UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018.**

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

COMMISSION FILE NUMBER: 001-36790

PRECISION THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Delaware	**33-1007393**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

2915 Commers Drive, Suite 900
Eagan, Minnesota 55121
(Address and Zip Code of principal executive offices)

(Registrant's telephone number, including area code): **(651) 389-4800**

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

Common Stock par value $0.01 per share	NASDAQ Capital Market

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

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrants most recently completed second fiscal quarter: $13,584,316.47 as of June 30, 2018, based upon 12,089,446 shares at $1.13 per share as reported on NASDAQ Capital Market.

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

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

(APPLICABLE ONLY TO CORPORATE REGISTRANTS)

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the last practicable date: As of March 26, 2019, the registrant had 15,792,586 shares of common stock, par value $.01 per share outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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PART I

ITEM 1. BUSINESS.

Overview

Precision Therapeutics Inc (the "Company" or "Precision") is a healthcare products and services company that is expanding its business to take advantage of emerging areas of the dynamic healthcare market through sales of its products, through its partnership and its pending merger with Helomics Holding Corporation ("Helomics") and through pursuit of other strategic relationships to build value. Precision's business highlights include:

- Precision produces and sells the STREAMWAY® System, which it considers to be the best solution to solve the issue of medical waste disposal, with a cost-effective and environmentally friendly technology which provides infection control associated with toxic waste management. Precision has historically focused on growing the market for this product in the U.S. and are developing international markets.

- Precision has acquired 25% of the capital stock of Helomics and intends to consummate a merger with Helomics that is described elsewhere in this report, a pioneering Contract Research Organization ("CRO") Services company that bridges two significant areas of the healthcare industry: "Precision Medicine" and "Big Data". Precision has identified the CRO market as a burgeoning sector with significant growth potential. Precision is also partnering with Helomics in creating joint venture arrangements.

- In February 2018, Precision announced that Precision had formed a wholly-owned subsidiary, TumorGenesis Inc., to develop the next generation, patient derived ("PDx") tumor models for precision cancer therapy and drug development. Precision formed TumorGenesis to develop a new, rapid approach to growing tumors in the laboratory, which essentially "fools" the cancer cells into thinking they are still growing inside the patient. This approach should provide a much more relevant model of the patient tumor that may be used for testing of drugs for personalized therapy or for the development of new drugs. Testing of the TumorGenesis PDx tumors will take place in collaboration with Helomics. Precision entered into licensing agreements with three medical technology companies in that regard.

- Through Precision's Skyline-Helomics collaboration, it has also partnered with GLG Pharma, a biotechnology company focused on precision medicine, to add a collection method to the STREAMWAY System, using GLG's Capture, Culture and Screening capabilities. Precision also continues to explore other opportunities to partner with revenue-generating companies and create near-term and long-term value for its shareholders.

Corporate History

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. On February 1, 2018, we filed with the Secretary of State of Delaware a Certificate of Amendment to our Certificate of Incorporation to change our corporate name from Skyline Medical Inc. to Precision Therapeutics Inc. Because of this change, our common stock trades under the new ticker symbol "AIPT" effective February 2, 2018. Skyline Medical ("Skyline") remains a division of Precision Therapeutics Inc. and principally manufactures the STREAMWAY® System.

Our address is 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121. Our telephone number is 651-389-4800, and our website address is www.precisiontherapeutics.com. Information on our website is not included or incorporated by reference in this report.

Pending Merger with Helomics; Matters Approved at Special Stockholders Meeting

At a special meeting of stockholders held on March 22, 2019, our stockholders approved the Amended and Restated Agreement and Plan of Merger, dated as of October 26, 2018, by and among Precision, Helomics Acquisition, Inc. ("Merger Sub") and Helomics Holding Corporation ("Helomics") (the "Merger Agreement"), and the transactions contemplated thereby, including (a) the merger of Helomics with and into Merger Sub (the "Merger") and the issuance of shares of our common stock and Series D convertible preferred stock to Helomics' security holders pursuant to the terms of the Merger Agreement and (b) the issuance of shares of our common stock and warrants to the holders of Helomics notes and warrants pursuant to the Company's exchange offer described in the Form S-4 registration statement as amended on January 24, 2019 (the "Exchange Offer"). The stockholders also approved amendments to our Certificate of Incorporation to increase the number of authorized shares of common stock from 50,000,000 to 100,000,000 and to create a classified board of directors; a related amendment to our Amended and Restated Bylaws, and an amendment to our Amended and Restated 2012 Stock Incentive Plan to increase the reserve of shares of common stock authorized for issuance thereunder to 10,000,000. These approvals have satisfied certain conditions to the consummation of the Merger under the Merger Agreement.

In addition, in the Exchange Offer that was completed on March 22, 2019, the holders of $7.3 million in principal amount of the Helomics notes, representing 96% of the aggregate principal amount of the Helomics notes, have accepted the Exchange Offer. Such acceptance satisfied a further condition to consummation of the Merger. The exchange of the securities under the Exchange Offer will be effective as of the effective date of the Merger.

Upon the satisfaction or waiver of the remaining conditions under the Merger Agreement, we expect the Merger and the Exchange Offer to be completed, and Helomics will become our wholly owned subsidiary. We expect the Merger to become effective during the first part of April 2019. On the effective date of the Merger, we will issue a significant number of shares of our Common Stock, Series D convertible preferred stock ("Series D Preferred Stock") and warrants to purchase our Common Stock in connection with the Merger and the Exchange Offer, referred to herein as the "Merger Issuance." See Item 10, "Management's Discussion and Analysis of Financial Condition and Results of Operations," under "Overview."

STREAMWAY System Business

Overview

We manufacture an environmentally-conscious system for the collection and disposal of infectious fluids resulting from surgical and other medical procedures. We have been granted patents in the United States, Canada and Europe, for the STREAMWAY System. We distribute our products to medical facilities where bodily and irrigation fluids produced during medical 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 industry 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 direct sales force. The Company has one VP of Sales & Marketing, one VP of International Sales, and seven regional sales managers on staff as of March 2019. We have twelve independent distributors in the United States, Canada and overseas. We incorporated Skyline Medical Europe with an office in Belgium in February 2018 and hired a direct salesperson to cover Germany and France. We have contracted with two General Purchasing Organizations in the United States (Vizient and Intalere) providing customer exposure to more than 10,000 hospitals. The Company has contracted with Alliant Enterprises, LLC, a Service Disabled Veterans Owned Small Business supplier to the federal government. We have executed contracts with eleven international distributors: Quadromed, a Canadian distributor; MediBridge Sarl, a Swiss distributor; Device Technologies Australia PTY LTD, is an Australian distributor representing us throughout Australia, New Zealand, Fiji and the Pacific Islands; Century Scientific and Equipment Company in Kuwait; Mediurge in Pakistan; Prenit World in India; Sesneber in Saudi Arabia; Winner Scientific in Taiwan; Anifco in Bangladesh; Aras in the United Arab Emirates and Alfaisal Scientific Bureau in Iraq.

The STREAMWAY System is a wall-mounted fully-automated system that disposes an unlimited amount of suction fluid providing uninterrupted performance for physicians while virtually eliminating healthcare workers' exposure to potentially-infectious fluids collected during surgical and other patient procedures. The system also provides an innovative way to dispose of ascites and pleural fluid with no evac bottles, suction canisters, transport or risk of exposure. The Company also manufactures and sells two disposable products required for the operation: a bifurcated dual port procedure filter with tissue trap and a single use bottle of cleaning solution. Both items are utilized on a single procedure basis and must be discarded after use.

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

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

Precision 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 System eliminates the need for cleaning of those canisters. The System reduces safety issues facing healthcare workers, i.e. the cost of the handling process, and the amount of infectious waste generated versus the traditional method of disposing of canisters. The System 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 the fluid waste management 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 healthcare personnel to potentially infectious material.

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. OSHA's Bloodborne Pathogens Standard 29 CFR 1910.1030 requires employers to adopt engineering and work practice controls that would eliminate or minimize employee exposure from hazards associated with 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 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 via direct contact of blood materials or, more indirectly, via splash and spray. One STREAMWAY System user stated "While working at a different facility, contaminated fluid splashed in my eye while changing a full suction canister. The patient was HIV-positive, so I had to be tested for the next 18 months. Luckily, I was not infected. But no one should have to go through that."

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.

OSHA issued a 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. Based on the number of surgical procedures per 100,000 people published by The Lancet Commission on Global Surgery, the number of surgeries in the United States, using 2016 census data, was 98,634,510 (almost 100,000,000). Using the 2018 census projected population number, the US would see approximately 100 million surgical procedures.

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 and 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 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, which stated, "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 approximately 40,000 operating rooms and surgical centers in the U.S. (AHA, Hospital Statistics, 2008). The hospital market has typically been 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.

An even more cumbersome and dangerous method of fluid removal uses a product called an evacuated glass container often referred to as an evac bottle. These bottles have long been the accepted practice for fluid removal in procedure rooms where paracentesis and thoracentesis procedures are performed. The bottles have a 1-liter capacity and 5-8 of them are used on average for a large volume paracentesis. Procedure costs for the glass bottles alone can climb to $50 or $60. Furthermore, the added weight of the glass and fluid makes glass bottles one of the most expensive collection options on the market. The composition of the bottles makes these containers one of the most dangerous to handle.

Current protection and disposal techniques are helpful but fall short of providing adequate protection for the healthcare workers exposed to infectious waste. A major spill of fluid from a canister, causing direct or indirect contact to blood-borne pathogens is a major concern and is one of the most serious risks any healthcare worker may face in the performance of his or her job. Once a spill occurs, the entire area must be cleaned and disinfected and the exposed worker faces a potential of infection from bloodborne pathogens. These pathogens include, but are not limited to, Hepatitis B and C, HIV/AIDS, HPV, and other infectious agents. Given the current legal liability environment, the hospital, unable to identify at-risk patients due to concerns over patient rights and confidentiality, must treat every exposure incident as a potentially infectious incident and treat the exposed employee according to a specific protocol that is both costly to the facility and stressful to the affected employee and his or her co-workers. In cases of possible exposure to communicable disease, the employee could be placed on paid administrative leave, frequently involving worker's compensation, and additional workers must be assigned to cover the affected employee's responsibilities. The facility bears the cost of both the loss of the affected worker and the replacement healthcare worker in addition to any ongoing health screening and testing of the affected worker to confirm if any disease has been contracted from the exposure incident. Canisters are the most prevalent means of collecting and disposing of infectious fluids in hospitals today. Traditional, non-powered canisters and related suction and fluid disposable products are exempt and do not require FDA clearance.

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

In addition to the traditional canister method of waste fluid disposal, several other 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 an 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 emerging growth company like ours. We believe that Stryker Instruments has the dominant market share position.

Products

The STREAMWAY Fluid Waste Management System ("System") – Direct-to-Drain Medical Fluid Disposal

The STREAMWAY System suctions surgical waste fluid from the patient using standard surgical tubing. The waste fluid passes through our proprietary disposable filters and into our device. The STREAMWAY System maintains continuous suction to the procedural field at all times. A simple, easy to use Human Interface Display screen guides the user through the simple 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 System 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 System 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 the operating room personnel to 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 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 System 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 solution is attached to the System and an automatic cleaning cycle ensues, making the device ready for the next procedure. The cleaning solution bottle and its contents are used to clean the internal fluid pathway in the device to which personnel have no exposure. During the cleaning cycle, the cleaning solution is pulled from the bottle into the device, and then disposed in the same manner as the waste fluid from the medical procedure. At the end of the cleaning cycle, the bottle is discarded and is 100% recyclable. The filter and any suction tubing used during the procedure will 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 System eliminates the need for cleaning of canisters for re-use. The System 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 System 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 System 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 System is the only known direct-to-drain system that is wall-mounted and designed to collect, measure and dispose of, surgical waste. Other systems on the market are portable, meaning that they are rolled to the bedside for the surgical case and then rolled to a cleaning area, after the surgery is complete, and use canisters, which still require processing or require a secondary device (such as a docking station) to dispose of the fluid in the sanitary sewer after it has been collected. They are essentially powered canisters. A comparison of the key features of the devices currently marketed and the System is presented in the table below.

Key Feature Comparison

Feature	Skyline Medical Inc.	Stryker Instruments	DeRoyal	Dornoch Medical Systems, Inc. (Zimmer)	MD Technologies, Inc.
Portable to Bedside vs. Fixed Installation	Fixed	Portable	Fixed	Portable	Fixed
Uses Canisters	No	Yes	Yes	Yes	No
Secondary Installed Device Required for Fluid Disposal	No	Yes	Yes	Yes	No
Numeric Fluid Volume Measurement	Yes	Yes	No	Yes	Optional
Unlimited Fluid Capacity	Yes	No	No	No	Yes
Continuous, Uninterrupted Vacuum	Yes	No	No	No	No
Installation Requirements:					
Water	No	Yes	Yes	Yes	No
Sewer	Yes	Yes	Yes	Yes	Yes
Vacuum	Yes	No	No	No	Yes

The System may be installed on or in the wall during new hospital construction or renovation and is installed in any 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 System in position and minimal labor. The fluid collection chamber is internal to the device unit and requires no separate installation. Based upon our consultations with several architects, we believe there is no appreciable incremental expense in planning for the System during construction.

For on-the-wall installation in a current operating room, the location of the System 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 System is mounted on the wall using a mounting bracket supplied with the system and standard stud or drywall attachments.

Once installed, the System 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 System 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.

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 costlier.

A summary of the features of the wall unit include:

- Minimal Human Interaction. The wall-mounted System 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 device.

- 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 physician and nursing 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 System for the next use, reducing operating room turnover time. The cleaning solution is intended to clean the internal tubing, pathways, and chamber within the system. The cleaning solution bottle is easily attached to the STREAMWAY System by inserting the bottle into the mount located on the front of the unit and inverting the bottle. The automated cleaning process takes less than five minutes and requires minimal staff intervention. The disposable cleaning solution 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 solution, and only our cleaning solution, must be used with the STREAMWAY System following each surgical case. The warranty is voided if any other solution is used.

- Procedure Filters. One or two filters, depending on the type of procedure, will be used for every surgical procedure. The filter was developed by us, is proprietary to the STREAMWAY System and is only sold by us. The filter is a two port, bifurcated, disposable filter that contains check valves and 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 solution and filter disposables are expected to be a substantial revenue generator for the life of the STREAMWAY System.

- Ease of Use. The System 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 System 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 arrange installation of the System through a partnership or group of partnerships. Such partners will include, but will not be limited to, local plumbers, distribution partners, manufacturer's representatives, hospital supply companies and the like. We train our partners and standardize the procedure to ensure the seamless installation of our products. The System is designed for minimal interruption of operating room and surgical room utilization. Plug-and-play features of the design allow for almost immediate connection and hook up to hospital utilities for wall-mounted units allowing for quick start-up post-installation.

- Sales Channel Partners. The System is sold to end-users through a combination of independent stocking distributors, manufacturer's representatives, and direct sales personnel. We intend that all personnel involved in direct contact with the end-user have extensive training and are approved by Skyline. We 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 are reviewed on an annual basis and we expect that such agreements will contain provisions allowing them to be terminated at any time by Skyline based on certain specified conditions.

The Disposables

The Skyline disposables are a critical component of our business model. The disposables consist of a proprietary, pre-measured amount of cleaning solution in a plastic bottle that attaches to the System. The disposables also include a 2-port bifurcated single use in-line filter. The proprietary cleaning solution, placed in the specially designed holder, is attached and shall be used following each surgical procedure. Due to the nature of the fluids and particles removed during surgical procedures, the System should be cleaned following each use. The disposables have the "razor blade business model" characteristic with an ongoing stream of revenue for every System unit installed, and revenues from the sale of the disposables are expected to be significantly higher over time than the revenues from the sale of the unit. Our disposable bifurcated filter is designed specifically for use only on our System. The filter is used only once per procedure followed by immediate disposal. Our operating instructions and warranty require that a Skyline filter is used for every procedure. We have exclusive distribution rights to the disposable solution and facilitate the use of only our solution for cleaning following procedures by incorporating a special container to connect the fluid to the connector on the System. We also tie the fluid usage, which we keep track of with the System software, to the product warranty.

Intellectual Property

We believe that 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 intellectual property rights and other measures to protect our intellectual property.

We spent approximately $526,000 in 2018 and $289,000 in 2017 on research and development. On January 25, 2014, the Company filed a non-provisional PCT Application No. PCT/US2014/013081 claiming priority from the U.S. Provisional Patent Application, number 61756763 which was filed one year earlier on January 25, 2013. The Patent Cooperation Treaty ("PCT") allows an applicant to file a single patent application to seek patent protection for an invention simultaneously in each of the 148-member countries of the PCT, including the United States. By filing this single "international" patent application through the PCT system, it becomes easier and more cost effective than by filing separate applications directly with each national or regional patent office in the various countries in which patent protection is desired.

The United States Patent Office has assigned application #14/763,459 to our previously filed PCT application.

As of November 22, 2017, the Company was informed that the European Patent Office allowed all our claims for application #14743665.3-1651 and we received a Notice of Intent to Grant.

As of July 11, 2018, the Company was informed that the European Patent #EP2948200 was granted and published validating in the following countries: Belgium, Germany, Spain, France, United Kingdom, Ireland, Italy, Netherlands, Norway, Poland and Sweden.

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 System 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 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. 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 he devices 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 continuous 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 to collect the fluid in the second container while the fluid in the first container is drained. When the second container becomes full, the vacuum is again switched back to the first container to collect fluid while the second container is drained, and so on. Even though the switching of the vacuum between containers is automated in certain MD Technology models, the automated switching results 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 STREAMWAY models: US7469727, US8123731 and US Publication No. US20090216205 (collectively, the “Patents”). These Patents will begin to expire on August 8, 2023.

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

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

Strategy *for STREAMWAY Business*

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.*

- *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.*

- *Provide a hybrid sales force utilizing direct salespersons, manufacturing representatives and distributors.*

- *Continue to utilize operating room consultants, builders and architects as referrals to hospitals and day surgery centers.*

Other strategies may also include:

  - *Partnering with leading GPO's (Group Purchasing Organizations) to gain access to the majority of hospital systems in the United States.*

  - *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 disposables 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. It consists of the 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 and their contents currently being used in many cases, 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 most 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 healthcare workers, putting them at risk for direct contact with these potentially-infectious agents through spillage of the contents or via splash when the liquid is poured into a hopper – a specially designated sink for the disposal of infectious fluids. Once the infectious fluids are disposed of into the hopper, the empty canister is sent to central processing for re-sterilization (glass and certain plastics) or for disposal with the bio-hazardous/infectious waste generated by the hospital (red-bagged).

- *Conversion to Gel for Red-Bag Disposal.* In many hospital systems, the handling of liquid waste has become a liability issue due to worker exposure incidents and in some cases, has even been a point of contention during nurse contract negotiations. Industry has responded to concerns of nurses over splash and spillage contamination by developing a powder that, when added to the fluid in the canisters, produces a viscous, gel-like substance that can be handled more safely. After the case is completed and final blood loss is calculated, a port on the top of each canister is opened and the powder is poured into it. It takes several minutes for the gel to form, after which the canisters are placed on a service cart and removed to the red-bag disposal area for disposal with the other infectious waste. There are four major drawbacks to this system:

    - It does not ensure protection for healthcare workers, as there remains the potential for splash when the top of the canister is opened.

    - Based on industry pricing data, the total cost per canister increases by approximately $2.00.

    - Disposal costs to the hospital increase dramatically as shipping, handling and landfill costs are based upon weight rather than volume in most municipalities. The weight of an empty 2,500 ml canister is about 1 pound. A canister and its gelled contents weigh about 7.5 pounds, and the typical cost to dispose of medical waste is approximately $.30 per pound.

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

Despite the increased cost of using gel and the marginal improvement in 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. Most of these newer products are currently sold with 510(k) 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 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 higher 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. It is estimated that a range of two to eight canisters are used in each procedure, depending on the operation. Our System is designed to replace the use of canisters and render them unnecessary, as storage and disposal would be performed automatically by the System. In addition, we believe our true competitive advantage 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 System 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 System significantly reduces 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 the cost of our cleaning solution 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 costs 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 System saves 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 port(s) of the disposable filter on the STREAMWAY System. 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 System, 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 to bloodborne pathogens by healthcare workers, 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; 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 STREAMWAY System.

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 System, a unit must be purchased and installed in each room where it is intended to be used.

Marketing and Sales

Distribution

We sell the System and procedure disposables through various methods that include a direct sales force and independent distributors covering the clear majority of major U.S. markets. Currently we have one VP of Sales and eight regional sales managers selling, and demonstrating the System for prospective customers and distributors, as well as, supporting our current customer base for disposable resupply. We have signed contracts with two hospital purchasing groups; Vizient and Intalere. We have signed a contract with a SDVOSB distributor, Alliant Enterprises, LLC to distribute to the Veterans Administration, Department of Defense and other government contractors. We hired a Vice President of International Sales, in Q1 2018, who incorporated Skyline Medical Europe, a wholly owned subsidiary of Skyline Medical Inc. and hired a direct sales representative to handle Germany and France. We have contracted with distributors in Canada, Kuwait, Australia, the Pacific Islands, New Zealand, Switzerland, Pakistan, India, Saudi Arabia, Taiwan, Bangladesh, The United Arab Emirates and Iraq. Our targeted customer base includes nursing administration, operating room managers, interventional radiology 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 has been to introduce the System 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 System provides a convenient and cost-effective way to collect and dispose of this highly contaminated material.

Most of our distributors have installation and service capability, and we contract those functions with an independent service/maintenance company. We hired both distributors and service companies regarding these installation requirements. We established extensive training and standards for the service and installation of the System to ensure consistency and dependability in the field. Users of the system require a minimal amount of training to operate the System. 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 System in protecting medical personnel from inadvertent exposure. We are leveraging this medical awareness and concern with education of regulatory agencies at the local, state and federal levels about the advantages of the System.

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 and presenting at major scientific meetings where large numbers of potential users are in attendance. The theme of our trade show booths focusses 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 the American Healthcare Radiology Administrators ("AHRA"). We also attended Medica in Dusseldorf, Germany and Cirse in Lisbon, Portugal in 2018. We feature information on protection of the healthcare worker on our website as well as links to other relevant sites. We 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.

Pricing

We believe prices for the System and its disposables 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 System 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 solution is part of the return on investment equation. The 2-port disposable filter is also integral to our STREAMWAY System and is also part of the return on investment equation. 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 solution bottle used in the System can be recycled or disposed with the rest of the facility's plastics.

The System lists for $24,900 per system (one per operating room) 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 $11,000 docking station and requires a disposable component with an approximate cost of $25 - $50 per procedure and a proprietary cleaning solution (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 System 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 System 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 System 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 and that can produce six times the amount of System's produced in-house at our facility monthly as sales increase.

The disposables, including a bottle of proprietary cleaning solution and a 2-port disposable filter, are sourced through Diversified Manufacturing Corporation (cleaning solution) situated in Prescott, Wisconsin and MPP Corporation (filters), located in Osceola, Wisconsin that has tooled to manufacture our own newly designed disposable filter.

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 60601-1 3rd edition certification for our STREAMWAY System is valid and enables us to continue to market and sell our product domestically and internationally.

Skyline Medical contracted with TUV (a nationally recognized testing laboratory-NRTL) to certify our STREAMWAY System to the new 60601-1 3rd Edition in late 2016. We attained certification to the new standard, and then submitted it to our Notified Body (BSI) for recommendation for our CE Mark, which we received in June 2017, allowing us to sell products outside of the United States.

Effective November 21, 2016, the Company received a Medical Device Establishment License to sell the STREAMWAY System and related disposables in Canada.

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 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 System is a Class II device, which is less stringently reviewed as that of a Class III device. Our Senior Vice President of Operations has numerous years' of 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 System 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.

Skyline Medical has successfully passed FDA audits over the past few years, with no observations or 483 warning letters issued.

ISO Certification

Skyline Medical hired BSI (British Standards Institute) to be its Notified Body and to audit the Company to ISO 13485:2003 Standards. On June 1, 2016, Skyline successfully passed the audit of our Quality Management System and received its Certificate of Registration for ISO 13485:2016. Our certificate number is FM 649810.

The CRO Business

Investment in and Partnership with and pending merger with Helomics – CRO Services

Our CRO services business is committed to improving the effectiveness of cancer therapy using the power of artificial intelligence ("AI") applied to rich data diseases databases. We have identified the CRO market as a burgeoning sector with significant growth potential. We have acquired 25% of the capital stock of Helomics®, a Contract Research Organization ("CRO") Services company that bridges two significant areas of the healthcare industry: "Precision Medicine" and "Big Data". On March 22, 2019, our stockholders approved the pending Merger. We and Helomics believe that the Merger will enable both companies to enhance potential value for stockholders, and that both companies will benefit from the Merger.

Helomics Holding Corporation is the successor to Helomics Corporation, which was incorporated on November 17, 2016 in Delaware. On December 7, 2016, Helomics, through its wholly-owned subsidiary Helomics Intermediate Corporation, acquired all of the outstanding shares of the Helomics Corporation. Since that time, Helomics has gone through a reorganization to reset the business model as well as bring the cost structure in line with Helomics' new mission.

Helomics is a personalized medicine company that harnesses the patient's own tumor to provide actionable insights to help guide oncologist's treatment decisions. Helomics has a platform it believes to be unique, that interrogates the patient's living tumor using a set of genomic and functional tests that determine how the tumor responds to drugs. This tumor profile is then compared with an extensive in-house knowledgebase of over 150,000 cancer cases to help individualize treatment, using an AI powered analytics platform. This unique functional approach offers more powerful insights for precision medicine compared to just knowing gene variations of the tumor, which are often not actionable with currently approved drugs or drugs in trials.

Helomics focuses its precision medicine approach on six specific cancers (ovarian, breast, pancreatic, colon, lung and brain cancer), and Helomics intends to be the world leader in the artificial intelligence for those six cancers, providing actionable data that can facilitate the development of precision therapies. The Helomics business comprises three key strategic areas:

Precision Oncology Insights. The Helomics Precision Oncology Insight service provides an actionable roadmap for patients and their oncologist to guide therapy and positively impact patient outcomes using AI-driven evidence-based molecular decision making. Our approach combines comprehensive molecular profiling of the patient tumor using NGS and other technologies, together with testing the drug response of the patient tumor grown in the laboratory using Helomics' proprietary TruTumor™ model. Our D-CHIP AI-driven bioinformatics platform uses this data to continually learn which approved Standard-of-Care drugs will work best for a particular tumor profile. We then provide an actionable roadmap to guide patient therapy to the oncologist partnering with them to understand outcomes and improve and enrich the D-CHIP platform. Specializing in Ovarian cancer, Helomics offers oncologists the value of the accumulated knowledge of all tumors tested to their patients.

