Inc. As Representative of the several Underwriters named on Schedule 1 attached hereto 1 North Federal Highway, 5<sup>th</sup> Floor Boca Raton, FL 33432

# Ladies and Gentlemen:

The undersigned, Skyline Medical Inc., a corporation formed under the laws of the State of Delaware (the "<u>Company</u>"), hereby confirms its agreement (this "<u>Agreement</u>") with Dawson James Securities, Inc. (the "<u>Representative</u>") and with the other underwriters named on <u>Schedule 1</u> hereto, if any, for which the Representative is acting as representative (the Representative and such other underwriters being collectively called the "<u>Underwriters</u>" or, individually, an "<u>Underwriter</u>") as follows:

#### 1. <u>Purchase and Sale of Firm Units</u>.

(a) <u>Common Stock and Series D Warrants</u>.

#### (i) <u>Nature and Purchase of Common Stock and Series D Warrants.</u>

(A) On the basis of the representations and warranties herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue and sell to the several Underwriters, an aggregate of 1,750,000 units ("<u>Units</u>") of securities, each such Unit consisting of (a) one share of the Company's common stock, par value \$0.01 per share (the "<u>Common Stock</u>") and (c) 0.2 Series D Warrants, which each whole Series D Warrant is exercisable to purchase one share of Common Stock (the "<u>Firm Warrants</u>"). The 1,750,000 Units referred to in this Section 1(a) (the "<u>Firm Units</u>"), and the Common Stock included within the Unit and the Firm Warrants comprising the Firm Units, as well as the shares of Common Stock issuable upon exercise of the Firm Warrants, are hereinafter referred to together as the "<u>Firm Securities</u>".

(B) The Underwriters, severally and not jointly, agree to purchase from the Company the number of Firm Units set forth opposite their respective names on Schedule 1 attached hereto and made a part hereof at a purchase price of  $\{\bullet\}$  (the "<u>Purchase Price</u>") per Unit (91% of the public offering price per Unit). The Units are to be offered initially to the public at the offering price set forth on the cover page of the Prospectus (as defined in Section 2(a)(i)(A) hereof).

# (ii) <u>Unit Payment and Delivery</u>.

(A) Delivery and payment for the Firm Units shall be made prior to 1:00 p.m., Eastern time, on the third (3<sup>rd</sup>) Business Day following the effective date (the "<u>Effective Date</u>") of the Registration Statement (as defined in Section 2(a)(i)(A) below) (or the fourth (4<sup>th</sup>) Business Day following the Effective Date if the Registration Statement is declared effective after 4:01 p.m., Eastern time) or at such earlier time as shall be agreed upon by the Representative and the Company, at the offices of Schiff Hardin LLP, 901 K Street NW, Suite 700, Washington DC 20001 ("<u>Representative Counsel</u>"), or at such other place (or by electronic transmission) as shall be agreed upon by the Representative and the Company. The hour and date of delivery and payment for the Firm Units is called the "<u>Closing Date</u>."

(B) Payment for the Firm Units shall be made on the Closing Date by wire transfer in federal (same day) funds, payable to the order of the Company upon delivery of the certificates (in form and substance satisfactory to the Underwriters) representing the Common Stock and Firm Warrants comprising the Firm Units (or through the facilities of the Depository Trust Company ("DTC")), for the account of the Underwriters. The securities comprising the Firm Units shall be registered in such name or names and in such authorized denominations as the Representative may request in writing two (2) full Business Days prior to the Closing Date. The Company shall not be obligated to sell or deliver the Firm Units except upon tender of payment by the Representative for all of the Firm Units or via delivery versus payment for the Firm Units. The term "Business Day" means any day other than a Saturday, a Sunday or a legal holiday or a day on which banking institutions are authorized or obligated by law to close in New York.

# (b) <u>Over-Allotment Option</u>.

(i) <u>Option Securities</u>. For the purposes of covering any over-allotments in connection with the distribution and sale of the Firm Units, the Representative is hereby granted an option (the "<u>Over-Allotment Option</u>") to purchase, in the aggregate, (a) up to 175,000 shares of Common Stock (10% of the Common Stock included in the Firm Units) at a purchase price of \$[•] per one share (the "<u>Option Shares</u>" and together with the Common Stock included in the Firm Units, the "<u>Shares</u>"), and/or (b) Warrants to purchase up to 35,000 shares of Common Stock (10% of the Warrants included in the Firm Units) (the "<u>Option Warrants</u>" and together with the Firm Warrants, the "<u>Warrants</u>"), which may be purchased in any combination of Option Shares and/or the Option Warrants. The Option Shares and the Option Warrants, as well as the Common Stock issuable upon exercise of the Option Warrants, are hereinafter referred to together as the "<u>Option Securities</u>." The Firm Securities and the Option Securities are collectively referred to as the "<u>Public Securities</u>." The Public Securities shall be issued directly by the Company and shall have the rights and privileges described in the Registration Statement, the Pricing Disclosure Package and the Prospectus referred to below. The offering and sale of the Public Securities is herein referred to as the "<u>Offering</u>."

(ii) Exercise of Option. The Over-allotment Option granted pursuant to Section 1(b)(i) hereof may be exercised by the Representative as to all (at any time) or any portion (from time to time) of the Option Securities within 45 days after the Effective Date. The purchase price to be paid per Option Securities shall be equal to the Purchase Price. The Underwriters shall not be under any obligation to purchase any Option Securities prior to the exercise of the Over-allotment Option. The Over-allotment Option granted hereby may be exercised by the giving of oral notice to the Company from the Representative, which shall be confirmed in writing by overnight mail or facsimile or other electronic transmission, setting forth the number of Option Securities to be purchased and the date and time for delivery of and payment for the Option Securities (the "Option Closing Date"), which shall not be later than five (5) full Business Days after the date of the notice or such other time as shall be agreed upon by the Company and the Representative, at the offices of Representative. If such delivery and payment for the Option Securities does not occur on the Closing Date, the Option Closing Date will be as set forth herein, (i) the Company shall become obligated to sell to the Underwriters the number of Option Securities specified in such notice and (ii) each of the Underwriters, acting severally and not jointly, shall purchase the same percentage of Option Securities as the percentage of Firm Units that it purchased purchase the Same percentage of Option Securities as the percentage of Firm Units that it purchase the same percentage of Option Securities as the percentage of Firm Units that it purchased purchase to Securities as the percentage of Firm Units that it purchased purchase does not Option Securities as the percentage of Firm Units that it purchased purchase does not Option Securities as the percentage of Firm Units that it purchased purchase does not Option Securities as the percentage of Firm Units that it purchased

(iii) Payment and Delivery. Payment for the Option Securities shall be made on the Option Closing Date by wire transfer in Federal (same day) funds, payable to the order of the Company upon delivery of the certificates (in form and substance satisfactory to the Underwriters) representing the Option Securities (or through the facilities of DTC) for the account of the Underwriters. The Option Securities shall be registered in such name or names and in such authorized denominations as the Representative may request in writing at least one (1) full Business Day prior to the Option Closing Date. The Company shall not be obligated to sell or deliver the Option Securities except upon tender of payment by the Representative for applicable Option Securities. The Option Closing Date may be simultaneous with, but not earlier than, the Closing Date.

2. <u>Representations and Warranties of the Company</u>. The Company represents and warrants to the Underwriters as of the Applicable Time (as defined below) and as of the Closing Date, as follows:

(a) <u>Filing of Registration Statement</u>.

(i) <u>Pursuant to the Securities Act</u>.

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(A) The Company has filed with the U.S. Securities and Exchange Commission (the "<u>Commission</u>") a registration statement, and an amendment or amendments thereto, on Form S-1 (File No. 333-215005), including any related prospectus or prospectuses, for the registration of the Public Securities under the Securities Act of 1933, as amended (the "<u>Securities Act</u>"), which registration statement and amendment or amendments have been prepared by the Company in conformity in all material respects with the requirements of the Securities Act and the rules and regulations of the Commission under the Securities Act (the "<u>Securities Act Regulations</u>") and will contain all material statements that are required to be stated therein in accordance with the Securities Act and the Securities Act Regulations. Except as the context may otherwise require, such registration statement, as amended, on file with the Commission at the time the registration statement became effective (including the Preliminary Prospectus included in the registration deemed to be a part thereof as of the Effective Date pursuant to paragraph (b) of Rule 430A of the Securities Act Regulations (the "<u>Registration Statement</u>." If the Company files any registration statement pursuant to Rule 462(b) of the Securities Act Regulations, then after such filing, the term "<u>Registration Statement</u>" shall include such registration statement filed pursuant to Rule 462(b). The Registration Statement has been declared effective by the Commission on the date hereof.

(B) Each prospectus used prior to the effectiveness of the Registration Statement, and each prospectus that omitted the Rule 430A Information that was used after such effectiveness and prior to the execution and delivery of this Agreement, is herein called a "<u>Preliminary</u> <u>Prospectus</u>." The Preliminary Prospectus, subject to completion, dated August 19, 2015, that was included in the Registration Statement immediately prior to the Applicable Time is hereinafter called the "<u>Prospectus</u>." The final prospectus in the form first furnished to the Underwriters for use in the Offering is hereinafter called the "<u>Prospectus</u>." Any reference to the "most recent Preliminary Prospectus" shall be deemed to refer to the latest Preliminary Prospectus included in the Registration Statement.

# (C) "Applicable Time" means 4:30 p.m., Eastern time, on the date of this Agreement.

(D) <u>"Issuer Free Writing Prospectus</u>" means any "issuer free writing prospectus," as defined in Rule 433 of the Securities Act Regulations ("Rule 433"), including without limitation any "free writing prospectus" (as defined in Rule 405 of the Securities Act Regulations) relating to the Public Securities that is (i) required to be filed with the Commission by the Company, (ii) a "road show that is a written communication" within the meaning of Rule 433(d)(8)(i), whether or not required to be filed with the Commission, or (iii) exempt from filing with the Commission pursuant to Rule 433(d)(5)(i) because it contains a description of the Public Securities or of the Offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g).

(E) "<u>Issuer General Use Free Writing Prospectus</u>" means any Issuer Free Writing Prospectus that is intended for general distribution to prospective investors (other than a "*bona fide* electronic road show," as defined in Rule 433 (the "<u>Bona Fide Electronic Road Show</u>"), as evidenced by its being specified in <u>Schedule 2-B</u> hereto.

(F) "Issuer Limited Use Free Writing Prospectus" means any Issuer Free Writing Prospectus that is not an Issuer General Use Free Writing Prospectus.

(G) "<u>Pricing Disclosure Package</u>" means any Issuer General Use Free Writing Prospectus issued at or prior to the Applicable Time, the Pricing Prospectus and the information included on <u>Schedule 2-A</u> hereto, all considered together.

(ii) <u>Pursuant to the Exchange Act</u>. The Company has filed with the Commission a Form 8-A providing for the registration pursuant to Section 12(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), of the Units. The registration of the Units under the Exchange Act has been declared effective by the Commission on or prior to the date hereof. The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Units under the Exchange Act, nor has the Company received any notification that the Commission is contemplating terminating such registration.

(b) <u>Stock Exchange Listing</u>. The shares of Common Stock are approved for listing on The NASDAQ Capital Market (the "<u>Exchange</u>") and the Company has taken no action designed to, or likely to have the effect of, delisting the shares of Common Stock from the Exchange, nor has the Company received any notification that the Exchange is contemplating terminating either such listing.

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(c) <u>No Stop Orders, etc.</u> Neither the Commission nor, to the Company's knowledge, any state regulatory authority has issued any order preventing or suspending the use of the Registration Statement, any Preliminary Prospectus or the Prospectus or has instituted or, to the Company's knowledge, threatened to institute, any proceedings with respect to such an order. The Company has complied with each request (if any) from the Commission for additional information.

# (d) <u>Disclosures in Registration Statement</u>.

# (i) <u>Compliance with Securities Act and 10b-5 Representation</u>.

(A) Each of the Registration Statement and any post-effective amendment thereto, at the time it became effective, complied in all material respects with the requirements of the Securities Act and the Securities Act Regulations. Each Preliminary Prospectus, including the prospectus filed as part of the Registration Statement as originally filed or as part of any amendment or supplement thereto, and the Prospectus, at the time each was filed with the Commission, complied in all material respects with the requirements of the Securities Act and the Securities Act Regulations. Each Preliminary Prospectus delivered to the Underwriters for use in connection with this Offering and the Prospectus was or will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(B) Neither the Registration Statement nor any amendment thereto, at its effective time, as of the Applicable Time or at the Closing Date or at any Option Closing Date, contained, contains or will contain an untrue statement of a material fact or omitted, omits or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading.

(C) The Pricing Disclosure Package, as of the Applicable Time or at the Closing Date or at any Option Closing Date, did not, does not and will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; and each Issuer Limited Use Free Writing Prospectus does not conflict with the information contained in the Registration Statement, any Preliminary Prospectus, the Pricing Prospectus or the Prospectus, and each such Issuer Limited Use Free Writing Prospectus, as supplemented by and taken together with the Pricing Prospectus as of the Applicable Time, did not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to statements made or statements of use in the Registration Statement, the Pricing Prospectus or the Prospectus or the Prospectus or the Prospectus or any amendment thereof or supplement thereto. The parties acknowledge and agree that such information provided by or on behalf of any Underwriter consists solely of the following disclosure contained in the "Underwriting" section; "– Discounts, Commissions, Expenses"; "– Price Stabilization, Short Positions and Penalty Bids"; and "– Electronic Distribution" (the "<u>Underwriters' Information</u>"); and

(D) Neither the Prospectus nor any amendment or supplement thereto (including any prospectus wrapper), as of its issue date, at the time of any filing with the Commission pursuant to Rule 424(b) or at the Closing Date or at any Option Closing Date, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to the Underwriters' Information.

Disclosure of Agreements. The agreements and documents described in the Registration Statement, the Pricing Disclosure Package and the Prospectus conform in all material respects to the descriptions thereof contained therein and there are no agreements or other documents required by the Securities Act and the Securities Act Regulations to be described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or to be filed with the Commission as exhibits to the Registration Statement, that have not been so described or filed. Each agreement or other instrument (however characterized or described) to which the Company is a party or by which it is or may be bound or affected and (i) that is referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus, and (ii) is material to the Company's business, has been duly authorized and validly executed by the Company, is in full force and effect in all material respects and is enforceable against the Company and, to the Company's knowledge, the other parties thereto, in accordance with its terms, except (x) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally, (y) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws, and (z) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought. None of such agreements or instruments has been assigned by the Company, and neither the Company nor, to the Company's knowledge, any other party is in material default thereunder and, to the Company's knowledge, no event has occurred that, with the lapse of time or the giving of notice, or both, would constitute a material default thereunder, except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus. To the Company's knowledge, performance by the Company of the material provisions of such agreements or instruments will not result in a violation of any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company or any of its assets or business (each, a "Governmental Entity"), including, without limitation, those relating to environmental laws and regulations.



(iii) <u>Prior Securities Transactions</u>. Since January 1, 2014, no securities of the Company have been sold by the Company or by or on behalf of, or for the benefit of, any person or persons controlling, controlled by or under common control with the Company, except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Preliminary Prospectus.

(iv) <u>Regulations</u>. The disclosures in the Registration Statement, the Pricing Disclosure Package and the Prospectus concerning the effects of federal, state, local and all foreign laws, rules and regulations relating to the Company's business as currently contemplated are correct in all material respects and no other such regulations are required to be disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus which are not so disclosed.

# (e) <u>Changes After Dates in Registration Statement.</u>

(i) <u>No Material Adverse Change</u>. Since the respective dates as of which information is given in the Registration Statement, the Pricing Disclosure Package and the Prospectus, except as otherwise specifically stated therein: (i) there has been no material adverse change in the financial position or results of operations of the Company, nor any change or development that, singularly or in the aggregate, would involve a material adverse change, in or affecting the condition (financial or otherwise), results of operations, business, assets or prospects of the Company (a "<u>Material Adverse</u> <u>Change</u>"); (ii) there have been no material transactions entered into by the Company, other than as contemplated pursuant to this Agreement; and (iii) no officer or director of the Company has resigned from any position with the Company.

(ii) <u>Recent Securities Transactions, etc.</u> Subsequent to the respective dates as of which information is given in the Registration Statement, the Pricing Disclosure Package and the Prospectus, and except as may otherwise be indicated or contemplated herein or disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has not: (i) issued any securities (other than (i) grants under any stock compensation plan and (ii) shares of common stock issued upon exercise or conversion of option, warrants or convertible securities described in the Registration Statement, the Pricing Disclosure Package and the Prospectus) or incurred any liability or obligation, direct or contingent, for borrowed money; or (ii) declared or paid any dividend or made any other distribution on or in respect to its capital stock.

(f) Independent Accountants. To the knowledge of the Company, Olsen Thielen & Co., Ltd.(the "Auditor"), whose report is filed with the Commission as part of the Registration Statement, the Pricing Disclosure Package and the Prospectus, is an independent registered public accounting firm as required by the Securities Act and the Securities Act Regulations and the Public Company Accounting Oversight Board. The Auditor has not, during the periods covered by the financial statements included in the Registration Statement, the Pricing Disclosure Package and the Prospectus, provided to the Company any non-audit services, as such term is used in Section 10A(g) of the Exchange Act.

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SEC Reports; Financial Statements, etc. As of their respective dates, the reports, schedules, forms, statements and other documents (g) required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the "SEC Reports") complied as to form in all material respects with the requirements of the Securities Act and the Exchange Act and the rules and regulations of the Commission promulgated thereunder, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The financial statements, including the notes thereto and supporting schedules included in the Registration Statement, the Pricing Disclosure Package and the Prospectus, fairly present in all material respects the financial position and the results of operations of the Company at the dates and for the periods to which they apply; and such financial statements have been prepared in conformity with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), consistently applied throughout the periods involved (provided that unaudited interim financial statements are subject to year-end audit adjustments that are not expected to be material in the aggregate and do not contain all footnotes required by GAAP); and the supporting schedules included in the Registration Statement present fairly in all material respects the information required to be stated therein. Except as included therein, no historical or pro forma financial statements are required to be included in the Registration Statement, the Pricing Disclosure Package or the Prospectus under the Securities Act or the Securities Act Regulations. The pro forma and pro forma as adjusted financial information and the related notes, if any, included in the Registration Statement, the Pricing Disclosure Package and the Prospectus have been properly compiled and prepared in all material respects in accordance with the applicable requirements of the Securities Act and the Securities Act Regulations and present fairly in all material respects the information shown therein, and the assumptions used in the preparation thereof are reasonable and the adjustments used therein are appropriate to give effect to the transactions and circumstances referred to therein. All disclosures contained in the Registration Statement, the Pricing Disclosure Package or the Prospectus regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission), if any, comply with Regulation G of the Exchange Act and Item 10 of Regulation S-K of the Securities Act, to the extent applicable. Each of the Registration Statement, the Pricing Disclosure Package and the Prospectus discloses all material off-balance sheet transactions, arrangements, obligations (including contingent obligations), and other relationships of the Company with unconsolidated entities or other persons that may have a material current or future effect on the Company's financial condition, changes in financial condition, results of operations, liquidity, capital expenditures, capital resources, or significant components of revenues or expenses. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (a) the Company has not incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions other than in the ordinary course of business, (b) the Company has not declared or paid any dividends or made any distribution of any kind with respect to its capital stock, (c) there has not been any change in the capital stock of the Company (other than (i) grants under any stock compensation plan and (ii) shares of common stock issued upon exercise or conversion of option, warrants or convertible securities described in the Registration Statement, the Pricing Disclosure Package and the Prospectus), and (d) there has not been any Material Adverse Change in the Company's long-term or short-term debt.

(h) <u>Authorized Capital; Options, etc.</u> The Company had, at the date or dates indicated in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the duly authorized, issued and outstanding capitalization as set forth therein. Based on the assumptions stated in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company will have on the Closing Date the adjusted stock capitalization set forth therein. Except as set forth in, or contemplated by, the Registration Statement, the Pricing Disclosure Package and the Prospectus, on the Effective Date, as of the Applicable Time and on the Closing Date, there will be no stock options, warrants, or other rights to purchase or otherwise acquire any authorized, but unissued shares of Common Stock of the Company or any security convertible or exercisable into shares of Common Stock of the Company, or any contracts or commitments to issue or sell shares of Common Stock or any such options, warrants, rights or convertible securities.

#### (i) <u>Valid Issuance of Securities, etc.</u>

(i) <u>Outstanding Securities</u>. All issued and outstanding securities of the Company issued prior to the transactions contemplated by this Agreement have been duly authorized and validly issued and are fully paid and non-assessable; the holders thereof have no rights of rescission with respect thereto, and are not subject to personal liability by reason of being such holders; and except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, none of such securities were issued in violation of the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. The authorized shares of Common Stock and other securities of the Company to be outstanding upon consummation of the Offering conform in all material respects to all statements relating thereto contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus. The offers and sales of the outstanding shares of Common Stock were at all relevant times either registered under the Securities Act and the applicable state securities or "blue sky" laws or, based in part on the representations and warranties of the purchasers of such shares, exempt from such registration requirements.

(ii) <u>Securities Sold Pursuant to this Agreement</u>. The Public Securities have been duly authorized for issuance and sale and, when issued and paid for, will be validly issued, fully paid and non-assessable; the holders thereof are not and will not be subject to personal liability by reason of being such holders; the Public Securities are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company; and all corporate action required to be taken for the authorization, issuance and sale of the Public Securities has been duly and validly taken; the shares of Common Stock issuable upon exercise of the Warrants included in the Public Securities (the "<u>Underlying Common Stock</u>") have been duly authorized and reserved for issuance by all necessary corporate action on the part of the Company and when issued in accordance with such Warrants, such shares of Underlying Common Stock will be validly issued, fully paid and non-assessable; the Public Securities conform in all material respects to all statements with respect thereto contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(j) <u>Registration Rights of Third Parties</u>. Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, no holders of any securities of the Company or any rights exercisable for or convertible or exchangeable into securities of the Company have the right to require the Company to register any such securities of the Company under the Securities Act or to include any such securities in a registration statement to be filed by the Company (except for any such rights that have been waived).

(k) <u>Validity and Binding Effect of Agreements</u>. This Agreement and the Series D Warrant Agreement by and between the Company and Corporate Stock Transfer, Inc. (the "<u>Warrant Agreement</u>") have been duly and validly authorized by the Company, and, when executed and delivered, will constitute, the valid and binding agreements of the Company, enforceable against the Company in accordance with their respective terms, except: (i) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally; (ii) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws; and (iii) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

(1) No Conflicts, etc. The execution, delivery and performance by the Company of this Agreement, the Warrant Agreement and all ancillary documents, the consummation by the Company of the transactions herein and therein contemplated and the compliance by the Company with the terms hereof and thereof do not and will not, with or without the giving of notice or the lapse of time or both: (i) result in a breach of, or conflict with any of the terms and provisions of, or constitute a material default under, or result in the creation, modification, termination or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to the terms of any agreement or instrument to which the Company is a party; (ii) result in any violation of the provisions of the Company's Certificate of Incorporation (as the same may be amended or restated from time to time, the "<u>Charter</u>") or the by-laws of the Company (as the same may be amended or restated from time to time, the "<u>Charter</u>") or the provision of the U.S. Department of Health and Human Services (the "<u>FDA</u>") or by any foreign, federal, state or local regulatory authority performing functions similar to those performed by the FDA, except in the cases of clauses (i) and (iii) for such breaches, conflicts or violations which would not reasonably be expected to have a Material Adverse Change.

Regulatory. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or as would not (m) reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change: (i) the Company has not received any FDA Form 483, notice of adverse finding, warning letter or other correspondence or notice from the FDA or any other Governmental Entity alleging or asserting noncompliance with any Applicable Laws (as defined in clause (ii) below) or Authorizations (as defined in clause (iii) below); (ii) the Company is and has been in material compliance with statutes, laws, ordinances, rules and regulations applicable to the Company for the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company, including without limitation, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., similar laws of other Governmental Entities and the regulations promulgated pursuant to such laws (collectively, "Applicable Laws"); (iii) the Company possesses all licenses, certificates, approvals, clearances, consents, authorizations, qualifications, registrations, permits, and supplements or amendments thereto required by any such Applicable Laws and/or to carry on its businesses as now conducted ("Authorizations") and such Authorizations are valid and in full force and effect and the Company is not in violation of any term of any such Authorizations; (iv) the Company has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Entity or third party alleging that any product, operation or activity is in violation of any Applicable Laws or Authorizations or has any knowledge that any such Governmental Entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding, nor, to the best of the Company's knowledge, has there been any material noncompliance with or violation of any Applicable Laws by the Company that could reasonably be expected to require the issuance of any such communication or result in an investigation, corrective action, or enforcement action by FDA or similar Governmental Entity; (v) the Company has not received notice that any Governmental Entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations or has any knowledge that any such Governmental Entity has threatened or is considering such action; (vi) the Company has filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete, correct and not misleading on the date filed (or were corrected or supplemented by a subsequent submission); and (vii) the Company has not, either voluntarily or involuntarily, initiated, conducted or issued, or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company's knowledge, no third party has initiated, conducted or intends to initiate or conduct such notice or action. Neither the Company nor, to the Company's knowledge, any of its directors, officers, employees or agents has been convicted of any crime under any Applicable Laws or has been the subject of an FDA debarment proceeding. The Company has not been or is now subject to FDA's Application Integrity Policy. To the Company's knowledge, neither the Company, nor any of its directors, officers, employees or agents, has made, or caused the making of, any false statements on, or material omissions from, any other records or documentation prepared or maintained to comply with the requirements of the FDA or any other Governmental Entity. Neither the Company nor, to the Company's knowledge, any of its directors, officers, employees or agents, have with respect to each of the following statutes, or regulations promulgated thereto, as applicable: (i) engaged in activities under 42 U.S.C. §§ 1320a-7b or 1395nn; (ii) knowingly engaged in any activities under 42 U.S.C. § 1320a-7b or the Federal False Claims Act, 31 U.S.C. § 3729; or (iii) knowingly and willfully engaged in any activities under 42 U.S.C. § 1320a-7b, which are prohibited, cause for civil penalties, or mandatory or permissive exclusion from Medicare, Medicaid, or any other State Health Care Program or Federal Health Care Program.

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(n) <u>No Defaults: Violations</u>. No material default exists in the due performance and observance of any term, covenant or condition of any material license, contract, indenture, mortgage, deed of trust, note, loan or credit agreement, or any other agreement or instrument evidencing an obligation for borrowed money, or any other material agreement or instrument to which the Company is a party or by which the Company may be bound or to which any of the properties or assets of the Company is subject. The Company is not (i) in violation of any term or provision of its Charter or Bylaws, or (ii) in violation of any franchise, license, permit, applicable law, rule, regulation, judgment or decree of any Governmental Entity applicable to the Company.

## (o) <u>Corporate Power; Licenses; Consents</u>.

(i) <u>Conduct of Business</u>. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has all requisite corporate power and authority, and has all necessary authorizations, approvals, orders, licenses, certificates and permits of and from all governmental regulatory officials and bodies that it needs as of the date hereof to conduct its business purpose as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(ii) <u>Transactions Contemplated Herein</u>. The Company has all corporate power and authority to enter into this Agreement and to carry out the provisions and conditions hereof, and all consents, authorizations, approvals and orders required in connection therewith have been obtained. No consent, authorization or order of, and no filing with, any court, government agency or other body is required for the valid issuance, sale and delivery of the Public Securities and the consummation of the transactions and agreements contemplated by this Agreement, and as contemplated by the Registration Statement, the Pricing Disclosure Package and the Prospectus, except with respect to applicable federal and state securities laws and the rules and regulations of the Financial Industry Regulatory Authority, Inc. ("FINRA").

(p) <u>D&O Questionnaires</u>. To the Company's knowledge, all information contained in the questionnaires (the "<u>Questionnaires</u>") completed by each of the Company's directors and officers immediately prior to the Offering (the "<u>Insiders</u>") as supplemented by all information concerning the Company's directors, officers and principal stockholders as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, provided to the Underwriters, is true and correct in all material respects and the Company has not become aware of any information which would cause the information disclosed in the Questionnaires to become materially inaccurate and incorrect.

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(q) <u>Litigation: Governmental Proceedings</u>. There is no material action, suit, proceeding, inquiry, arbitration, investigation, litigation or governmental proceeding pending or, to the Company's knowledge, threatened against, or involving the Company or, to the Company's knowledge, any executive officer or director which has not been disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus which is required to be disclosed.

(r) <u>Good Standing</u>. The Company has been duly organized and is validly existing as a corporation and is in good standing under the laws of the State of Delaware as of the date hereof, and is duly qualified to do business and is in good standing in each other jurisdiction in which its ownership or lease of property or the conduct of business requires such qualification, except where the failure to qualify, singularly or in the aggregate, would not have or reasonably be expected to result in a Material Adverse Change.

(s) Insurance. The Company carries or is entitled to the benefits of insurance, with, to the Company's knowledge, reputable insurers, and in such amounts and covering such risks which the Company believes are reasonably adequate, and all such insurance is in full force and effect. The Company has no reason to believe that it will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not result in a Material Adverse Change.

### (t) <u>Transactions Affecting Disclosure to FINRA</u>.

(i) <u>Finder's Fees.</u> Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, there are no claims, payments, arrangements or understandings relating to the payment of a finder's, consulting or origination fee by the Company or any Insider with respect to the sale of the Public Securities hereunder or any other arrangements, agreements or understandings of the Company or, to the Company's knowledge, any of its stockholders that may affect the Underwriters' compensation, as determined by FINRA.

(ii) <u>Payments Within Six (6) Months</u>. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has not made any direct or indirect payments (in cash, securities or otherwise) to: (i) any person, as a finder's fee, consulting fee or otherwise, in consideration of such person raising capital for the Company or introducing to the Company persons who raised or provided capital to the Company; (ii) any FINRA member; or (iii) any person or entity that has any direct or indirect affiliation or association with any FINRA member, within the six (6) months prior to the Effective Date, other than the payment to the Underwriters as provided hereunder in connection with the Offering.

(iii) <u>Use of Proceeds</u>. None of the net proceeds of the Offering will be paid by the Company to any participating FINRA member or its affiliates, except as specifically authorized herein.

(iv) <u>FINRA Affiliation</u>. There is no (i) officer or director of the Company, (ii) to the Company's knowledge, beneficial owner of 5% or more of any class of the Company's securities or (iii) to the Company's knowledge, beneficial owner of the Company's unregistered equity securities which were acquired during the 180-day period immediately preceding the filing of the Registration Statement that, in each case, is an affiliate or associated person of a FINRA member participating in the Offering (as determined in accordance with the rules and regulations of FINRA).

(v) Information. All information provided by the Company in its FINRA Questionnaire to Representative Counsel specifically for use by Representative Counsel in connection with its Public Offering System filings (and related disclosure) with FINRA is true, correct and complete in all material respects.

(u) <u>Foreign Corrupt Practices Act</u>. Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any other person acting on behalf of the Company, has, directly or indirectly, given or agreed to give any money, gift or similar benefit (other than legal price concessions to customers in the ordinary course of business) to any customer, supplier, employee or agent of a customer or supplier, or official or employee of any governmental agency or instrumentality of any government (domestic or foreign) or any political party or candidate for office (domestic or foreign) or other person who was, is, or may be in a position to help or hinder the business of the Company (or assist it in connection with any actual or proposed transaction) that (i) might subject the Company to any damage or penalty in any civil, criminal or governmental litigation or proceeding, (ii) if not given in the past, might have had a Material Adverse Change or (iii) if not continued in the future, might adversely affect the assets, business, operations or prospects of the Company. The Company has taken reasonable steps to ensure that its accounting controls and procedures are sufficient to cause the Company to comply in all material respects with the Foreign Corrupt Practices Act of 1977, as amended.

(v) <u>Compliance with OFAC</u>. Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any other person acting on behalf of the Company, is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury ("<u>OFAC</u>"), and the Company will not, directly or indirectly, use the proceeds of the Offering hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(w) <u>Money Laundering Laws</u>. The operations of the Company are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the "<u>Money Laundering Laws</u>"); and no action, suit or proceeding by or before any Governmental Entity involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(x) Officers' Certificate. Any certificate signed by any duly authorized officer of the Company and delivered to you or to Representative Counsel shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

- (y) <u>Reserved.</u>
- (z) <u>Subsidiaries</u>. The Company has no direct or indirect subsidiaries and does not hold any equity interests in any other entity.

(aa) <u>Related Party Transactions</u>. There are no business relationships or related party transactions involving the Company or any other person required to be described in the Registration Statement, the Pricing Disclosure Package and the Prospectus that have not been described as required.