Boutique Contract Research Services. With a 17,400-square foot state-of-art, BSL-2, CLIA regulated laboratory in Pittsburgh, PA, Helomics offers a wide range of genomic (NGS, Microarray), proteomic, digital pathology, tissue culture and biorepository services to pharmaceutical and diagnostics clients. Helomics' CRO services address a range of needs from discovery, through clinical and translational research, to clinical trials and diagnostics development and validation. Using our unique proprietary TruTumor patient derived tumor model we are able to offer a high throughput, high content approach to screening for new therapies, biomarker discovery and diagnostic development. Coupled with our D-CHIP platform we also offer bioinformatics services for in-depth data analysis and reporting for clinical and translational research

D-CHIP AI-platform. The Helomics D-CHIP platform is an AI-powered bioinformatics engine coupled to a multi-Helomics database of biochemical and clinical information on patients with cancer. D-CHIP uses deep learning to understand the association between the mutational profile of the patient's tumor and the drug response profile of tumor grown in the lab. This approach generates actionable insights that deliver a comprehensive picture of which mutations in the tumor are associated with drugs to which the tumor is sensitive. Helomics partners with pharmaceutical, diagnostic and healthcare clients in projects that use D-CHIP for to drive patient recruitment and selection, biomarker discovery and development, and drug repurposing initiatives.

Precision Therapeutics and Helomics announced a proposed joint venture with GLG Pharma focused on using their combined technologies to bring personalized medicines and testing to ovarian and breast cancer patients, especially those who present with ascites fluid (over one-third of patients). This partnership will add a collection method to the STREAMWAY System, using GLG's Capture, Culture and Screening capabilities. We also continue to explore other opportunities to partner with revenue-generating companies and create near-term and long-term value for our shareholders. The growth strategy in this business includes securing new partnerships and considering acquisitions in the precision medicine space.

TumorGenesis Business – Development of PDx Tumor Models

We recently formed a subsidiary, TumorGenesis, to pursue a new rapid approach to growing tumors in the laboratory, which essentially "fools" the cancer cells into thinking they are still growing inside the patient. TumorGenesis intends to develop next generation, patient derived, ("PDx") tumor models for precision cancer therapy and drug development. This approach should provide a much more relevant model of the patient tumor that may be used for testing of drugs for personalized therapy or for the development of new drugs. We have entered into licensing arrangements with three medical technology companies in that regard.

TumorGenesis has secured a license agreement with 48Hour Discovery ("48HD") which grants it access to 48HD's ligand discovery technology. This follows a license agreement with SyntArray, LLC and is the latest milestone in the Company's strategy to bring together ground-breaking technologies to develop the next generation of patient derived ("PDx") tumor models for precision cancer therapy and drug development. TumorGenesis is developing a new approach to growing tumor models in the laboratory that is faster, less costly and more closely mimics the characteristics of the patient's tumor, than the traditional PDx animal models that are currently on the market. TumorGenesis' innovative approach is comprised of three key steps: first, the tumor cells from the patient tumor biopsy are tagged using peptides targeted to the patient's specific cancer cells; second, the tags adhere the cells to a 3D biomimetic support in the well of a standard 96 well microplate; and third, the tumor cells are grown in the 3D culture system until ready for testing. The 48HD ligand discovery technology is vital to the first step in this process as it screens the patient's tumor cells against large peptide libraries to identify the specific peptide ligands that bind to those cells. Once identified by 48HD's technology, SyntArray's targeted peptide cell capture technology screens these peptides to determine the best combination that will capture the cancer cells and allow them to attach and grow on the 3D biomimetic support.

We believe TumorGenesis is developing a better way to grow tumors outside the human body so they mimic the environment inside the patients' body as closely as possible. This model is expected to create more accurate results when testing drugs for personalized therapy and when developing new drugs, compared to testing with traditional animal or cell culture models. The innovative 48HD technology allows us to capture all the heterogeneity of the tumor, including both the cancerous and non-cancerous cells. This is key to reassembling the tumor on an artificial 'scaffold', or 3D biomimetic support, so it grows in a way that closely mimics the patient's body. This will allow us to offer a superior clinical testing environment which should drive lucrative partnerships with pharmaceutical companies as they develop new precision medicines and cancer therapies.

Testing of patient tumors using the TumorGenesis approach is expected to: (a) provide a personalized therapy protocol for a patient, (b) provide high-quality data on cancer tumors for a platform based on the D-CHIP Artificial Intelligence platform of Helomics Corporation, pursuant to Precision Therapeutics' partnership with Helomics, and (c) drive partnerships with pharma companies for the development of new therapies, generating revenues for Precision Therapeutics. The TumorGenesis PDx model will initially be developed for three orphan cancers, Multiple Myeloma, Triple-Negative Breast cancer (TNBC) and Ovarian cancers, all of which are areas that have a high unmet need for new and effective treatments that are tailored to patients' unique tumor profiles. Testing of the TumorGenesis PDx tumors will take place in collaboration with Helomics.

Employees

Precision has 24 employees, all of whom are full-time.

ITEM 1A. RISK FACTORS.

You should carefully consider the risks described below before making an investment decision. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Form 10-K, including our financial statements and related notes.

We will require additional financing to finance operating expenses and fulfill our business plan. Such financing will be dilutive. Our independent public accounting firm has indicated in their audit opinion, contained in our financial statements, that they have serious doubts about our ability to remain a going concern.

We have not achieved profitability and anticipate that we will continue to incur net losses at least through the first two quarters of 2019. We had revenues of $1,412,000 in 2018, but we had negative operating cash flows of $5.3 million. In January 2018, we received proceeds of $2.5 million because of our public offering. In June 2018 and July 2018, we received proceeds of $0.5 million because of warrants exercised from a previous private placement. In October 2018, we received $1.8 million from a bridge loan. In December 2018, the Company received a short-term loan from our CEO for $370,000. Our cash and cash equivalents balance was $0.2 million as of December 31, 2018, and our accounts payable and accrued expenses were an aggregate $0.9 million. We are currently incurring negative operating cash flows of approximately $441,000 per month. Although we are attempting to curtail our expenses, there is no guarantee that we will be able to reduce these expenses significantly, and expenses for some periods may be higher as we prepare our product for broader sales, increase our sales efforts and maintain adequate inventories.

As of December 31, 2018, the Company had debt totaling $1.7 million. The Company received a bridge loan that net of discount is due $1.3 million and a short-term loan from the CEO equaling $0.4 million. In January 2019, the Company received an additional loan for $950,000 and an investment of $50,000 from our CEO. In February 2019, the CEO advanced another $300,000 under the same loan agreement.

We will require additional funding to finance operating expenses and to invest in our sales organization and new product development and to compete in 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.

Because of the above factors, our independent registered public accounting firm has indicated in their audit opinion, contained in our consolidated financial statements included in this Annual Report on Form 10-K, that they have substantial 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.”

In connection with developing our CRO business, we have committed and will continue to commit significant capital to investments in early stage companies, all of which may be lost, and which may require us to raise significant additional capital, and our entering into new lines of business will result in significant diversion of management resources, all of which may result in failure of our business.

We have committed significant capital and management resources to developing our CRO business and other new business areas, and we intend to continue to devote significant and management resources to new businesses. In total, we have provided approximately $1,165,013 in financing to Helomics, of which $500,000 in principal amount has been converted into an equity interest in Helomics and $665,013 in principal amount is subject to secured notes that remain outstanding. In 2019, the Company provided an additional $305,000, with the expectation that more funds will be required over the coming months. In addition, in August 2017, we entered into a merger agreement with CytoBioscience, which was subsequently terminated in November 2017. From July 2017 through November 2017, we advanced $1,070,000 to CytoBioscience in the form of secured notes, which are still outstanding. CytoBioscience has defaulted on the notes, but in January 2019 reached repayment agreement with the Company and remitted approximately $61,000 covering a portion of principal, interest and legal bills toward collection processes. CytoBioscience made a second payment of $65,458 in March 2019 bringing the note current pursuant to the repayment agreement. The Company has a Confession of Judgment and UCC protection on collateral, however this does not guarantee timely or full payment on the notes. It is likely that we will make further investments and advances in other businesses as we develop our CRO business and other business models. There can be no assurance that any of the outstanding balances of our existing promissory notes or future advances will be repaid. Further, there is no assurance that our equity investment in Helomics or other investments in new businesses will result in significant value for the Company. Therefore, we could invest significant capital in other business enterprises with no certainty when or whether we will realize a return on these investments. Investments in cash will deplete our capital resources, meaning that we will be required to raise significant amounts of new capital. There is no assurance that we will be successful in raising sufficient capital, and the terms of any such financing will be dilutive to our stockholders. We may also acquire technologies or companies by issuing stock or other equity securities rather than or in addition to payment of cash, which may have the result of diluting the investment of our stockholders. Further, the energy and resources of our officers and personnel are being substantially diverted to these new lines of business, which are unproven. If these businesses are unsuccessful or require too great of a financial investment to be profitable, our business may fail regardless of the level of success of our STREAMWAY business.

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.

STREAMWAY Business Risk Factors

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 could 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 could be prevented from marketing our products. While we are currently not subject to any material intellectual property litigation, any future litigation alleging intellectual property infringement could be costly, particularly in light of our limited resources. Similarly, if we determine that third parties are infringing on our patents or other intellectual property rights, our limited resources may prevent us from litigating or otherwise taking actions to enforce our rights. Any such litigation or inability to enforce our rights could require us to change our business practices, hinder or prevent our ability to deliver our products and services, and result in a negative impact to our business. Expansion of our business via product line enhancements or new product lines to drive increased growth in current or new markets may be inhibited by the intellectual property rights of our competitors and/or suppliers. Our inability to successfully mitigate those factors may significantly reduce our market opportunity and subsequent growth.

We face significant competition, including competition from companies with considerably greater resources than ours, and if we are unable to compete effectively with these companies, our market share may decline and our business could be harmed.

Our industry is highly competitive with numerous competitors ranging from well-established manufacturers to innovative start-ups. A number of our competitors have significantly greater financial, technological, engineering, manufacturing, marketing and distribution resources than we do. Their greater capabilities in these areas may enable them to compete more effectively on the basis of price and production and more quickly develop new products and technologies.

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 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 products 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 costlier 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 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 products 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 solution and in-line filter.

Because of these and other factors, our products 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 System, following GMP compliance regulations of the FDA, at our own facility and anticipate the capability of producing the STREAMWAY System 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.

Precision's success depends on the skills, experience and performance of key members of its management team. Precision heavily depends on its management team: Carl Schwartz, Precision's Chief Executive Officer ("CEO"), and Bob Myers, Precision's Chief Financial Officer ("CFO"). Precision has entered into employment agreements with the CEO and the CFO of the senior management team and may expand the relatively small number of executives in its company. Were Precision to lose one or more of these key individuals, it 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 Precision's business plan and the diversion of its limited working capital. Precision can give no assurance that it can find satisfactory replacements for these key individuals at all, or on terms that are not unduly expensive or burdensome to Precision.

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.

Security breaches, loss of data and other disruptions to Precision or its third-party service providers could compromise sensitive information related to Precisions' business or prevent Precision from accessing critical information and expose it to liability, which could adversely affect Precisions' business and reputation .

Precisions' business requires that Precision collect and store sensitive data including credit card information, and Precisions' proprietary business and financial information. Precision faces a number of risks relative to Precisions' protection of, and Precisions' service providers' protection of, this critical information, including loss of access, inappropriate disclosure and inappropriate access, as well as risks associated with Precisions' ability to identify and audit such events. The secure processing, storage, maintenance and transmission of this critical information are vital to Precisions' operations and business strategy, and Precision devotes significant resources to protecting such information. Although Precision takes measures to protect sensitive information from unauthorized access or disclosure, Precisions' information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While Precision has not experienced any such attack or breach, if such event would occur and cause interruptions in Precisions' operations, Precisions' networks would be compromised and the information Precision stores on those networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Unauthorized access, loss or dissemination could disrupt Precisions' operations, including collecting, processing and preparing company financial information, manage the administrative aspects of Precisions' business and damage Precisions' reputation, any of which could adversely affect Precisions' business. In addition, the interpretation and application of consumer, health-related and data protection laws in the United States are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with Precisions' practices. Complying with these various laws could cause Precision to incur substantial costs or require Precision to change its business practices, systems and compliance procedures in a manner adverse to Precisions' business.

Costs incurred because Precision is a public company may affect its profitability.

As a public company, Precision incurs significant legal, accounting, and other expenses and it is 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. Full compliance with such rules and regulations requires significant legal and financial compliance costs and makes some activities more time-consuming and costlier, which may negatively impact its financial results. To the extent Precision's earnings suffer as a result of the financial impact of its SEC reporting or compliance costs, its ability to develop an active trading market for its securities could be harmed.

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; investors must rely on stock appreciation for any return on investment in the Company's common stock.

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, investors must rely on stock appreciation and a liquid trading market for any return on investment in the Company's 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.

When established, the market for our common stock may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will be more volatile than a seasoned issuer for the indefinite future. In addition, there is no assurance that the price of our common stock will not be volatile. In the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources.

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

Our authorized capital includes 20 million shares of preferred stock. Of this amount, 18,950 shares have been designated as Series B Convertible Preferred Stock, 1,213,819 shares have been designated as Series C Preferred Stock and the remaining authorized shares are undesignated preferred stock. Our Board of Directors have 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.

Acquisitions involve risks that could result in adverse changes to operating results, cash flows and liquidity.

Precision intends to make strategic acquisitions in addition to the Merger. However, Precision may not be able to identify suitable acquisition opportunities or may be unable to obtain the consent of Precision's stockholders and therefore, may not be able to complete such acquisitions. Precision may pay for acquisitions with its common stock or with convertible securities, which may dilute shareholders' investment in its common stock or it may decide to pursue acquisitions that investors may not agree with. In connection with potential Precision's acquisitions, Precision may agree to substantial earn-out arrangements. To the extent it defers the payment of the purchase price for any acquisition through a cash earn-out arrangement, it will reduce cash flows in subsequent periods. In addition, acquisitions may expose Precision to operational challenges and risks, including:

- the ability to profitably manage acquired businesses or successfully integrate the operations of acquired businesses, as well as the acquired business's financial reporting and accounting control systems into its existing platforms;

- increased indebtedness and contingent purchase price obligations associated with an acquisition;

- the ability to fund cash flow shortages that may occur if anticipated revenue is not realized or is delayed, whether by general economic or market conditions, or unforeseen internal difficulties;
- the availability of funding sufficient to meet increased capital needs;
- diversion of management's time and attention from existing operations; and
- the ability to retain or hire qualified personnel required for expanded operations.

Completing acquisitions may require significant management time and financial resources because Precision may need to assimilate widely dispersed operations with different corporate cultures. In addition, acquired companies may have liabilities that it failed to or were unable to discover in the course of performing due diligence investigations. Precision cannot assure the shareholders' that the indemnification granted by sellers of acquired companies will be sufficient in amount, scope or duration to fully offset the possible liabilities associated with businesses or properties it assumes upon consummation of an acquisition. Precision may learn additional information about its acquired businesses that could have a material adverse effect on Precision, such as unknown or contingent liabilities and liabilities related to compliance with applicable laws. Any such liabilities, individually or in the aggregate, could have a material adverse effect on its business. Failure to successfully manage the operational challenges and risks associated with, or resulting from, acquisitions could adversely affect Precision's results of operations, cash flows and liquidity. Borrowings or issuances of convertible securities associated with these acquisitions may also result in higher levels of indebtedness, which could adversely impact Precision's ability to service its debt within the scheduled repayment terms.

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.

On November 16, 2018, we received a letter from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") informing us that because the closing bid price for our common stock listed on Nasdaq was below $1.00 for 30 consecutive trading days, we do not comply with the minimum closing bid price requirement for continued listing on The Nasdaq Capital Market under Nasdaq Marketplace Rule 5550(a)(2), requiring a minimum bid price of $1.00 per share (the "Minimum Bid Price Requirement"). The notification has no immediate effect on the listing of our common stock.

In accordance with Nasdaq's Marketplace Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until May 15, 2019, to regain compliance with the Minimum Bid Price Requirement. If at any time before May 18, 2019 the bid price of the Company's common stock closes at or above $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that the Company has achieved compliance with the Minimum Bid Price Requirement. However, the Company has been advised that Nasdaq has discretion to extend this required period to 20 consecutive business days or to impose other requirements.

The letter also disclosed that in the event we do not regain compliance with the Minimum Bid Price Requirement by May 15, 2019, we may be eligible for additional time. To qualify for additional time, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to the Staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, the Staff would notify us that our securities would be subject to delisting. In the event of such notification, we may appeal the Staff's determination to delist its securities, but there can be no assurance the Staff would grant our request for continued listing.

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.

Precision's ability to obtain and/or utilize financing to fund our ongoing operations may be limited by the terms of our certain outstanding Amended and Restated Senior Secured Promissory Notes.

Effective September 28, 2018, Precision issued one-year convertible promissory notes to each of two institutional investors (the "Investors") (together, the "Notes") in the original principal amount of an aggregate $2,297,728. The Notes accrue interest at a rate of 8% per annum (with twelve months of interest guaranteed). The Notes may be prepaid in any amount, provided that any amounts that are repaid from and after January 26, 2019 (including repayment at maturity and mandatory prepayments discussed below) will be subject to a 25% repayment penalty.

Effective February 7, 2019, Precision entered into a Forbearance Agreement with each of the Investors pursuant to which, among other things, the Investors agreed to forbear on their rights to accelerate the Notes based on an event of default and a claimed event of default. In connection with such forbearance, Precision issued Amended and Restated Senior Secured Promissory Notes that replaced the Notes and, among other things, increased the aggregate principal amount of our indebtedness to the Investors to $2,642,387.

As long as the Amended and Restated Notes remain outstanding, if Precision receives cash proceeds from any source other than (i) sales of our products or (ii) the first $2,000,000 of proceeds from securities offering transactions, Precision is required to inform the Investors of such receipt. Investor will have the right to require that Precision apply up to 50% of such proceeds to repay outstanding amounts owed under their Note. Precision has already received $1,620,000 in aggregate cash proceeds from securities offering transactions as of February 26, 2019. As a result, proceeds from future securities offering transactions may be subject to the Investors' repayment rights. The aforementioned criteria may negatively impact Precision's ability to obtain financing from securities offering transactions until repayment or conversion of the Notes. To the extent we are able to obtain such financing, this arrangement may limit Precision's ability to use the proceeds thereof to fund its operations. If we are unable to obtain financing or use the proceeds to fund its operations, Precision will be forced to limit its business activities, which will have a material adverse effect on Precision's results of operations and financial condition.

Precision may fail prevent further defaults under the Amended and Restated Notes, which could result in material penalties and acceleration of the Amended and Restated Notes, and the Investors could assert their rights as secured creditors.

Effective February 7, 2019, Precision entered into a Forbearance Agreement with each of the Investors in connection with (1) the Investors' claim that Precision failed to timely comply with the requirements of a registration rights agreement with the Investors and (2) a default resulting from Precision's failure to obtain stockholder approval on or before December 31, 2018 for Precision's pending Merger with Helomics. Under the Forbearance Agreements and the Amended and Restated Notes, Precision issued an aggregate of 166,667 shares to the Investors, and a total of $344,659 was added to the principal amount of Precision's indebtedness to the Investors, resulting in aggregate principal of $2,642,387. Interest on the Amended and Restated Notes accrued at a default rate of 18% beginning as of November 15, 2018 and continuing through the date of the Default Cure (as defined below).

Under the Forbearance Agreements, if (a) Precision obtains shareholder approval of the pending merger transaction with Helomics by March 31, 2019, (b) Precision maintains the effectiveness of its currently effective registration statement on Form S-3 that registers the resale of certain shares that we issued to the Investors as an inducement for their investment, and (c) there are no other defaults under the Amended and Restated Notes and related documents, then the above defaults will be considered cured (the "Default Cure"), the Amended and Restated Notes will not be accelerated and no additional default penalties will be paid. If Precision fails to satisfy these conditions, the forbearance will terminate, the Amended and Restated Notes will accelerate, and the Investors may assert all of their rights. The Company believes that, as a result of the effectiveness of such registration statement on February 13, 2019 and the stockholder approval of the Merger on March 22, 2019, the Default Cure has been achieved. However, there can be no assurance that there will not be additional defaults under terms of the Amended and Restated Notes. Upon a default, among other things, the Amended and Restated Notes become immediately due and payable, Precision is required to pay to the holder 135% (plus an additional 5% per each additional event of default) multiplied by the then outstanding balance of the Amended and Restated Notes plus default interest at 18%. Further, the Investors have a security interest in substantially all of Precision's assets and those of Helomics. In the event of a default, we may attempt to refinance the payment of the balance of the Amended and Restated Notes and applicable penalties; however, there is no assurance that such refinancing will be available. Therefore, defaults on the Amended and Restated Notes would have a material adverse effect on our financial condition, including the Investors' rights to seize our assets or those of Helomics in the event we cannot satisfy our obligations under the Amended and Restated Notes.

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 agreement 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.

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. Thus, 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.

Risks Related to the Proposed Merger with Helomics Holding Corporation (the "Merger")

On October 26, 2018, Precision entered into an Amended and Restated Agreement and Plan of Merger with Helomics Acquisition, Inc. ("Merger Sub"), a wholly owned subsidiary of Precision, and Helomics Holding Corporation ("Helomics") (the "Merger Agreement"). Under the Merger Agreement, Helomics will merge with and into Merger Sub, with Merger Sub, to be renamed Helomics Holding Corporation, surviving as a wholly-owned subsidiary of Precision (the "Merger"). The following risks relate to the Merger. The Merger is more fully described in Amendment No. 2 to Precision's Registration Statement on Form S-4, filed with the Securities and Exchange Commission on January 24, 2019 (SEC File no. 333-228031) (the "Form S-4 Registration Statement").

Completion of the pending Merger and the Merger Issuance will result in the issuance of a large number of our shares and warrants, which will significantly dilute the percentage of stock held by existing holders of our common stock.

On the effective date of the pending Merger, we will issue 4.0 million shares of our Common Stock and 3.5 million shares of Series D Preferred Stock to holders of Helomics capital stock. This issuance is in addition to the 1.1 million shares of Precision Common Stock previously issued to Helomics as consideration for Precision's prior acquisition of a twenty percent ownership interest in Helomics; these 1.1 million shares will remain outstanding and will be distributed to holders of Helomics capital stock. Each share of Precision Series D Preferred Stock is convertible into one share of Precision Common Stock starting one year after issuance, subject to adjustment. In the Exchange Offer, based on the exchange of $8.6 million in outstanding promissory notes and the associated Helomics warrants, we will issue: (1) approximately 8.6 million additional shares of our Common Stock, (2) approximately 14.2 warrants to purchase our Common Stock at an exercise price of $1.00 per share and (3) 0.6 million warrants to purchase Common Stock at an exercise price of $0.01 per share. The Merger Issuance will include issuance of the 4.0 million shares of our Common Stock and 3.5 million shares of Series D Preferred Stock in the Merger and the issuance of the 8.6 million shares of our Common Stock and the aggregate 14.8 million Precision warrants in the Exchange Offer. Immediately after the Merger Issuance, the former Helomics security holders will own approximately 44.4% of the issued and outstanding shares of Common Stock and Precision stockholders will own approximately 55.6% of the issued and outstanding shares of Common Stock. The former holders of Helomics warrants will hold warrants that would represent 31.7% of the outstanding shares of the Precision Common Stock if exercised. After such exercise, pre-merger Precision stockholders would own 33.8% of the outstanding Precision shares, historic Helomics stockholders would own 16.1% of the outstanding shares, and the former Helomics noteholders would own 50.1% of the outstanding shares. Therefore, as a result of the Merger and the Exchange Offer, the percentage of our stock held be existing holders of our common stock will be significantly diluted. See Item 10, "Management's Discussion and Analysis of Financial Condition and Results of Operations," under "Overview."

Precision may not complete the Merger, which could negatively impact Precision's stock price and future operations.

If the Merger is not completed for any reason, Precision and Helomics may each be subjected to a number of material risks. The price of Precision common stock may decline to the extent that the current market price of the Precision's common stock reflects a market assumption that the Merger will be completed. Some costs related to the Merger, such as legal, accounting, filing, printing and mailing, must be paid and expended even if the Merger is not completed. In addition, if the Merger is not completed and the Precision's Board of Directors determines to seek another merger or business combination, there can be no assurance that the Board of Directors will be able to find a partner willing to agree to more attractive terms than those which have been negotiated for in the Merger.

The Merger Consideration is not adjustable based on the market price of Precision common stock so the consideration received (a) in connection with the Merger at the Closing of the Merger and/or (b) in connection with the Exchange Offer may have a greater or lesser value than at the time the Merger Agreement was signed.

Changes in the market price of Precision common stock before the completion of the Merger will not affect the number of shares Helomics security holders will be entitled to receive pursuant to the Merger Agreement (the "Merger Consideration") and/or the related exchange offer (the "Exchange Offer"). Therefore, if, before the completion of the Merger, the market price of Precision common stock declines from the market price on the date of the Merger Agreement, then Helomics security holders could receive consideration with substantially lower value in connection with the Merger, the Exchange Offer or both. Similarly, if before the completion of the Merger, the market price of Precision common stock increases from the market price on the date of the Merger Agreement, then Helomics security holders could receive consideration with substantially more value for their shares of Helomics capital stock than the parties had anticipated.

If the conditions to the Merger are not met, the Merger may not occur.

Even though the Merger has been approved by the stockholders of both Precision and Helomics and certain other conditions have been satisfied, specified conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement and described in our Form 8-K report filed on October 30, 2018. Neither Precision nor Helomics can assure you that all the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or may be delayed, and Precision and Helomics each may lose some or all the intended benefits of the Merger.

The Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes and other causes.

In general, either Precision or Helomics can refuse to complete the Merger if there is a material adverse change affecting the other party between October 26, 2018, the date of the Merger Agreement, and the closing of the Merger. However, certain types of changes do not permit either party to refuse to complete the Merger, even if such change could be said to have a material adverse effect on Precision or Helomics, including:

1. conditions generally affecting the industries in which Helomics or Precision participates or the U.S. or global economy as a whole, to the extent that such conditions do not have a disproportionate impact on Precision or Helomics and their respective subsidiaries, taken as a whole, as compared to other industry participants;

2. general conditions in the financial markets, and any changes therein (including any changes arising out of acts of terrorism, war, weather conditions or other force majeure events), to the extent that such conditions do not have a disproportionate impact on Precision or Helomics and their respective subsidiaries, taken as a whole, as compared to other industry participants; and

3. any change in accounting requirements or principles or any change in applicable legal requirements.