(bb) <u>Board of Directors</u>. The Board of Directors of the Company is comprised of the persons set forth under the heading of the Pricing Prospectus and the Prospectus captioned "Management." The qualifications of the persons serving as board members and the overall composition of the board comply with the Exchange Act, the Exchange Act Regulations, the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder (the "<u>Sarbanes-Oxley Act</u>") applicable to the Company and the listing rules of the Exchange. At least one member of the Audit Committee of the Board of Directors of the Company qualifies as an "audit committee financial expert," as such term is defined under Regulation S-K and the listing rules of the Exchange. In addition, at least a majority of the persons serving on the Board of Directors qualify as "independent," as defined under the listing rules of the Exchange.

### (cc) <u>Sarbanes-Oxley Compliance</u>.

(i) <u>Disclosure Controls</u>. The Company has developed and currently maintains disclosure controls and procedures that will comply with Rule 13a-15 or 15d-15 under the Exchange Act Regulations applicable to it, and such controls and procedures are effective to ensure that all material information concerning the Company will be made known on a timely basis to the individuals responsible for the preparation of the Company's Exchange Act filings and other public disclosure documents.

(ii) <u>Compliance</u>. The Company is, or at the Applicable Time and on the Closing Date will be, in material compliance with the provisions of the Sarbanes-Oxley Act applicable to it, and has implemented or will implement such programs and taken reasonable steps to ensure the Company's future compliance (not later than the relevant statutory and regulatory deadlines therefor) with all of the material provisions of the Sarbanes-Oxley Act.

(dd) Accounting Controls. The Company maintains systems of "internal control over financial reporting" (as defined under Rules 13a-15 and 15d-15 under the Exchange Act Regulations) that comply in all material respects with the requirements of the Exchange Act and have been designed by, or under the supervision of, its principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company have been advised of: (i) all significant deficiencies and material weaknesses, if any, in the design or operation of internal controls over financial reporting which are known to the Company's management and that have adversely affected or are reasonably likely to adversely affect the Company' ability to record, process, summarize and report financial information; and (ii) any fraud, if any, known to the Company's management, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls over financial reporting.

(ee) <u>No Investment Company Status</u>. The Company is not and, after giving effect to the Offering and the application of the proceeds thereof as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, will not be, required to register as an "investment company," as defined in the Investment Company Act of 1940, as amended.

#### (ff) <u>No Labor Disputes</u>. No labor dispute with the employees of the Company exists or, to the knowledge of the Company, is imminent.

Intellectual Property Rights. To the Company's knowledge, the Company has, or can acquire on reasonable terms, ownership of and/or (gg)license to, or otherwise has the right to use, all inventions, know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures), patents and patent rights trademarks, service marks and trade names, copyrights, (collectively "Intellectual Property") material to carrying on its businesses as described in the Pricing Prospectus. The Company has not received any correspondence relating to any Intellectual Property, including notice of: (A) infringement or misappropriation of, or conflict with, any Intellectual Property of a third party; (B) asserted rights of others with respect to any Intellectual Property of the Company; (C) assertions that any Intellectual Property of the Company is invalid or otherwise inadequate to protect the interest of the Company, that in each case (if the subject of any unfavorable decision, ruling or finding), individually or in the aggregate, would have or would reasonably be expected to have a Material Adverse Change. There are no third parties who have been able to establish any material rights to any Intellectual Property, except for the retained rights of the owners or licensors of any Intellectual Property that is licensed to the Company. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the validity, enforceability or scope of any Intellectual Property of the Company or (B) challenging the Company's rights in or to any Intellectual Property or (C) that the Company materially infringes, misappropriates or otherwise violates or conflicts with any Intellectual Property or other proprietary rights of others. The Company has complied in all material respects with the terms of each agreement described in the Registration Statement, Pricing Disclosure Package or Prospectus pursuant to which any Intellectual Property is licensed to the Company, and all such agreements related to products currently made or sold by the Company, or to product candidates currently under development, are in full force and effect. All patents issued in the name of, or assigned to, the Company, and all patent applications made by or on behalf of the Company (collectively, the "Company Patents") have been duly and properly filed. The Company is not aware of any material information that was required to be disclosed to the United States Patent and Trademark Office (the "PTO") but that was not disclosed to the PTO with respect to any issued Company Patent, or that is required to be disclosed and has not yet been disclosed in any pending application in the Company Patents and that would preclude the grant of a patent on such application. To the Company's knowledge, the Company is the sole owner of the Company Patents.

(hh) Taxes. The Company has filed all returns (as hereinafter defined) required to be filed with taxing authorities prior to the date hereof or has duly obtained extensions of time for the filing thereof. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has paid all taxes (as hereinafter defined) shown as due on such returns that were filed and has paid all taxes imposed on or assessed against the Company, except for such exceptions as would not be expected, individually or in the aggregate, to have a Material Adverse Change. The provisions for taxes payable, if any, shown on the financial statements filed with or as part of the Registration Statement are sufficient for all accrued and unpaid taxes, whether or not disputed, and for all periods to and including the dates of such consolidated financial statements. Except as disclosed in writing to the Underwriters, (i) no issues have been raised (and are currently pending) by any taxing authority in connection with any of the returns or taxes asserted as due from the Company, and (ii) no waivers of statutes of limitation with respect to the returns or collection of taxes have been given by or requested from the Company. The term "taxes" mean all federal, state, local, foreign and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments or charges of any kind whatever, together with any interest and any penalties, additions to tax or additional amounts with respect thereto. The term "returns" means all returns, declarations, reports, statements and other documents required to be filed in respect to taxes.

(ii) <u>Employee Benefit Laws</u>. The operations of the Company are and have been conducted at all times in material compliance with the Employee Retirement Income Security Act of 1974, as amended, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "<u>Employee Benefit Laws</u>"). Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or its subsidiaries with respect to the Employee Benefit Laws is pending or, to the knowledge of the Company, threatened.

Compliance with Laws. The Company: (A) is and at all times has been in compliance with all Applicable Laws, except as would not, (jj) individually or in the aggregate, reasonably be expected to have a Material Adverse Change; (B) has not received any correspondence from any Governmental Entity alleging or asserting noncompliance with any Applicable Laws or any Authorizations; (C) possesses all material Authorizations and such Authorizations are valid and in full force and effect and the Company is not in material violation of any term of any such Authorizations, in each case except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Change; (D) has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Entity or third party alleging that any product operation or activity is in violation of any Applicable Laws or Authorizations and has no knowledge that any such Governmental Entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (E) has not received written notice that any Governmental Entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations; (F) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct in all material respects on the date filed (or were corrected or supplemented by a subsequent submission); and (G) has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company's knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

(ll) <u>Industry Data</u>. The statistical and market-related data included in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus are based on or derived from sources that the Company reasonably and in good faith believes are reliable and accurate or represent the Company's good faith estimates that are made on the basis of data derived from such sources.

(mm) <u>Website</u>. None of the information on (or hyperlinked from) the Company's website at www.skylinemedical.com includes or constitutes a "free writing prospectus" as defined in Rule 405 under the Securities Act.

(nn) <u>Forward-Looking Statements</u>. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) contained in the Registration Statement, the Pricing Disclosure Package or the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(oo) <u>Margin Securities</u>. The Company owns no "margin securities" as that term is defined in Regulation U of the Board of Governors of the Federal Reserve System (the "<u>Federal Reserve Board</u>"), and none of the proceeds of Offering will be used, directly or indirectly, for the purpose of purchasing or carrying any margin security, for the purpose of reducing or retiring any indebtedness which was originally incurred to purchase or carry any margin security or for any other purpose which might cause any of the shares of Underlying Common Stock to be considered a "purpose credit" within the meanings of Regulation T, U or X of the Federal Reserve Board.

(pp) Integration. Neither the Company, nor any of its affiliates, nor any person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause the Offering to be integrated with prior offerings by the Company for purposes of the Securities Act that would require the registration of any such securities under the Securities Act.

(qq) <u>Confidentiality and Non-Competition</u>. To the Company's knowledge, no director, officer, key employee or consultant of the Company is subject to any confidentiality, non-disclosure, non-competition agreement or non-solicitation agreement with any employer or prior employer that could reasonably be expected to materially affect his ability to be and act in his respective capacity of the Company or be expected to result in a Material Adverse Change.

(rr) <u>Smaller Reporting Company</u>. As of the time of filing of the Registration Statement, the Company was a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act Regulations.

### 3. <u>Covenants of the Company</u>. The Company covenants and agrees as follows:

(a) <u>Amendments to Registration Statement</u>. The Company shall deliver to the Representative, prior to filing, any amendment or supplement to the Registration Statement or Prospectus proposed to be filed after the Effective Date and not file any such amendment or supplement to which the Representative shall reasonably object in writing; provided however, that this Section 3(a) shall not be applicable with respect to any supplements to the Registration Statement filed solely for the purpose of supplementing the Registration Statement or Prospectus with a report filed with the Commission by the Company pursuant to the Exchange Act.

### (b) <u>Federal Securities Laws</u>.

(i) <u>Compliance</u>. The Company shall comply with the requirements of Rule 430A of the Securities Act Regulations, and will notify the Representative promptly, and confirm the notice in writing, (i) when any post-effective amendment to the Registration Statement shall become effective or any amendment or supplement to the Prospectus shall have been filed; (ii) of the receipt of any comments from the Commission; (iii) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Prospectus or for additional information; (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment or of any order preventing or suspending the use of any Preliminary Prospectus or the Prospectus, or of the suspension of the qualification of the Public Securities for offering or sale in any jurisdiction, or of the initiation or, to the Company's knowledge, threatening, of any proceedings for any of such subject of a proceeding under Section 8(d) or 8(e) of the Securities Act concerning the Registration Statement and (v) if the Company becomes the subject of a proceeding under Section 8A of the Securities Act in connection with the Offering of the Public Securities. The Company shall effect all filings required under Rule 424(b) of the Securities Act Regulations, in the manner and within the time period required by Rule 424(b) (without reliance on Rule 424(b)(8)), and shall take such steps as it deems necessary to ascertain promptly whether the form of prospectus. The Company shall use its best efforts to prevent the issuance of any stop order, prevention or suspension and, if any such order is issued, to obtain the lifting thereof at the earliest possible moment.



Continued Compliance. The Company shall comply with the Securities Act, the Securities Act Regulations, the Exchange (ii) Act and the Exchange Act Regulations so as to permit the completion of the distribution of the Public Securities as contemplated in this Agreement and in the Registration Statement, the Pricing Disclosure Package and the Prospectus. If at any time when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172 of the Securities Act Regulations ("Rule 172"), would be) required by the Securities Act to be delivered in connection with sales of the Public Securities, any event shall occur or condition shall exist as a result of which it is necessary, in the opinion of counsel for the Underwriters or for the Company, to (i) amend the Registration Statement in order that the Registration Statement will not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; (ii) amend or supplement the Pricing Disclosure Package or the Prospectus in order that the Pricing Disclosure Package or the Prospectus, as the case may be, will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in the light of the circumstances existing at the time it is delivered to a purchaser or (iii) amend the Registration Statement or amend or supplement the Pricing Disclosure Package or the Prospectus, as the case may be, in order to comply with the requirements of the Securities Act or the Securities Act Regulations, the Company will promptly (A) give the Representative notice of such event; (B) prepare any amendment or supplement as may be necessary to correct such statement or omission or to make the Registration Statement, the Pricing Disclosure Package or the Prospectus comply with such requirements and, a reasonable amount of time prior to any proposed filing or use, furnish the Representative with copies of any such amendment or supplement and (C) file with the Commission any such amendment or supplement; provided that the Company shall not file or use any such amendment or supplement to which the Representative or counsel for the Underwriters shall reasonably object. The Company will furnish to the Underwriters such number of copies of such amendment or supplement as the Underwriters may reasonably request. The Company has given the Representative notice of any filings made pursuant to the Exchange Act or the Exchange Act Regulations within 48 hours prior to the Applicable Time. The Company shall give the Representative notice of its intention to make any such filing from the Applicable Time until the Closing Date and the exercise in full or expiration of the Over-allotment Option specified in Section 1 Error! Reference source not found. hereof and will furnish the Representative with copies of the related document(s) a reasonable amount of time prior to such proposed filing, as the case may be, and will not file or use any such document to which the Representative or counsel for the Underwriters shall reasonably object.

(iii) <u>Exchange Act Registration</u>. Until the earlier of five (5) years after the date of this Agreement or the date on which no Warrants are outstanding, the Company shall use its reasonable efforts to maintain the registration of the shares of Underlying Common Stock under the Exchange Act. The Company shall not deregister the shares of Underlying Common Stock under the Exchange Act without the prior written consent of the Representative.

(iv) <u>Free Writing Prospectuses</u>. The Company agrees that, unless it obtains the prior written consent of the Representative, it shall not make any offer relating to the Public Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a "free writing prospectus," or a portion thereof, required to be filed by the Company with the Commission or retained by the Company under Rule 433; provided that the Representative shall be deemed to have consented to each Issuer General Use Free Writing Prospectus and any "road show that is a written communication" within the meaning of Rule 433(d)(8)(i) that has been reviewed by the Representative. The Company represents that it has treated or agrees that it will treat each such free writing prospectus consented to, or deemed consented to, by the Underwriters as an "issuer free writing prospectus," as defined in Rule 433, and that it has complied and will comply with the applicable requirements of Rule 433 with respect thereto, including timely filing with the Commission where required, legending and record keeping. If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Underwriters and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(c) <u>Delivery to the Underwriters of Registration Statements</u>. The Company has delivered or made available or shall deliver or make available to the Representative and counsel for the Representative, without charge, signed copies of the Registration Statement as originally filed and each amendment thereto (including exhibits filed therewith) and signed copies of all consents and certificates of experts, and will also deliver to the Underwriters, without charge, a conformed copy of the Registration Statement as originally filed and each amendment thereto (without exhibits) for each of the Underwriters. The copies of the Registration Statement and each amendment thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(d) Delivery to the Underwriters of Prospectuses. The Company has delivered or made available or will deliver or make available to each Underwriter, without charge, as many copies of each Preliminary Prospectus as such Underwriter reasonably requested, and the Company hereby consents to the use of such copies for purposes permitted by the Securities Act. The Company will furnish to each Underwriter, without charge, during the period when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the Securities Act, such number of copies of the Prospectus (as amended or supplemented) as such Underwriter may reasonably request. The Prospectus and any amendments or supplements thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(c) Effectiveness and Events Requiring Notice to the Representative. The Company shall use its commercially reasonable efforts to cause the Registration Statement to remain effective with a current prospectus through and including the expiration date of the Warrants (or the date all Warrants have been exercised or duly called, if earlier), and shall notify the Representative immediately and confirm the notice in writing: (i) of the effectiveness of the Registration Statement and any amendment thereto; (ii) of the issuance by the Commission of any stop order or of the initiation, or to the Company's knowledge, the threatening, of any proceeding for that purpose; (iii) of the issuance by any state securities commission of any proceedings for the suspension of the qualification of the Public Securities for offering or sale in any jurisdiction or of the initiation, or to the Registration Statement or Prospectus; (v) of the receipt of any comments or request for any additional information from the Commission; and (vi) of the happening of any event during the period described in this Section 3(e) that, in the judgment of the Company, makes any statement of a material fact made in the Registration Statement, the Pricing Disclosure Package or the Prospectus untrue or that requires the making of any changes in (a) the Registration Statement in order to make the statements therein, in light of the currunstances under which they were made, not misleading. If the Commission or any state securities commission shall enter a stop order or suspend such

(f) <u>Listing</u>. The Company shall use its commercially reasonable efforts to maintain the listing of the Common Stock on the Exchange for until the earlier of five (5) years after the date of this Agreement or the date on which no Warrants are outstanding.

### (g) <u>Reports to the Representative</u>.

(i) <u>Periodic Reports, etc.</u> For a period of three (3) years after the date of this Agreement, the Company shall furnish to the Representative copies of such financial statements and other periodic and special reports as the Company from time to time furnishes generally to holders of any class of its securities and also promptly furnish to the Representative: (i) a copy of each periodic report the Company shall be required to file with the Commission under the Exchange Act and the Exchange Act Regulations; (ii) a copy of every press release and every news item and article with respect to the Company or its affairs which was released by the Company and filed or furnished on a Current Report on Form 8-K; (iii) a copy of each Current Report on Form 8-K prepared and filed by the Company; and (iv) five copies of each registration statement filed by the Company under the Securities Act. Documents filed with the Commission pursuant to its EDGAR system or otherwise filed with the Commission or made publicly available shall be deemed to have been delivered to the Representative pursuant to this Section 3(g)(i).

(ii) <u>Transfer and Warrant Agent</u>. The Company shall maintain a transfer agent and registrar for the Common Stock and a warrant agent and registrar for the Warrants.

(h) <u>Payment of Expenses</u>.

General Expenses Related to the Offering. The Company hereby agrees to pay on the Closing Date and the Option Closing (i) Date, to the extent not paid at the Closing Date, all expenses incident to the performance of the obligations of the Company under this Agreement, including, but not limited to: (a) all filing fees and communication expenses relating to the registration of the Public Securities to be sold in the Offering with the Commission; (b) all actual Public Offering Filing System filing fees associated with the review of the Offering by FINRA; (c) all fees and expenses relating to the listing of the Public Securities and the Underlying Common Stock on the Exchange; (d) all fees, expenses and disbursements relating to the registration or qualification of the Public Securities under the "blue sky" securities laws of such states and other jurisdictions as the Representative may reasonably designate (including, without limitation, all filing and registration fees, and the reasonable fees and disbursements of "blue sky" counsel, which will be Representative Counsel, it being agreed that such fees and expenses will be limited to a payment of \$25,000 to such counsel at Closing); (e) all actual fees, expenses and disbursements relating to the registration, qualification or exemption of the Public Securities under the securities laws of such foreign jurisdictions as the Representative may reasonably designate; (f) the costs of all mailing and printing of the Registration Statements, Prospectuses and all amendments, supplements and exhibits thereto and as many preliminary and final Prospectuses as the Representative may reasonably deem necessary; (g) the costs of preparing, printing and delivering certificates representing the Public Securities; (h) fees and expenses of the transfer agent for the Common Stock and the warrant agent for the Warrants; (i) stock transfer and/or stamp taxes, if any, payable upon the transfer of securities from the Company to the Underwriters; (j) the fees and expenses of the Company's accountants; (k) the fees and expenses of the Company's legal counsel and other agents and representatives; and (1) the fees and expenses of the Underwriter's legal counsel not to exceed \$50,000. Notwithstanding the foregoing, the Company's obligations to reimburse the Representative for any out-of-pocket expenses actually incurred as set forth in the preceding sentence shall not exceed \$75,000 in the aggregate, including but not limited to the reasonable legal fees as described in clauses (d) and (l) herein. The Representative may deduct from the net proceeds of the Offering payable to the Company on the Closing Date, or any Option Closing Date, the expenses set forth herein (as limited by this Section 3(h)(i)) to be paid by the Company to the Underwriters, provided, however, that in the event that the Offering is terminated, the Company agrees to reimburse the Underwriters pursuant to Section 8(c) hereof.

(i) <u>Application of Net Proceeds</u>. The Company shall apply the net proceeds from the Offering received by it in a manner consistent with the application thereof described under the caption "Use of Proceeds" in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(j) <u>Rule 158</u>. The Company will timely file such reports pursuant to the Exchange Act as are necessary in order to make generally available to its security holders as soon as practicable an earnings statement for the purposes of, and to provide to the Underwriters the benefits contemplated by, Rule 158(a) under Section 11(a) of the Securities Act.

(k) <u>Stabilization</u>. Neither the Company nor, to its knowledge, any of its employees, directors or stockholders (without the consent of the Representative) has taken or shall take, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result in, under Regulation M of the Exchange Act, or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Public Securities.

(1) Internal Controls. The Company shall maintain a system of internal accounting controls sufficient to provide reasonable assurances that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary in order to permit preparation of financial statements in accordance with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(m) <u>Accountants</u>. The Company shall retain an independent registered public accounting firm reasonably acceptable to the Representative, and the Company shall continue to retain a nationally recognized independent registered public accounting firm for a period of at least three (3) years after the date of this Agreement. The Representative acknowledges that Olsen Thielen & Co., Ltd. is acceptable to the Representative.

(n) <u>FINRA</u>. For a period of 90 days from the later of the Closing Date or the Option Closing Date, the Company shall advise the Representative (who shall make an appropriate filing with FINRA) if it is or becomes aware that (i) any officer or director of the Company, (ii) any beneficial owner of 5% or more of any class of the Company's securities or (iii) any beneficial owner of the Company's unregistered equity securities which were acquired during the 180 days immediately preceding the filing of the Registration Statement is or becomes an affiliate or associated person of a FINRA member participating in the Offering (as determined in accordance with the rules and regulations of FINRA).

(o) <u>No Fiduciary Duties</u>. The Company acknowledges and agrees that the Underwriters' responsibility to the Company is solely contractual in nature and that none of the Underwriters or their affiliates or any selling agent shall be deemed to be acting in a fiduciary capacity, or otherwise owes any fiduciary duty to the Company or any of its affiliates in connection with the Offering and the other transactions contemplated by this Agreement.

# (p) <u>Reserved</u>.

(q) <u>Blue Sky Qualifications</u>. The Company shall use its reasonable best efforts, in cooperation with the Underwriters, if necessary, to qualify the Public Securities for offering and sale under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Representative may designate and to maintain such qualifications in effect so long as required to complete the distribution of the Public Securities; provided, however, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.

(r) <u>Reporting Requirements</u>. The Company, during the period when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the Securities Act, will file all documents required to be filed with the Commission pursuant to the Exchange Act within the time periods required by the Exchange Act and Exchange Act Regulations. Additionally, the Company shall report the use of proceeds from the issuance of the Public Securities as may be required under Rule 463 under the Securities Act Regulations.

4. <u>Conditions of Underwriters' Obligations</u>. The obligations of the Underwriters to purchase and pay for the Public Securities, as provided herein, shall be subject to (i) the continuing accuracy of the representations and warranties of the Company as of the date hereof and as of each of the Closing Date and Option Closing Date; (ii) the accuracy of the statements of officers of the Company made pursuant to the provisions hereof; (iii) the performance by the Company of its obligations hereunder; and (iv) the following conditions:

# (a) <u>Regulatory Matters</u>.

(i) Effectiveness of Registration Statement; Rule 430A Information. The Registration Statement has become effective not later than 5:00 p.m., Eastern time, on the date of this Agreement or such later date and time as shall be consented to in writing by the Representative, and, at the Closing Date and any Option Closing Date, no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto shall have been issued under the Securities Act, no order preventing or suspending the use of any Preliminary Prospectus or the Prospectus shall have been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated by the Commission. The Company has complied with each request (if any) from the Commission for additional information. The Prospectus containing the Rule 430A Information shall have been filed with the Commission in the manner and within the time frame required by Rule 424(b) (without reliance on Rule 424(b)(8)) or a post-effective amendment providing such information shall have been filed with, and declared effective by, the Commission in accordance with the requirements of Rule 430A.

(ii) <u>FINRA Clearance</u>. On or before the date of this Agreement, the Representative shall have received clearance from FINRA as to the amount of compensation allowable or payable to the Underwriters as described in the Registration Statement.

(iii) <u>Exchange Stock Market Clearance</u>. On the Closing Date, the additional listing application for the Common Stock and Underlying Common Stock shall have been approved by the Exchange, subject only to official notice of issuance. On each Option Closing Date (if any), the Option Shares and Underlying Common Stock shall have been approved for listing on the Exchange, subject only to official notice of issuance.

(b) <u>Company Counsel Matters</u>.

(i) <u>Closing Date Opinion of Counsel</u>. On the Closing Date, the Representative shall have received the favorable opinion of Maslon LLP, counsel to the Company, dated the Closing Date and addressed to the Representative, substantially in form and substance reasonably satisfactory to the Representative.

(ii) <u>Option Closing Date Opinions of Counsel</u>. On each Option Closing Date, if any, the Representative shall have received the favorable opinion of Maslon LLP, dated the Option Closing Date, addressed to the Representative and in form and substance reasonably satisfactory to the Representative, confirming as of the Option Closing Date, the statements made by such counsels in their respective opinions delivered on the Closing Date.

(iii) Reliance. In rendering such opinions, such counsel may rely: (i) as to matters involving the application of laws other than the laws of the United States and jurisdictions in which they are admitted, to the extent such counsel deems proper and to the extent specified in such opinion, if at all, upon an opinion or opinions (in form and substance reasonably satisfactory to the Representative) of other counsel reasonably acceptable to the Representative, familiar with the applicable laws; and (ii) as to matters of fact, to the extent they deem proper, on certificates or other written statements of officers of the Company and officers of departments of various jurisdictions having custody of documents respecting the corporate existence or good standing of the Company, provided that copies of any such statements or certificates shall be delivered to Representative Counsel if requested.

### (c) <u>Comfort Letters</u>.

(i) <u>Comfort Letter</u>. At the time this Agreement is executed the Representative shall have received a cold comfort letter containing statements and information of the type customarily included in accountants' comfort letters with respect to the financial statements and certain financial information contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus, addressed to the Representative and in form and substance satisfactory in all respects to the Representative and to the Auditor, dated as of the date of this Agreement.

(ii) <u>Bring-down Comfort Letter</u>. At the Closing Date and each Option Closing Date, if any, the Representative shall have received from the Auditor a letter, dated as of the Closing Date or the Option Closing Date, as applicable, to the effect that such Auditor reaffirms the statements made in the letter furnished pursuant to Section 4(c)(i), except that the specified date referred to shall be a date not more than three (3) business days prior to the Closing Date or the Option Closing Date, as applicable.

### (d) <u>Officers' Certificates</u>.

(i) Officers' Certificate. The Company shall have furnished to the Representative a certificate, dated the Closing Date and any Option Closing Date (if such date is other than the Closing Date), of its President and Chief Executive Officer, and its Chief Financial Officer stating on behalf of the Company and not in an individual capacity that (i) such officers have carefully examined the Registration Statement, the Pricing Disclosure Package, any Issuer Free Writing Prospectus and the Prospectus and, in their opinion, the Registration Statement and each amendment thereto, as of the Applicable Time and as of the Closing Date and any Option Closing Date (if such date is other than the Closing Date), did not include any untrue statement of a material fact and did not omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, and the Pricing Disclosure Package, as of the Applicable Time and as of the Closing Date and any Option Closing Date (if such date is other than the Closing Date), any Issuer Free Writing Prospectus as of its date and as of the Closing Date or any Option Closing Date (if such date is other than the Closing Date), the Prospectus and each amendment or supplement thereto, as of the respective date thereof and as of the Closing Date and any Option Closing Date (if such date is other than the Closing Date), did not include any untrue statement of a material fact and did not omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances in which they were made, not misleading, (ii) since the effective date of the Registration Statement, no event has occurred which should have been set forth in a supplement or amendment to the Registration Statement, the Pricing Disclosure Package or the Prospectus, (iii) to their knowledge after reasonable investigation, as of the Closing Date and any Option Closing Date (if such date is other than the Closing Date), the representations and warranties of the Company in this Agreement are true and correct in all material respects (except for those representations and warranties qualified as to materiality, which shall be true and correct in all respects and except for those representations and warranties which refer to facts existing at a specific date, which shall be true and correct as of such date) and the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date and any Option Closing Date (if such date is other than the Closing Date), and (iv) there has not been, subsequent to the date of the most recent audited financial statements included in the Pricing Disclosure Package, any Material Adverse Change in the financial position or results of operations of the Company, or any change or development that, singularly or in the aggregate, would involve a Material Adverse Change, in or affecting the condition (financial or otherwise), results of operations, business, assets or prospects of the Company, except as set forth in the Prospectus.

(ii) <u>Secretary's Certificate</u>. At each of the Closing Date and any Option Closing Date, the Representative shall have received a certificate of the Company signed by the Secretary of the Company, dated the Closing Date, certifying: (i) that each of the Charter and Bylaws is true and complete, has not been modified and is in full force and effect; (ii) that the resolutions of the Company's Board of Directors relating to the Offering are in full force and effect and have not been modified; (iii) the good standing of the Company; and (iv) as to the incumbency of the officers of the Company. The documents referred to in such certificate shall be attached to such certificate.

(e) <u>No Material Changes</u>. Prior to and on the Closing Date and each Option Closing Date: (i) there shall have been no Material Adverse Change or development involving a prospective Material Adverse Change in the condition or prospects or the business activities, financial or otherwise, of the Company from the latest dates as of which such condition is set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus; (ii) no action, suit or proceeding, at law or in equity, shall have been pending or threatened against the Company or any Insider before or by any court or federal or state commission, board or other administrative agency wherein an unfavorable decision, ruling or finding would reasonably be expected to result in a Material Adverse Change, except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus; (iii) no stop order shall have been issued under the Securities Act and no proceedings therefor shall have been initiated or threatened by the Commission; and (iv) the Registration Statement, the Pricing Disclosure Package and the Prospectus and any amendments or supplements thereto shall contain all material respects to the requirements of the Securities Act and the Securities Act and the Securities Act Regulations and shall conform in all material respects to the Prospectus nor any amendment or supplement thereto shall contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or supplement thereto shall contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or supplement therein, in light of the circumstances under which they were made, not misleading.

(f) <u>Additional Documents</u>. At the Closing Date and at each Option Closing Date, Representative Counsel shall have been furnished with such documents and opinions as they may require for the purpose of enabling Representative Counsel to deliver an opinion to the Underwriters, or in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Public Securities as herein contemplated shall be satisfactory in form and substance to the Representative Counsel.

#### 5. <u>Indemnification.</u>

(a) Indemnification of the Underwriters. The Company agrees to indemnify and hold harmless each Underwriter, its affiliates and each person controlling such Underwriter (within the meaning of Section 15 of the Securities Act), and the directors, officers, agents and employees of each Underwriter, its affiliates and each such controlling person (each Underwriter, and each such entity or person hereafter is referred to as an "Indemnified Person") from and against any losses, claims, damages, judgments, assessments, costs and other liabilities (collectively, the "Liabilities"), and shall reimburse each Indemnified Person for all fees and expenses (including the reasonable fees and expenses of counsel for the Indemnified Persons, except as otherwise expressly provided in this Agreement) (collectively, the "Expenses") and agrees to advance payment of such Expenses as they are incurred by an Indemnified Person in investigating, preparing, pursuing or defending any actions, whether or not any Indemnified Person is a party thereto, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in (i) the Registration Statement, the Pricing Disclosure Package, the Preliminary Prospectus, the Prospectus or in any Issuer Free Writing Prospectus (as from time to time each may be amended and supplemented); (ii) any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the Offering, including any "road show" or investor presentations made to investors by the Company (whether in person or electronically); or (iii) any application or other document or written communication (in this Section 5, collectively called "application") executed by the Company or based upon written information furnished by the Company in any jurisdiction in order to qualify the Public Securities under the securities laws thereof or filed with the Commission, any state securities commission or agency, the Exchange or any other national securities exchange; or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, unless such statement or omission was made in reliance upon, and in conformity with, the Underwriters' Information. The Company also agrees to reimburse each Indemnified Person for all Expenses as they are incurred in connection with such Indemnified Person's enforcement of his or its rights under this Agreement.

Procedure. Upon receipt by an Indemnified Person of actual notice of an action against such Indemnified Person with respect to which (h)indemnity may reasonably be expected to be sought under this Agreement, such Indemnified Person shall promptly notify the Company in writing; provided that failure by any Indemnified Person so to notify the Company shall not relieve the Company from any obligation or liability which the Company may have on account of this Section 5 or otherwise to such Indemnified Person, except to the extent the Company is materially prejudiced as a proximate result of such failure. The Company shall have the right to assume the defense of any such action (including the employment of counsel designated by the Company and reasonably satisfactory to the Representative). Any Indemnified Person shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Indemnified Person unless: (i) the Company has failed promptly to assume the defense and employ counsel reasonably satisfactory to the Representative for the benefit of the Underwriters and the other Indemnified Persons or (ii) such Indemnified Person shall have been advised that in the opinion of counsel that there is an actual or potential conflict of interest that prevents (or makes it imprudent for) the counsel engaged by the Company for the purpose of representing the Indemnified Person, to represent both such Indemnified Person and any other person represented or proposed to be represented by such counsel. The Company shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing all Indemnified Persons who are parties to such action), which counsel (together with any local counsel) for the Indemnified Persons shall be selected by the Representative. The Company shall not be liable for any settlement of any action effected without its written consent (which shall not be unreasonably withheld). In addition, the Company shall not, without the prior written consent of the Underwriters, settle, compromise or consent to the entry of any judgment in or otherwise seek to terminate any pending or threatened action in respect of which advancement, reimbursement, indemnification or contribution may be sought hereunder (whether or not such Indemnified Person is a party thereto) unless such settlement, compromise, consent or termination (i) includes an unconditional release of each Indemnified Person, from all Liabilities arising out of such action for which indemnification or contribution may be sought hereunder and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act, by or on behalf of any Indemnified Person. The advancement, reimbursement, indemnification and contribution obligations of the Company required hereby shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as every Liability and Expense is incurred and is due and payable, and in such amounts as fully satisfy each and every Liability and Expense as it is incurred (and in no event later than 30 days following the date of any invoice therefore).