If material adverse changes occur and Precision and Helomics still complete the Merger, the stock price of the combined company may suffer. This in turn may reduce the value of the Merger and/or the Exchange Offer to the stockholders of Precision, Helomics or both.

The Merger may not occur if either Precision or Helomics or both is not satisfied with the results of due diligence.

Both (a) Precision's satisfaction with the results of its due diligence regarding Helomics and its subsidiary entities and (b) Helomics' satisfaction with the results of its due diligence regarding Precision are conditions that must be satisfied or waived to complete the Merger. Neither Precision nor Helomics can assure the shareholders' that these conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or may be delayed, and Precision and Helomics each may lose some or all the intended benefits of the Merger.

Precision stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

If the combined organization is unable to realize the full strategic and financial benefits currently anticipated from the Merger, Precision stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined organization is able to realize only part of the strategic and financial benefits currently anticipated from the Merger.

Prior to the Merger, each of Helomics and Precision is obligated pursuant to the Merger Agreement to conduct their respective business and operations in the ordinary course and in accordance in all material respects with past practices, which could limit favorable opportunities available to Helomics and/or Precision, which could adversely affect their respective businesses.

Covenants in the Merger Agreement requires each of Helomics and Precision to conduct their respective business and operations in the ordinary course, which may impede the ability of each of Helomics and Precision to enter into other transactions that are not in the ordinary course of business, pending completion of the Merger. As a result, if the Merger is not completed, the parties may be at a relative disadvantage to their competitors during that period.

Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit Helomics from soliciting competing proposals or cooperating with persons making unsolicited takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

Because the lack of a public market for Helomics' capital stock makes it difficult to evaluate the fairness of the Merger, the stockholders of Helomics may receive consideration (a) in the Merger and/or (b) the Exchange Offer that is less than the fair market value of Helomics' capital stock and/or Precision may pay more than the fair market value of Helomics' capital stock.

The outstanding capital stock of Helomics is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Helomics' capital stock. Because the percentage of Precision equity to be issued to Helomics stockholders was determined based on negotiations between the parties, it is possible that the value of the Precision common stock to be received by Helomics stockholders will be less than the fair market value of Helomics' capital stock, or Precision may pay more than the aggregate fair market value for Helomics' capital stock.

Costs associated with the Merger are difficult to estimate, may be higher than expected, and may harm the financial results of the combined company.

Both Precision and Helomics will incur substantial direct transaction costs associated with the Merger and additional costs associated with consolidation and integration of operations. If the total costs of the Merger exceed estimates, or the benefits of the Merger do not exceed the total costs of the Merger, Precision's consolidated financial results could be adversely affected.

The Merger may result in disruption of Precision and Helomics' existing businesses, distraction of their management and diversion of other resources.

The integration of Precision's and Helomics' operations may divert management time and resources from the main businesses of both companies. After the Merger, management will likely be required to spend significant time integrating Precision's and Helomics' operations. This diversion of time and resources could cause the combined business to suffer.

Any delay in completion of the Merger may significantly reduce the benefits expected to be obtained from the Merger.

The Merger is subject to approval of Helomics' shareholders, and it is subject to a number of other conditions beyond the control of Precision and Helomics and that may prevent, delay or otherwise materially affect its completion. Precision and Helomics cannot predict whether or when these other conditions will be satisfied. Any delay in completing the Merger may significantly reduce the synergies and other benefits that Precision and Helomics expect to achieve if they successfully complete the Merger within the expected timeframe and integrate their respective businesses.

The market price of Precision's common stock may decline as a result of the Merger.

The market price of Precision's common stock may decline as a result of the Merger if the integration of Precision's and Helomics' businesses is unsuccessful or if the costs of implementing the integration are greater than expected. The market price also may decline if Precision does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts, or shareholders, or if the effect of the Merger on Precision's financial results is not consistent with the expectations of financial or industry analysts, or shareholders.

Each of Precision, Helomics and the combined company will incur substantial transaction-related costs relating to the Merger.

Precision and Helomics have incurred, and expect to continue to incur, significant non-recurring transaction-related costs associated with completing the Merger and combining the two companies. These fees and costs have been, and will continue to be, substantial. Non-recurring transaction costs include, but are not limited to, fees paid to legal, financial and accounting advisors, severance and benefit costs, filing fees and printing costs. Additional unanticipated costs may be incurred in the integration of the operations of Precision and Helomics, which may be higher than expected and could have a material adverse effect on the combined company's financial condition and operating results.

Precision's ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code and may be subject to further limitation because of prior or future offerings of Precision's stock or other transactions.

Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended (the "Code") contain rules that limit the ability of a company that undergoes an ownership change, which is generally an increase in the ownership percentage of certain stockholders in the stock of a company by more than 50% over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change, as defined by Section 382 of the Code, occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term tax-exempt rate and the value of the company's stock immediately before the ownership change. The Merger will result in such an ownership change. As a result, Precision will not be able to use its pre-Merger losses or credit carryovers or certain built-in losses to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383 of the Code, which may result in the expiration of a portion of Precision's tax attributes before utilization.

Precision will incur significantly increased costs as a result of the completion of the Merger.

Following completion of the merger, Precision's operating expenses are likely to increase significantly as Helomics continues to develop and grow its business. These increases are most likely to be in the areas of sales and marketing, compensation and research and product development. There also may be increases in legal, accounting, insurance and compliance costs. As a result, the combined company is expected to report operating losses until Helomics can significantly increase its revenues. This may have a material adverse impact on the market price of Precision common stock following the Merger. Additionally, the integration of the operations of Precision and Helomics may result in unanticipated costs, which may be higher than expected and could have a material adverse effect on the combined company's financial condition and operating results.

The combined company will not be able to continue operating without additional financing.

Both Precision and Helomics have been operating at a loss. In order to continue operating and remain a going concern, the combined company will need to obtain additional financing, either through borrowings, public offerings, private offerings, or some type of business combination (e.g., merger, buyout, etc.), and there can be no assurance that it will be successful in such pursuits with terms satisfactory to management and Precision's board of directors. In the past, both companies have actively pursued a variety of funding sources including private offerings and have consummated certain transactions in order to address their respective capital requirements. Precision recently completed a private offering of securities and loaned a portion of the proceeds to Helomics. However, the combined company anticipates the need for additional capital beyond the recent offering and may not be able to acquire such additional funding. Accordingly, if the combined company is unable to generate adequate cash from operations, and if it is unable to find sources of funding, it may be necessary for it to sell one or more lines of business or all or a portion of its assets, enter into a business combination, reduce or eliminate operations, liquidate assets, or seek relief through a filing under the U.S. Bankruptcy Code. These possibilities, to the extent available, may be on terms that result in significant dilution to the combined company's existing shareholders or that result in its existing shareholders losing all of their investment in the combined company.

Precision may fail to realize the anticipated benefits of the Merger.

The success of the Merger will depend, in part, on Precision's ability to realize the anticipated growth opportunities and synergies from combining Precision and Helomics. The integration of Precision and Helomics will be a time consuming and expensive process and may disrupt their operations if it is not completed in a timely and efficient manner. In addition, Precision may not achieve anticipated synergies or other benefits of the Merger. Following the Merger, Precision and Helomics must operate as a combined organization utilizing common information and communication systems, operating procedures, financial controls and human resources practices. The combined company may encounter the following integration difficulties, resulting in costs and delays:

- failure to successfully manage relationships with customers and other important relationships;
- failure of customers to continue using the services of the combined company;
- difficulties in successfully integrating the management teams and employees of Precision and Helomics;
- challenges encountered in manager larger operations;
- losses of key employees;
- failure to manage the growth and growth strategies of Precision and Helomics;
- diversion of the attention of management from other ongoing business concerns;
- incompatibility of technologies and systems;
- impairment charges incurred to write down the carrying amount of intangible assets generated as a result of the Merger; and
- incompatibility of business cultures.

If the combined company's operations after the Merger do not meet the expectations of existing or prospective customers of Precision and Helomics, then these customers and prospective customers may cease doing business with the combined company altogether, which would harm its results of operations, financial condition and business prospects. If the management team is not able to develop strategies and implement a business plan that successfully addresses these difficulties, Precision may not realize the anticipated benefits of the Merger.

Risk Relating to Our Investment in or Acquisition of Helomics

Helomics molecular diagnostics business has limited revenue, and Helomics expects to incur net losses for the foreseeable future and Helomics may never achieve or sustain profitability.

The revenue generated from Helomics' molecular diagnostics business was $425,065, for the nine months ended September 30, 2018 and for the same fiscal period, Helomics' molecular diagnostics business had operating losses of approximately $3.8 million. Although Helomics expects the revenue generated from Helomics' molecular diagnostics business to grow in the future, there can be no assurance that Helomics will achieve revenue sufficient to offset expenses. Additionally, Helomics is engaged in activities to expand and diversify its revenue base. Helomics expects that a significant portion of Helomics revenue will come from certain service efforts being offered to pharmaceutical, diagnostic and biotech companies as well as academic institutions. Helomics' business may never achieve or sustain profitability, and Helomics' failure to achieve and sustain profitability in the future could have a material adverse effect on Helomics' business, financial condition and results of operations.

Helomics has a limited operating history as a molecular diagnostics company, which may make it difficult to evaluate the success of Helomics' business to date and to assess Helomics' future viability.

Helomics has operated as a molecular diagnostics company since the beginning of 2017. Helomics is building a new business foundation which may make it difficult to evaluate the success of Helomics' business to date and to assess its future viability.

If one or more significant payors stops providing reimbursement or decreases the amount of reimbursement for Helomics' molecular diagnostic tests, Helomics' revenue could decline.

Although Helomics has entered into contracts with certain third-party payors which establish in-network allowable rates of reimbursement for its molecular diagnostic tests, payors may suspend or discontinue reimbursement at any time, may require or increase co-payments from patients, or may reduce the reimbursement rates paid to Helomics. Any such actions could have a negative effect on Helomics' revenue.

If payors do not provide reimbursement, rescind or modify their reimbursement policies or delay payments for Helomics' tests, or if Helomics is unable to successfully negotiate additional reimbursement contracts, Helomics' commercial success could be compromised.

Physicians may not order Helomics' tests unless payors reimburse a substantial portion of the test price. There is uncertainty concerning third-party reimbursement of any test incorporating new molecular diagnostic technology. Reimbursement by a payor may depend on a number of factors, including a payor's determination that tests such as Helomics' molecular diagnostic tests are: (a) not experimental or investigational; (b) pre-authorized and appropriate for the patient; (c) cost-effective; (d) supported by peer-reviewed publications; and (e) included in clinical practice guidelines. Since each payor makes its own decision as to whether to establish a policy or enter into a contract to reimburse Helomics' tests, seeking these approvals is a time-consuming and costly process. Also, payor consolidation is underway and creates uncertainty as to whether coverage and contracts with existing payors will remain in effect. Finally, commercial payors may tie their allowable rates to Medicare rates, and should Medicare reduce their rates, Helomics may be negatively impacted. If Helomics fails to establish broad adoption of and reimbursement for its molecular diagnostic tests, or if Helomics is unable to maintain existing reimbursement from payors, its ability to generate revenue could be harmed and this could have a material adverse effect on Helomics' business, financial condition and results of operations.

Helomics may experience limits on its revenue if physicians decide not to order its molecular diagnostic tests.

If Helomics is unable to create or maintain demand for its molecular diagnostic tests in sufficient volume, it may not become profitable. To generate demand, Helomics will need to continue to educate physicians and the medical community on the value and benefits of its molecular diagnostic tests in order to change clinical practices through published papers, presentations at scientific conferences and one-on-one education by Helomics' internal sales force. In addition, Helomics' ability to obtain and maintain adequate reimbursement from third-party payors will be critical to generating revenue. In many cases, practice guidelines in the United States have recommended therapies or surgery to determine if a patient's condition is malignant or benign. Accordingly, physicians may be reluctant to order a diagnostic test that may suggest surgery is unnecessary. In addition, Helomics' molecular diagnostic tests are performed at Helomics' laboratories rather than by a pathologist in a local laboratory, so pathologists may be reluctant to support Helomics' molecular diagnostic tests. In addition, guidelines for the diagnosis and treatment of thyroid nodules may change to recommend another type of treatment protocol, and these changes may result in medical practitioners deciding not to use Helomics' molecular diagnostic tests. These facts may make physicians reluctant to convert to using Helomics' molecular diagnostic tests, which could limit Helomics' ability to generate revenue and achieve profitability which could have a material adverse effect on its business, financial condition and results of operations.

Helomics may experience limits on its revenue if patients decide not to use its molecular diagnostic tests.

Some patients may decide not to use Helomics' molecular diagnostic tests due to price, all or part of which may be payable directly by the patient if the patient's insurer denies reimbursement in full or in part. Many insurers seek to shift more of the cost of healthcare to patients in the form of higher co-payments or premiums. In addition, the current economic environment in the United States has and may continue to result in the loss of healthcare coverage. Implementation of provisions of the Patient Protection and Affordable Care Act, or PPACA (also known as the Affordable Care Act) also resulted in the loss of health insurance, and increases in premiums and reductions in coverage, for some patients. These events may result in patients delaying or forgoing medical checkups or treatment due to their inability to pay for Helomics' test, which could have an adverse effect on Helomics' revenue.

If Helomics' sales efforts are less successful than anticipated, its business expansion plans, including its service offerings, could suffer and its ability to generate revenues could be diminished. In addition, Helomics has limited history selling its molecular diagnostics tests on a direct basis and Helomics' limited history makes forecasting difficult.

If Helomics' sales efforts are not successful, or new additions to its sales initiatives fail to gain traction among customers, Helomics may not be able to increase market awareness and sales of its molecular diagnostic tests or its service offerings. If Helomics fails to establish its molecular diagnostic tests in the marketplace, it could have a negative effect on its ability to sell subsequent molecular diagnostic tests and hinder the desired expansion of its business. Helomics has limited historical experience forecasting the direct sales of its molecular diagnostics products and service offerings. Helomics' ability to produce product quantities that meet customer demand is dependent upon its ability to forecast accurately and plan production and processing accordingly.

Helomics relies on sole suppliers for some of the materials used in its molecular diagnostic tests, and it may not be able to find replacements or transition to alternative suppliers in a timely manner.

Helomics relies on sole suppliers for certain materials that it uses to perform its molecular diagnostic tests. Helomics also purchases reagents used in its molecular diagnostic tests from sole-source suppliers. While Helomics has developed alternate sourcing strategies for these materials and vendors, Helomics cannot be certain whether these strategies will be effective or the alternative sources will be available in a timely manner. If these suppliers can no longer provide Helomics with the materials it needs to perform its molecular diagnostic tests, if the materials do not meet its quality specifications, or if it cannot obtain acceptable substitute materials, an interruption in molecular diagnostic test processing could occur. Any such interruption may directly impact Helomics' revenue and cause it to incur higher costs.

Helomics may experience problems in scaling its operations, or in delays or reagent and supply shortages that could limit the growth of its revenue.

If Helomics encounters difficulties in scaling its operations as a result of, among other things, quality control and quality assurance issues and availability of reagents and raw material supplies, it will likely experience reduced sales of its molecular diagnostic tests, increased repair or re-engineering costs, and defects and increased expenses due to switching to alternate suppliers, any of which would reduce Helomics' revenues and gross margins. Although Helomics attempts to match its capabilities to estimates of marketplace demand, to the extent demand materially varies from Helomics' estimates, Helomics may experience constraints in its operations and delivery capacity, which could adversely impact revenue in a given fiscal period. Should Helomics' need for raw materials and reagents used in its molecular diagnostic tests fluctuate, Helomics could incur additional costs associated with either expediting or postponing delivery of those materials or reagents.

If Helomics is unable to support demand for its molecular diagnostic tests or any of its future tests or solutions, Helomics' business could suffer.

As demand for Helomics' molecular diagnostic tests grow, Helomics will need to continue to scale its testing capacity and processing technology, to expand its customer service, billing and systems processes and to enhance its internal quality assurance program. Helomics will also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of its molecular diagnostic tests. Helomics cannot guarantee that increases in scale, related improvements and quality assurance will be implemented successfully or that appropriate personnel will be available. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing tests or inability to meet demand. There can be no assurance that Helomics will be able to perform its testing on a timely basis at a level consistent with demand, or that Helomics' efforts to scale its operations will not negatively affect the quality of test results. If Helomics encounters difficulty meeting market demand or quality standards its reputation could be harmed, and its future prospects and business could suffer, causing a material adverse effect on Helomics' business, financial condition and results of operations.

If Helomics is unable to compete successfully, Helomics may be unable to increase or sustain its revenue or achieve profitability.

Helomics competes with physicians and the medical community who use traditional diagnostic methods. In many cases, practice guidelines in the United States have recommended therapies or surgery to determine if a patient's condition is malignant or benign. As a result, Helomics believes it will need to continue to educate physicians and the medical community on the value and benefits of its molecular diagnostic tests in order to change clinical practices. In addition, Helomics faces competition from other companies that offer diagnostic tests. It is also possible that Helomics faces future competition from laboratory-developed tests, or LDTs, developed by commercial laboratories such as Quest and/or other diagnostic companies developing new molecular diagnostic tests or technologies. Furthermore, Helomics may be subject to competition as a result of the new, unforeseen technologies that can be developed by Helomics' competitors in its diagnostic tests space.

To compete successfully Helomics must be able to demonstrate, among other things, that its molecular diagnostic test results are accurate and cost effective, and Helomics must secure a meaningful level of reimbursement for its tests. Many of Helomics' potential competitors have stronger brand recognition and greater financial capabilities than Helomics does. Others may develop tests with a lower price than Helomics that could be viewed by physicians and payors as functionally equivalent to Helomics' molecular diagnostic tests or offer a test at prices designed to promote market penetration, which could force Helomics to lower the price of its molecular diagnostic tests and affect its ability to achieve and maintain profitability. If Helomics is unable to compete successfully against current and future competitors, it may be unable to increase market acceptance of its molecular diagnostic tests and overall sales, which could prevent Helomics from increasing its revenue or achieving profitability and cause the market price of its common stock to decline. As Helomics adds new molecular diagnostic tests and services, it will face many of these same competitive risks for these new molecular diagnostic tests and services.

Developing new molecular diagnostic tests involves a lengthy and complex process, and Helomics may not be able to commercialize on a timely basis, or at all, other molecular diagnostic tests Helomics is developing. Developing new molecular diagnostic tests and solutions will require Helomics to devote considerable resources to research and development. Helomics may face challenges obtaining sufficient numbers of samples to validate a newly acquired or developed molecular diagnostic test. In order to develop and commercialize new molecular diagnostic tests, Helomics needs to:

- expend significant funds to conduct substantial research and development;

- conduct successful analytical and clinical studies;
- scale Helomics' laboratory processes to accommodate new molecular diagnostic tests; and
- build the commercial infrastructure to market and sell new molecular diagnostic tests.

Typically, few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, Helomics may abandon development of a molecular diagnostic test or Helomics may be required to expend considerable resources repeating clinical studies, which would adversely affect the timing for generating revenue from such test. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study or if Helomics fails to sufficiently demonstrate analytical validity, Helomics might choose to abandon the development of the molecular diagnostic test, which could harm its business. In addition, competitors may develop and commercialize new competing molecular diagnostic tests faster than Helomics or at a lower cost, which could have a material adverse effect on Helomics' business, financial condition and results of operations.

If Helomics is unable to develop or acquire molecular diagnostic tests to keep pace with rapid technological, medical and scientific change, its operating results and competitive position could be affected.

Recently, there have been numerous advances in technologies relating to diagnostics, particularly diagnostics that are based on genomic information. These advances require Helomics to continuously develop its technology and to work to develop new solutions to keep pace with evolving standards of care. Helomics' solutions could become obsolete unless it continually innovates and expands its product offerings to include new clinical applications. If Helomics is unable to develop or acquire new molecular diagnostic tests or to demonstrate the applicability of its molecular diagnostic tests for other diseases, Helomics' sales could decline and its competitive position could be harmed.

If the United States Food and Drug Administration ("FDA") begins to enforce regulation of Helomics' molecular diagnostic tests, Helomics could incur substantial costs and delays associated with trying to obtain pre-market clearance or approval and costs associated with complying with post-market requirements.

Clinical laboratory tests like Helomics' molecular diagnostic tests are regulated under CLIA as well as by applicable state laws. Most Laboratory Developed Tests ("LDTs") are currently not subject to the FDA's, regulation (although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation). In October 2014, the FDA issued two draft guidance documents: "Framework for Regulatory Oversight of Laboratory Developed Tests", which provides an overview of how the FDA would regulate LDTs through a risk-based approach, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests", which provides guidance on how the FDA intends to collect information on existing LDTs, including adverse event reports. On January 13, 2017, the FDA also issued a discussion paper on LDTs. Pursuant to the Framework for Regulatory Oversight draft guidance, LDT manufacturers would be subject to medical device registration, listing, and adverse event reporting requirements. The risk-based classification considers the LDT's intended use, technological characteristics, and the risk to patients if the LDT were to fail. The FDA has indicated in its guidance that screening devices for malignant cancers are LDTs of higher concern to the FDA and for which enforcement of pre-market and post-market review requirements would likely commence before other LDT types.

Pursuant to the Framework for Regulatory Oversight draft guidance, LDT manufacturers would be required to either submit a pre-market application and receive the FDA's approval before an LDT may be marketed or submit a pre-market notification in advance of marketing. These requirements would be phased in, starting with higher risk LDTs, following the issuance of the FDA's final guidance on this topic, which the FDA has identified as a priority. The draft guidance provides that LDTs that are already marketed at the time the final guidance is issued would not be withdrawn from the market during the FDA's review process. There is no timeframe within which the FDA must issue its final guidance, but issuance of this final guidance has been identified among a list of the FDA's priorities for 2016. As of the date of the filing of this proxy statement/prospectus/information statement, the FDA has not issued its final guidance. How the final guidance would affect Helomics' business is not yet known. Helomics cannot provide any assurance that the FDA regulation will not be required in the future for its tests, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated, or guidance could be issued by the FDA which may result in increased regulatory burdens for Helomics to continue to offer its molecular diagnostic tests or to develop and introduce new tests. Helomics cannot predict the timing or content of future legislation enacted, regulations promulgated, or guidance issued regarding LDTs, or how it will affect Helomics' business.

If pre-market review is required by the FDA or if Helomics decides to voluntarily pursue the FDA's pre-market review of Helomics' tests, there can be no assurance that Helomics' molecular diagnostic tests or any tests Helomics may develop or acquire in the future will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with Helomics' current claims or adequate to support continued adoption of and reimbursement for its tests. If pre-market review is required, Helomics' business could be negatively impacted as a result of commercial delay that may be caused by the new requirements. The cost of conducting clinical trials and otherwise developing data and information to support pre-market applications may be significant. If Helomics is required to submit applications for its currently-marketed tests, Helomics may be required to conduct additional studies, which may be time-consuming and costly and could result in Helomics' currently-marketed tests being withdrawn from the market. If Helomics' tests are allowed to remain on the market but there is uncertainty in the marketplace about its tests, if Helomics is required by the FDA to label them investigational, or if labeling claims the FDA allows Helomics to make are limited, orders may decline, and reimbursement may be adversely affected. Continued compliance with the FDA's regulations would increase the cost of conducting Helomics' business, and subject Helomics to heightened regulation by the FDA and penalties for failure to comply with these requirements. Helomics cannot predict the timing or form of any such guidance or regulation, or the potential effect on Helomics' existing molecular diagnostic tests or Helomics' tests in development, or the potential impact of such guidance or regulation on Helomics' business, financial condition and results of operations.

If Helomics fails to comply with Federal, State and foreign laboratory licensing requirements, Helomics could lose the ability to perform its tests or experience disruptions to Helomics' business.

Helomics is subject to Clinical Laboratory Improvement Amendments ("CLIA"), a Federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management and quality assurance. CLIA certification is also required in order for Helomics to be eligible to bill Federal and State healthcare programs, as well as many private third-party payors, for its molecular diagnostic tests. To renew these certifications, Helomics is subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of Helomics' clinical reference laboratories. Helomics is also required to maintain State licenses to conduct testing in its Pittsburgh, Pennsylvania laboratories. Pennsylvania laws require that Helomics maintain a license and establish standards for the day-to-day operation of Helomics' clinical reference laboratory in Pittsburgh, Pennsylvania. In addition, Helomics' Pittsburgh and New Haven laboratories are required to be licensed on a test-specific basis by certain other states. If Helomics were unable to obtain or lose its CLIA certificate or State licenses for its laboratories, whether as a result of revocation, suspension or limitation, Helomics would no longer be able to perform its molecular diagnostic tests, which could have a material adverse effect on Helomics' business, financial condition and results of operations. If Helomics were to lose its licenses issued by the States in which Helomics is required to hold licenses, Helomics would not be able to test specimens from those States. New molecular diagnostic tests Helomics may develop may be subject to new approvals by governmental bodies, and Helomics may not be able to offer its new molecular diagnostic tests to patients in such jurisdictions until such approvals are received.

Complying with numerous statutes and regulations pertaining to Helomics' molecular diagnostics business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Helomics is subject to regulation by both the Federal government and the States in which Helomics conducts its molecular diagnostics business, including:

- The Food, Drug and Cosmetic Act, as supplemented by various other statutes;
- The Prescription Drug Marketing Act of 1987, the amendments thereto, and the regulations promulgated thereunder and contained in 21 C.F.R. Parts 203 and 205, or the PDMA;
- CLIA and State licensing requirements;
- Manufacturing and promotion laws;
- Medicare billing and payment regulations applicable to clinical laboratories;
- The Federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a Federal healthcare program;
- The Federal Stark physician self-referral law (and state equivalents), which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition;
- The Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, and amendments made in 2013 to HIPAA under the Health Information Technology for Economic and Clinical Health Act, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- The Federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- The Federal False Claims Act, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- Other Federal and State fraud and abuse laws, prohibitions on self-referral, fee-splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payor, including private insurers;
- The prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- The rules regarding billing for diagnostic tests reimbursable by the Medicare program, which prohibit a physician or other supplier from marking up the price of the technical component or professional component of a diagnostic test ordered by the physician or other supplier and supervised or performed by a physician who does not "share a practice" with the billing physician or supplier; and

- State laws that prohibit other specified practices related to billing such as billing physicians for testing that they order, waiving coinsurance, co-payments, deductibles, and other amounts owed by patients, and billing a State Medicaid program at a price that is higher than what is charged to other payors.

Helomics has implemented policies and procedures designed to comply with these laws and regulations. Helomics periodically conducts internal reviews of its compliance with these laws. Helomics' compliance is also subject to governmental review. The growth of Helomics' business may increase the potential of violating these laws, regulations or Helomics' internal policies and procedures. The risk of Helomics being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Violations of Federal or State regulations may incur investigation or enforcement action by the FDA, Department of Justice, State agencies, or other legal authorities, and may result in substantial civil, criminal, or other sanctions. Any action brought against Helomics for violation of these or other laws or regulations, even if Helomics successfully defend against it, could cause Helomics to incur significant legal expenses and divert Helomics' managements' attention from the operation of its business. If Helomics' operations are found to be in violation of any of these laws and regulations, Helomics may be subject to civil and criminal penalties, damages and fines, Helomics could be required to refund payments received by it, Helomics could face possible exclusion from Medicare, Medicaid and other Federal or State healthcare programs and Helomics could even be required to cease its operations. Any of the foregoing consequences could have a material adverse effect on Helomics' business, financial condition and results of operations.

If Helomics uses hazardous materials in a manner that causes contamination or injury, Helomics could be liable for resulting damages.

Helomics is subject to Federal, State and local laws, rules and regulations governing the use, discharge, storage, handling and disposal of biological material, chemicals and waste. Helomics cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, Helomics could be held liable for any resulting damages, remediation costs and any related penalties or fines, and any liability could exceed Helomics' resources or any applicable insurance coverage Helomics may have. The cost of compliance with these laws and regulations may become significant, and Helomics' failure to comply may result in substantial fines or other consequences, and either could have a significant impact on Helomics' operating results.

Security breaches, loss of data and other disruptions to Helomics or its third-party service providers could compromise sensitive information related to Helomics' business or prevent Helomics from accessing critical information and expose it to liability, which could adversely affect Helomics' business and reputation.

Helomics' business requires that Helomics and its third-party service providers collect and store sensitive data, including legally protected health information, personally identifiable information about patients, credit card information, and Helomics' proprietary business and financial information. Helomics faces a number of risks relative to Helomics' protection of, and Helomics' service providers' protection of, this critical information, including loss of access, inappropriate disclosure and inappropriate access, as well as risks associated with Helomics' ability to identify and audit such events. The secure processing, storage, maintenance and transmission of this critical information are vital to Helomics' operations and business strategy, and Helomics devotes significant resources to protecting such information. Although Helomics takes measures to protect sensitive information from unauthorized access or disclosure, Helomics' information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While Helomics has not experienced any such attack or breach, if such event would occur and cause interruptions in Helomics' operations, Helomics' networks would be compromised and the information Helomics stores on those networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Unauthorized access, loss or dissemination could disrupt Helomics' operations, including Helomics' ability to process tests, provide test results, bill payors or patients, process claims, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about Helomics' solution and other patient and physician education and outreach efforts, manage the administrative aspects of Helomics' business and damage Helomics' reputation, any of which could adversely affect Helomics' business. In addition, the interpretation and application of consumer, health-related and data protection laws in the United States are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with Helomics' practices. Complying with these various laws could cause Helomics to incur substantial costs or require Helomics to change its business practices, systems and compliance procedures in a manner adverse to Helomics' business.

If Helomics is sued for product liability or errors and omissions liability, Helomics could face substantial liabilities that exceed its resources.

The marketing, sale and use of Helomics' molecular diagnostic tests could lead to product liability claims if someone were to allege that the molecular diagnostic test failed to perform as it was designed. Helomics may also be subject to liability for errors in the results Helomics provides to physicians or for a misunderstanding of, or inappropriate reliance upon, the information Helomics provides. A product liability or errors and omissions liability claim could result in substantial damages and be costly and time consuming for Helomics to defend. Although Helomics maintains product liability and errors and omissions insurance, Helomics cannot be certain that its insurance would fully protect it from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of such claims. Any product liability or errors and omissions liability claim brought against Helomics, with or without merit, could increase its insurance rates or prevent it from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to Helomics' reputation or cause Helomics to suspend sales of its products and solutions. The occurrence of any of these events could have a material adverse effect on Helomics' business, financial condition and results of operations.

Billing for Helomics' diagnostic solutions is complex, and Helomics must dedicate substantial time and resources to the billing process to be paid for its molecular diagnostic tests.

Billing for clinical laboratory testing services is complex, time consuming and expensive. Depending on the billing arrangement and applicable law, Helomics bills various payors, including Medicare, insurance companies and patients, all of which have different billing requirements. To the extent laws or contracts require Helomics to bill patient co-payments or co-insurance, Helomics must also comply with these requirements. Helomics may also face increased risk in its collection efforts, including write-offs of doubtful accounts and long collection cycles, which could have a material adverse effect on Helomics' business, results of operations and financial condition. Among others, the following factors make the billing process complex:

- differences between the list price for Helomics' molecular diagnostic tests and the reimbursement rates of payors;
- compliance with complex Federal and State regulations related to billing Medicare;
- disputes among payors as to which party is responsible for payment;
- differences in coverage among payors and the effect of patient co-payments or co-insurance;
- differences in information and billing requirements among payors;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

As Helomics introduces new molecular diagnostic tests, it will need to add new codes to the billing process as well as to Helomics' financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect Helomics' revenue and cash flow. Additionally, Helomics' billing activities require it to implement compliance procedures and oversight, train and monitor its employees, challenge coverage and payment denials, assist patients in appealing claims, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. These billing complexities, and the related uncertainty in obtaining payment for Helomics' diagnostic solution, could negatively affect Helomics' revenue and cash flow, Helomics' ability to achieve profitability, and the consistency and comparability of Helomics' results of operations.

Helomics relies on a third-party to process and transmit claims to payors, and any delay in either could have an adverse effect on Helomics' revenue.

Helomics relies on a third-party provider to provide overall processing of claims and to transmit the actual claims to payors based on the specific payor billing format. If claims for Helomics' molecular diagnostic tests are not submitted to payors on a timely basis, or if Helomics is required to switch to a different provider to handle claim submissions, Helomics may experience delays in its ability to process these claims and receipt of payments from payors, which could have a material adverse effect on Helomics' business, financial condition and results of operations.

Enacted healthcare reform legislation may increase Helomics' costs, impair Helomics' ability to adjust its pricing to match any such increased costs, and therefore could materially and adversely affect its business, financial condition and results of operations.

PPACA entails sweeping healthcare reforms with staggered effective dates from 2010 through 2018, although certain of these effective dates have been delayed by action of the current administration. While some guidance has been issued under PPACA over the past several years, many provisions in PPACA require the issuance of additional guidance from the U.S. Department of Labor, the Internal Revenue Service, the U.S. Department of Health & Human Services, and State governments. This reform includes, but is not limited to: the implementation of a small business tax credit; required changes in the design of Helomics' healthcare policy including providing insurance coverage to part-time workers working on average thirty (30) or more hours per week; "grandfathering" provisions for existing policies; "pay or play" requirements; a "Cadillac plan" excise tax; and specifically required "essential benefits," that must be included in "qualified plans," which benefits include coverage for laboratory tests.

Effective January 1, 2014, each State was required to participate in the PPACA marketplace and make health insurance coverage available for purchase by eligible individuals through a website. While these websites were subject to significant administrative issues leading up to their inception dates (and, in some cases, thereafter), it is currently estimated that in excess of 11 million individuals nationwide had enrolled in health insurance coverage through these exchanges as of the end of 2015. It is unclear, however, how many of these individuals are becoming insured after previously not having health insurance coverage, versus maintaining their plans purchased on the exchanges in 2014 or switching from other health insurance plans.

PPACA also requires "Applicable Manufacturers" to disclose to the Secretary of the Department of Health & Human Services drug sample distributions and certain payments or transfers of value to covered recipients (physicians and teaching hospitals) on an annual basis. "Applicable Manufacturers" and "Applicable Group Purchasing Organizations" must also disclose certain physician ownership or investment interests. The data submitted will ultimately be made available on a public website. Based upon the structure of Helomics' relationship with its clients, Helomics may be included in the definition of "Applicable Manufacturer" for purposes of the disclosure requirements or may provide services that include the transfer of drug samples and/or other items of value to covered recipients. As such, Helomics may be required to disclose or provide information that is subject to disclosure. There may be certain risks and penalties associated with the failure to properly make such disclosures, including but not limited to the specific civil liabilities set forth in PPACA, which allows for a maximum civil monetary penalty per "Applicable Manufacturer" of $1,150,000 per year. There may be additional risks and claims made by third parties derived from an improper disclosure that are difficult to ascertain at this time.

While PPACA may increase the number of patients who have insurance coverage, its cost containment measures could also adversely affect reimbursement for any of Helomics' molecular diagnostic tests. Cost control initiatives also could decrease the price that Helomics' receives for any molecular diagnostic tests Helomics may develop in the future. If Helomics' molecular diagnostic tests are not considered cost-effective or if Helomics is unable to generate adequate third-party reimbursement for the users of its molecular diagnostic tests, then Helomics may be unable to maintain revenue streams sufficient to realize its targeted return on investment for its molecular diagnostic tests.

Helomics is currently unable to determine the long-term, direct or indirect impact of such legislation on its business. Since the effect of many of the provisions of PPACA may not be determinable for a number of years, Helomics does not expect PPACA to have a material adverse impact on its near-term results of operations. However, healthcare reform as mandated and implemented under PPACA and any future Federal or State mandated healthcare reform could materially and adversely affect its business, financial condition and operations by increasing Helomics' operating costs, including its costs of providing health insurance to Helomics' employees, decreasing Helomics' revenue, impeding Helomics' ability to attract and retain customers, requiring changes to Helomics' business model, or causing Helomics to lose certain current competitive advantages.

Changes in governmental regulation could negatively impact Helomics' business operations and increase its costs.

The pharmaceutical, biotechnology and healthcare industries are subject to a high degree of governmental regulation. Significant changes in these regulations affecting Helomics' business could result in the imposition of additional restrictions on Helomics' business, additional costs to Helomics in providing Helomics' molecular diagnostic tests to its customers or otherwise negatively impact Helomics' business operations. Changes in governmental regulations mandating price controls and limitations on patient access to Helomics' products could also reduce, eliminate or otherwise negatively impact Helomics' sales.

If Helomics does not increase its revenues and successfully manage the size of its operations, Helomics' business, financial condition and results of operations could be materially and adversely affected.

The majority of Helomics' operating expenses are personnel-related costs such as employee compensation and benefits, reagents and disposable supplies as well as the cost of infrastructure to support Helomics' operations, including facility space and equipment. Helomics continuously reviews its personnel to determine whether they are fully utilizing their services. If Helomics is unable to achieve revenue growth in the future or fail to adjust its cost infrastructure to the appropriate level to support its revenues, Helomics' business, financial condition and results of operations could be materially and adversely affected.

If Helomics research and development (R&D) efforts for its TruTumor and D-CHIP artificial intelligence platform take longer than expected the commercial revenues from the service offerings that use these platforms could also be delayed.

Helomics CRO business offers various services to pharma, diagnostics and biotech companies. These services use its TruTumor Patient derived tumor platform and its D-CHIP AI platform. These platforms are the subject of active R&D to further improve and validate them for commercial use in order to help Helomics' clients in their drug discovery, biomarker and clinical trial activities. Helomics could face delays in this R&D, for example; Helomics may not be able to secure access to and approval to use clinical data from academic hospital partners required to validate the D-CHIP platform in a timely manner; clinical testing volume (number of specimens coming to Helomics for testing) may not grow sufficiently to drive data generation for D-CHIP as well as further development of the TruTumor platform; patient consent to use the patient's data and tumor material for R&D may not be sufficient to support Helomics R&D; Helomics may not be able to attract and retain the appropriately qualified staff to perform the necessary R&D. Helomics has a limited operating history with the CRO and Informatics business which makes it difficult to forecast the revenue of these business units. While Helomics is committed to the buildout of both the CRO and D-CHIP services for the long term, the company cannot predict at this time, with any certainty, the future viability of either business unit.

If Helomics' information technology and communications systems fail or Helomics experiences a significant interruption in its operation, its reputation, business and results of operations could be materially and adversely affected.

The efficient operation of Helomics' business is dependent on Helomics' information technology and communications systems. The failure of these systems to operate as anticipated could disrupt its business and result in decreased revenue and increased overhead costs. In addition, Helomics does not have complete redundancy for all of its systems and its disaster recovery planning cannot account for all eventualities. Helomics' information technology and communications systems, including the information technology systems and services that are maintained by third party vendors, are vulnerable to damage or interruption from natural disasters, fire, terrorist attacks, malicious attacks by computer viruses or hackers, power loss or failure of computer systems, Internet, telecommunications or data networks. If these systems or services become unavailable or suffer a security breach, Helomics may expend significant resources to address these problems, and Helomics' reputation, business and results of operations could be materially and adversely affected.

If Helomics is unable to protect its intellectual property effectively, Helomics' business would be harmed.

Helomics relies on patent protection as well as trademark, trade secret and other intellectual property rights protection and contractual restrictions to protect Helomics' proprietary technology. If Helomics' fails to protect its intellectual property, third parties may be able to compete more effectively against it and Helomics may incur substantial litigation costs in its attempts to recover or restrict use of its intellectual property. While Helomics applies for patents covering its products and technologies and uses thereof, Helomics may fail to apply for patents on important products and technologies in a timely fashion or at all, or Helomics may fail to apply for patents in relevant jurisdictions. Others could seek to design around Helomics' current or future patented technologies. Helomics may not be successful in defending any challenges made against Helomics' patents or patent applications. Any successful third-party challenge to Helomics' patents could result in the unenforceability or invalidity of such patents and increased competition to Helomics' business. The outcome of patent litigation can be uncertain and any attempt by Helomics to enforce its patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert Helomics' efforts and attention from other aspects of its business.

Monitoring unauthorized disclosure is difficult, and Helomics does not know whether the steps Helomics has taken to prevent such disclosure are, or will be, adequate. If Helomics were to enforce a claim that a third-party had illegally obtained and was using its trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. Further, competitors could willfully infringe Helomics' intellectual property rights, design around its protected technology or develop their own competitive technologies that arguably fall outside of Helomics' intellectual property rights. Others may independently develop similar or alternative products and technologies or replicate any of Helomics' products and technologies. If Helomics' intellectual property does not adequately protect it against competitors' products and methods, Helomics' competitive position could be adversely affected, as could Helomics' business and the results of its operations. To the extent Helomics' intellectual property offers inadequate protection, or is found to be invalid or unenforceable, Helomics would be exposed to a greater risk of competition. If Helomics' intellectual property does not provide adequate coverage of its competitors' products, Helomics' competitive position could be adversely affected, as could its overall business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

Helomics may be involved in litigation related to intellectual property, which could be time-intensive and costly and may adversely affect its business, operating results or financial condition.

Helomics may receive notices of claims of direct or indirect infringement or misappropriation or misuse of other parties' proprietary rights from time to time and some of these claims may lead to litigation. Helomics cannot assume that it will prevail in such actions, or that other actions alleging misappropriation or misuse by Helomics of third-party trade secrets, infringement by Helomics of third-party patents and trademarks or other rights, or the validity of Helomics' patents, trademarks or other rights, will not be asserted or prosecuted against it. Helomics might not have been the first to make the inventions covered by each of Helomics' pending patent applications and Helomics might not have been the first to file patent applications for these inventions. No assurance can be given that other patent applications will not have priority over Helomics' patent applications. If third parties bring these proceedings against Helomics' patents, Helomics could incur significant costs and experience management distraction. Litigation may be necessary for Helomics to enforce its patents and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to Helomics, and Helomics might not be able to obtain licenses to technology that it requires on acceptable terms or at all. In addition, if Helomics resorts to legal proceedings to enforce its intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if Helomics were to prevail. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on Helomics' business, financial condition and operating results.

In the event of a successful claim of infringement against Helomics, Helomics may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling its products. Helomics may not be able to obtain these licenses on acceptable terms, if at all. Helomics could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect Helomics' financial results. In addition, Helomics' agreements with some of its customers, suppliers or other entities with whom Helomics' does business require it to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. If Helomics is required or agrees to defend or indemnify third parties in connection with any infringement claims, Helomics could incur significant costs and expenses that could have a material adverse effect on Helomics' business, financial condition, and results of operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 2. PROPERTIES.

Our corporate offices are located at 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121. On November 22, 2017, the Company signed a second amendment to our lease last amended on January 28, 2013. The lease as amended has an additional three-year term effective February 1, 2018 ending January 31, 2021. 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, 2021. We expect that this space will be adequate for our current office and manufacturing needs.

Skyline Medical Europe's offices are located at 9 Chemin de la Fraite – 1380 Ohain, Belgium. The lease agreement was signed April 24, 2018 and started on June 15, 2018. We lease around 2,000 square feet at this location, 300 of which is used for storage and 1,250 for office space. The lease is effective through June 14, 2027. We expect that this space will be adequate for our current office and storage needs.

ITEM 3. LEGAL PROCEEDINGS.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCK HOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Effective February 2, 2018, our common stock was listed on the NASDAQ Capital Market under the symbol "AIPT". Prior to this our common stock was 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. The bid prices reflect inter-dealer quotations, do not include retail markups, markdowns, or commissions, and do not necessarily reflect actual transactions.

Holders

As of March 26, 2019, there were approximately 134 stockholders of record of our common stock.

Dividend Policy

We follow a policy of retaining earnings, if any, to finance the expansion of our business. We have not paid, and do not expect to declare or pay, cash dividends on common stock in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

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

Recent Sales of Unregistered Securities

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

In May 2016, the Company issued 135,995 shares of common stock, par value $0.01, at $3.75 per share to a vendor for Investment Banking Services.

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 was 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.

In September 2016, the Company issued 26,000 shares of common stock, par value $0.01, at $4.50 per share to a vendor for Investment Relations Services.

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 of 1933 and/or Rule 506 promulgated thereunder, based on the Company's belief that the offer and the sale of the shares did not involve a public offering.

On April 19, 2017, the Company terminated the agreement with GLG Pharma, LLC. As a result, the Company received back the 400,000 shares of common stock, par value $0.01, that was held in escrow regarding the Partnership and Exclusive Reseller Agreement with GLG Pharma, LLC.

On April 24, 2017, the Company issued 100,000 shares of common stock, par value $0.01, at $2.20 per share to a vendor for Consulting Services.

On July 20, 2017, the Company issued an additional 43,333 shares of common stock, par value $0.01, at $1.49 per share for the same consulting services pursuant to the April contract that included a conditional reset during the first nine months of the term of the agreement.

On October 13, 2017, the Company issued 50,000 shares of common stock, par value $0.01, at $1.58 per share to a vendor for Investor Relations Services.

On January 12, 2018, the Company issued 1,100,000 shares of common stock, par value $0.01, at $0.9497 per share, in exchange for 2,500,000 shares of Helomics Holding Corporation Series A Preferred Stock. The 1,100,000 shares of Company common stock are being held in escrow by Corporate Stock Transfer, Inc. as escrow agent. While the Company shares are held in escrow, the shares are voted as directed by the Company's board of directors and management. The Company shares will be released to Helomics following a determination the Helomics' revenues in any 12-month period have been equal to or greater than $8,000,000. The exchange of shares resulted in the Company owning 20% of Helomics outstanding stock.

On July 10, 2018, the Company issued 150,000 shares of common stock and 100,000 shares of common stock, par value $0.01, at $1.18 per share to consultants, pursuant to a License Agreement, for their services.

On July 11, 2018, the Company issued 750,000 shares of common stock, par value $0.01, at $1.17 per share pursuant to a License Agreement. The 750,000 shares of Company common stock are being held in escrow by Corporate Stock Transfer, Inc. as an escrow agent. A portion of the shares will be released from escrow to each licensor or their designee upon each instance that certain milestones have been completed.

On September 28, 2018, we issued a convertible promissory note to each of two investors in the original principal amount of an aggregate $2,297,727.50 in exchange for an investment of $2,000,000, less commissions, with net proceeds to the Company of $1,815,000. As additional consideration for the investment, the Company issued an aggregate 650,000 inducement shares (subsequently registered) of its common stock to the investors or their affiliates plus warrants to acquire up to an aggregate 1,071,776 shares of the Company's common stock at an exercise price of $1.155 per share. Upon certain events, each investor obtained the right to convert its note subject to an exchange cap described below. On February 7, 2019, we entered into a: (1) a forbearance agreement with each investor and an amended and restated note with each of the investors which increased the principal amount of the existing notes by an aggregate $344,659. On February 11, 2019, the Company issued an aggregate 166,667 additional shares of common stock to the investors for forbearance in connection with an event of default and a claimed event of default. The notes upon conversion are subject to a cap on the number of shares that can be issued upon conversion such that the sum of (a) the total number of conversion shares plus (b) the number of inducement shares plus (c) the number of forbearance shares is limited to an aggregate 2,678,328 shares.

On October 17, 2018, the Company issued 43,409 shares of common stock, par value $0.01, at $0.9291 per share in lieu of paid salary to the Vice President of Sales & Marketing.

On November 30, 2018, our CEO, Carl Schwartz, made an investment of $370,000 in the Company and received a note and a common stock purchase warrant for 221,292 warrant shares at $0.836 per share. Effective as of January 8, 2019, Dr. Schwartz made an additional investment of $950,000 and received an amended and restated note in the original principal amount of $1,320,000 and an amended and restated warrant, which added a second tranche of 742,188 warrant shares at an exercise price of $0.704. Each tranche is exercisable beginning on the sixth month anniversary of the date of the related investment through the fifth-year anniversary of the date of the related investment. On January 8, 2019, Dr. Schwartz also purchased 78,125 shares of the Company's common stock in a private investment for $50,000, representing a price of $0.64 per share, pursuant to a subscription agreement. On February 6, 2019, Dr. Schwartz made an additional investment of $300,000 in the Company and received an amended and restated note in the original principal amount of $1,620,000 and an amended and restated warrant, which added a third tranche of 138,889 warrant shares at an exercise price of $1.188 per share. On February 1, 2019 and the first day of each calendar month thereafter while the note and the warrant remain outstanding, a number of additional shares will be added to the second tranche and the third tranche equal to (1) one-half percent (1/2%) of the outstanding principal balance of the Note on such date, divided by (2) the closing price of the Company's common stock on that date. The number of warrant shares will be subject to a share limit such that the total of (a) the 78,128 shares of common stock purchased by Dr. Schwartz on January 8, 2019, and (b) the total number of warrant shares (1,108,596 warrant shares as of February 6, 2019) may not exceed 2,818,350 shares (equal to 19.9% of the outstanding shares of Common Stock on January 8, 2019). If the second tranche and/or third tranche cannot be increased as required herein due to the share limit, then in lieu of any such increase, the Company shall pay to Dr. Schwartz a cash amount equal to one-half percent (1/2%) of the principal balance of the Schwartz note in lieu of such increase.

Unless otherwise specified above, the Company believes that all of the above transactions were transactions not involving any public offering within the meaning of Section 4(2) of the Securities Act, since (a) each of the transactions involved the offering of such securities to a substantially limited number of persons; (b) each person took the securities as an investment for his/her/its own account and not with a view to distribution; (c) each person had access to information equivalent to that which would be included in a registration statement on the applicable form under the Securities Act; and (d) each person had knowledge and experience in business and financial matters to understand the merits and risk of the investment; therefore no registration statement needed to be in effect prior to such issuances.

ITEM 6. SELECTED FINANCIAL DATA.

Not Required.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Information Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements" that indicate certain risks and uncertainties related to the Company, many of which are beyond the Company's control. The Company's actual results could differ materially and adversely from those anticipated in such forward-looking statements as a result of certain factors, including those set forth below and elsewhere in this report. Important factors that may cause actual results to differ from projections include:

- Current negative operating cash flows;
- The terms of any further financing, which may be highly dilutive and may include onerous terms;
- Risks related to the proposed merger with Helomics, including the fact that we may not complete the merger; we do not have complete information about Helomics; the combined company will not be able to continue operating without additional financing; possible failure to realize anticipated benefits of the merger; costs associated with the merger may be higher than expected; the merger may result in the disruption of the Company's and Helomics' existing businesses; distraction of management and diversion of resources; delay in completion of the merger may significantly reduce the expected benefits; and the market price of the Company's common stock may decline as a result of the merger.
- Risks related to our partnerships with other companies, including the need to negotiate the definitive agreements; possible failure to realize anticipated benefits of these partnerships; and costs of providing funding to our partner companies, which may never be repaid or provide anticipated returns.
- Risk that we will be unable to protect our intellectual property or claims that we are infringing on others' intellectual property;
- The impact of competition, the obtaining and maintenance of any necessary regulatory clearances applicable to applications of the Company's technology;
- Inability to attract or retain qualified senior management personnel, including sales and marketing personnel;
- Risk that we never become profitable if our product is not accepted by potential customers;
- Possible impact of government regulation and scrutiny;
- Unexpected costs and operating deficits, and lower than expected sales and revenues, if any;
- Adverse results of any legal proceedings;
- The volatility of our operating results and financial condition, and,
- Other specific risks that may be alluded to in this report.

All statements, other than statements of historical facts, included in this report regarding the Company's growth strategy, future operations, financial position, estimated revenue or losses, projected costs, prospects and plans and objectives of management are forward-looking statements. When used in this report, the words "will," "may," "believe," "anticipate," "intend," "estimate," "expect," "project," "plan" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain such identifying words. All forward-looking statements speak only as of the date of this report. The Company does not undertake any obligation to update any forward-looking statements or other information contained herein. Potential investors should not place undue reliance on these forward-looking statements. Although Precision believes that its plans, intentions and expectations reflected in or suggested by the forward-looking statements in this report are reasonable, the Company cannot assure potential investors that these plans, intentions or expectations will be achieved. The Company discloses important factors that could cause the Company's actual results to differ materially from its expectations in the "Risk Factors" section and elsewhere in this report. These cautionary statements qualify all forward-looking statements attributable to the Company or persons acting on its behalf.

Information regarding market and industry statistics contained in this report is included based on information available to the Company that it believes is accurate. It is generally based on academic and other publications that are not produced for purposes of securities offerings or economic analysis. The Company has not reviewed or included data from all sources, and the Company cannot assure potential investors of the accuracy or completeness of the data included in this report. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and the additional uncertainties accompanying any estimates of future market size, revenue and market acceptance of products and services. The Company has no obligation to update forward-looking information to reflect actual results or changes in assumptions or other factors that could affect those statements.

Overview

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. On February 1, 2018, we filed with the Secretary of State of Delaware a Certificate of Amendment to our Certificate of Incorporation to change our corporate name from Skyline Medical Inc. to Precision Therapeutics Inc., effective February 1, 2018. Because of this change, our common stock trades under the new ticker symbol "AIPT," effective February 2, 2018.

We are a healthcare products and services company that is expanding its business to take advantage of emerging areas of the dynamic healthcare market through sales of its products, through its partnership with Helomics Holding Corporation and through pursuit of other strategic relationships to build value. In our STREAMWAY business we manufacture an environmentally conscious 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 ("System") and use of our proprietary cleaning solution and bifurcated filter.