(c) Indemnification of the Company. Each Underwriter, severally and not jointly, agrees to indemnify and hold harmless the Company, its directors, its officers who signed the Registration Statement and persons who control the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all Liabilities, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions made in the Registration Statement, any Preliminary Prospectus, the Pricing Disclosure Package or Prospectus or any amendment or supplement thereto or in any application, in reliance upon, and in strict conformity with, the Underwriters' Information. In case any action shall be brought against the Company or any other person so indemnified based on any Preliminary Prospectus, the Registration Statement, the Pricing Disclosure Package or Prospectus or any amendment or supplement thereto or in any application, and in respect of which indemnity may be sought against any Underwriter, such Underwriter shall have the rights and duties given to the Company, and the Company and each other person so indemnified shall have the rights and duties given to the Company agrees promptly to notify the Representative of the commencement of any litigation or proceedings against the Company or any of its officers, directors or any person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, in connection with the issuance and sale of the Public Securities or in connection with the Registration Statement, the Pricing Disclosure Package, the Prospectus or any Jesue Free Writing Prospectus; provided that failure by the Company so to notify the Representative shall not relieve any Underwriter from any obligation or liability which such Underwriter may have on account of this Section 5 or otherwise to the Company, except to the extent such Underwriter is materially prejudiced as a proximate result of such failure.

Contribution. If the indemnification provided for in this Section 5 shall for any reason be unavailable to or insufficient to hold harmless (d) an indemnified party under Section 5(a) or 5(c) in respect of any Liabilities and Expenses referred to therein, then each indemnifying party shall, in lieu of indemnifying such indemnified party, contribute to the amount paid or payable by such indemnified party as a result of such Liabilities and Expenses, (i) in such proportion as shall be appropriate to reflect the relative benefits received by the Company, on the one hand, and each of the Underwriters, on the other hand, from the Offering, or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Underwriters, on the other hand, in connection with the matters as to which such Liabilities or Expenses relate, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriters, on the other, with respect to such Offering shall be deemed to be in the same proportion as the total proceeds from the Offering purchased under this Agreement (before deducting expenses) received by the Company bear to the total underwriting discount and commissions actually received by the Underwriters in connection with the Offering, in each case as set forth in the table on the cover page of the Prospectus. The relative fault of the Company, on the one hand, and the Underwriters, on the other, shall be determined by reference to. among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Underwriters, on the other, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such untrue statement, omission, act or failure to act; provided that the parties hereto agree that the written information furnished to the Company through the Representative by or on behalf of any Underwriter for use in any Preliminary Prospectus, any Registration Statement or the Prospectus, or in any amendment or supplement thereto, consists solely of the Underwriters' Information. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this subsection (d) were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take into account the equitable considerations referred to above in this subsection (d). Notwithstanding the above, no person guilty of fraudulent misrepresentation within the meaning of Section 11(f) of the Securities Act shall be entitled to contribution from a party who was not guilty of fraudulent misrepresentation.

(e) <u>Limitation</u>. The Company also agrees that no Indemnified Person shall have any liability (whether direct or indirect, in contract or tort or otherwise) to the Company for or in connection with advice or services rendered or to be rendered by any Indemnified Person pursuant to this Agreement, the transactions contemplated thereby or any Indemnified Person's actions or inactions in connection with any such advice, services or transactions, except to the extent that a court of competent jurisdiction has made a finding that Liabilities (and related Expenses) of the Company have resulted primarily from such Indemnified Person's gross negligence or willful misconduct in connection with any such advice, actions, inactions or services.

(f) <u>Survival</u>. The advancement, reimbursement, indemnity and contribution obligations set forth in this Section 5 shall remain in full force and effect regardless of any termination of, or the completion of any Indemnified Person's services under or in connection with, this Agreement.

### 6. <u>Default by an Underwriter.</u>

(a) Default Not Exceeding 10% of Units. If any Underwriter or Underwriters shall default in its or their obligations to purchase the Firm Units or the Option Securities , if the Over-allotment Option is exercised hereunder, and if the number of the Firm Units or Option Securities with respect to which such default relates does not exceed in the aggregate 10% of the number of Firm Units or Option Securities that all Underwriters have agreed to purchase hereunder, then such Firm Units or Option Securities to which the default relates shall be purchased by the non-defaulting Underwriters in proportion to their respective commitments hereunder.

(b) Default Exceeding 10% of Units. In the event that the default addressed in Section 6(a) relates to more than 10% of the Firm Units or Option Securities, the Representative may in its discretion arrange for itself or for another party or parties to purchase such Firm Units or Option Securities to which such default relates on the terms contained herein. If, within one (1) Business Day after such default relating to more than 10% of the Firm Units or Option Securities, the Representative does not arrange for the purchase of such Firm Units or Option Securities , then the Company shall be entitled to a further period of one (1) Business Day within which to procure another party or parties satisfactory to the Representative to purchase said Firm Units or Option Securities on such terms. In the event that neither the Representative nor the Company arrange for the purchase of the Firm Units or Option Securities to which a default relates as provided in this Section 6, this Agreement will automatically be terminated by the Representative or the Company without liability on the part of the Company (except as provided in Sections 3(h) and 5 hereof) or the several Underwriters (except as provided in Section 5 hereof); provided, however, that if such default occurs with respect to the Option Securities , this Agreement will not terminate as to the Firm Units; and provided, further, that nothing herein shall relieve a defaulting Underwriter of its liability, if any, to the other Underwriters and to the Company for damages occasioned by its default hereunder.



(c) <u>Postponement of Closing Date</u>. In the event that the Firm Units or Option Securities to which the default relates are to be purchased by the non-defaulting Underwriters, or are to be purchased by another party or parties as aforesaid, the Representative or the Company shall have the right to postpone the Closing Date for a reasonable period, but not in any event exceeding five (5) Business Days, in order to effect whatever changes may thereby be made necessary in the Registration Statement, the Pricing Disclosure Package or the Prospectus or in any other documents and arrangements, and the Company agrees to file promptly any amendment to the Registration Statement, the Pricing Disclosure Package or the Prospectus that in the opinion of counsel for the Underwriter may thereby be made necessary. The term "<u>Underwriter</u>" as used in this Agreement shall include any party substituted under this Section 6 with like effect as if it had originally been a party to this Agreement with respect to such Securities.

### 7. <u>Additional Covenants.</u>

(a) <u>Prohibition on Press Releases and Public Announcements</u>. The Company shall not issue press releases or engage in any other publicity, without the Representative's prior written consent, for a period ending at 5:00 p.m., Eastern time, on the first (1<sup>st</sup>) Business Day following the forty-fifth (45<sup>th</sup>) day after the Closing Date, other than normal and customary releases issued in the ordinary course of the Company's business.

#### 8. Effective Date of this Agreement and Termination Thereof.

(a) Effective Date. This Agreement shall become effective when both the Company and the Representative have executed the same and delivered counterparts of such signatures to the other party.

(b) Termination. The Representative shall have the right to terminate this Agreement at any time prior to any Closing Date, (i) if any domestic or international event or act or occurrence has materially disrupted, or in Representative's opinion will in the immediate future materially disrupt, general securities markets in the United States; or (ii) if trading on the New York Stock Exchange or the NASDAQ Stock Market LLC shall have been suspended or materially limited, or minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required by FINRA or by order of the Commission or any other government authority having jurisdiction; or (iii) if the United States shall have become involved in a new war or an increase in major hostilities; or (iv) if a banking moratorium has been declared by a New York State or federal authority; or (v) if a moratorium on foreign exchange trading has been declared which materially adversely impacts the United States securities markets; or (ivi) if the Company shall have been insured, will, in Representative opinion, make it inadvisable to proceed with the delivery of the Units; or (vii) if the Company is in material breach of any of its representations, warranties or covenants hereunder; or (viii) if the Representative shall have become aware after the date hereof of a Material Adverse Change in the conditions or prospects of the Company, or such adverse material change in general market conditions as in the Representative's judgment would make it impracticable to proceed with the offering, sale and/or delivery of the Public Securities or to enforce contracts made by the Underwriters for the sale of the Public Securities. Section 5 of this Agreement shall survive any termination of this Agreement.

(c) Expenses. Notwithstanding anything to the contrary in this Agreement, except in the case of a default by the Underwriters pursuant to Section 6(b) above, in the event that this Agreement shall not be carried out for any reason whatsoever, within the time specified herein or any extensions thereof pursuant to the terms herein, the Company shall be obligated to pay to the Underwriters their actual and accountable out-of-pocket expenses related to the transactions contemplated herein then due and payable and upon demand the Company shall pay the full amount thereof to the Representative on behalf of the Underwriters; provided, that the fees and expenses of the Underwriter's legal counsel shall not exceed \$75,000; and provided, however, that such expense cap in no way limits or impairs the indemnification and contribution provisions of this Agreement. Notwithstanding the foregoing, any advance received by the Representative will be reimbursed to the Company to the extent not actually incurred in compliance with FINRA Rule 5110(f)(2)(C).

(d) <u>Indemnification</u>. Notwithstanding any contrary provision contained in this Agreement, any election hereunder or any termination of this Agreement, and whether or not this Agreement is otherwise carried out, the provisions of Section 5 shall remain in full force and effect and shall not be in any way affected by, such election or termination or failure to carry out the terms of this Agreement or any part hereof.

(e) <u>Representations, Warranties, Agreements to Survive</u>. All representations, warranties and agreements contained in this Agreement or in certificates of officers of the Company submitted pursuant hereto, shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of any Underwriter or its Affiliates or selling agents, any person controlling any Underwriter, its officers or directors or any person controlling the Company or (ii) delivery of and payment for the Public Securities.

### 9. <u>Miscellaneous.</u>

(a) Notices. All communications hereunder, except as herein otherwise specifically provided, shall be in writing and shall be mailed (registered or certified mail, return receipt requested), or personally delivered and shall be deemed given when so delivered or if mailed, two (2) days after such mailing.

If to the Representative:

Dawson James Securities, Inc. 1 North Federal Highway, 5<sup>th</sup> Floor Boca Raton, FL 33432 Attention: Robert D. Keyser, Jr.

If to the Company:

Skyline Medical Inc. 2915 Commers Drive, Suite 900 Eagan, Minnesota 55121 Attention: Joshua Komberg, Chief Executive Officer with copies to:

Maslon LLP 3300 Wells Fargo Center/90 South Seventh Street Minneapolis, Minnesota 55402 Attention: Martin Rosenbaum, Esq. Fax No: 612-672-8397

(b) <u>Headings</u>. The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of this Agreement.

(c) <u>Amendment</u>. This Agreement may only be amended by a written instrument executed by each of the parties hereto.

(d) <u>Entire Agreement</u>. This Agreement (together with the other agreements and documents being delivered pursuant to or in connection with this Agreement) constitutes the entire agreement of the parties hereto with respect to the subject matter hereof and thereof, and supersedes all prior agreements and understandings of the parties, oral and written, with respect to the subject matter hereof. This Agreement shall replace and supersede the Engagement Letter, including, without limitation, any terms which survive termination thereof pursuant to Section 9 thereof.

(e) <u>Binding Effect</u>. This Agreement shall inure solely to the benefit of and shall be binding upon the Representative, the Underwriters, each Indemnified Person referred to in Section 5, the Company and the controlling persons, directors and officers referred to in Section 5 hereof, and their respective successors, legal representatives, heirs and assigns, and no other person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Agreement or any provisions herein contained. The term "successors and assigns" shall not include a purchaser, in its capacity as such, of securities from any of the Underwriters.

(f) Governing Law; Consent to Jurisdiction; Trial by Jury. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to conflict of laws principles thereof. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Agreement shall be brought and enforced in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. Any such process or summons to be served upon the Company may be served by transmitting a copy thereof by registered or certified mail, return receipt requested, postage prepaid, addressed to it at the address set forth in Section 9(a) hereof. Such mailing shall be deemed personal service and shall be legal and binding upon the Company in any action, proceeding or claim. The Company agrees that the prevailing party(ies) in any such action shall be entitled to recover from the other party(ies) all of its reasonable attorneys' fees and expenses relating to such action or proceeding and/or incurred in connection with the preparation therefor. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

(g) Execution in Counterparts. This Agreement may be executed in one or more counterparts, and by the different parties hereto in separate counterparts, each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same agreement, and shall become effective when one or more counterparts has been signed by each of the parties hereto and delivered to each of the other parties hereto. Delivery of a signed counterpart of this Agreement by email/pdf transmission shall constitute valid and sufficient delivery thereof.

(h) <u>Waiver, etc.</u> The failure of any of the parties hereto to at any time enforce any of the provisions of this Agreement shall not be deemed or construed to be a waiver of any such provision, nor to in any way effect the validity of this Agreement or any provision hereof or the right of any of the parties hereto to thereafter enforce each and every provision of this Agreement. No waiver of any breach, non-compliance or non-fulfillment of any of the provisions of this Agreement shall be effective unless set forth in a written instrument executed by the party or parties against whom or which enforcement of such waiver is sought; and no waiver of any such breach, non-compliance or non-fulfillment shall be construed or deemed to be a waiver of any other or subsequent breach, non-compliance or non-fulfillment.

[Signature Page Follows]

If the foregoing correctly sets forth the understanding between the Underwriters and the Company, please so indicate in the space provided below.

Very truly yours,

# Skyline Medical Inc.

By:

Name: Title:

Confirmed as of the date first written above mentioned, on behalf of itself and as Representative of the several Underwriters named on <u>Schedule 1</u> hereto:

Dawson James Securities, Inc.

By:

Name: Robert D. Keyser, Jr. Title: Chief Executive Officer On behalf of each of the Underwriters

> [Signature Page] Skyline Medical Inc. – Underwriting Agreement

# SCHEDULE 1

Underwriter	Total Number of Units to be Purchased	Number of Units to be Purchased if the Over-Allotment Option is Fully Exercised
Dawson James Securities, Inc.	1,750,000	175,000
Total	1,750,000	175,000

### **SCHEDULE 2-A**

### **Pricing Information**

Number of Firm Units: 1,750,000

Number of shares of Common Stock included in each Firm Unit: One (1) share of Common Stock

Number of Series D Warrants included in each Firm Unit: 0.2 Series D Warrants

Shares underlying each whole Series D Warrant: One (1) share of Common Stock

Public Offering Price per Firm Unit: \$[•]

Underwriting Discount per Firm Unit: \$[•] (9% per Firm Unit)

Proceeds to Company per Firm Unit (before expenses): \$[•]

Number of Option Shares: 175,000

Number of Option Warrants: 35,000

Public Offering Price per Option Share: \$[•]

Public Offering Price per Option Warrant: \$0.01

Underwriting Discount per Option Share: \$[•] (9% per Option Share)

Underwriting Discount per Option Warrant: \$0.0009 (9% per Option Warrant)

# SCHEDULE 2-B

# Issuer General Use Free Writing Prospectuses

None.

### WARRANT AGENCY AGREEMENT

WARRANT AGENCY AGREEMENT, dated as of [\_\_\_\_], 2017 ("<u>Agreement</u>"), between Skyline Medical Inc., a Delaware corporation (the "<u>Company</u>") and Corporate Stock Transfer, Inc. (the "<u>Warrant Agent</u>").

### <u>WITNESSETH</u>

WHEREAS, pursuant to a registered offering by the Company of shares of common stock, par value \$0.01 per share (the "<u>Common Stock</u>") and Series D warrants to purchase shares of Common Stock (the "<u>Warrants</u>"), pursuant to an effective registration statement on Form S-1 (File No. 333-215005) (the "<u>Registration Statement</u>"), the Company wishes to issue Warrants in book entry form entitling the respective holders of the Warrants (the "<u>Holders</u>", which term shall include a Holder's transferees, successors and assigns and "Holder" shall include, if the Warrants are held in "street name", a Participant (as defined below) or a designee appointed by such Participant) to purchase an aggregate of up to 350,000 shares of Common Stock upon the terms and subject to the conditions hereinafter set forth (the "<u>Offering</u>");

WHEREAS, the shares of Common Stock and Warrants to be issued in connection with the Offering shall be immediately separable and will be issued separately, but will be purchased together in the Offering; and

WHEREAS, the Company wishes the Warrant Agent to act on behalf of the Company, and the Warrant Agent is willing so to act, in connection with the issuance, registration, transfer, exchange, exercise and replacement of the Warrants and, in the Warrant Agent's capacity as the Company's transfer agent, the delivery of the Warrant Shares.

NOW, THEREFORE, in consideration of the premises and the mutual agreements herein set forth, the parties hereby agree as follows:

Section 1. Certain Definitions. For purposes of this Agreement, the following terms have the meanings indicated:

(a) "Affiliate" has the meaning ascribed to it in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

(b) "<u>Business Day</u>" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which the Nasdaq Stock Market is authorized or required by law or other governmental action to close.

(c) "<u>Close of Business</u>" on any given date means 5:00 p.m., New York City time, on such date; <u>provided</u>, <u>however</u>, that if such date is not a Business Day it means 5:00 p.m., New York City time, on the next succeeding Business Day.

(e) "<u>Person</u>" means an individual, corporation, association, partnership, limited liability company, joint venture, trust, unincorporated organization, government or political subdivision thereof or governmental agency or other entity.

(j) "<u>Warrant Certificate</u>" means a certificate in substantially the form attached as <u>Exhibit 1</u> hereto, representing such number of Warrant Shares as is indicated therein, provided that any reference to the delivery of a Warrant Certificate in this Agreement shall include delivery of notice from the Depositary or a Participant (each as defined below) of the transfer or exercise of Warrant in the form of a Global Warrant (as defined below).

(k) "Warrant Shares" means the shares of Common Stock underlying the Warrants and issuable upon exercise of the Warrants.

All other capitalized terms used but not otherwise defined herein shall have the meaning ascribed to such terms in the Warrant Certificate.

Section 2. <u>Appointment of Warrant Agent</u>. The Company hereby appoints the Warrant Agent to act as agent for the Company in accordance with the terms and conditions hereof, and the Warrant Agent hereby accepts such appointment. The Company may from time to time appoint a Co-Warrant Agent with the prior consent of the Warrant Agent, such consent to not be unreasonably withheld, delayed or conditioned. The Warrant Agent shall have no duty to supervise, and will in no event be liable for the acts or omissions of, any co-Warrant Agent.

### Section 3. Global Warrants.

(a) The Warrants shall be issuable in book entry form (the "<u>Global Warrants</u>"). All of the Warrants shall initially be represented by one or more Global Warrants deposited with the Warrant Agent and registered in the name of Cede & Co., a nominee of The Depository Trust Company (the "<u>Depositary</u>"), or as otherwise directed by the Depositary. Ownership of beneficial interests in the Warrants shall be shown on, and the transfer of such ownership shall be effected through, records maintained by (i) the Depositary or its nominee for each Global Warrant or (ii) institutions that have accounts with the Depositary (such institution, with respect to a Warrant in its account, a "<u>Participant</u>").

(b) If the Depositary subsequently ceases to make its book-entry settlement system available for the Warrants, the Company may instruct the Warrant Agent regarding other arrangements for book-entry settlement. In the event that the Warrants are not eligible for, or it is no longer necessary to have the Warrants available in, book-entry form, the Warrant Agent shall provide written instructions to the Depositary to deliver to the Warrant Agent for cancellation each Global Warrant, and the Company shall instruct the Warrant Agent to deliver to each Holder a Warrant Certificate.

(c) A Holder has the right to elect at any time or from time to time a Warrant Exchange (as defined below) pursuant to a Warrant Certificate Request Notice (as defined below). Upon written notice by a Holder to the Warrant Agent for the exchange of some or all of such Holder's Global Warrants for a Warrant Certificate evidencing the same number of Warrants, which request shall be in the form attached hereto as Annex A (a "Warrant Certificate Request Notice" and the date of delivery of such Warrant Certificate Request Notice by the Holder, the "Warrant Certificate Request Notice Date" and the deemed surrender upon delivery by the Holder of a number of Global Warrants for the same number of Warrants evidenced by a Warrant Certificate, a "Warrant Exchange"), the Warrant Agent shall promptly effect the Warrant Exchange and shall promptly issue and deliver to the Holder a Warrant Certificate for such number of Warrants in the name set forth in the Warrant Certificate Request Notice. Such Warrant Certificate shall be dated the original issue date of the Warrants, shall be manually executed by an authorized signatory of the Company, shall be in the form attached hereto as Exhibit 1, and shall be reasonably acceptable in all respects to such Holder. In connection with a Warrant Exchange, the Company agrees to deliver, or to direct the Warrant Agent to deliver, the Warrant Certificate to the Holder within three (3) Business Days of the Warrant Certificate Request Notice pursuant to the delivery instructions in the Warrant Certificate Request Notice ("Warrant Certificate Delivery Date"). If the Company fails for any reason to deliver to the Holder the Warrant Certificate subject to the Warrant Certificate Request Notice by the Warrant Certificate Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares evidenced by such Warrant Certificate (based on the VWAP (as defined in the Warrants) of the Common Stock on the Warrant Certificate Request Notice Date), \$10 per Business Day for each Business Day after such Warrant Certificate Delivery Date until such Warrant Certificate is delivered or, prior to delivery of such Warrant Certificate, the Holder rescinds such Warrant Exchange. The Company covenants and agrees that, upon the date of delivery of the Warrant Certificate Request Notice, the Holder shall be deemed to be the holder of the Warrant Certificate and, notwithstanding anything to the contrary set forth herein, the Warrant Certificate shall be deemed for all purposes to contain all of the terms and conditions of the Warrants evidenced by such Warrant Certificate and the terms of this Agreement, other than Sections 3(c) and 9 herein, shall not apply to the Warrants evidenced by the Warrant Certificate. For purposes of this Section 3(c) only, the term "Holder" shall be deemed to be the owner of record of the Warrant.

Section 4. Form of Warrant Certificates. The Warrant Certificate, together with the form of election to purchase Common Stock ("Exercise Notice") and the form of assignment to be printed on the reverse thereof, shall be in the form of Exhibit 1 hereto.

#### Section 5. Countersignature and Registration.

(a) The Warrant Certificates shall be executed on behalf of the Company by its Chief Executive Officer, Chief Financial Officer or Vice President, either manually or by facsimile signature. The Warrant Certificates shall be countersigned by the Warrant Agent either manually or by facsimile signature and shall not be valid for any purpose unless so countersigned. In case any officer of the Company who shall have signed any of the Warrant Certificates shall cease to be such officer of the Company before countersignature by the Warrant Agent and issuance and delivery by the Company, such Warrant Certificates, nevertheless, may be countersigned by the Warrant Agent, issued and delivered with the same force and effect as though the person who signed such Warrant Certificate had not ceased to be such officer of the Company; and any Warrant Certificate may be signed on behalf of the Company by any person who, at the actual date of the execution of such Warrant Certificate, shall be a proper officer of the Company to sign such Warrant Certificate, although at the date of the execution of this Warrant Agreement any such person was not such an officer.



(b) The Warrant Agent will keep or cause to be kept, at one of its offices, or at the office of one of its agents, books for registration and transfer of the Warrant Certificates issued hereunder. Such books shall show the names and addresses of the respective Holders of the Warrant Certificates, the number of warrants evidenced on the face of each of such Warrant Certificate and the date of each of such Warrant Certificate. The Warrant Agent will create a special account for the issuance of Warrant Certificates.

#### Section 6. Transfer, Split Up, Combination and Exchange of Warrant Certificates; Mutilated, Destroyed, Lost or Stolen Warrant Certificates.

(a) With respect to the Global Warrant, subject to the provisions of the Warrant Certificate and the last sentence of this first paragraph of Section 6 and subject to applicable law, rules or regulations, at any time after the closing date of the Offering, and at or prior to the Close of Business on the Termination Date (as such term is hereinafter defined), any Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants may be transferred, split up, combined or exchanged for another Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants, entitling the Holder to purchase a like number of shares of Common Stock as the Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrant surrendered then entitled such Holder to purchase. Any Holder desiring to transfer, split up, combine or exchange any Warrant Certificate or Global Warrant shall make such request in writing delivered to the Warrant Agent, and shall surrender the Warrant Certificate or Warrant Certificates to be transferred, split up, combined or exchanged at the principal office of the Warrant Agent, provided that no such surrender is applicable to the Holder of a Global Warrant. Any requested transfer of Warrants, whether in book-entry form or certificate form, shall be accompanied by reasonable evidence of authority of the party making such request that may be required by the Warrant Agent. Thereupon the Warrant Agent shall, subject to the last sentence of this first paragraph of Section 6, countersign and deliver to the Person entitled thereto a Warrant Certificate or Warrant Certificates, as the case may be, as so requested. The Company may combination or exchange of Warrant Certificates. The Company shall compensate the Warrant Agent per the fee schedule mutually agreed upon by the parties hereto and provided separately on the date hereof.

(b) Upon receipt by the Warrant Agent of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of a Warrant Certificate, which evidence shall include an affidavit of loss, or in the case of mutilated certificates, the certificate or portion thereof remaining, and, in case of loss, theft or destruction, of indemnity in customary form and amount, provision of a bond and satisfaction of any other reasonable requirements established by Section 8-405 of the Uniform Commercial Code as in effect in the State of Delaware, and reimbursement to the Company and the Warrant Agent of all reasonable expenses incidental thereto, and upon surrender to the Warrant Agent and cancellation of the Warrant Certificate if mutilated, the Company will make and deliver a new Warrant Certificate of like tenor to the Warrant Agent for delivery to the Holder in lieu of the Warrant Certificate so lost, stolen, destroyed or mutilated.

### Section 7. Exercise of Warrants; Exercise Price; Termination Date.

(a) The Warrants shall be exercisable commencing on the Initial Exercise Date. The Warrants shall cease to be exercisable and shall terminate and become void, and all rights thereunder and under this Agreement shall cease, at or prior to the Close of Business on the Termination Date. Subject to the foregoing and to Section 7(b) below, the Holder of a Warrant may exercise the Warrant in whole or in part upon surrender of the Warrant Certificate, if required, with the executed Exercise Notice and payment of the Exercise Price, which may be made, at the option of the Holder, by wire transfer or by certified or official bank check in United States dollars, to the Warrant Agent at the principal office of the Warrant Agent or to the office of one of its agents as may be designated by the Warrant Agent from time to time. In the case of the Holder of a Global Warrant, the Holder shall deliver the executed Exercise Notice and the payment of the Exercise Price as described herein. Notwithstanding any other provision in this Agreement, a holder whose interest in a Global Warrant is a beneficial interest in a Global Warrant held in book-entry form through the Depositary (or another established clearing corporation performing similar functions), shall effect exercises by delivering to the Depositary (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by the Depositary (or such other clearing corporation, as applicable). The Company acknowledges that the bank accounts maintained by the Warrant Agent in connection with the services provided under this Agreement will be in its name and that the Warrant Agent may receive investment earnings in connection with the investment at Warrant Agent risk and for its benefit of funds held in those accounts from time to time. Neither the Company nor the Holders will receive interest on any deposits or Exercise Price. Notwithstanding anything herein to the contrary, the Company acknowledges and agrees that upon delivery of an Exercise Notice or upon a Holder instructing its Participant to exercise, such Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to such exercise, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) by 12:00 p.m. Eastern Time on the third Trading Day (as defined in the Warrant Certificate) and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in the Warrant Certificate), following delivery of the Exercise Notice.

(b) Upon receipt of an Exercise Notice for a Cashless Exercise, the Company will promptly calculate and transmit to the Warrant Agent the number of Warrant Shares issuable in connection with such Cashless Exercise and deliver a copy of the Exercise Notice to the Warrant Agent, which shall issue such number of Warrant Shares in connection with such Cashless Exercise.

(c) Upon the Warrant Agent's receipt of a Warrant Certificate at or prior to the Close of Business on the Termination Date set forth in such Warrant Certificate, with the executed Exercise Notice, accompanied by payment of the Exercise Price for the shares to be purchased (other than in the case of a Cashless Exercise) and an amount equal to any applicable tax, governmental charge or expense reimbursement referred to in Section 6 in cash, or by certified check or bank draft payable to the order of the Company (or, in the case of the Holder of a Global Warrant, the delivery of the executed Exercise Notice and the payment of the Exercise Price (other than in the case of a Cashless Exercise) and any other applicable amounts as set forth herein), the Warrant Agent shall cause the Warrant Shares underlying such Warrant Certificate or Global Warrant to be delivered to or upon the order of the Holder of such Warrant Certificate or Global Warrant, registered in such name or names as may be designated by such Holder, no later than the Warrant Share Delivery Date. If the Company is then a participant in the DWAC system of the Depositary and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) the Warrant is being exercised via Cashless Exercise, then the certificates for Warrant Shares shall be transmitted by the Warrant Agent to the Holder by crediting the account of the Holder's broker with the Depositary through its DWAC system. For the avoidance of doubt, if the Company becomes obligated to pay any amounts to any Holders pursuant to Section 2(d)(i) or 2(d)(iv) of the Warrant Certificate, such obligation shall be solely that of the Company and not that of the Warrant Agent. Notwithstanding anything else to the contrary in this Agreement, except in the case of a Cashless Exercise, if any Holder fails to duly deliver payment to the Warrant Agent of an amount equal to the aggregate Exercise Price of the Warrant Shares to be purchased upon exercise of such Holder's Warrant as set forth in Section 7(a) hereof, the Warrant Agent will not obligated to deliver certificates representing any such Warrant Shares (via DWAC or otherwise) until following receipt of such payment, and the applicable Warrant Share Delivery Date shall be deemed extended by one day for each day (or part thereof) until such payment is delivered to the Warrant Agent.

(d) The Warrant Agent shall deposit all funds received by it in payment of the Exercise Price for all Warrants in the account of the Company maintained with the Warrant Agent for such purpose (or to such other account as directed by the Company in writing) and shall advise the Company via telephone at the end of each day on which funds for the exercise of any Warrant are received of the amount so deposited to its account. The Warrant Agent shall promptly confirm such telephonic advice to the Company in writing.

(e) In case the Holder of any Warrant Certificate shall exercise fewer than all Warrants evidenced thereby, a new Warrant Certificate evidencing the number of Warrants equivalent to the number of Warrants remaining unexercised may be issued by the Warrant Agent to the Holder of such Warrant Certificate or to his duly authorized assigns in accordance with Section 2(d)(ii) of the Warrant Certificate, subject to the provisions of Section 6 hereof.

Section 8. <u>Cancellation and Destruction of Warrant Certificates</u>. All Warrant Certificates surrendered for the purpose of exercise, transfer, split up, combination or exchange shall, if surrendered to the Company or to any of its agents, be delivered to the Warrant Agent for cancellation or in canceled form, or, if surrendered to the Warrant Agent, shall be canceled by it, and no Warrant Certificates shall be issued in lieu thereof except as expressly permitted by any of the provisions of this Agreement. The Company shall deliver to the Warrant Agent for cancellation and retirement, and the Warrant Agent shall so cancel and retire, any other Warrant Certificate purchased or acquired by the Company otherwise than upon the exercise thereof.

Section 9. Certain Representations; Reservation and Availability of Shares of Common Stock or Cash.

(a) This Agreement has been duly authorized, executed and delivered by the Company and, assuming due authorization, execution and delivery hereof by the Warrant Agent, constitutes a valid and legally binding obligation of the Company enforceable against the Company in accordance with its terms, and the Warrants have been duly authorized, executed and issued by the Company and, assuming due authentication thereof by the Warrant Agent pursuant hereto and payment therefor by the Holders as provided in the Registration Statement, constitute valid and legally binding obligations of the Company enforceable against the Company in accordance with their terms and entitled to the benefits hereof; in each case except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium and other similar laws relating to or affecting creditors' rights generally or by general equitable principles (regardless of whether such enforceability is considered in a proceeding in equity or at law).

(b) As of the date hereof, the authorized common stock of the Company consists of [\_\_\_\_] shares of Common Stock, of which [\_\_\_\_] of Common Stock are issued and outstanding, and [\_\_\_\_] shares of Common Stock are reserved for issuance upon exercise of the Warants. Except as disclosed in the Registration Statement, there are no other outstanding obligations, warrants, options or other rights to subscribe for or purchase from the Company any class of capital stock of the Company.

(c) The Company covenants and agrees that it will cause to be reserved and kept available out of its authorized and unissued shares of Common Stock or its authorized and issued shares of Common Stock held in its treasury, free from preemptive rights, the number of shares of Common Stock that will be sufficient to permit the exercise in full of all outstanding Warrants.

(d) The Warrant Agent will create a reserve account, into which shall be reserved such number of shares of Common Stock that are issuable upon the exercise of the Warrants in full, and from such reserve account shall the Common Stock be issued upon the exercise of Warrants.

(e) The Company further covenants and agrees that it will pay when due and payable any and all federal and state transfer taxes and charges which may be payable in respect of the original issuance or delivery of the Warrant Certificates or certificates evidencing Common Stock upon exercise of the Warrants. The Company shall not, however, be required to pay any tax or governmental charge which may be payable in respect of any transfer involved in the transfer or delivery of Warrant Certificates or the issuance or delivery of certificates for Common Stock in a name other than that of the Holder of the Warrant Certificate evidencing Warrants surrendered for exercise or to issue or deliver any certificate for shares of Common Stock upon the exercise of any Warrants until any such tax or governmental charge shall have been paid (any such tax or governmental charge being payable by the Holder of such Warrant Certificate at the time of surrender) or until it has been established to the Company's reasonable satisfaction that no such tax or governmental charge is due.