We sell our STREAMWAY products through an experienced direct sales force. The Company has one VP of Sales & Marketing, one VP of International Sales, and seven regional sales managers on staff as of March 2019. We have twelve independent distributors in the United States, Canada and overseas. We incorporated Skyline Medical Europe with an office in Belgium in February 2018 and hired a direct salesperson to cover Germany and France. We have contracted with two General Purchasing Organizations in the United States, Vizient and Intalere, providing customer exposure to more than 10,000 hospitals. The Company has contracted with Alliant Enterprises, LLC, a Service Disabled Veterans Owned Small Business supplier to the federal government. We have executed contracts with eleven international distributors: Quadromed, a Canadian distributor; MediBridge Sarl, a Swiss distributor; Device Technologies Australia PTY LTD, is an Australian distributor representing us throughout Australia, New Zealand, Fiji and the Pacific Islands; Century Scientific and Equipment Company in Kuwait; Mediurge in Pakistan; Prenit World in India; Sesneber in Saudi Arabia; Winner Scientific in Taiwan; Anifco in Bangladesh; Aras in the United Arab Emirates and Alfaisal Scientific Bureau in Iraq.

Since inception, we have been unprofitable. We incurred net losses of approximately $10.1 million and $6.0 million for the years ended December 31, 2018, and December 31, 2017, respectively. As of December 31, 2018, and December 31, 2017, we had an accumulated deficit of approximately $63.1 million and $53.0 million, respectively. We received approval from the FDA in April 2009 to commence sales and marketing activities of the STREAMWAY System and shipped the first system in 2009. However, there was no significant revenue prior to 2011, primarily due to lack of funds to build and ship the product. We have sold one hundred forty-eight STREAMWAY units through December 2018. We expect the revenue for STREAMWAY System units to increase at such time as the hospitals approve the use of the units for their applications and place orders for billable units.

Precision's CRO services business is committed to improving the effectiveness of cancer therapy using the power of artificial intelligence applied to rich data diseases databases. Precision has identified the CRO market as a burgeoning sector with significant growth potential. Precision acquired 25% of the capital stock of Helomics®, a pioneering Contract Research Organization Services company that bridges two significant areas of the healthcare industry: "Precision Medicine" and "Big Data". Precision is also partnering with Helomics in creating joint venture arrangements. On March 22, 2019, our stockholders approved the pending Merger. We believe that the Merger will enable both companies to enhance potential value for stockholders, and that both companies will benefit from the Merger.

On January 11, 2018, Precision engaged in a share exchange transaction with Helomics in which Precision acquired beneficial ownership of 20% of Helomics' outstanding stock. On February 27, 2018, Precision exchanged $500,000 in promissory notes of Helomics for an additional 5% of Helomics' stock. As a result, Precision is required to record net income or loss to investee, based on a percentage of the net income or loss equal to the Company's percentage ownership. Helomics' net loss from continuing operations was $9,452,835 for the year ended December 31, 2018. As a result, Precision recorded net loss of $2,293,580 relating to the Helomics investment for the year ended December 31, 2018. Helomics' loss for the year ended December 31, 2018 is due to a reduction of revenue by reserving a substantial amount of third-party revenue from insurance companies on diagnostic income. Helomics is a development stage company that may experience losses in future periods that will result in net loss to investors. For periods following the consummation of the proposed Merger in which Helomics experiences losses, such losses will have a material adverse effect on Precision's financial position and results of operations.

Upon completion of the Merger with Helomics, we expect that our operating cash needs will increase significantly. We anticipate that, after completion of the Merger, we will conduct one or more financing transactions, including 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 may 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.

On the effective date of the Merger, we will issue 4.0 million shares of Precision Common Stock and 3.5 million shares of Precision Series D convertible preferred stock ("Series D Preferred Stock") to holders of Helomics capital stock. This issuance is in addition to the 1.1 million shares of our Common Stock previously issued to Helomics as consideration for our prior acquisition of a 20 percent ownership interest in Helomics; these 1.1 million shares will remain outstanding and will be distributed to holders of Helomics capital stock. Each share of Series D Preferred Stock is convertible into one share of our Common Stock starting one year after issuance, subject to adjustment. In the Exchange Offer, based on the exchange of $8.6 million in outstanding promissory notes and the associated Helomics warrants, we will issue: (1) approximately 8.6 million additional shares of our Common Stock, (2) approximately 14.2 million warrants to purchase our Common Stock at an exercise price of $1.00 per share and (3) 0.6 million warrants to purchase our Common Stock at an exercise price of $0.01 per share. We believe Merger will close in the first part of April 2019, subject to the satisfaction or waiver of the remaining conditions to closing. The pending issuance of the 4.0 million shares of our Common Stock and 3.5 million shares of Series D Preferred Stock in the Merger and the issuance of the 8.6 million shares of our Common Stock and the aggregate 14.8 million warrants we will issue in the Exchange Offer are referred to in this report as the "Merger Issuance."

Immediately after the Merger Issuance, the former Helomics security holders will own approximately 44.4% of the issued and outstanding shares of Common Stock and Precision stockholders will own approximately 55.6% of the issued and outstanding shares of Common Stock. The former holders of Helomics warrants will hold warrants that would represent 31.7% of the outstanding shares of the Precision Common Stock if exercised. After such exercise, pre-merger Precision stockholders would own 33.8% of the outstanding Precision shares, historic Helomics stockholders would own 16.1% of the outstanding shares, and the former Helomics noteholders would own 50.1% of the outstanding shares.

Precision recently formed a subsidiary, TumorGenesis, to pursue a new rapid approach to growing tumors in the laboratory, which essentially "fools" the cancer cells into thinking they are still growing inside the patient. TumorGenesis intends to develop next generation, patient derived, ("PDx") tumor models for precision cancer therapy and drug development. This approach should provide a much more relevant model of the patient tumor that may be used for testing of drugs for personalized therapy or for the development of new drugs. Precision has entered into licensing arrangements with three medical technology companies in that regard.

We have never generated sufficient revenues to fund our capital requirements. We have funded our operations through a variety of debt and equity instruments. See “Liquidity and Capital Resources – Liquidity, Plan of Financing and Going Concern Qualification” and “Liquidity and Capital Resources – Financing Transactions” below.

Our future cash requirements and the adequacy of available funds depend on our ability to sell our products and the availability of future financing to fulfill our business plans. See “Plan of Financing; Going Concern Qualification” below.

As a company, our limited history of operations makes prediction of future operating results difficult. We believe that period to period comparisons of our operating results should not be relied on as predictive of our future results.

Results of Operations

Comparison of Year Ended December 31, 2018 with Year Ended December 31, 2017

Revenue for December 31,

2018	2017	$ Difference	% Difference
$1,411,655	$ 654,836	$ 756,819	116%

Revenue. We recorded revenue of $1,412,000 in 2018, compared to $655,000 in 2017. Revenue in 2018 included the sale of forty-one STREAMWAY systems and disposable supplies to operate the STREAMWAY. The revenue in 2017 included the sale of ten STREAMWAY systems and disposable supplies to operate the STREAMWAY. Our revenues and product sales increased in 2018 due to our increased sales force and the full initiation of brand awareness. We also sold our first STREAMWAY unit internationally.

Cost of sales. Cost of sales was $416,000 in 2018 compared to $148,000 in 2017. The gross profit margin was 71% in 2018 and 77% in 2017. In 2017, we experienced a higher gross profit percentage than in 2018 as the Company began assisting some customers with the installation costs. In turn, this added value cost to our customers resulted in higher sales. The Company has developed ways to reduce costs through tooling parts and purchasing different components that improved the STREAMWAY Systems while costing less. As our revenues increase through System sales we expect costs to decline as a percentage of our revenue due to our volume discount purchasing agreements with our suppliers.

General and Administrative expense. General and administrative (G&A) expense primarily consists of management salaries, professional fees, consulting fees, travel expense, administrative fees and general office expenses.

G&A expense increased to $4,627,000, for 2018 from $4,050,000 in 2017. Increased expenses included higher legal and auditing expenses of $411,000 and $422,000, respectively, for merger expenses and associated SEC filings. Precision incurred penalty expenses of $503,000 due to a negotiated forbearance agreement with noteholders; the agreement provided for a possible cure for a default. In return the noteholders received, among other things, a fifteen percent increase to the principal balance of the note and 166,667 inducement shares of common stock. Investor relations increased by $376,000 due to a public offering in January 2018, a final payment for a private placement originating in 2017 and hiring more investor relations firms. Recruiting fees increased by $79,000 due to hiring additional sales people. Depreciation and amortization expenses increased by $76,000 particularly due to a licensing agreement for TumorGenesis. Other expenses that increased were rent and repairs by $31,000 due to our European office, office supplies by $16,000, travel by $14,000 and outside service fees by $12,000. A large decrease was in stock based compensation as the Company reduced such expenses by $974,000. In 2017 the Company awarded stock options to its directors and employees in a comprehensive package that vested predominantly in 2017, but continued to vest in 2018, but less expansively. Consulting decreased by $271,000 as we no longer relied upon outside sources to develop business. The Company received a tax credit from Delaware in 2018 for prior overpayments thus decreasing our expense by $52,000. Salaries, bonuses, benefits and taxes decreased by $35,000 and stock-based consulting was decreased by $31,000 as there were no expenses in 2018.

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

Operations expense increased to $1,861,000 in 2018 compared to $1,415,000 in 2017. The $446,000 increase in operations expense in 2018 was primarily due to $391,000 in consulting expenses most of which were for TumorGenesis pursuant to a licensing agreement and contracting for the TumorGenesis Chief Operating Officer. Research and development increased by $237,000 predominantly to make the Company’s new Generation 3 STREAMWAY system market ready in 2019. Salaries, bonuses, payroll taxes and employee benefits increased by $72,000 because of additional hiring. Testing expenses increased by $22,000 in accordance with our new production. Shipping increased by $23,000 and travel expenses increased by $12,000. Stock based compensation decreased by $298,000 because in 2017 the Company awarded a comprehensive stock option distribution to the employees that primarily vested in 2017 and this was reduced in 2018.

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

Sales and marketing expenses increased to $2,369,000 in 2018 compared to $1,095,000 in 2017. The $1,274,000 increase is a result of $623,000 for hiring a new Vice President of Sales & Marketing and significant increases in the sales staff. As a result of increased sales, commissions were up by $162,000. As a result of the increased sales presence travel expenses increased by $171,000. Stock compensation expense increased by $98,000 in order to competitively provide the new employees with stock options. The Company developed a new website that increased expenses by $129,000. Accordingly, our public relations, marketing and advertising costs increased by $166,000. The only offset was a $80,000 decrease in sales consulting as we no longer required outside sources for domestic sales support.

Other income. The Company earned other income in 2018 of $510,000 predominantly due to $372,000 from an unrealized gain on the derivative liability incurred from the warrants on the bridge loan.

Other expense. The Company incurred $442,000 in other expense in 2018 predominantly due to the amortization of original issue discounts associated with the sale of convertible notes to two investors and a loan from the CEO.

Liquidity and Capital Resources

Cash Flows for the Year Ended December 31, 2018

Net cash used in operating activities was $5,288,000 for 2018, compared with net cash used of $4,460,000 for 2017. The Company increased sales, which brought in additional cash, but this was offset by the cash required to support the emergence of Skyline Europe and TumorGenesis, both subsidiaries 100% owned by the Company. Skyline Europe incurred approximately $450,000 in cash expenses and TumorGenesis approximately $116,000 in cash expenses during 2018.

Cash flows used in investing activities was $1,111,000 for 2018 and $1,653,000 in 2017. In 2018 the activity was primarily for notes receivable pertaining to the secured loan to Helomics.

Net cash provided by financing activities was $5,795,000 for 2018 compared to net cash provided of $5,115,000 for 2017. In 2018, the Company received $650,000 due to the exercise of warrants issued from previous financial offerings. The Company received $2,185,000 from debt issuance due to the sale of convertible notes to two investors in September 2018 netting the Company $1,815,000 and from an additional loan from the Company CEO for $370,000. The Company also had gross proceeds from a public offering in January 2018 receiving $2,960,000.

Payment Obligations Under Separation Agreement with Former CEO

Effective May 5, 2016, Joshua Kornberg resigned as the Chief Executive Officer and President and an employee of the Company. In connection with Mr. Kornberg's resignation, the Company and Mr. Kornberg entered into a separation agreement on June 13, 2016 (the "Separation Agreement"). Pursuant to the Separation Agreement, on July 15, 2016, the Company was required to pay Mr. Kornberg: (a) $15,443.20 less any required tax withholdings in a lump sum on July 15, 2016; and (b) $75,000 less any required tax withholdings on July 15, 2016. The Company was required to pay Mr. Kornberg an additional $75,000 less any required tax withholdings payable in 6 monthly installments of $12,500, due on the first regular payday of each month, starting on August 15, 2016; and (d) an additional $450,000 less any required tax withholdings payable in 11 monthly installments of $40,909, due on the first regular payday of each month, starting on February 15, 2017. The Company issued to Mr. Kornberg a restricted stock award (the "Award") under the Company's stock incentive plan consisting of 20,000 shares. The Award vested on July 15, 2016. The value of the Award for purposes of the Separation Agreement (the "Award Value") was $90,351. Mr. Kornberg agreed that the withholding taxes in connection with the Award will be offset against cash payments otherwise due to him in four monthly installments. In addition, the Company agreed to, at its option, decided to pay Mr. Kornberg $309,649 (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. 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 Company satisfied all the obligations under this agreement during 2018.

Liquidity, Plan of Financing and Going Concern Qualification

Since our inception, we have incurred significant losses, and our accumulated deficit was approximately $63.1 million as of December 31, 2018. 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 registered direct offering raising a net $1,712,000 in 2016 and a qualified public offering raising a net $13,555,003, after deducting underwriting discounts, commissions and expenses in 2015. The Company raised an additional net of $3,509,000 in January 2017 because of a public offering. Another Company raise resulted in $1,213,819 net proceeds in November 2017. In January 2018, the Company received $2,755,087 net proceeds from a firm commitment underwritten public offering. The Company incurred secured debt through the sale of convertible notes to two investors in September 2018 netting the Company $1,815,000. Additionally, the Company borrowed $370,000 from the Company's CEO in November 2018.

In January and February 2019, the Company received an additional loan and investment equaling $1,300,000 from the Company's CEO. On March 1, 2019 the Company closed on a public offering receiving a net $1,111,880; see Note 13- Subsequent Events. The Company advanced $420,000 from this funding to Helomics for operating expenses. On March 29, 2019 the Company closed on a public offering receiving a net $1,053,360; see Note 13 – Subsequent Events. The Company will continue to fund Helomics and will require additional funding as we have not achieved profitability and anticipate that we will continue to incur net losses at least through the first two quarters of 2019. The Company has classified such advances to Helomics as notes receivable on the Company's balance sheet, however all such receivables will be eliminated upon the Company's acquisition of Helomics.

We had revenues of $1,412,000 in 2018, but we had negative operating cash flows of $5.3 million. Our cash balance was $0.2 million as of December 31, 2018, and our accounts payable and accrued expenses were an aggregate $1.7 million. Additionally, the debt agreements the Company entered into in 2018 and 2019 are all due within one year. A total of $3,967,727 is due under such agreements between September 2019 and February 2020. We are currently incurring negative operating cash flows of approximately $441,000 per month. Although we are attempting to curtail our expenses, there is no guarantee that we will be able to reduce these expenses significantly, and expenses for some periods may be higher as we prepare our product for broader sales, increase our sales efforts and maintain adequate inventories.

We will require additional funding to finance operating expenses of our STREAMWAY business to invest in our sales organization and new product development and to pursue sales in the international marketplace. We have committed significant capital and management resources to develop our CRO business and other new business areas, and we intend to continue to devote significant management resources to new businesses. Our businesses will need to increase revenue to generate necessary cash flows for the Company to sufficiently fund its operations without external financing. There is no assurance that we will be successful in raising sufficient capital, and the terms of any such financing will be dilutive to our stockholders. We may also acquire technologies or companies by issuing stock or other equity securities rather than or in addition to payment of cash, which may have the result of diluting the investment of our stockholders. Further, the energy and resources of our officers and personnel are being substantially diverted to these new lines of business, which are unproven. If these businesses are unsuccessful or require too great of a financial investment to be profitable, our business may fail regardless of the level of success of our STREAMWAY business.

If necessary, 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 over the next 12 months. Such additional financing may 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, we have concluded that there is substantial doubt about our ability to continue as a going concern. The financial statements have been prepared assuming the Company will continue as a going concern. Furthermore, our independent registered public accounting firm has indicated in their audit opinion, contained in our financial statements included in this Annual Report on Form 10-K within Item 8, that there is substantial doubt about our ability to continue as a going concern.

Financing Transactions

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

January 2017 Public Offering of Units

On January 19, 2017, the Company closed a firm commitment underwritten public offering of 1,750,000 Units at an offering price of $2.25 per Unit, with each Unit consisting of one share of the Company's 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 $2.25 per whole share. The shares of the common stock and the Series D Warrants were immediately separable and were issued separately. Gross proceeds to the Company from the offering were approximately $3,937,500 before deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. The Company also granted the underwriter 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 and/or (ii) additional warrants to purchase up to 35,000 shares of Common Stock at a purchase price of $0.001 per warrant to cover over-allotments, if any. Subsequently, the underwriter exercised the over-allotment option in full to purchase 175,000 additional shares of Common Stock and Series D Warrants to purchase 35,000 additional shares of Common Stock. The closing of the exercise of the over-allotment option occurred on February 22, 2017. Gross proceeds to the Company were approximately $393,750. Net proceeds to the Company were approximately $358,312 after deducting underwriting discounts and commissions and before deducting estimated offering expenses payable by the Company.

November 2017 Private Placement of Preferred Stock and Warrants

On November 30, 2017, the Company closed a private placement of a newly-created series of preferred stock designated as "Series C Convertible Preferred Stock" with a New York based Family Office. Pursuant to the Securities Purchase Agreement, the investor purchased 1,213,819 shares of Series C stock at a purchase price of $1.071 per Series C Share, together with a warrant to purchase up to 606,910 shares of common stock. The warrant has an exercise price of $1.26 per share, subject to adjustment, has a five- and one-half-year term and is exercisable commencing six months following the date of issuance. Total gross proceeds to Precision were $1,300,000 before deducting expenses and will be used for general working capital. In connection with the Offering and pursuant to a registration rights agreement, the Company has agreed to file a "resale" registration statement covering all of the shares of common stock issuable upon conversion of the warrant. Pursuant to the Securities Purchase agreement, and as of this filing date, all the Preferred Series C shares were converted at a conversion rate of 1.167 to a maximum of 1,250,269 shares of common stock. The remaining 142,466 shares of Preferred Series C stock were cancelled with a redemption payment to the holder for $189,285.

January 2018 Public Offering of Common Stock and Warrants

In January 2018, the Company completed a firm commitment underwritten public offering of 2,900,000 Units at an offering price of $0.95 per Unit, with each Unit consisting of one share of the Company's Common Stock and 0.3 of a Series E Warrant, with each whole Series E Warrant purchasing one share of common stock at an exercise price of $1.00 per whole share. The shares of Common Stock and Series E Warrants were immediately separable and were issued separately. Gross proceeds were approximately $2,755,000, before deducting expenses. The Company granted the underwriter a 45-day option to purchase an additional (i) up to 290,000 additional shares of Common Stock at the public offering price per Unit less the price of the Series E Warrant included in the Units and less the underwriting discount and/or (ii) additional Series E Warrants to purchase up to 87,000 additional shares of common stock at a purchase price of $0.001 per Series E Warrant to cover over-allotments, if any. On February 21, 2018, the underwriter exercised on 215,247 shares of common stock, par value $0.01, at $0.9497 per share as described in the Underwriting Agreement. The Company received net proceeds of $188,066 after deductions of $16,354 representing the Underwriter's discount of 8% of the purchase price of the shares.

September 2018 Senior Secured Promissory Notes

On September 28, 2018 (the "Effective Date"), Precision Therapeutics Inc. entered into a Securities Purchase Agreement with each of L2 Capital, LLC ("L2") and Peak One Opportunity Fund, LP ("Peak One" and, together with L2, the "Investors") (together, the "Securities Purchase Agreements"). Pursuant to the Securities Purchase Agreements, as of September 28, 2018, the Company issued a convertible promissory note to each of the Investors (together, the "Notes") in the original principal amount of an aggregate $2,297,728 in exchange for an investment of $2,000,000, less commissions, with net proceeds to the Company of $1,815,000. Pursuant to a Security Agreement between the Company and each of the Investors (the "Security Agreements"), the Company has granted to each of the Investors a security interest in its assets to secure repayment of the Notes. The Company has agreed to loan one-half of the net proceeds to Helomics Holding Corporation. The Securities Purchase Agreements also provide for a second investment of an aggregate of $500,000 by the Investors at the consummation of the Company's pending merger transaction with Helomics Holding Corporation, at which point if the second tranche is funded, the aggregate principal amounts of the Notes will become $2,865,909.

As additional consideration for the investment, the Company issued an aggregate 650,000 shares of its common stock (the "Inducement Shares") to the Investors or their affiliates plus warrants (the "Warrants") to acquire up to an aggregate 1,071,776 shares of the Company's common stock (the "Warrant Shares") at an exercise price of $1.155 per share. Upon the closing of the second tranche investment, the Warrants would be increased to cover an aggregate total of 1,336,805 shares. Each Warrant is exercisable by the Investor beginning on the sixth month anniversary of the Effective Date through the fifth-year anniversary thereof.

The maturity date of the Notes is twelve months from the Effective Date. The Notes accrue interest at a rate of 8% per annum (with twelve months of interest guaranteed). The Notes may be prepaid in any amount, subject to the following prepayment penalties: (1) during the first 30 days after the Effective Date, any amount prepaid will be subject to a 5% prepayment penalty; (2) during the next 30 days thereafter, any amount prepaid will be subject to a 10% prepayment penalty; (3) during the next 30 days thereafter, any amount prepaid will be subject to a 15% prepayment penalty; (4) during the next 30 days thereafter, any amount prepaid will be subject to a 20% prepayment penalty; and (5) any amount prepaid after the 120th calendar day after the Effective Date will be subject to a 25% prepayment penalty.

Upon the earlier to occur of an Event of Default (as defined in the Notes) or the filing of certain registration statements, each Investor will have the right at any time thereafter to convert all or any part of its Note into shares of the Company's common stock at a conversion price which is equal to the lesser of: (i) $1.00 and (ii) 70% of the lowest volume-weighted average price of the Company's common stock during the 20-trading day period ending on either the last complete trading day prior to the conversion date, or the conversion date ("Conversion Shares"). The number of Conversion Shares that may be issued is subject to an exchange cap such that the sum of (a) the total number of Conversion Shares plus (b) the number of Inducement Shares is limited to an aggregate 2,678,328 shares.

Pursuant to a Registration Rights Agreement between the Company and each of the Investors (the "Registration Rights Agreements"), the Company has agreed, among other things, to file with the SEC a registration statement covering the Inducement Shares and any other shares issuable under the transaction documents and to use its reasonable best efforts to cause such registration statement to become effective before November 15, 2018. No later than January 31, 2019, the Company must also cause the Conversion Shares to be registered on a registration statement with the SEC.

Forbearance Agreements with Prior Investors and Amended and Restated Notes.

Effective as of February 7, 2019 (the "Effective Date"), Precision Therapeutics Inc. entered into a: (1) a Forbearance Agreement with each of L2 Capital, LLC and Peak One Opportunity Fund, LP (together, the "Forbearance Agreements"), and (2) an Amended and Restated Senior Secured Promissory Note with each of the Investors (together, the "Amended and Restated Notes").

The Amended and Restated Notes amend and restate in their entirety the Senior Secured Promissory Notes dated September 28, 2018 issued by the Company to the Investors on September 28, 2018 (together, the "Notes"). The Notes were in the original principal amount of an aggregate $2,297,728 and were issued in exchange for a $2,000,000 (less commissions) investment by the Investors in the Company, with net proceeds to the Company of $1,815,000 (the "Note Offering"). In connection with the Note Offering, the Company entered into, among other things, a Registration Rights Agreement with each of the Investors (together, the "Registration Rights Agreements").

Pursuant to the Forbearance Agreements, the Investors will forbear on their rights to accelerate the Notes and the Company will pay default penalties in connection with (1) a claimed event of default under the Registration Rights Agreements from the timing of filing a registration statement to register the Investors' shares of the Company's common stock issuable in connection with the Offering and (2) an event of default under the Notes from failing to obtain shareholder approval of the Company's proposed merger with Helomics Holding Corporation by January 1, 2019.

On the Effective Date, the principal amount of the Notes (and as amended and restated, the Amended and Restated Notes) was increased by 15% of the current principal amount (i.e., by $242,386 for L2 and $102,273 for Peak One). On February 11, 2019, the Company issued 116,667 additional shares of common stock to L2 and 50,000 additional shares of common stock to Peak One (collectively, the "Forbearance Shares"). Pursuant to the Forbearance Agreements, the Company also agreed to use its best efforts to file with the SEC a registration statement covering the Forbearance Shares and to cause such registration statement to become effective as quickly as practicable.

The Company and the Investors also agreed that if (a) the Company obtains shareholder approval of the Merger by March 31, 2019, (b) the Registration Statement on Form S-3 filed by the Company on December 19, 2013 covering the transaction shares stays effective and (c) there are no other defaults under the Notes (and as amended and restated, the Amended and Restated Notes), the Registration Rights Agreements or any document issued in connection with the Offering, then the above defaults will be considered cured (the "Default Cure"), and the Amended and Restated Notes will not be accelerated and no additional default penalties will be paid. The Company believes that, as a result of the effectiveness of such registration statement on February 13, 2019 and the stockholder approval of the Merger on March 22, 2019, the Default Cure has been achieved. However, there can be no assurance that there will not be additional defaults under terms of the Amended and Restated Notes. If there is any other default under the transaction documents, the Amended and Restated Notes will accelerate, and the Investors may assert all of their rights.

Interest on the Notes (and as amended and restated, the Amended and Restated Notes) accrued at a default rate of 18% beginning November 15, 2018 through the date of the Default Cure. Upon certain financings, the Company is required to apply a portion of the proceeds to repayment of the Amended and Restated Notes.

November 2018 Investment by Carl Schwartz

Effective as of November 30, 2018, Carl Schwartz, our CEO, made an investment of $370,000 in Precision Therapeutics Inc. (the "Company") and received a Promissory Note (the "Note") and a Common Stock Purchase Warrant (the "Warrant"). The Note is currently in the principal amount of $370,000. Dr. Schwartz will make another investment of $130,000 on a mutually agreed date, at which time the total principal amount will be $500,000. The Note bears interest at the rate of eight percent (8%) per annum on the principal amount. The maturity date for the Note shall be the earlier of (a) the date five (5) business days after the closing of the Company's sale of equity or debt securities of the Company resulting in gross proceeds of at least $1,000,000, or (b) twelve (12) months from the date that the Note is issued, and is the date upon which the principal sum, as well as any accrued and unpaid interest and other fees, shall be due and payable.