Section 10. <u>Common Stock Record Date</u>. Each Person in whose name any certificate for shares of Common Stock is issued (or to whose broker's account is credited shares of Common Stock through the DWAC system) upon the exercise of Warrants shall for all purposes be deemed to have become the holder of record for the Common Stock represented thereby on, and such certificate shall be dated the date upon which the Warrant Certificate evidencing such Warrant was duly surrendered (but only if required herein) and payment of the Exercise Price (and any applicable transfer taxes) and submission of the Exercise Notice was made; <u>provided</u>, <u>however</u>, that if the date of such surrender (if applicable), payment and submission is a date upon which the Common Stock transfer books of the Company are closed, such Person shall be deemed to have become the record holder of such shares on, and such certificate shall be dated, the next succeeding day on which the Common Stock transfer books of the Company are open.

Section 11. Adjustment of Exercise Price, Number of Shares of Common Stock or Number of the Company Warrants. The Exercise Price, the number of shares covered by each Warrant and the number of Warrants outstanding are subject to adjustment from time to time as provided in Section 3 of the Warrant Certificate. In the event that at any time, as a result of an adjustment made pursuant to Section 3 of the Warrant Certificate, the Holder of any Warrant thereafter exercised shall become entitled to receive any shares of capital stock of the Company other than shares of Common Stock, thereafter the number of such other shares so receivable upon exercise of any Warrant shall be subject to adjustment from time to time in a manner and on terms as nearly equivalent as practicable to the provisions with respect to the shares contained in Section 3 of the Warrant Certificate, and the provisions of Sections 7, 9 and 13 of this Agreement with respect to the shares of Common Stock shall apply on like terms to any such other shares. All Warrants originally issued by the Company subsequent to any adjustment made to the Exercise Price pursuant to the Warrant Certificate shall evidence the right to purchase, at the adjusted Exercise Price, the number of shares of Common Stock purchasable from time to time hereunder upon exercise of the Warrants, all subject to further adjustment as provided herein.

Section 12. <u>Certification of Adjusted Exercise Price or Number of Shares of Common Stock</u>. Whenever the Exercise Price or the number of shares of Common Stock issuable upon the exercise of each Warrant is adjusted as provided in Section 11 or 13, the Company shall (a) promptly prepare a certificate setting forth the Exercise Price of each Warrant as so adjusted, and a brief statement of the facts accounting for such adjustment, (b) promptly file with the Warrant Agent and with each transfer agent for the Common Stock a copy of such certificate and (c) instruct the Warrant Agent to send a copy thereof to each Holder of a Warrant Certificate.

Section 13. Fractional Shares of Common Stock.

(a) The Company shall not issue fractions of Warrants or distribute Warrant Certificates which evidence fractional Warrants. Whenever any fractional Warrant would otherwise be required to be issued or distributed, the actual issuance or distribution shall reflect a rounding of such fraction to the nearest whole Warrant (rounded down).

(b) The Company shall not issue fractions of shares of Common Stock upon exercise of Warrants or distribute stock certificates which evidence fractional shares of Common Stock. Whenever any fraction of a share of Common Stock would otherwise be required to be issued or distributed, the actual issuance or distribution in respect thereof shall be made in accordance with Section 2(d)(v) of the Warrant Certificate.

Section 14. <u>Conditions of the Warrant Agent's Obligations</u>. The Warrant Agent accepts its obligations herein set forth upon the terms and conditions hereof, including the following to all of which the Company agrees and to all of which the rights hereunder of the Holders from time to time of the Warrant Certificates shall be subject:

- (a) Compensation and Indemnification. The Company agrees promptly to pay the Warrant Agent the compensation detailed on Exhibit 2 hereto for all services rendered by the Warrant Agent and to reimburse the Warrant Agent for reasonable out-of-pocket expenses (including reasonable counsel fees) incurred without gross negligence, bad faith or willful misconduct by the Warrant Agent in connection with the services rendered hereunder by the Warrant Agent. The Company also agrees to indemnify the Warrant Agent for, and to hold it harmless against, any loss, liability or expense incurred without gross negligence, bad faith or willful misconduct on the part of the Warrant Agent, arising out of or in connection with its acting as Warrant Agent hereunder, including the reasonable costs and expenses of defending against any claim of such liability.
- (b) Agent for the Company. In acting under this Warrant Agreement and in connection with the Warrant Certificates, the Warrant Agent is acting solely as agent of the Company and does not assume any obligations or relationship of agency or trust for or with any of the Holders of Warrant Certificates or beneficial owners of Warrants.
- (c) Counsel. The Warrant Agent may consult with counsel satisfactory to it, which may include counsel for the Company, and the written advice of such counsel shall be full and complete authorization and protection in respect of any action taken, suffered or omitted by it hereunder in good faith and in accordance with the advice of such counsel.
- (d) Documents. The Warrant Agent shall be protected and shall incur no liability for or in respect of any action taken or omitted by it in reliance upon any Warrant Certificate, notice, direction, consent, certificate, affidavit, statement or other paper or document reasonably believed by it to be genuine and to have been presented or signed by the proper parties.
- (e) Certain Transactions. The Warrant Agent, and its officers, directors and employees, may become the owner of, or acquire any interest in, Warrants, with the same rights that it or they would have if it were not the Warrant Agent hereunder, and, to the extent permitted by applicable law, it or they may engage or be interested in any financial or other transaction with the Company and may act on, or as depositary, trustee or agent for, any committee or body of Holders of Warrant Securities or other obligations of the Company as freely as if it were not the Warrant Agent hereunder. Nothing in this Warrant Agreement shall be deemed to prevent the Warrant Agent from acting as trustee under any indenture to which the Company is a party.
- (f) No Liability for Interest. Unless otherwise agreed with the Company, the Warrant Agent shall have no liability for interest on any monies at any time received by it pursuant to any of the provisions of this Agreement or of the Warrant Certificates.
- (g) No Liability for Invalidity. The Warrant Agent shall have no liability with respect to any invalidity of this Agreement or any of the Warrant Certificates (except as to the Warrant Agent's countersignature thereon).
- (h) No Responsibility for Representations. The Warrant Agent shall not be responsible for any of the recitals or representations herein or in the Warrant Certificates (except as to the Warrant Agent's countersignature thereon), all of which are made solely by the Company.
- (i) No Implied Obligations. The Warrant Agent shall be obligated to perform only such duties as are herein and in the Warrant Certificates specifically set forth and no implied duties or obligations shall be read into this Agreement or the Warrant Certificates against the Warrant Agent. The Warrant Agent shall not be under any obligation to take any action hereunder which may tend to involve it in any expense or liability, the payment of which within a reasonable time is not, in its reasonable opinion, assured to it. The Warrant Agent shall not be accountable or under any duty or responsibility for the use by the Company of any of the Warrant Certificates authenticated by the Warrant Agent and delivered by it to the Company pursuant to this Agreement or for the application by the Company of the proceeds of the Warrant Certificates. The Warrant Agent shall have no duty or responsibility in case of any default by the Company in the performance of its covenants or agreements contained herein or in the Warrant Certificates or in the case of the receipt of any written demand from a Holder of a Warrant Certificate with respect to such default, including, without limiting the generality of the foregoing, any duty or responsibility to initiate or attempt to initiate any proceedings at law.

### Section 15. Purchase or Consolidation or Change of Name of Warrant Agent.

(a) Any corporation into which the Warrant Agent or any successor Warrant Agent may be merged or with which it may be consolidated, or any corporation resulting from any merger or consolidation to which the Warrant Agent or any successor Warrant Agent shall be party, or any corporation succeeding to the corporate trust business of the Warrant Agent or any successor Warrant Agent, shall be the successor to the Warrant Agent under this Agreement without the execution or filing of any paper or any further act on the part of any of the parties hereto, provided that such corporation would be eligible for appointment as a successor Warrant Agent under the provisions of Section 17. In case at the time such successor Warrant Agent shall succeed to the agency created by this Agreement any of the Warrant Certificates shall have been countersigned but not delivered, any such successor Warrant Agent may adopt the countersignature of the predecessor Warrant Agent and deliver such Warrant Certificates so countersigned; and in case at that time any of the Warrant Certificates shall not have been countersigned, any successor Warrant Agent may adopt the name of the successor Warrant Agent; and in all such cases such Warrant Certificates shall have the full force provided in the Warrant Certificates and in this Agreement.

(b) In case at any time the name of the Warrant Agent shall be changed and at such time any of the Warrant Certificates shall have been countersigned but not delivered, the Warrant Agent may adopt the countersignature under its prior name and deliver Warrant Certificates so countersigned; and in case at that time any of the Warrant Certificates shall not have been countersigned, the Warrant Agent may countersign such Warrant Certificates shall not have been countersigned. The Warrant Agent may countersign such Warrant Certificates and in its prior name or in its changed name; and in all such cases such Warrant Certificates shall have the full force provided in the Warrant Certificates and in this Agreement.

Section 16. Duties of Warrant Agent. The Warrant Agent undertakes the duties and obligations imposed by this Agreement upon the following terms and conditions, by all of which the Company, by its acceptance hereof, shall be bound:

(a) The Warrant Agent may consult with legal counsel reasonably acceptable to the Company (who may be legal counsel for the Company), and the opinion of such counsel shall be full and complete authorization and protection to the Warrant Agent as to any action taken or omitted by it in good faith and in accordance with such opinion.

(b) Whenever in the performance of its duties under this Agreement the Warrant Agent shall deem it necessary or desirable that any fact or matter be proved or established by the Company prior to taking or suffering any action hereunder, such fact or matter (unless other evidence in respect thereof be herein specifically prescribed) may be deemed to be conclusively proved and established by a certificate signed by the Chief Executive Officer, Chief Financial Officer or Vice President of the Company; and such certificate shall be full authentication to the Warrant Agent for any action taken or suffered in good faith by it under the provisions of this Agreement in reliance upon such certificate.

(c) Subject to the limitation set forth in Section 14, the Warrant Agent shall be liable hereunder only for its own gross negligence, bad faith or willful misconduct, or for a breach by it of this Agreement.

(d) The Warrant Agent shall not be liable for or by reason of any of the statements of fact or recitals contained in this Agreement or in the Warrant Certificates (except its countersignature thereof) by the Company or be required to verify the same, but all such statements and recitals are and shall be deemed to have been made by the Company only.

(e) The Warrant Agent shall not be under any responsibility in respect of the validity of this Agreement or the execution and delivery hereof (except the due execution hereof by the Warrant Agent) or in respect of the validity or execution of any Warrant Certificate (except its countersignature thereof); nor shall it be responsible for any breach by the Company of any covenant or condition contained in this Agreement or in any Warrant Certificate; nor shall it be responsible for the adjustment of the Exercise Price or the making of any change in the number of shares of Common Stock required under the provisions of Section 11 or 13 or responsible for the manner, method or amount of any such change or the ascertaining of the existence of facts that would require any such adjustment or change (except with respect to the exercise of Warrants evidenced by Warrant Certificates after actual notice of any adjustment of the Exercise Price); nor shall it by any act hereunder be deemed to make any representation or warranty as to the authorization or reservation of any shares of Common Stock will, when issued, be duly authorized, validly issued, fully paid and nonassessable.

(f) Each party hereto agrees that it will perform, execute, acknowledge and deliver or cause to be performed, executed, acknowledged and delivered all such further and other acts, instruments and assurances as may reasonably be required by the other party hereto for the carrying out or performing by any party of the provisions of this Agreement.

(g) The Warrant Agent is hereby authorized to accept instructions with respect to the performance of its duties hereunder from the Chief Executive Officer, Chief Financial Officer or Vice President of the Company, and to apply to such officers for advice or instructions in connection with its duties, and it shall not be liable and shall be indemnified and held harmless for any action taken or suffered to be taken by it in good faith in accordance with instructions of any such officer, provided Warrant Agent carries out such instructions without gross negligence, bad faith or willful misconduct.

(h) The Warrant Agent and any shareholder, director, officer or employee of the Warrant Agent may buy, sell or deal in any of the Warrants or other securities of the Company or become pecuniarily interested in any transaction in which the Company may be interested, or contract with or lend money to the Company or otherwise act as fully and freely as though it were not Warrant Agent under this Agreement. Nothing herein shall preclude the Warrant Agent from acting in any other capacity for the Company or for any other legal entity.

(i) The Warrant Agent may execute and exercise any of the rights or powers hereby vested in it or perform any duty hereunder either itself or by or through its attorney or agents, and the Warrant Agent shall not be answerable or accountable for any act, default, neglect or misconduct of any such attorney or agents or for any loss to the Company resulting from any such act, default, neglect or misconduct, provided reasonable care was exercised in the selection and continued employment thereof.

Section 17. Change of Warrant Agent. The Warrant Agent may resign and be discharged from its duties under this Agreement upon 30 days' notice in writing sent to the Company and to each transfer agent of the Common Stock, and to the Holders of record of the Warrant Certificates. The Company may remove the Warrant Agent or any successor Warrant Agent upon 30 days' notice in writing, sent to the Warrant Agent or successor Warrant Agent, as the case may be, and to each transfer agent of the Common Stock, and to the Holders of the Warrant Certificates. If the Warrant Agent shall resign or be removed or shall otherwise become incapable of acting, the Company shall appoint a successor to the Warrant Agent. If the Company shall fail to make such appointment within a period of 30 days after such removal or after it has been notified in writing of such resignation or incapacity by the resigning or incapacitated Warrant Agent or by the Holder of a Warrant Certificate (who shall, with such notice, submit his Warrant Certificate for inspection by the Company), then the Holder of any Warrant Certificate may apply to any court of competent jurisdiction for the appointment of a new Warrant Agent, provided that, for purposes of this Agreement, the Company shall be deemed to be the Warrant Agent until a new warrant agent is appointed. Any successor Warrant Agent, whether appointed by the Company or by such a court, shall be a corporation organized and doing business under the laws of the United States or of a state thereof, in good standing, which is authorized under such laws to exercise corporate trust powers and is subject to supervision or examination by federal or state authority and which has at the time of its appointment as Warrant Agent a combined capital and surplus of at least \$50,000,000. After appointment, the successor Warrant Agent shall be vested with the same powers, rights, duties and responsibilities as if it had been originally named as Warrant Agent without further act or deed; but the predecessor Warrant Agent shall deliver and transfer to the successor Warrant Agent any property at the time held by it hereunder, and execute and deliver any further assurance, conveyance, act or deed necessary for the purpose. Not later than the effective date of any such appointment, the Company shall file notice thereof in writing with the predecessor Warrant Agent and each transfer agent of the Common Stock, and mail a notice thereof in writing to the Holders of the Warrant Certificates. However, failure to give any notice provided for in this Section 17, or any defect therein, shall not affect the legality or validity of the resignation or removal of the Warrant Agent or the appointment of the successor Warrant Agent, as the case may be.

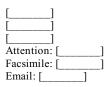
Section 18. <u>Issuance of New Warrant Certificates</u>. Notwithstanding any of the provisions of this Agreement or of the Warrants to the contrary, the Company may, at its option, issue new Warrant Certificates evidencing Warrants in such form as may be approved by its Board of Directors to reflect any adjustment or change in the Exercise Price per share and the number or kind or class of shares of stock or other securities or property purchasable under the several Warrant Certificates made in accordance with the provisions of this Agreement.

Section 19. Notices. Notices or demands authorized by this Agreement to be given or made (i) by the Warrant Agent or by the Holder of any Warrant Certificate to or on the Company, (ii) subject to the provisions of Section 17, by the Company or by the Holder of any Warrant Certificate to or on the Warrant Agent or (iii) by the Company or the Warrant Agent to the Holder of any Warrant Certificate, shall be deemed given (a) on the date delivered, if delivered personally, (b) on the first Business Day following the deposit thereof with Federal Express or another recognized overnight courier, if sent by Federal Express or another recognized overnight courier, (c) on the fourth Business Day following the mailing thereof with postage prepaid, if mailed by registered or certified mail (return receipt requested), and (d) the date of transmission, if such notice or communication is delivered via facsimile or email attachment on a day that is not a Business Day or later than 5:30 p.m. (New York City time) on any Business Day, in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice):

#### (a) If to the Company, to:

Skyline Medical Inc.
2915 Commers Drive, Suite 900
Eagan, Minnesota 55121
Attention: []
Fax: []
Email: []

(b) If to the Warrant Agent, to:



For any notice delivered by email to be deemed given or made, such notice must be followed by notice sent by overnight courier service to be delivered on the next business day following such email, unless the recipient of such email has acknowledged via return email receipt of such email.