As additional consideration for the investment, the Company issued the Warrant for a prorated number of shares of common stock based upon each tranche funded, which number is currently 221,292 warrant shares, and would be 299,043 warrant shares (representing an additional 77,751 warrant shares) if that the second tranche of $130,000 under the Note is funded. The exercise price is $0.836 per share, which was 110% of the closing sale price of the common stock on the date of issuance. The Warrant is exercisable beginning on the sixth month anniversary of the date of issuance through the fifth-year anniversary thereof.

Additional Investments in 2019 by Carl Schwartz

On January 8, 2019, Dr. Carl Schwartz, our Chief Executive officer, made an additional investment of $950,000 in a loan and $50,000 in a common stock purchase in the Company. On February 6, 2019, Dr. Schwartz, made an additional investment of $300,000 in the Company, following his November 30, 2018 and January 8, 2019 investments in the Company now aggregating $1,670,000. In connection with the new investment, Dr. Schwartz received a Second Amended and Restated Promissory Note in the original principal amount of $1,620,000. (the "Schwartz Note") and a Second Amended and Restated Common Stock Purchase Warrant (the "Schwartz Warrant"). The Schwartz Note and the Schwartz Warrant amend and restate the amended and restated promissory note and amended and restated common stock purchase warrant issued to Dr. Schwartz in connection with the previous investments.

The Schwartz Note bears interest at the rate of eight percent (8%) per annum on the principal amount. The maturity date for the Schwartz Note is February 6, 2020, and is the date upon which the principal sum, as well as any accrued and unpaid interest and other fees, shall be due and payable. The Schwartz Note may be prepaid in whole or in part at any time, and upon certain financings, the Company is required to apply a portion of the proceeds to repayment of the Schwartz Note.

As additional consideration for the investment, the Company issued the Schwartz Warrant with an exercise price of $0.836 per share for the initial 221,292 shares that related to the November 2018 investment (the "First Tranche"), an exercise price of $0.704 per share for the additional 748,415 shares (subject to increase as described below) relating to the second investment (the "Second Tranche"), and an exercise price of $1.188 per share for the additional 138,889 shares (subject to increase as described below) relating to the current investment (the "Third Tranche"). The exercise price in each case is equal to 110% of the closing sale price of the common stock on the date of the applicable investment. Each tranche of the Schwartz Warrant is exercisable beginning on the sixth month anniversary of the date of the related investment through the fifth-year anniversary of the date of the related investment.

On February 1, 2019, and the first day of each calendar month thereafter, while the Schwartz Note and the Schwartz Warrant remain outstanding, a number of additional shares will be added to the Second Tranche and the Third Tranche equal to (1) one-half percent (1/2%) of the outstanding principal balance of the Schwartz Note on such date, divided by (2) the closing price of the Company's common stock on that date. The number of warrant shares will be subject to a share limit such that the total of (a) the 78,128 shares of common stock purchased by Dr. Schwartz on January 8, 2019, and (b) the total number of warrant shares (1,108,596 warrant shares as of February 6, 2019) may not exceed 2,818,350 shares (equal to 19.9% of the outstanding shares of Common Stock on January 8, 2019). If the Second Tranche and/or Third Tranche cannot be increased as required herein due to the share limit, then in lieu of any such increase, the Company shall pay to Dr. Schwartz a cash amount equal to one-half percent (1/2%) of the principal balance of the Schwartz Note in lieu of such increase.

March 1, 2019 Registered Sale of Common Stock and Warrants

On February 27, 2019, we entered into a placement agency agreement pursuant to which Dawson James Securities, Inc. ("Dawson James") served as placement agent on a "best efforts" basis for a registered direct offering in which the Company sold 1,385,000 shares of common stock and warrants to purchase up to 692,500 shares of 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 0.5 of a share of our Common Stock at an exercise price of $1.00 per whole share. The Warrants are exercisable at any time on or after the date of issuance and expire on the fifth anniversary of issuance. The units were sold at a price of $0.90 per unit, resulting in gross proceeds to the Company of approximately $1.25 million, before deducting placement agent fees and estimated offering expenses. The net offering proceeds to the Company, after deducting the placement agent's fees and other estimated offering expenses payable by the Company, were $1.1 million. The closing of this offering occurred on March 1, 2019. Pursuant to the placement agency agreement, Dawson James received cash compensation of $134,720 for commissions and expenses. Also pursuant to the placement agency agreement, the Company entered into unit purchase option agreements, dated as of March 1, 2019, pursuant to which the Company granted Dawson James or its assigns the right to purchase from the Company up to an aggregate of 69,250 units (which represents 5% of the units sold to investors in the offering) at an exercise price equal to 125% of the public offering price of the units in the offering, or $1.125 per unit. The unit purchase options shall expire on February 27, 2024.

March 29, 2019 Registered Sale of Common Stock and Warrants

On March 26, 2019, we entered into a placement agency agreement pursuant to which Dawson James Securities, Inc. served as placement agent on a "best efforts" basis for a registered direct offering in which the Company sold 1,478,750 shares of common stock and warrants to purchase up to 739,375 shares of 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 0.5 of a share of our Common Stock at an exercise price of $1.00 per whole share. The Warrants are exercisable at any time on or after the date of issuance and expire on the fifth anniversary of issuance. The units were sold at a price of $0.80 per unit, resulting in gross proceeds to the Company of approximately $1.2 million, before deducting placement agent fees and estimated offering expenses. The net offering proceeds to the Company, after deducting the placement agent's fees and other estimated offering expenses payable by the Company, were $1.05 million. The closing of this offering occurred on March 29, 2019. Pursuant to the placement agency agreement, Dawson James received cash compensation of $129,640 for commissions and expenses. Also pursuant to the placement agency agreement, the Company entered into unit purchase option agreements, dated as of March 29, 2019, pursuant to which the Company granted Dawson James or its assigns the right to purchase from the Company up to an aggregate of 73,938 units (which represents 5% of the units sold to investors in the offering) at an exercise price equal to 125% of the public offering price of the units in the offering, or $1.00 per unit. The unit purchase options shall expire on March 29, 2024.

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 primarily due to incorrect sales forecasting. We utilize a pipeline generated by our sales team and speak directly with all departments regarding estimates and assumptions. If, for any reason, those estimates and assumptions vary substantially it would also impact our cost of goods and associated operating expenses. The other volatile area for estimates and assumptions is determining financing needs. Depending on how the Company chooses to fund will affect numerous expense categories so the potential for underestimating those expenses is a viable concern.

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.

Effective January 1, 2018, we adopted Accounting Standards Update ("ASU") *No. 2014-09, Revenue from Contracts with Customers (Topic 606),* which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. The standard's core principle is that an entity will recognize revenue when it transfers 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.

Our product sales consist of a single performance obligation that the Company satisfies at a point in time. We recognize product revenue when the following events have occurred: (a) the Company has transferred physical possession of the products, (b) the Company has a present right to payment, (c) the customer has legal title to the products, and (d) the customer bears significant risks and rewards of ownership of the products. Based on the shipping terms specified in the sales agreements and purchase orders, these criteria are generally met when the products are shipped from the Company's facilities ("FOB origin", which is the Company's standard shipping terms). As a result, we determined that the customer is able to direct the use of, and obtain substantially all of the benefits from, the products at the time the products are shipped. We may, at our discretion, negotiate different shipping terms with customers which may affect the timing of revenue recognition. Standard payment terms for our customers are generally 30 to 60 days after the Company transfers control of the product to its customer.

Customers may also purchase a maintenance plan from the Company, which requires that we service the STREAMWAY System for a period of one year subsequent to the one-year anniversary date of the original STREAMWAY System invoice. The maintenance plan is considered a separate performance obligation from the product sale, is charged separately from the product sale, and is recognized over time (ratably over the one-year period) as maintenance services are provided. A time-elapsed output method is used to measure progress because we transfer control evenly by providing a stand-ready service. We have determined that this method provides a faithful depiction of the transfer of services to our customers.

We record receivables when we have an unconditional right to receive consideration after the performance obligations are satisfied. As of December 31, 2018, and December 31, 2017, accounts receivable totaled $232,602 and $137,499, respectively. For the year ended December 31, 2018, we did not incur material impairment losses with respect to our receivables.

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. In the case of options and warrants issued to consultants and investors we used the legal term of the option/warrant as the estimated term unless there was a compelling reason to use a shorter term. The measurement date for employee and non-employee options and warrants is the grant date of the option or warrant. The vesting period for options that contain service conditions is based upon management's best estimate as to when the applicable service condition will be achieved. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognized. The assumptions we use in calculating the fair value of stock-based payment awards represent our best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our equity-based compensation expense could be materially different in the future. See "Note 4 – 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. The Company has been on the NASDAQ Capital Market since 2015 and has had a volatile stock including reverse stock splits. 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.

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.

Notes Receivable. We review open notes receivable balances for collectability each reporting period. If it is determined that it is probable that we will not collect the full amount due under a note agreement, we record reserves against the note receivable balance in accordance with ASC 310 – *Receivables*. In order to reasonably conclude on the collectability of such balances, we consider the borrower's current status on payments received, the financial health and other sources of funding available to each borrower, our ability to secure assets collateralized by contractual agreements, as well as other factors.

Recent Accounting Developments

See “Note 1 - Summary of Significant Accounting Policies - Recent Accounting Developments” in Notes to Financial Statements of this Annual Report on Form 10-K.

Off-Balance Sheet Transactions

We have no off-balance sheet transactions.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not required.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our financial statements and supplementary data are included on pages F-1 to F-22 of this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

The Company’s management, with the participation of the Company’s Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company’s disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as of December 31, 2018. Based on that evaluation, the Company’s Chief Executive Officer and Chief Financial Officer concluded that the Company’s disclosure controls and procedures were effective as of December 31, 2018.

Management’s Report on Internal Control Over Financial Reporting

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we carried out an evaluation of the effectiveness of our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) as of December 31, 2018 based on the criteria in “Internal Control - Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in 2013. Based upon this evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2018.

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

Changes in Internal Control Over Financial Reporting

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

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

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

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

Executive Officers and Directors of the Registrant

The following table identifies our current executive officers and directors:

Name		Age	Position Held
Carl Schwartz	(4)	78	Chief Executive Officer and Director
Bob Myers		64	Chief Financial Officer
Thomas J. McGoldrick	(2) (3) (4)	77	Director
Andrew P. Reding	(1)	49	Director
J. Melville Engle	(1) (2)	69	Director
Timothy A. Krochuk	(1) (3) (4)	49	Director
Richard L. Gabriel	(4)	70	Director

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Governance/Nominating Committee
(4) Member of the Merger & Acquisition Committee

Each director will serve until their successors are elected and have duly qualified.

There are no family relationships among our directors and executive officers. Our executive officers are appointed by our Board of Directors and serve at the Board's discretion.

Classified Board of Directors

On March 22, 2019, Company's stockholders approved amendments to the Certificate of Incorporation and the Precision Bylaws to establish a classified Board of Directors, and the Company filed the Amended and Restated Certificate of Incorporation. The amendments to Precision's Certificate of Incorporation and the Precision Bylaws provide for the division of the members of Precision's Board into three classes, with each class consisting of two directors. As a result of this stockholder approval, three classes of directors were created: Class I continuing for a term expiring in 2019, Class II for a term expiring in 2020, and Class III for a term, expiring in 2021. Beginning with the 2019 annual meeting of the Precision stockholders, the class of directors up for election or reelection will be elected to three-year terms. The Board has divided the directors into classes as follows:

CLASS I	**CLASS II**	**CLASS III**
(term expiring in 2019)	(term expiring in 2020)	(term expiring in 2021)
Tim Krochuk	Andy Reding	Dr. Carl Schwartz
Tom McGoldrick	J. Melville Engle	Richard Gabriel

Business Experience

Carl Schwartz, **Chief Executive Officer and Director.** Dr. 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. In 1988 Dr. Schwartz joined a family business becoming chief executive officer of Plastics Research Corporation, a Flint, Michigan, manufacturer of structural foam molding, a low-pressure injection molding process. While there he led its growth from $2 million in revenues and 20 employees, to it becoming the largest manufacturer of structural foam molding products under one roof in the U.S. with more than $60 million in revenues and 300 employees when he retired in 2001. He holds B.A. and D.D.S. degrees from the University of Detroit.

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

Thomas J. McGoldrick, Director. Mr. McGoldrick has served as a Director of the Company since 2005. Prior to that, he served as Chief Executive Officer of Monteris Medical Inc. from November 2002 to November 2005. He has been in the medical device industry for over 30 years and was co-founder and Chief Executive Officer of Fastitch Surgical in 2000. Fastitch is a start-up medical device company with unique technology in surgical wound closure. Prior to Fastitch, Mr. McGoldrick was President and Chief Executive Officer of Minntech from 1997 to 2000. Minntech was a $75 million per year publicly traded (NASDAQ-MNTX) medical device company offering services for the dialysis, filtration, and separation markets. Prior to employment at Minntech from 1970 to 1997, he held senior marketing, business development and international positions at Medtronic, Cardiac Pacemakers, Inc. and Johnson & Johnson. Mr. McGoldrick is on the Board of Directors of two other start-up medical device companies.

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.

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., 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 CFO, at Allergan, Inc. 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 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, was a Board Member of the Napa Valley Community Foundation, and at the Napa College Foundation. He was also Vice Chair of the Thunderbird Global Council at the Thunderbird School of Global Management in Glendale, Arizona.

Timothy A. Krochuk, Director. Mr. Krochuk is Co-Founder, Managing Member and Co-CEO of Shepherd Kaplan Krochuk, one of the largest privately held wealth management firms. As Co-CEO, he is actively involved in the development of the firm's intellectual property, consulting tools and technological capabilities. Mr. Krochuk is a portfolio manager for the private equity and real estate investment funds. He has been involved in investment management and research since 1992 and was previously the youngest diversified portfolio manager in the history of Fidelity Investments. During his tenure at Fidelity, he used advanced quantitative techniques to study a variety of industries. He was responsible for the development, programming and implementation of investment models used in managing over $20 billion in public mutual funds. Mr. Krochuk holds the Chartered Financial Analyst designation, and serves on the board of, or in an advisory capacity to, a number of private and public companies in the United States and Canada. He is a member of the Young Presidents' Organization (YPO) and holds the Master Professional Director Certification. Mr. Krochuk holds an A.B. in Economics from Harvard College.

Richard L. Gabriel, Director. Mr. Gabriel was appointed to the Board of Directors on December 1, 2016. He has more than 40 years of relevant healthcare experience, including two decades of executive leadership and as a director and 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. Mr. Gabriel holds an MBA from Suffolk University in Boston, and a BS in Chemistry from Ohio Dominican College in Columbus.

Shortly after the Merger, the Precision Board is expected to consist of seven directors, of which one will be designated by Helomics. Helomics has stated that it intends to designate Gerald J. Vardzel, Jr. to serve as a director.

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

Audit Committee

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

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

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

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

Our Audit Committee currently consists of Mr. Krochuk, as the chairperson, Mr. Reding and Mr. Engle. 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 2018.

Audit Committee Financial Expert

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

Report of the Audit Committee of the Board of Directors

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

(1) reviewed and discussed the audited financial statements with management and the independent auditors;

(2) discussed with the independent auditors the material required to be discussed by Statement on Auditing Standards No. 114, as amended (AICPA, Professional Standards, Vol. 1, AU section 380), as adopted by the Public Company Accounting Oversight Board in Rule 3200T, with and without management present; and

(3) received the written disclosures and the letter from the independent auditors required by applicable requirements of the Public Company Accounting Oversight Board regarding the independent accountant's communications with the Audit Committee concerning independence and discussed with the independent accountant the independent accountant's independence.

Based upon the review and discussions referred to above, the Audit Committee recommended to the Board of Directors that the audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, as filed with the Securities and Exchange Commission.

Compensation Committee

The Compensation Committee of the Board of Directors currently consists of two directors, Mr. Engle, as the chairperson, and Mr. McGoldrick. All members of the Compensation Committee were appointed by the Board of Directors and consist entirely of directors who are "outside directors" for purposes of Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Code"), "non-employee directors" for purposes of Rule 16b-3 under the Exchange Act and "independent" as independence is currently defined in Rule 4200(a) (15) of the NASDAQ listing standards. In fiscal 2018, the Compensation Committee met four 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 shall be elected annually by the Board. Committee members may be removed for any reason or no reason at the discretion of the Board, and the Board may fill any Committee vacancy that is created by such removal or otherwise. The Committee's chairperson shall be designated by the full Board or, if it does not do so, the Committee members shall elect a chairperson upon the affirmative vote of a majority of the directors serving on the Committee.

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

In furtherance of its purposes, the Committee:

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

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

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

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

Merger & Acquisition Committee

The Merger & Acquisition Committee of the Board of Directors currently consists of Dr. Carl Schwartz, as the chairperson, Mr. Timothy Krochuk, Mr. Richard Gabriel and Mr. Thomas McGoldrick, two of whom are "independent directors" as such item 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. Dr. Schwartz and Mr. Gabriel are not deemed to be independent. The Merger & Acquisition Committee is a newly formed committee constructed in December 2016 with the function of advising the Company toward any considered mergers, acquisitions, joint ventures and/or consolidations of any type.

Diversity

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires the Company's officers and directors, and persons who own more than ten percent of a registered class of the Company's equity securities, to file reports of ownership and changes in ownership of such securities with the Securities and Exchange Commission. Officers, directors and greater than ten percent stockholders are required by Securities and Exchange Commission regulations to furnish the Company with copies of all Section 16(a) forms they file. Based solely on review of the copies of Forms 3 and 4 and amendments thereto furnished to the Company during the fiscal year ended December 31, 2017 and Forms 5 and amendments thereto furnished to the Company with respect to such fiscal year, or written representations that no Forms 5 were required, the Company believes that the following is the list of its officers, directors and greater than ten percent beneficial owners who have failed to file on a timely basis all Section 16(a) filing requirements during the fiscal year ended December 31, 2017: Andrew Reding 4 late reports covering 4 transactions; Thomas J. McGoldrick 4 late reports covering 4 transactions; Timothy Krochuk 4 late reports covering 4 transactions; Richard Gabriel 3 late reports covering 3 transactions; J. Melville Engle 3 late reports covering 3 transactions; Carl Schwartz 1 late report covering 1 transaction.

ITEM 11. EXECUTIVE COMPENSATION.

Overview

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

Summary Compensation Table for Fiscal 2018 and 2017

The following table provides information regarding the compensation earned during the fiscal years ended December 31, 2018 and December 31, 2017 by each of the Named Executive Officers:

Name and Principal Position	Year	Salary	Bonus	Stock Awards	(1) Option Awards	All Other Compensation	Total Compensation
Carl Schwartz, CEO [4]	2018	$ -	$ -	$ -	$ 242,636	$ -	$ 242,636
	2017	$ 83,375	$ -	$ -	$ 437,466	$ -	$ 520,841
David O. Johnson, former COO; current Sr. VP of Operations [2]	2018	$ 194,069	$ 21,000	$ -	$ -	$ -	$ 215,069
	2017	$ 180,800	$ 36,000	$ -	$ 345,798	$ -	$ 562,598
Bob Myers, CFO [3]	2018	$ 198,467	$ 19,250	$ -	$ -	$ -	$ 217,717
	2017	$ 165,800	$ 43,000	$ -	$ 328,194	$ -	$ 536,994

(1) Represents the actual compensation cost granted during 2018 and 2017 as determined pursuant to FASB ASC 718 – Stock Compensation utilizing the assumptions discussed in Note 4, "Stock Options and Warrants," in the notes to the financial statements included in this report.

(2) Mr. Johnson received a salary increase on August 1, 2018 to $225,000 annually. Mr. Johnson received $36,000 paid in 2018 for 2017 accrued bonus. Mr. Johnson's minimum bonus for 2018 was 20% of his original base salary for 2018 for seven months of the fiscal year, or $21,000 that was accrued in 2018. Mr. Johnson's minimum bonus for 2017 was 20% of his base salary or $36,000 that was accrued in 2017; his minimum bonus for 2016 was 20% of his base salary, or $36,000 that was accrued in 2016. During 2017 he received $36,000 in recognition of bonus amounts accrued in 2016; in 2016 he received $36,000 in income from additional bonuses in recognition of bonus amounts from 2015. In 2017, he also received bonus options to purchase 320,422 shares of common stock at $1.47 per share. In 2017, 154,422 shares vested with the remainder vesting at 20,750 shares quarterly throughout 2018 and 2019. As Senior Vice President of Operations, Mr. Johnson is no longer an officer.

(3) Mr. Myers received a salary increase on August 1, 2018 to $250,000 annually. Mr. Myers received $33,000 paid in 2018 for 2017 accrued bonus. Mr. Myers's minimum bonus for 2018 was 20% of his original base salary for 2018 for seven months of the fiscal year, or $19,250 that was accrued in 2018. Mr. Myers's minimum bonus for 2017 was 20% of his base salary or $33,000 that was accrued in 2017; his minimum bonus for 2016 was 20% of his base salary, or $33,000 that was accrued in 2016. During 2017 he received $43,000 in bonus amounts $33,000 that was accrued in 2016; in 2016 he received $33,000 in income from additional bonuses in recognition of bonus amounts from 2015. In 2017, he also received bonus options to purchase 304,110 shares of common stock at $1.47 per share. In 2017, 138,110 shares vested with the remainder vesting at 20,750 shares quarterly throughout 2018 and 2019.

(4) 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 received a salary increase to $400,000 annually on August 1, 2018 and has opted to take the entire 2018-year salary as stock options in lieu of cash. In 2018, Dr. Schwartz received options to purchase 308,334 shares of common stock in lieu of a cash salary for serving as Chief Executive officer. The shares all vest in 2018 and range from $0.97 price per share to $1.16 price per share. In 2017, Dr. Schwartz received options to purchase 2,381 shares of common stock as fees for serving on the Board of Directors. He also received options to purchase 166,000 shares of common stock at $1.47 vesting at 20,750 shares per quarter throughout 2018 and 2019. Additionally, Dr. Schwartz received options to purchase 239,230 shares of common stock at $1.47 per share all vesting in 2017 in lieu of cash compensation for all 2017 and part of 2016.

Outstanding Equity Awards at Fiscal Year-end for Fiscal 2018

The following table sets forth certain information regarding outstanding equity awards held by the named executive officers as of December 31, 2018:

	Grant Date	Number of Securities Underlying Options Exercisable	Number of Securities Underlying Options Unexercisable	Option Exercise Price	Option Expiration Date
Carl Schwartz	7/19/2013	71		$ 281.25	7/19/2023
	6/30/2015	516		$ 77.50	6/30/2025
	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	8,929		$ 2.80	12/31/2026
	3/31/2017	2,381		$ 2.10	3/31/2027
	6/22/2017	376,886		$ 1.47	6/22/2027
	11/10/2017	28,344		$ 1.47	11/10/2027
	1/2/2018	141,753		$ 0.97	1/2/2028
	6/30/2018	121,682		$ 1.13	6/30/2028
	8/1/2018	44,899		$ 1.16	8/1/2028
David O. Johnson	8/13/2012	534		$ 150.00	8/13/2022
	3/18/2013	507		$ 148.25	3/18/2023
	3/6/2014	167		$ 431.25	3/6/2024
	9/16/2016	3,574		$ 4.20	9/16/2026
	6/22/2017	320,422		$ 1.47	6/22/2027
Bob Myers	8/13/2012	534		$ 150.00	8/13/2022
	3/18/2013	422		$ 148.25	3/18/2023
	3/6/2014	140		$ 431.25	3/6/2024
	9/16/2016	3,574		$ 4.20	9/16/2026
	6/22/2017	304,110		$ 1.47	6/22/2027

Executive Compensation Components for Fiscal 2018

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.

Bonuses. Until 2018 the Chief Financial Officer and the former Chief Operating Officer received 20% contractual cash bonuses. Any other bonus for the CFO and the former COO, as well as for the CEO, if offered, were determined by the compensation committee. The bonuses in past years were a combination of cash and employee stock options. The CFO and former COO signed amended contracts whereby the contractual bonuses were removed subsequent to August 1, 2018. All bonuses subsequent to 2018 will be part of a structured program established by the compensation committee and approved by the Board of Directors.

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.

Amendment to Stock Option Plan. On March 22, 2019, Company's stockholders approved amendments to the Amended and Restated 2012 Stock Incentive Plan (the "2012 Plan") to: (1) increase the share reserve under the 2012 Plan by an aggregate 5 million shares from the most recent reserve of 5 million shares to an aggregate 10 million shares, and (2) increase in certain thresholds for limitations on grants under the 2012 Plan (together, the "Amendments"). Currently, options to purchase 3,448,885 shares of common stock are subject to outstanding stock options under the 2012 Plan. In determining the amount of the increase in the 2012 Plan, the Precision Board took into account its intention to grant further equity awards to current and future executive officers and key employees and directors of Precision. Moreover, Precision is obligated under the Merger Agreement to grant 900,000 stock options to key personnel of Helomics in connection with the Merger.

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.

Employment Contracts

Employment Agreement with Chief Executive Officer.

On August 20, 2018, the Company entered into an amended employment agreement with Carl Schwartz, the Chief Executive Officer. The annualized base salary for Dr. Schwartz increased from $275,000 to $400,000 effective August 1, 2018.

Increase in vacation. Dr. Schwartz shall be entitled to five (5) weeks of paid vacation per each calendar year earned ratably over each calendar year, to be taken at such times as employee and company shall determine and provided that no vacation time shall unreasonably interfere with the duties required to be rendered by employee.

On November 10, 2017, the Company entered into an employment agreement with Carl Schwartz, who has served as Chief Executive officer since December 1, 2016. Under the agreement the employment of Dr. Schwartz with the Company is at will.

The annualized base salary for Dr. Schwartz in 2017 is $250,000, increasing to $275,000 in 2018. Such base salary 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.

Dr. Schwartz may receive stock options in lieu of his base salary. At least ten (10) days before the beginning of each six-month period ending June 30 or December 31 (a “Compensation Period”) during which Dr. Schwartz is employed under this agreement he may elect to receive non-qualified stock options under the 2012 Stock Incentive Plan or other applicable equity plan of the Company in effect at the time in payment of all or a portion of his base salary for such Compensation Period in lieu of cash. Stock options (i) will be granted on the first business day of such Compensation Period, (ii) will have an exercise price per share equal to the closing sale price of the Company’s common stock on the date of grant, (iii) will have an aggregate exercise price equal to the dollar amount of base salary to be received in options, (iv) will have a term of ten years, and (v) will vest pro rata on a monthly basis over the period of time during which the base salary would have been earned.

For each fiscal year during the term of the agreement, beginning in 2017, Dr. Schwartz shall be eligible to receive an annual incentive bonus determined annually at the discretion of the Compensation Committee of the Board. For 2017, the Compensation Committee will award a bonus based on performance of Dr. Schwartz and the Company, including the completion of acquisitions and other factors deemed appropriate by the Compensation Committee. For 2018 and subsequent years, the bonus will be subject to the attainment of certain objectives, which shall be established in writing by Dr. Schwartz and the Board prior to each bonus period. The maximum bonus that may be earned by Dr. Schwartz for any year will not be less than 150% of Dr. Schwartz’s then-current base salary.

If the Company terminates the Dr. Schwartz’s employment without cause or if the he terminates his employment for “good reason,” he shall be entitled to receive from Company severance pay in an amount equal to six 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 Dr. Schwartz’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; Dr. Schwartz embezzles or misappropriates assets of Company or any of its subsidiaries; Dr. Schwartz’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 Dr. Schwartz and the Company or to which Company and the Dr. Schwartz are parties, or a breach of his fiduciary responsibility to the Company; commission by of fraud or other willful conduct that adversely affects the business or reputation of Company; or, Company has a reasonable belief the executive engaged in some form of harassment or other improper conduct prohibited by Company policy or the law. “Good reason” is defined as (i) a material diminution in Employee’s position, duties, base salary, and responsibilities; or (ii) Company’s notice to Employee that his or her position will be relocated to an office which is greater than 100 miles from Employee’s prior office location. In all cases of Good Reason, Employee must have given notice to Company that an alleged Good Reason event has occurred and the circumstances must remain uncorrected by Company after the expiration of 30 days after receipt by Company of such notice.

During Dr. Schwartz'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.

Employment Agreement with Chief Financial Officer.

On August 20, 2018, the Company entered into an amendment to employment agreement with Bob Myers the Chief Financial Officer. Effective August 1, 2018, Mr. Myers received an annualized base salary of $250,000. Effective August 1, 2019, Mr. Myers will receive an annualized base salary of $300,000.

Increase in vacation. Mr. Myers shall be entitled to five (5) weeks of paid vacation per each calendar year earned ratably over each calendar year, to be taken at such times as employee and company shall determine and provided that no vacation time shall unreasonably interfere with the duties required to be rendered by employee

On August 13, 2012, the Company entered into an employment agreements with Bob Myers, who has served as Chief Financial Officer since July 1, 2012 (Messrs. Myers is referred to as the "executive"). Under the agreement the employment of each of this individual with the Company is at will.

Base salaries for Mr. Myers 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 executive 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.

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

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

Potential Payments Upon Termination or Change of Control

Most of our stock option agreements provide for an acceleration of vesting in the event of a change in control as defined in the agreements and in the 2012 Stock Incentive Plan. However, the stock option agreements awarded to each of Carl Schwartz and Bob Myers provide that upon the termination of such employee's employment without cause or for good reason, such employee's options shall become fully vested, and the vested shares may be purchased for up to five years after such termination (or such lesser period for the option). In addition, in the event of such employee's retirement, death or disability, such employee's options shall become fully vested, and the vested shares may be purchased for the entire remaining period of the option. Additionally, the restricted stock agreements that were awarded to management and directors in 2013 also provide for an acceleration of vesting in the event there is a change in control as defined in the 2012 Plan. Also, see "Employment Contracts" above for a description of certain severance compensation arrangements.

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 2018

The following table summarizes the compensation paid to each non-employee director in the fiscal year ended December 31, 2018:

	Fees Paid or Earned in Cash	Stock Awards	Option Awards	Total
Thomas McGoldrick	$ -	$ -	$ 37,117(1)	$ 37,117
Andrew Reding	$ -	$ -	$ 22,286(2)	$ 22,286
Richard Gabriel	$ -	$ -	$ 22,286(3)	$ 22,286
Tim Krochuk	$ -	$ -	$ 37,117(4)	$ 37,117
J. Melville Engle	$ -	$ -	$ 29,702(5)	$ 29,702

(1) Mr. McGoldrick was awarded options to purchase 70,222 shares of common stock both for serving on the Board and for participating on the Compensation, Corporate Governance, and Merger & Acquisition Committees.
(2) Mr. Reding was awarded options to purchase 37,917 shares of common stock both for serving on the Board and for participating on the Audit Committee.
(3) Mr. Gabriel was awarded options to purchase 37,917 shares of common stock for serving on the Board and for participating on the Merger & Acquisition Committee.
(4) Mr. Krochuk was awarded options to purchase 70,222 shares of common stock for serving on the Board and for participating on the Audit, Governance and Merger & Acquisition Committees.
(5) Mr. Engle was awarded options to purchase 54,070 shares of common stock for serving on the Board and the Audit and Compensation Committees.

Equity Compensation Plan Information

The following table presents the equity compensation plan information as of December 31, 2018:

	Number of securities to be issued upon exercise of outstanding restricted stock, warrants and options (a)	Weighted-average exercise price of outstanding options, warrants (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (c)
Equity compensation plans approved by security holders (1)	937,746	$ 1.01	6,255,072
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. On December 28, 2017 the Company's shareholders approved an amendment to the Company's Amended and Restated 2012 Stock Incentive Plan to increase the reserve of shares of common stock authorized for issuance thereunder to 5,000,000. On March 22, 2019, the Company's shareholders approved an amendment to the Company's Amended and Restated 2012 Stock Incentive Plan to increase the reserve of shares of common stock authorized for issuance thereunder to 10,000,000.

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

The following table sets forth as of December 31, 2018 certain information regarding beneficial ownership of our common stock by:

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

We have determined beneficial ownership in accordance with Rule 13d-3 under the Exchange Act. Beneficial ownership generally means having sole or shared voting or investment power with respect to securities. Unless otherwise indicated in the footnotes to the table, each stockholder named in the table has sole voting and investment power with respect to the shares of common stock set forth opposite the stockholder's name. We have based our calculation of the percentage of beneficial ownership on 6,943,283 shares of the Company's common stock outstanding on December 31, 2018. Unless otherwise noted below, the address for each person or entity listed in the table is c/o Precision Therapeutics Inc., 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121.

Name of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
Officers and Directors		
Carl Schwartz [2]	810,643	5.49%
David Johnson [3]	263,828	1.84%
Bob Myers [4]	247,289	1.72%
Thomas J. McGoldrick [5]	331,055	2.30%
Andrew Reding [6]	258,486	1.80%
Timothy Krochuk [8]	240,884	1.68%
J. Melville Engle [9]	214,831	1.50%
Richard L. Gabriel [7]	194,076	1.36%
All directors and executive officers as a group (8 persons)	2,561,092	15.52%

1. Under Rule 13d-3, a beneficial owner of a security includes any person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares: (i) voting power, which includes the power to vote, or to direct the voting of shares; and (ii) investment power, which includes the power to dispose or direct the disposition of shares. Certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire the shares (for example, upon exercise of an option) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares outstanding is deemed to include the amount of shares beneficially owned by such person (and only such person) by reason of these acquisition rights. As a result, the percentage of outstanding shares of any person as shown in this table does not necessarily reflect the person's actual ownership or voting power with respect to the number of shares of common stock actually outstanding.

2. Includes (i) 142,298 shares owned directly, and (ii) 666,345 shares issuable upon exercise of options held by Dr. Schwartz that are exercisable within 60 days of December 31, 2018.

3. Includes options to purchase 262,952 shares that are exercisable within 60 days of December 31, 2018.

4. Includes options to purchase 246,528 shares that are exercisable within 60 days of December 31, 2018.

5. Includes options to purchase 330,991 shares that are exercisable within 60 days of December 31, 2018.

6. Includes options to purchase 258,433 shares that are exercisable within 60 days of December 31, 2018.

7. Includes options to purchase 189,076 shares that are exercisable within 60 days of December 31, 2018.

8. Includes options to purchase 240,884 shares that are exercisable within 60 days of December 31, 2018.

9. Includes options to purchase 214,831 shares that are exercisable within 60 days of December 31, 2018.

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

The Audit Committee has the responsibility to review and approve all transactions to which a related party and the Company may be a party prior to their implementation, to assess whether such transactions meet applicable legal requirements.

One of the Company's directors, Richard L. Gabriel, is the Chief Operating Officer and serves as a director of GLG Pharma ("GLG"). Another Company director, Tim Krochuk, is on the supervisory board for GLG. The Company and GLG have a partnership agreement with Helomics for the purpose of bringing together their proprietary technologies to build out personalized medicine platform for the diagnosis and treatment of women's cancer. There has been no revenue or expenses generated by this partnership to date.

Richard L. Gabriel is also contracted as the Chief Operating Officer for TumorGenesis the 100% wholly-owned subsidiary of the Company. Mr. Gabriel receives $12,000 per month pursuant to a renewable six-month contract. The contract extends to March 31, 2019.

Dr. Carl Schwartz, the Company Chief Executive Officer, loaned the Company $370,000 in December 2018. On January 8, 2019, Dr. Carl Schwartz, our Chief Executive officer, made an additional investment of $950,000 in a loan and $50,000 in a common stock purchase in the Company. On February 6, 2019, Dr. Schwartz, made an additional investment of $300,000 in the Company, following his November 30, 2018 and January 8, 2019 investments in the Company now aggregating $1,670,000. In connection with the new investment, Dr. Schwartz received a Second Amended and Restated Promissory Note in the original principal amount of $1,620,000. (the "Schwartz Note") and a Second Amended and Restated Common Stock Purchase Warrant (the "Schwartz Warrant"). The Schwartz Note and the Schwartz Warrant amend and restate the amended and restated promissory note and amended and restated common stock purchase warrant issued to Dr. Schwartz in connection with the previous investments.

The Schwartz Note bears interest at the rate of eight percent (8%) per annum on the principal amount. The maturity date for the Schwartz Note is February 6, 2020, and is the date upon which the principal sum, as well as any accrued and unpaid interest and other fees, shall be due and payable. The Schwartz Note may be prepaid in whole or in part at any time, and upon certain financings, the Company is required to apply a portion of the proceeds to repayment of the Schwartz Note.

As additional consideration for the investment, the Company issued the Schwartz Warrant with an exercise price of $0.836 per share for the initial 221,292 shares that related to the November 2018 investment (the "First Tranche"), an exercise price of $0.704 per share for the additional 748,415 shares (subject to increase as described below) relating to the second investment (the "Second Tranche"), and an exercise price of $1.188 per share for the additional 138,889 shares (subject to increase as described below) relating to the current investment (the "Third Tranche"). The exercise price in each case is equal to 110% of the closing sale price of the common stock on the date of the applicable investment. Each tranche of the Schwartz Warrant is exercisable beginning on the sixth month anniversary of the date of the related investment through the fifth-year anniversary of the date of the related investment.

On February 1, 2019 and the first day of each calendar month thereafter while the Schwartz Note and the Schwartz Warrant remain outstanding, a number of additional shares will be added to the Second Tranche and the Third Tranche equal to (1) one-half percent (1/2%) of the outstanding principal balance of the Schwartz Note on such date, divided by (2) the closing price of the Company's common stock on that date. The number of warrant shares will be subject to a share limit such that the total of (a) the 78,128 shares of common stock purchased by Dr. Schwartz on January 8, 2019, and (b) the total number of warrant shares (1,108,596 warrant shares as of February 6, 2019) may not exceed 2,818,350 shares (equal to 19.9% of the outstanding shares of Common Stock on January 8, 2019). If the Second Tranche and/or Third Tranche cannot be increased as required herein due to the share limit, then in lieu of any such increase, the Company shall pay to Dr. Schwartz a cash amount equal to one-half percent (1/2%) of the principal balance of the Schwartz Note in lieu of such increase.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

In connection with the audit of the fiscal 2018 financial statements, the Company entered into an engagement agreement with Deloitte & Touche LLP and in 2017 with Olsen Thielen & Co., Ltd., which sets forth the terms by which both companies will perform audit services for the Company.

The following table represents aggregate fees billed to the Company for the fiscal years ended December 31, 2018 and December 31, 2017, by Deloitte & Touche LLP and Olsen Thielen & Co., Ltd., the Company's principal accountants. All fees described below were approved by the Audit Committee. None of the hours expended on the audit of the 2018 financial statements were attributed to work performed by persons who were not employed full time on a permanent basis by Deloitte & Touche LLP.

	2018	2017
Audit Fees (1)	$ 401,000	$ 100,610
Audit-Related Fees (2)	-	-
Tax Fees (3)	25,000	5,705
All Other Fees (4)	-	-
	$ 426,000	$ 106,315

(1) Audit Fees were principally for services rendered for the audit and/or review of our consolidated financial statements. Also, includes fees for services rendered in connection with the filing of registration statements and other documents with the SEC, the issuance of accountant consents and comfort letters.

(2) There were no audit-related fees in 2018 and 2017.

(3) Tax Fees consist of fees billed in the indicated year for professional services performed by Deloitte & Touche LLP in 2018 and Olsen Thielen & Co., Ltd. In 2017 with respect to tax compliance.

(4) There were no Other Fees in 2018 and 2017.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

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

(1) Financial Statements

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

- Report of Independent Registered Public Accounting Firm dated April 1, 2019;
- Balance Sheets as of December 31, 2018 and December 31, 2017;
- Statements of Comprehensive Income for the Years Ended December 31, 2018 and December 31, 2017;
- Statements of Stockholders' Equity (Deficit) from December 31, 2016 to December 31, 2018;
- Statements of Cash Flows for the Years Ended December 31, 2018 and December 31, 2017; and
- Notes to Financial Statements.

(2) Financial Statement Schedules

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

(3) Exhibits

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

SIGNATURES

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

Dated: April 1, 2019

Precision Therapeutics Inc.

By /s/ Carl Schwartz
Carl Schwartz
Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	Title	
/s/ Carl Schwartz Carl Schwartz	Chief Executive Officer and Director (principal executive officer)	April 1, 2019
/s/ Bob Myers Bob Myers	Chief Financial Officer (principal financial and accounting officer)	April 1, 2019
/s/ Andrew P. Reding Andrew P. Reding	Director	April 1, 2019
/s/ Thomas J. McGoldrick Thomas J. McGoldrick	Director	April 1, 2019
/s/ Richard L. Gabriel Richard L. Gabriel	Director	April 1, 2019
/s/ Timothy A. Krochuk Timothy A. Krochuk	Director	April 1, 2019
/s/ J. Melville Engle J. Melville Engle	Director	April 1, 2019

EXHIBIT INDEX
PRECISION THERAPEUTICS INC.
FORM 10-K

Exhibit Number	Description
1.1	Placement Agency Agreement with Dawson James Securities, Inc. dated February 27, 2019 (47) Exhibit 1.1
2.1	Agreement and Plan of Merger, dated December 16, 2013, between Skyline Medical Inc., a Minnesota corporation, and the registrant (1) Exhibit 2.1
2.2	Amended and Restated Agreement and Plan of Merger dated October 22, 2018 (38) Exhibit 2.2
3.1	Certificate of Incorporation (1) Exhibit 3.1
3.2	Certificate of Amendment to Certificate of Incorporation to effect reverse stock split and reduction in authorized share capital filed with the Delaware Secretary of State on October 20, 2014 (19) Exhibit 3.2
3.3	Certificate of Amendment to Certificate of Incorporation regarding increase in share capital, filed with the Delaware Secretary of State on July 24, 2015 (20) Exhibit 3.3
3.4	Certificate of Amendment to Certificate of Incorporation to increase authorized share capital, filed with the Delaware Secretary of State on September 16, 2016 (27) Exhibit 3.4
3.5	Certificate of Amendment to Certificate of Incorporation to effect reverse stock split and reduction in authorized share capital, fled with the Delaware Secretary of State on October 26, 2016 (28) Exhibit 3.5
3.6	Certificate of Amendment to Certificate of Incorporation regarding increase in share capital, filed with the Delaware Secretary of State on January 26, 2017 (29) Exhibit 3.6
3.7	Certificate of Amendment to Certificate of Incorporation to effect reverse stock split, filed with the Delaware Secretary of State on January 2, 2018 (41) Exhibit 3.7
3.8	Certificate of Amendment to Certificate of Incorporation to effect name change, filed with the Delaware Secretary of State on February 1, 2018 (21) Exhibit 3.8
3.9	Certificate of Amendment to Certificate of Incorporation to increase authorized share capital and establish a classified Board of Directors (44) Exhibit 3.9
3.10	Amended and Restated Bylaws (21) Exhibit 3.10
3.11	First Amendment to Amended and Restated Bylaws (44) Exhibit 3.11
3.12	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (22) Exhibit 3.12
3.13	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (40) Exhibit 3.13

4.1	Form of Warrant (2)	Exhibit 4.1
4.2	Form of Warrant (7)	Exhibit 4.2
4.3	Form of Warrant (11)	Exhibit 4.3
4.4	Form of Warrant (15)	Exhibit 4.4
4.5	Form of Warrant (16)	Exhibit 4.5
4.6	Amended and Restated 2012 Stock Incentive Plan (3)**	Exhibit 4.6
4.7	Form of Senior Convertible Note (23)	Exhibit 4.7
4.8	Form of Warrant issued to investors of Convertible Notes (23)	Exhibit 4.8
4.9	Form of Registration Rights Agreement (23)	Exhibit 4.9
4.10	Form Waiver and Consent of, and Notice to, Holder of Preferred Stock of the registrant (23)	Exhibit 4.10
4.11	Form of Series A Warrant Agency Agreement by and between Skyline Medical Inc. and Corporate Stock Transfer, Inc. and Form of Warrant Certificate (24)	Exhibit 4.11
4.12	Form of Series A Warrant Certificate (included as part of Exhibit 4.11) (24)	Exhibit 4.12
4.13	Form of unit Purchase Option issued in connection with offering of Units (25)	Exhibit 4.13
4.14	Form of Exchange Agreement with holders of Series A Preferred Stock (26)	Exhibit 4.14
4.15	Form of Amendment to Senior Convertible Notes and Agreement by and between Skyline Medical Inc. and Senior Convertible Notes (26)	Exhibit 4.15
4.16	Form of specimen certificate evidencing shares of Series B Convertible Preferred Stock (25)	Exhibit 4.16
4.17	Form of Unit Agreement (including form of Unit Certificate) (24)	Exhibit 4.17
4.18	Form of New Warrant Agency Agreement by and between Skyline Medical Inc. and Form of Warrant Certificate for Series B Warrant (30)	Exhibit 4.18
4.19	Form of Series B Warrant Certificate (included as part of Exhibit 4.18)	Exhibit 4.19
4.20	Form of Series C Warrant (33)	Exhibit 4.20
4.21	Form of Unit Purchase Option (33)	Exhibit 4.21
4.22	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 (34)	Exhibit 4.22
4.23	Form of Series D Warrant Certificate (included as part of Exhibit 4.22)	Exhibit 4.23
4.24	Form of Amendment to Warrant (21)	Exhibit 4.24

4.25	Investor Warrant (40) Exhibit 4.25
4.26	Series E Warrant Agency Agreement by and between Skyline Medical Inc. and Corporate Stock Transfer, Inc. dated January 9, 2018 (42) Exhibit 4.26
4.27	Form of Series E Warrant Certificate (42) Exhibit 4.27
4.28	Common Stock Purchase Warrant issued to L2 Capital, LLC dated September 28, 2018 (44) Exhibit 4.28
4.29	Common Stock Purchase Warrant issued to Peak One Opportunity Fund, LP dated September 28, 2018 (44) Exhibit 4.29
4.30	Second Amended and Restated Common Stock Purchase Warrant issued to Carl Schwartz dated February 6, 2019 (46) Exhibit 4.30
4.31	Form of Warrant (47) Exhibit 4.31
4.32	Form of Unit Purchase Option (47) Exhibit 4.32
4.33	Common Stock Purchase Warrant issued to Carl Schwartz dated November 30, 2018 (48) Exhibit 4.33
4.34	Amended and Restated Common Stock Purchase Warrant issued to Carl Schwartz dated January 8, 2019 (49) Exhibit 4.34
10.1	Form of Securities Purchase Agreement, dated as of February 4, 2014, by and among the Company and certain Purchasers (2) Exhibit 10.1
10.2	Settlement Agreement and Mutual General Release dated September 18, 2013, entered into by and among Kevin Davidson, Skyline Medical Inc., Atlantic Partners Alliance, LLC, SOK Partners, LLC, Joshua Kornberg and Dr. Samuel Herschkowitz (4) Exhibit 10.2
10.3	Amended and Restated Executive Employment Agreement with Joshua Kornberg, signed on June 17, 2013 and effective March 14, 2013 (6)** Exhibit 10.3
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)** Exhibit 10.4
10.5	Form of Convertible Promissory Note (7) Exhibit 10.5
10.6	Promissory Note in the Principal amount of $100,000 in favor of Brookline Group, LLC, dated as of March 8, 2013 (9) Exhibit 10.6
10.7	Form of Securities Purchase Agreement (11) Exhibit 10.7
10.8	Office Lease Agreement between the registrant and Roseville Properties Management Company, as agent for Lexington Business Park, LLC (12) Exhibit 10.8
10.9	Form of Non-Qualified Stock Option Agreement under the 2012 Stock Incentive Plan (13)** Exhibit 10.9
10.10	Employment Agreement with Josh Kornberg dated July 24, 2012 (13)** Exhibit 10.10
10.11	Non-Qualified Stock Option Agreement with Josh Kornberg dated August 13, 2012 (13)** Exhibit 10.11

10.12	Employment Agreement with Robert Myers dated August 11, 2012 (13)**	Exhibit 10.12
10.13	Employment Agreement with David Johnson dated August 11, 2012 (13)**	Exhibit 10.13
10.14	Settlement Agreement and Mutual General Release with Kevin Davidson effective October 11, 2012 (13)**	Exhibit 10.14
10.15	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and BioDrain Medical, Inc. (14)	Exhibit 10.15
10.16	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and BioDrain Medical, Inc. (14)	Exhibit 10.16
10.17	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and BioDrain Medical, Inc. (14)	Exhibit 10.17
10.18	Note Purchase Agreement, dated as of November 6, 2012, between Dr. Samuel Herschkowitz and BioDrain Medical, Inc. (14)	Exhibit 10.18
10.19	Amended Lease with Roseville Properties Management Company, Inc. dated January 29, 2013 (14)	Exhibit 10.19
10.20	Form of Convertible Promissory Note (15)	Exhibit 10.20
10.21	Forbearance and Settlement Agreement among the registrant, Dr. Samuel Herschkowitz and SOK Partners, LLC dated August 15, 2012 (13)	Exhibit 10.21
10.22	Form of Securities Purchase Agreement (16)	Exhibit 10.22
10.23	Convertible Note Purchase Agreement between the Company and SOK Partners, LLC dated March 28, 2012, including the form of Convertible Promissory Grid Note (18)	Exhibit 10.23
10.24	Amended and Restated Note Purchase Agreement between the Company and Dr. Samuel Herschkowitz dated as of December 20, 2011, including the form of Convertible Promissory Note (issued in the amount of $240,000) (18)	Exhibit 10.24
10.25	Letter Agreement, dated August 22, 2013, among Dr. Samuel Herschkowitz, SOK Partners, LLC and Skyline Medical Inc. (5)	Exhibit 10.25
10.26	Letter Agreement, dated April 25, 2013, among Dr. Samuel Herschkowitz, SOK Partners, LLC and BioDrain Medical, Inc. (8)	Exhibit 10.26
10.27	Letter Agreement, dated March 14, 2013, among Dr. Samuel Herschkowitz, SOK Partners, LLC and BioDrain Medical, Inc. (10)	Exhibit 10.27
10.28	Form of Securities Purchase Agreement with investors in Convertible Notes (23)	Exhibit 10.28
10.29	Separation Agreement and Release between Skyline Medical Inc. and Joshua Kornberg, dated June 13, 2016 (31)	Exhibit 10.29
10.30	Amended and Restated 2012 Stock Incentive Plan (45)	Exhibit 10.30
10.31	Form of Common Stock Purchase Agreement (33)	Exhibit 10.31
10.32	Form of Stock Option Agreement effective as of July 1, 2016 (36)	Exhibit 10.32

10.33	Form of Stock Option Agreement for Executive Officers (39) Exhibit 10.33
10.34	Form of Stock Option Agreement for Directors (39) Exhibit 10.34
10.35	Securities Purchase Agreement dated November 28, 2017 (40) Exhibit 10.35
10.36	Registration Rights Agreement dated November 28, 2017 (40) Exhibit 10.36
10.37	Share Exchange Agreement between Skyline Medical Inc. and Helomics Holding Corporation, dated January 11, 2018, including the form of Certificate of Designation of Helomics Series A Preferred Stock and the form of Escrow Agreement (43) Exhibit 10.37
10.38	Securities Purchase Agreement by and between the Company and L2 Capital, LLC dated September 28, 2018 (44) Exhibit 10.38
10.39	Senior Secured Promissory Note issued to L2 Capital, LLC dated September 28, 2018 (44) Exhibit 10.39
10.40	Registration Rights Agreement by and between the Company and L2 Capital, LLC dated September 28, 2018 (44) Exhibit 10.40
10.41	Security Agreement by and between the Company and L2 Capital, LLC dated September 28, 2018 (44) Exhibit 10.41
10.42	Securities Purchase Agreement by and between the Company and Peak One Opportunity Fund, LP dated September 28, 2018 (44) Exhibit 10.42
10.43	Senior Secured Promissory Note issued to Peak One Opportunity Fund, LP dated September 28, 2018 (44) Exhibit 10.43
10.44	Registration Rights Agreement by and between the Company and Peak One Opportunity Fund, LP dated September 28, 2018 (44) Exhibit 10.44
10.45	Security Agreement by and between the Company and Peak One Opportunity Fund, LP dated September 28, 2018 (44) Exhibit 10.45

10.46	Amended and Restated Promissory Note issued to Carl Schwartz dated February 6, 2019 (46) Exhibit 10.46
10.47	Forbearance Agreement by and between L2 Capital, LLC and the Company dated February 7, 2019 (46) Exhibit 10.47
10.48	Forbearance Agreement by and between Peak One Opportunity Fund, LP and the Company dated February 7, 2019 (46) Exhibit 10.48
10.49	Amended and Restated Promissory Note issued to L2 Capital, LLC dated February 7, 2019 (46) Exhibit 10.49
10.50	Amended and Restated Promissory Note issued to Peak One Opportunity Fund, LP dated February 7, 2019 (46) Exhibit 10.50
10.51	Promissory Note issued to Carl Schwartz dated November 30, 2018 (48) Exhibit 10.51
10.52	Amended and Restated Promissory Note issued to Carl Schwartz dated January 8, 2019 (49) Exhibit 10.52
10.53	Subscription Agreement by and between Carl Schwartz and the Company dated January 8, 2019 (49) Exhibit 10.53
10.54	Employment Agreement by and between Carl Schwartz and Issuer dated November 10, 2017 (50)** Exhibit 10.54
10.55	Amendment to Employment Agreement by and between the Issuer and Carl Schwartz dated August 20, 2018 (50)** Exhibit 10.55
10.56*	Amendment to Employment Agreement by and between the Issuer and Bob Myers dated August 20, 2018**
14.1	Code of Ethics (17) Exhibit 14.1
23.1*	Consent of Independent Registered Public Accounting Firm: Deloitte & Touche LLP
23.2*	Consent of Independent Registered Public Accounting Firm: Olsen Thielen & Co., Ltd.
31.1*	Certification of principal executive officer required by Rule 13a-14(a)
31.2*	Certification of principal financial officer required by Rule 13a-14(a)
32.1*	Section 1350 Certification
99.1	Binding Letter of Intent with CytoBioscience, Inc. dated July 21, 2017 (37) Exhibit 99.1
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

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

(1) Filed on December 19, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(2) Filed on February 5, 2014 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(3) Filed on August 27, 2013 as an exhibit to our Proxy Statement on Schedule 14A and incorporated herein by reference.