(c) If to the Holder of any Warrant Certificate, to the address of such Holder as shown on the registry books of the Company. Any notice required to be delivered by the Company to the Holder of any Warrant may be given by the Warrant Agent on behalf of the Company. Notwithstanding any other provision of this Agreement, where this Agreement provides for notice of any event to a Holder of any Warrant, such notice shall be sufficiently given if given to the Depositary (or its designee) pursuant to the procedures of the Depositary or its designee.

Section 20. Supplements and Amendments.

(a) The Company and the Warrant Agent may from time to time supplement or amend this Agreement without the approval of any Holders of Global Warrant Certificates in order to add to the covenants and agreements of the Company for the benefit of the Holders of the Global Warrant Certificates or to surrender any rights or power reserved to or conferred upon the Company in this Agreement, provided that such addition or surrender shall not adversely affect the interests of the Holders of the Global Warrant Certificates in any material respect.

(b) In addition to the foregoing, with the consent of Holders of Warrants entitled, upon exercise thereof, to receive not less than a majority of the shares of Common Stock issuable thereunder, the Company and the Warrant Agent may modify this Agreement for the purpose of adding any provisions to or changing in any manner or eliminating any of the provisions of this Warrant Agreement or modifying in any manner the rights of the Holders of the Global Warrant Certificates; provided, however, that no modification of the terms (including but not limited to the adjustments described in Section 11) upon which the Warrants are exercisable or reducing the percentage required for consent to modification of this Agreement may be made without the consent of the Holder of each outstanding warrant certificate affected thereby. As a condition precedent to the Warrant Agent's execution of any amendment, the Company shall deliver to the Warrant Agent a certificate from a duly authorized officer of the Company that states that the proposed amendment complies with the terms of this Section 20.

Section 21. <u>Successors</u>. All covenants and provisions of this Agreement by or for the benefit of the Company or the Warrant Agent shall bind and inure to the benefit of their respective successors and assigns hereunder.

Section 22. <u>Benefits of this Agreement</u>. Nothing in this Agreement shall be construed to give any Person other than the Company, the Holders of Warrant Certificates and the Warrant Agent any legal or equitable right, remedy or claim under this Agreement; but this Agreement shall be for the sole and exclusive benefit of the Company, the Warrant Agent and the Holders of the Warrant Certificates.

Section 23. <u>Governing Law</u>. This Agreement and each Warrant Certificate issued hereunder shall be governed by, and construed in accordance with, the laws of the State of New York without giving effect to the conflicts of law principles thereof.

Section 24. <u>Counterparts</u>. This Agreement may be executed in any number of counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument.

Section 25. <u>Captions</u>. The captions of the sections of this Agreement have been inserted for convenience only and shall not control or affect the meaning or construction of any of the provisions hereof.

Section 26. <u>Information</u>. The Company agrees to promptly provide to the Holders of the Warrants any information it provides to the holders of the Common Stock, except to the extent any such information is publicly available on the EDGAR system (or any successor thereof) of the Securities and Exchange Commission.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

SKYLINE MEDICAL INC.

By:

Name: Title:

CORPORATE STOCK TRANSFER, INC.

By:

Name: Title:

### Annex A: Form of Warrant Certificate Request Notice

### WARRANT CERTIFICATE REQUEST NOTICE

To: [\_\_\_\_] as Warrant Agent for Skyline Medical, Inc. (the "Company")

The undersigned Holder of Common Stock Purchase Warrants ("Warrants") in the form of Global Warrants issued by the Company hereby elects to receive a Warrant Certificate evidencing the Warrants held by the Holder as specified below:

1. Name of Holder of Warrants in form of Global Warrants:

2. Name of Holder in Warrant Certificate (if different from name of Holder of Warrants in form of Global Warrants):

3. Number of Warrants in name of Holder in form of Global Warrants:

4. Number of Warrants for which Warrant Certificate shall be issued:

5. Number of Warrants in name of Holder in form of Global Warrants after issuance of Warrant Certificate, if any:

6. Warrant Certificate shall be delivered to the following address:

\_\_\_\_\_

The undersigned hereby acknowledges and agrees that, in connection with this Warrant Exchange and the issuance of the Warrant Certificate, the Holder is deemed to have surrendered the number of Warrants in form of Global Warrants in the name of the Holder equal to the number of Warrants evidenced by the Warrant Certificate.

[SIGNATURE OF HOLDER] Name of Investing Entity:
Signature of Authorized Signatory of Investing Entity:
Name of Authorized Signatory:
Title of Authorized Signatory:
Date:

Exhibit 1: Form of Warrant Certificate

### COMMON STOCK PURCHASE WARRANT

Warrant Shares: [•]

THIS COMMON STOCK PURCHASE WARRANT (the "<u>Warrant</u>") certifies that, for value received, \_\_\_\_\_\_\_ or its assigns (the "<u>Holder</u>") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the "<u>Initial Exercise Date</u>") and on or prior to the close of business on the fifth year anniversary of the Initial Exercise Date (the "<u>Termination Date</u>") but not thereafter, to subscribe for and purchase from **Skyline Medical Inc.**, a Delaware corporation (the "<u>Common Stock</u>"), up to [•] shares (as subject to adjustment hereunder, the "<u>Warrant Shares</u>") of Company common stock, par value \$0.01 per share (the "<u>Common Stock</u>"). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings set forth in this Section 1:

a) "<u>Affiliate</u>" means any Person that, directly or indirectly through one or more intermediaries, controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

b) "<u>Business Day</u>" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

c) "<u>Commission</u>" means the United States Securities and Exchange Commission.

d) "<u>Common Stock Equivalents</u>" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

e) "<u>Exchange Act</u>" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

f) "<u>Person</u>" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

g) "Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

h) "<u>Trading Day</u>" means a day on which the principal Trading Market is open for trading; provided, that in the event that the Common Stock is not listed or quoted for trading on a Trading Market on the date in question, then Trading Day shall mean any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

i) "<u>Trading Market</u>" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE MKT, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange, the OTC Bulletin Board, the OTCQB, the OTCQX, or the OTC Pink Marketplace maintained by the OTC Markets Group, Inc. (or any successors to any of the foregoing).

j) "Warrant Agency Agreement" means the warrant agency agreement, entered into between the Company and the Warrant Agent in connection with the Warrant.

k) "<u>Warrant Agent</u>" means Corporate Stock Transfer, Inc., and any successor warrant agent of the Company.

# Section 2. Exercise.

Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the a) Initial Exercise Date and on or before the Termination Date by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed facsimile copy (or e-mail attachment) of the Notice of Exercise in the form annexed hereto. No later than 12:00 p.m. Eastern Time within the earlier of (i) the third Trading Day and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein), following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.



b) <u>Exercise Price</u>. The exercise price per share of the Common Stock under this Warrant shall be **\$**[\_] subject to adjustment hereunder (the "<u>Exercise Price</u>").

c) <u>Cashless Exercise</u>. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

- (A) = the last VWAP immediately preceding the time of delivery of the Notice of Exercise giving rise to the applicable "cashless exercise", as set forth in the applicable Notice of Exercise (to clarify, the "last VWAP" will be the last VWAP as calculated over an entire Trading Day such that, in the event that this Warrant is exercised at a time that the Trading Market is open, the prior Trading Day's VWAP shall be used in this calculation);
- (B) = the Exercise Price of this Warrant, as adjusted hereunder; and
- (X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

"<u>WAP</u>" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

### d) <u>Mechanics of Exercise</u>.

Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to i. be transmitted by the Warrant Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earlier of (i) the earlier of (A) three (3) Trading Days after the delivery to the Company of the Notice of Exercise and (B) one (1) Trading Day after delivery of the aggregate Exercise Price and (ii) the number of Trading Days comprising the Standard Settlement Period (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) by 12:00 p.m. Eastern Time on the third Trading Day and (ii) the number of Trading Days comprising the Standard Settlement Period, following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$10 per Trading Day (increasing to \$20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. <u>Delivery of New Warrants Upon Exercise</u>. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. <u>Rescission Rights</u>. If the Company fails to cause the Warrant Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other iv. rights available to the Holder, if the Company fails to cause the Warrant Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. <u>No Fractional Shares or Scrip</u>. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. <u>Charges, Taxes and Expenses</u>. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; <u>provided</u>, <u>however</u>, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Warrant Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. <u>Closing of Books</u>. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and neither the Company nor the Warrant Agent shall have any obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Warrant Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within two Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 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 this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61<sup>st</sup> day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

# Section 3. Certain Adjustments.

a) <u>Stock Dividends and Splits</u>. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) <u>Reserved</u>.

c) <u>Subsequent Rights Offerings</u>. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "<u>Purchase Rights</u>"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issue or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder's right to participate in such Purchase Right to such extent (or beneficial ownership of such such sares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) <u>Pro Rata Distributions</u>. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "<u>Distribution</u>"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participate in such Distribution (<u>provided, however</u>, to the extent that the Holder's right to participate in any such Distribution to such excent (or in the beneficial Ownership I imitation, then Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation, such portion of the Distribution, such portion of the Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation, such portion of the Distribution shall be held in

Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or e) more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), 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 (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on

the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction, purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction. "Black Scholes Value" means the value of this Warrant based on the Black Scholes Option Pricing Model obtained from the "OV" function on Bloomberg, L.P. ("Bloomberg") determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg as of the Trading Day immediately following the public announcement of the applicable Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds within five Business Days of the Holder's election (or, if later, on the effective date of the Fundamental Transaction). The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(e) pursuant to written agreements reasonably satisfactory to the Holder prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein.

f) <u>Calculations</u>. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

#### g) <u>Notice to Holder</u>.

i. <u>Adjustment to Exercise Price</u>. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in ii. whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

# Section 4. Transfer of Warrant.

a) <u>Transferability</u>. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date the Holder delivers an assignment form to the Company assigning this Warrant full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) <u>New Warrants</u>. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) <u>Warrant Register</u>. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "<u>Warrant Register</u>"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

# Section 5. Miscellaneous.

a) <u>No Rights as Stockholder Until Exercise</u>. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) <u>Saturdays, Sundays, Holidays, etc.</u> If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

#### d) <u>Authorized Shares</u>.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of executing stock certificates to execute and issue the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. This Warrant shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to conflict of laws principles thereof. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Warrant shall be brought and enforced in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York located in the Borough of Manhattan in the City of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum.

f) <u>Restrictions</u>. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) <u>Nonwaiver and Expenses</u>. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) <u>Notices</u>. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the address set forth in the Warrant Register.

i) <u>Limitation of Liability</u>. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) <u>Remedies</u>. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) <u>Successors and Assigns</u>. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

 Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

m) <u>Severability</u>. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) <u>Headings</u>. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

o) <u>Conflicts</u>. In the event of a conflict between the terms of this Warrant and the Warrant Agency Agreement, the terms of this Warrant shall govern.

\*\*\*\*\*

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

SKYLINE MEDICAL INC.

By:

Name: Title:

## NOTICE OF EXERCISE

### TO: SKYLINE MEDICAL INC.

(1) The undersigned hereby elects to purchase \_\_\_\_\_ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[] in lawful money of the United States; or

[ ] if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

The Warrant Shares shall be delivered to the following DWAC Account Number:

[SIGNATURE OF HOLDER]

Name of Investing Entity:
Signature of Authorized Signatory of Investing Entity:
Name of Authorized Signatory:
Title of Authorized Signatory:
Date:

# ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name:

Address:

(Please Print)

(Please Print)

Phone Number:

Email Address:

Dated: \_\_\_\_\_ \_\_, \_\_\_\_ Holder's Signature: \_\_\_\_\_\_ Holder's Address: \_\_\_\_\_\_

#### MASLON LLP

January 10, 2017

Skyline Medical Inc. 2915 Commers Drive, Suite 900 Eagan, Minnesota 55121

Re: Amendment No. 1 to Registration Statement on Form S-1

#### Ladies and Gentlemen:

We have acted as counsel to Skyline Medical Inc., a Delaware corporation (the "*Company*"), in connection with (i) the offer and sale of an aggregate of up to 1,925,000 units ("*Units*") of securities, each such Unit consisting of (a) one share of the Company's common stock, par value \$0.01 per share (the "*Common Stock*") and (b) 0.2 of a Series D Warrant, with each whole Series D Warrant exercisable into one share of Common Stock (the "*Warrants*" and the shares underlying the Warrants, the "*Warrant Shares*"). The Common Stock, the Warrants and the Warrant Shares are registered on a registration statement on Form S-1 filed by the Company with the Securities and Exchange Commission (the "*Commission*") on December 9, 2016 (File No. 333-215005), as amended (the "*Registration Statement*"), under the Securities Act of 1933, as amended (the "*Securities Act*"). The 1,925,000 Units include 175,000 Units that may be issued pursuant to an over-allotment option of the Underwriter (as defined below).

In rendering the opinions expressed below, we have examined (a) the certificate of incorporation of the Company, as amended (the "*Certificate of Incorporation*"); (b) the bylaws of the Company; (c) the Registration Statement; (d) the prospectus included in the Registration Statement (the "*Prospectus*"); (e) resolutions of the board of directors of the Company; (f) the form of Series D Warrant Agency Agreement between the Company and Corporate Stock Transfer, Inc., including the form of Series D Warrant filed as exhibit 4.11 to the Registration Statement; (g) the form of Underwriting Agreement between the Company and Dawson James Securities, Inc. as the underwriter (the "*Underwriter*") filed as exhibit 1.1 to the Registration Statement; (the "*Underwriting Agreement*"); (h) the form of stock certificate for the Common Stock filed as exhibit 4.12 to the Registration Statement; and (i) such other documents, corporate records and instruments as we have deemed necessary or advisable for the purpose of this opinion. In addition, we have assumed the genuineness and authenticity of all documents submitted to us as original; the conformity to originals of all documents where due authorization, execution and delivery of all documents where due authorization, execution and delivery are prerequisites to the effectiveness of such documents. As to any facts material to the opinions expressed herein which we have not independently established or verified, we have relied upon statements and representations of officers and other representatives of the Company and others.

Subject to the foregoing and the other matters set forth herein, it is our opinion that, as of the date hereof,

- 1. When the shares of Common Stock shall have been duly registered on the books of the transfer agent and registrar therefor in the name or on behalf of the purchasers, and have been issued by the Company against payment therefor in the circumstances contemplated by the Underwriting Agreement, the issue and sale of the shares of Common Stock will have been duly authorized by all necessary corporate action of the Company, and the shares of Common Stock will be validly issued, fully paid and nonassessable.
- 2. When the Warrants have been duly executed and issued by the Company delivered against payment therefor in the manner contemplated by the Underwriting Agreement, the Warrants will constitute valid and binding obligations of the Company, enforceable against the Company in accordance with their terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other laws affecting the enforceability of creditors' rights generally and to court decisions with respect thereto and to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law).

3. The Warrant Shares have been duly authorized and if, as, and when such shares are issued and delivered by the Company upon exercise of such Warrants in accordance with the terms thereof and the Certificate of Incorporation, including, without limitation, the payment in full of applicable consideration, such Warrant Shares, will be validly issued, fully paid, and non-assessable.

This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K promulgated under the Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or the Prospectus, other than as expressly stated herein with respect to the issue of Shares.

The opinions expressed herein are limited to the federal laws of the United States and the General Corporation Law of the State of Delaware. Our opinion is based on these laws as in effect on the date hereof. We express no opinion as to whether the laws of any particular jurisdiction are applicable to the subject matter hereof.

The opinions and statements expressed herein are as of the date hereof. We assume no obligation to update or supplement this opinion letter to reflect any facts or circumstances that may hereafter come to our attention or any changes in applicable law which may hereafter occur.

This opinion is for your benefit in connection with the Registration Statement and may be relied upon only by you and by persons entitled to rely upon it pursuant to the applicable provisions of the Act. We consent to your filing this opinion as an exhibit to the Registration Statement, and to the reference to our firm in the Prospectus under the heading "Legal Matters." In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission thereunder.

Very truly yours,

/s/ Maslon LLP MASLON LLP

# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Amendment No. 1 to the Registration Statement on Form S-1 of our report dated March 16, 2016, relating to the financial statements of Skyline Medical Inc. appearing in the Prospectus which is a part of this Amendment No. 1 to the Registration Statement. We also consent to the reference to our Firm under captions "Experts" in the Prospectus.

Olsen Thielen & Co., Ltd.

/s/ Olsen Thielen & Co., Ltd.

St. Paul, Minnesota January 10, 2017