(4) Filed on November 14, 2013 as an exhibit to our Quarterly Report on Form 10-Q and incorporated herein by reference.

(5) Filed on August 28, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(6) Filed on June 18, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(7) Filed on June 12, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(8) Filed on May 1, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(9) Filed on March 14, 2013 as an exhibit to our Current report on Form 8-K and incorporated herein by reference.

(10) Filed on March 12, 2013 as an exhibit to our Current Report on Form 8-K (by incorporation by reference from the Schedule 13D/A filed by Dr. Herschkowitz and other parties on March 8, 2013) and incorporated herein by reference.

(11) Filed on February 26, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(12) Filed on November 12, 2008 as an exhibit to our Registration Statement on Form S-1 and incorporated herein by reference.

(13) Filed on November 5, 2012 as an exhibit to our Registration Statement on Form S-1 and incorporated herein by reference.

(14) Filed on February 8, 2013 as an exhibit to our Registration Statement on Form S-1 (except for Exhibit 10.19, by incorporation by reference from the Schedule 13D/A filed by Dr. Herschkowitz and other parties on November 8, 2012) and incorporated herein by reference.

(15) Filed on January 15, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(16) Filed on June 21, 2012 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(17) Filed on April 16, 2012 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference.

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

(19) Filed on October 24, 2014 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(20) Filed on June 30, 2015 as an appendix to our Information Statement on Schedule 14C and incorporated herein by reference.

(21) Filed on February 6, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

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

(23) Filed on July 24, 2014 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

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

(25) Filed on August 10, 2015 as an exhibit to our Registration Statement on Form S-1 (File No. 333-198962) and incorporated herein by reference.

(26) Filed on July 24, 2015 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(27) Filed on September 16, 2016 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(28) Filed on October 27, 2016 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(29) Filed on January 27, 2017 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(30) Filed on March 25, 2016 as an exhibit to our Registration Statement on Form S-4 (File No. 333-210398) and incorporated herein by reference.

(31) Filed on June 17, 2016 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(32) Filed on December 4, 2017 as an exhibit to our Proxy Statement on Schedule 14A and incorporated herein by reference.

(33) Filed on November 30, 2016 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(34) Filed on January 10, 2017 as an exhibit to our Registration Statement on Form S-1 (File No. 333-215005) and incorporated herein by reference.

(35) [Reserved]

(36) Filed on March 15, 2017 as an exhibit to our Registration Statement on Form S-8 and incorporated herein by reference.

(37) Filed on August 2, 2017 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(38) Filed on October 30, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(39) Filed on August 14, 2017 as an exhibit to our Quarterly Report on Form 10-Q and incorporated herein by reference.

(40) Filed on November 29, 2017 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(41) Filed on January 2, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(42) Filed on January 10, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(43) Filed on January 16, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(44) Filed on October 4, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(45) Filed on March 22, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(46) Filed on February 12, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(47) Filed on March 1, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(48) Filed on December 7, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(49) Filed on January 14, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(50) Filed on January 25, 2019 as an exhibit to the Schedule 13D report filed by Carl Schwartz and incorporated herein by reference.

The audited financial statements for the periods ended December 31, 2018 and December 31, 2017 are included on the following pages:

INDEX TO FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Precision Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Precision Therapeutics Inc. (the "Company") as of December 31, 2018, the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

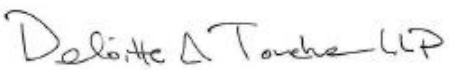
The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company does not expect to generate sufficient operating cashflows to sustain its operations in the near-term, and needs to raise significant additional capital to meet its operating needs, and pay debt obligations coming due, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provide a reasonable basis for our opinion.



Minneapolis, Minnesota
April 1, 2019
We have served as the Company's auditor since 2018.

PART 1. FINANCIAL INFORMATION
Item 1. Financial Statements

PRECISION THERAPEUTICS INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash & cash equivalents	$ 162,152	$ 766,189
Certificates of deposit	-	244,971
Accounts Receivable	232,602	137,499
Notes Receivable (inclusive of $452,775 in advances to Helomics)	497,276	667,512
Inventories	241,066	265,045
Prepaid Expense and other assets	318,431	289,966
Total Current Assets	1,451,527	2,371,182
Notes Receivable	1,112,524	1,070,000
Fixed Assets, net	180,453	87,716
Intangibles, net	964,495	95,356
Total Assets	$ 3,708,999	$ 3,624,254
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 445,689	$ 140,462
Notes Payable – Bridge Loan Net of Discount	1,327,942	-
Notes Payable – Net of Discount	306,972	-
Accrued Expenses	1,279,114	785,215
Derivative Liability	272,745	-
Deferred Revenue	23,065	6,663
Total Current Liabilities	3,655,527	932,340
Total Liabilities	3,655,527	932,340
Stockholders' Equity:		
Series B Convertible Preferred Stock, $.01 par value, 20,000,000 authorized, 79,246 and 79,246 outstanding	792	792
Series C Convertible Preferred Stock, $.01 par value, 20,000,000 authorized, 0 and 647,819 outstanding	-	6,479
Common Stock, $.01 par value, 50,000,000 authorized, 14,091,748 and 6,943,283 outstanding	140,917	69,432
Additional paid-in capital	63,019,708	55,636,680
Accumulated deficit	(63,107,945)	(53,021,469)
Total Stockholders' Equity	53,472	2,691,914
Total Liabilities and Stockholders' Equity	$ 3,708,999	$ 3,624,254

See Notes to Consolidated Financial Statements

PRECISION THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31,	
	2018	**2017**
Revenue	$ 1,411,655	$ 654,836
Cost of goods sold	415,764	148,045
Gross margin	995,891	506,791
General and administrative expense	4,626,997	4,050,307
Operations expense	1,861,121	1,414,774
Sales and marketing expense	2,369,152	1,095,232
Total operating loss	7,861,379	6,053,523
Other income	510,254	53,734
Other expense	441,772	3,228
Loss on equity method investment	(2,293,580)	-
Net loss available to common shareholders	$ (10,086,477)	$ (6,003,017)
Loss per common share - basic and diluted	$ (0.79)	$ (0.94)
Weighted average shares used in computation - basic and diluted	12,816,289	6,362,989

See Notes to Consolidated Financial Statements

PRECISION THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED
DECEMBER 31, 2018 and 2017

				Common Stock					
	Preferred Stock	# Shares Preferred C	# Shares Preferred B	Shares	Amount	Paid-in Capital	Deficit	Other Comprehensive Income	Total
Balance at 12/31/2016	$ 792	-	79,246	4,564,428	$ 45,644	$47,894,196	$(47,018,451)	$ 1,501	$ 923,682
Shares issued pursuant to the public offering, net				1,750,000	17,500	3,403,688			3,421,188
Shares issued pursuant to the overallotment agreement in the public offering				175,000	1,750	392,000			393,750
Vesting Expense						2,298,680			2,298,680
Reverse shares issued for escrow with GLG Pharma pursuant to the termination agreement				(400,000)	(4,000)				(4,000)
Shares issued pursuant to consulting agreement				100,000	1,000	219,000			220,000
Unrealized (loss) from marketable securities							(1)	(1,501)	(1,501)
Shares issued pursuant to consulting agreement				43,333	433	63,699			64,132
Shares issued at $1.58 per share to an investor relations consultant				50,000	500	78,500			79,000
Shares issued pursuant to a private placement	12,138	1,213,819				1,201,681			1,213,819
Preferred conversion to common shares pursuant to a private placement agreement	(5,659)	(566,000)		660,522	6,604	85,236			86,182
Net loss						.	(6,003,017)		(6,003,017)
Balance at 12/31/2017	$ 7,271	647,819	79,246	6,943,283	$ 69,432	$55,636,680	$(53,021,469)	$ -	$ 2,691,914
Preferred conversion to common shares pursuant to private placement agreement	(6,479)	(647,819)		589,747	5,897	582			-
Shares issued pursuant to S-3 public offering				2,900,000	29,000	2,726,087			2,755,087
Investment in Subsidiary pursuant to Helomics 20% acquisition				1,100,000	11,000	1,031,250			1,042,250
E Warrant exercises pursuant to S-3 public offering at $1.00 exercise price per share				145,396	1,454	143,942			145,396
Shares issued pursuant to S-3 public offering over-allotment option at $0.9497 exercise price per share				215,247	2,153	202,268	1		204,422
Re-priced warrant exercise pursuant to 2016 private investment				504,666	5,046	499,619			504,665
Shares issued pursuant to a consultant contract @ $1.18 per share				150,000	1,500	175,500			177,000
Shares issued pursuant to a consultant contract @ $1.18 per share				100,000	1,000	117,000			118,000
Shares issued in escrow pursuant to a contract with TumorGenesis @ $1.17 per share				750,000	7,500	870,000			877,500
Debt Discount on Warrants per Bridge Loan						183,187			183,187
Shares issued as inducement for Bridge Loan				650,000	6,500	200,105			206,605
Shares issued to employee in lieu of bonus				43,409	435	39,803			40,238
Warrants issued from loan by CEO						68,757			68,757
Vesting Expense						1,124,928			1,124,928
Net loss							(10,086,477)		(10,086,477)
Balance at 12/31/2018	$ 792	-	79,246	14,091,748	$140,917	$63,019,708	$(63,107,945)	$ -	$ 53,472

See Notes to Consolidated Financial Statements

PRECISION THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2018	**2017**
Cash flow from operating activities:		
Net loss	$ (10,086,477)	$ (6,003,017)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on equity method investment	2,293,580	-
Depreciation and amortization	147,628	71,562
Vesting expense for stock options and warrants	1,124,928	2,298,680
Equity instruments issued for management and consulting	335,238	359,133
Amortization of debt discount	385,111	-
Gain from sale of marketable securities	-	(1,837)
Gain on valuation of equity-linked instruments	(372,263)	-
Changes in assets and liabilities:		
Accounts receivable	(95,103)	(98,580)
Inventories	23,979	7,163
Prepaid expense and other assets	139,895	(141,329)
Accounts payable	305,227	(79,650)
Accrued expenses	493,899	(870,540)
Deferred revenue	16,402	(1,335)
Net cash used in operating activities:	(5,287,956)	(4,459,750)
Cash flow from investing activities:		
Proceeds from sale of marketable securities	-	284,665
Purchase of certificates of deposit	-	(3,084,971)
Redemption of certificates of deposit	244,971	2,940,000
Advances on notes receivable	(1,123,619)	(1,737,512)
Purchase of fixed assets	(177,732)	(45,093)
Purchase of intangibles	(54,271)	(10,179)
Net cash used in investing activities	(1,110,651)	(1,653,090)
Cash flow from financing activities:		
Proceeds from exercise of warrants into common stock	650,061	-
Proceeds from debt issuance	2,185,000	-
Net proceeds from issuance of preferred stock	-	1,300,001
Net proceeds from issuance of common stock	2,959,509	3,814,938
Net cash provided by financing activities	5,794,570	5,114,939
Net decrease in cash	(604,037)	(997,901)
Cash at beginning of period	766,189	1,764,090
Cash at end of period	$ 162,152	$ 766,189
Non-cash transactions in investing and financing activities		
Conversion of preferred stock to common stock	$ 6,479	$ -
Equity method investment – Helomics	1,542,250	-
Licensing fee for TumorGenesis	877,500	-

See Notes to Consolidated Financial Statements

PRECISION THERAPEUTICS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations and Continuance of Operations

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. On February 1, 2018, the Company filed with the Secretary of State of Delaware a Certificate of Amendment to the Certificate of Incorporation to change the Company's corporate name from Skyline Medical Inc. to Precision Therapeutics Inc., effective February 1, 2018. Because of this change, the Company's common stock began trading under the new ticker symbol "AIPT," effective February 2, 2018. Skyline Medical ("Skyline") remains as an incorporated division of Precision Therapeutics Inc.

As of December 31, 2018, the registrant had 14,091,748 shares of common stock, par value $.01 per share, outstanding. 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 its proprietary cleaning fluid and filters to users of the STREAMWAY systems. In April 2009, the Company received 510(k) clearance from the FDA to authorize the Company to market and sell its STREAMWAY System products.

The Company acquired 25% of the capital stock of Helomics Holding Corporation ("Helomics"), in transactions in the first quarter of 2018, and in April 2018 the Company entered into a letter of intent for a proposed merger transaction to acquire the remaining ownership of Helomics. In June 2018, the Company and Helomics entered into a definitive merger agreement – see Note 4. The Company's precision medicine services – designed to use artificial intelligence and a comprehensive disease database to improve the effectiveness of cancer therapy – were launched with the Company's investment in Helomics. Helomics' precision oncology services are based on its D-CHIP™ diagnostic platform, which combines a database of genomic and drug response profiles from over 149,000 tumors with an artificial intelligence based searchable bioinformatics platform. Once a patient's tumor is excised and analyzed, the D-CHIP platform compares the tumor profile with its database, and using its extensive drug response data, provides a specific therapeutic roadmap. In addition, the Company has formed a wholly-owned subsidiary, TumorGenesis Inc. ("TumorGenesis"), to develop the next generation, patient derived tumor models for precision cancer therapy and drug development. TumorGenesis, formed during the first quarter, is presented as part of the consolidated financial statements ("financial statements").

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. The Company has incurred recurring losses from operations and has an accumulated deficit of $63,107,945. The Company does not expect to generate sufficient operating revenue to sustain its operations in the near-term. In 2018, the Company incurred negative operating cash flows of approximately $441,000 per month. Although the Company has attempted to curtail expenses, there is no guarantee that the Company will be able to reduce these expenses significantly, and expenses may need to be higher to prepare product lines for broader sales in order to generate sustainable revenues.

The Company had cash and cash equivalents of $162,152 as of December 31, 2018 and needs to raise significant additional capital to meet its operating needs, pay debt obligations coming due, and the continued operating needs of Helomics, therefore there is substantial doubt about the Company's ability to continue as a going concern for one year after the date that the financial statements are issued. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company has available financing options including a shelf registration statement on Form S-3, with which the Company has raised approximately $2.1 million in net proceeds in early 2019. The Company may raise up to approximately $1.7 million in additional gross proceeds in the next calendar year using the shelf registration statement. This amount of available financing will increase to approximately $6.4 million in additional gross proceeds, once the Helomics acquisition is completed.

Since inception to December 31, 2018, the Company raised approximately $36,490,000 in equity and $7,870,000 in debt financing. Equity raises include: a January 2017 public offering of units with gross proceeds to the Company of $3,937,500; a November 2017 private placement with gross proceeds of $1,300,000; and, a January 2018 public offering with gross proceeds of $2,755,000. Included in debt financing were raises in September 2018 on senior secured promissory notes with net proceeds of $1,815,000, and in November 2018 the Company received a loan from the CEO for $370,000. Subsequent to December 31, 2018, the Company's CEO made an additional loan to the Company and made a private investment in the Company's common stock, which in total, generated an additional $1,300,000.

The Company has no commitments or contingencies.

Recent Accounting Developments

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.

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") *No. 2014-09, Revenue from Contracts with Customers (Topic 606)*, which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. The standard's core principle is that an entity will recognize revenue when it transfers 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 Company adopted the standard on January 1, 2018 using the modified retrospective method applied to those contracts which were not completed as of December 31, 2017. Results for reporting periods beginning January 1, 2018 are presented under Topic 606, while prior-period amounts have not been retrospectively adjusted and continue to be reported in accordance with Topic 605, *Revenue Recognition*. Based upon the Company's contracts which were not completed as of December 31, 2017, the Company was not required to make an adjustment to the opening balance of retained earnings as of January 1, 2018, and there was no material impact. See Note 3 for further discussion.

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 Company adopted the standard as of January 1, 2018. As of December 31, 2018, there is no material impact on the Company's 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. The Company adopted ASU 2016-02 on January 1, 2019, using the transition relief to the modified retrospective approach, presenting prior year information based on the previous standard. The adoption resulted in no material impact to the Company's balance sheet, results of operations, equity or cash flows.

In 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 adopted the standard as of January 1, 2018. As of December 31, 2018, there is no material impact on the Company's financial statements and disclosures.

Valuation of Intangible Assets

The Company reviews identifiable intangible assets for impairment in accordance with ASC 360 — Intangibles —Goodwill and Other, whenever events or changes in circumstances indicate the carrying amount may not be recoverable. The Company's intangible assets are definite lived and currently solely the costs of obtaining licensing fees, 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 the Company operates.

Advertising

Advertising costs are expensed as incurred. Advertising expenses were $43,548 in 2018 and $37,060 in 2017.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs were approximately $526,000 and $289,000 for 2018 and 2017, respectively.

Revenue Recognition

The Company's revenue consists primarily of sales of the STREAMWAY System, as well as sales of the proprietary cleaning fluid and filters for use with the STREAMWAY System. The Company sells its products directly to hospitals and other medical facilities using employed sales representatives and independent contractors. Purchase orders, which are governed by sales agreements in all cases, state the final terms for unit price, quantity, shipping and payment terms. The unit price is considered the observable stand-alone selling price for the arrangements. The Company sales agreement, Terms and Conditions, is a dually executed contract providing explicit criteria supporting the sale of the STREAMWAY System. The Company considers the combination of a purchase order and the Terms and Conditions to be a customer's contract in all cases.

The Company recognizes revenue when it satisfies a performance obligation by transferring control of the promised goods or services to its customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Sales taxes are imposed on the Company's sales to nonexempt customers. The Company collects the taxes from the customers and remits the entire amounts to the governmental authorities. The Company has elected the accounting policy to exclude sales taxes from revenue and expenses.

Product sales consist of a single performance obligation that the Company satisfies at a point in time. The Company recognizes product revenue when the following events have occurred: (a) the Company has transferred physical possession of the products, (b) the Company has a present right to payment, (c) the customer has legal title to the products, and (d) the customer bears significant risks and rewards of ownership of the products. Based on the shipping terms specified in the sales agreements and purchase orders, these criteria are generally met when the products are shipped from the Company's facilities ("FOB origin", which is the Company's standard shipping terms). As a result, the Company determined that the customer is able to direct the use of, and obtain substantially all of the benefits from, the products at the time the products are shipped. The Company may, at its discretion, negotiate different shipping terms with customers which may affect the timing of revenue recognition. The Company's standard payment terms for its customers are generally 30 to 60 days after the Company transfers control of the product to its customer. The Company allows returns of defective disposable merchandise if the customer requests a return merchandise authorization from the Company.

Customers may also purchase a maintenance plan from the Company, which requires the Company to service the STREAMWAY System for a period of one year subsequent to the one-year anniversary date of the original STREAMWAY System invoice. The maintenance plan is considered a separate performance obligation from the product sale, is charged separately from the product sale, and is recognized over time (ratably over the one-year period) as maintenance services are provided. A time-elapsed output method is used to measure progress because the Company transfers control evenly by providing a stand-ready service. The Company has determined that this method provides a faithful depiction of the transfer of services to its customers.

All amounts billed to a customer in a sales transaction related to shipping and handling, if any, represent revenues earned for the goods provided, and these amounts have been included in revenue. Costs related to such shipping and handling billing are classified as cost of goods sold.

Variable Consideration

The Company records revenue from distributors and direct end customers in an amount that reflects the transaction price it expects to be entitled to after transferring control of those goods or services. The Company's current contracts do not contain any features that create variability in the amount or timing of revenue to be earned.

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.

Fair Value Measurements

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

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

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

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

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

The fair value of the Company's investment securities, which in 2018 are cash equivalents only, 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 net realizable value, with cost determined on a first-in, first-out basis. Inventory balances are as follows:

	December 31, 2018	December 31, 2017
Finished goods	$ 58,701	$ 62,932
Raw materials	127,003	141,028
Work-In-Process	55,362	61,085
Total	$ 241,066	$ 265,045

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. Depreciation is shown in the financial statements under fixed assets, net on the balance sheet, and amortization is shown under intangibles, net on the balance sheet. Estimated useful asset life by classification is as follows:

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

The Company's investment in fixed assets consists of the following:

	December 31, 2018	December 31, 2017
Computers and office equipment	$ 204,903	$ 183,528
Leasehold Improvements	140,114	25,635
Manufacturing Tooling	108,955	108,955
Demo Equipment	85,246	43,368
Total	539,218	361,486
Less: Accumulated Depreciation	358,765	273,770
Total Fixed Assets, Net	$ 180,453	$ 87,716

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.

Depreciation expense was $84,995 in 2018 and $58,872 in 2017.

Intangible Assets

The components of intangible assets all of which are finite-lived were as follows:

	12/31/2018			12/31/2017		
	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount
Patents & Trademarks	$ 318,304	$ (182,559)	$ 135,745	$ 264,032	$ (168,676)	$ 95,356
Licensing Fees	877,500	(48,750)	828,750	-	-	-
Total	$ 1,195,804	$ (231,309)	$ 964,495	$ 264,032	$ (168,676)	$ 95,356

The following table outlines the estimated future amortization expense related to intangible assets held as of December 31, 2018

Year ending	Expense
2019	72,383
2020	72,383
2021	72,383
2022	72,383
2023	72,383
Thereafter	602,580
Total	964,495

Intangible assets consist of trademarks, patent costs and licensing fees. Amortization expense was $62,633 in 2018 and $12,689 in 2017. The assets are reviewed for impairment annually, and impairment losses, if any, are charged to operations when identified.

Income Taxes

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (Tax Reform Act) was signed into law making significant changes to the Internal Revenue Code. Changes include a reduction in the corporate tax rates, changes to operating loss carry-forwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the U.S. corporate income tax rates from 34% to 21%. As a result of the enacted law, the Company was required to value its deferred tax assets and liabilities at the new enacted rate. There was no income tax impact from the re-measurement due to the 100% valuation allowance on the Company's deferred tax assets.

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.

Offering Costs

Costs incurred which are direct and incremental to an offering of the Company's securities are deferred and charged against the proceeds of the offering, unless such costs are deemed to be insignificant in which case they are expensed as incurred.

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 no credit risk concentration because there are no funds in excess of insurance limits in a single bank.

Product Warranty Costs

In 2018 and in 2017, the Company incurred approximately $10,682 and $6,209, respectively in warranty costs.

Segments

The Company operates in two segments for the sale of its medical device and consumable products. These segments are its domestic operations and international operations. Substantially all the Company's assets, revenues, and expenses for the years ended December 31, 2018 and 2017 were located at or derived from operations in the United States. In 2018 and 2017, business activity within the Company's international segment was immaterial.

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 – EQUITY METHOD INVESTMENT

The Company has an equity method investment in Helomics. Summarized financial information for Helomics is presented below:

Helomics Holdings Corporation

	December 31, 2018
Current assets	$ 419,266
Non-current assets	$ 2,046,347
Total assets	$ 2,465,613
Current liabilities	$ 12,247,174
Total liabilities	$ 12,247,174

	For the Year-ended Ended December 31, 2018
Revenue	$ 523,546
Gross margin	$ 214,426
Net loss on operations	$ (5,056,725)
Net loss	$ (9,452,835)
Net Loss to investee	$ (7,159,255)[1]

[1]The loss to investee was calculated at 80% for the initial period of ownership, January 11, 2018 – February 27, 2018, and then at 75% for the remainder of the twelve-month period at the current equity investment percentage owned by the Company.

Helomics' first year predominantly included diagnostic revenue only. The contract research organization and D-CHIP Artificial Intelligence products are in the process of launching and have generated approximately $31,000 of revenue in the year-to-date.

The Helomics loss reduces the equity method investment asset on the balance sheet. The recorded investor losses have exceeded the equity method investment originally recorded total. As such, the equity method investment recorded to the balance sheet has been reduced to zero, and all subsequent losses reduced the note receivable due from Helomics. The note receivable on the balance sheet includes $413,683, not including interest, for Helomics. The actual note due to the Company as of December 31, 2018 is $1,165,013. The amount exceeding the original equity method investment and thus reducing the note receivable balance is $751,330.

NOTE 3 – REVENUE RECOGNITION

Revenue from Product Sales

The Company's revenue consists primarily of sales of the STREAMWAY System, as well as sales of the proprietary cleaning fluid and filters for use with the STREAMWAY System. The Company sells its products directly to hospitals and other medical facilities using employed sales representatives and independent contractors. Purchase orders, which are governed by sales agreements in all cases, state the final terms for unit price, quantity, shipping and

payment terms. The unit price is considered the observable stand-alone selling price for the arrangements. The Company sales agreement, Terms and Conditions, is a dually executed contract providing explicit criteria supporting the sale of the STREAMWAY System. The Company considers the combination of a purchase order and the Terms and Conditions to be a customer’s contract in all cases.

The Company recognizes revenue when it satisfies a performance obligation by transferring control of the promised goods or services to its customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Sales taxes are imposed on the Company's sales to nonexempt customers. The Company collects the taxes from the customers and remits the entire amounts to the governmental authorities. The Company has elected the accounting policy to exclude sales taxes from revenue and expenses.

Product sales consist of a single performance obligation that the Company satisfies at a point in time. The Company recognizes product revenue when the following events have occurred: (a) the Company has transferred physical possession of the products, (b) the Company has a present right to payment, (c) the customer has legal title to the products, and (d) the customer bears significant risks and rewards of ownership of the products. Based on the shipping terms specified in the sales agreements and purchase orders, these criteria are generally met when the products are shipped from the Company's facilities ("FOB origin", which is the Company's standard shipping terms). As a result, the Company determined that the customer is able to direct the use of, and obtain substantially all of the benefits from, the products at the time the products are shipped. The Company may, at its discretion, negotiate different shipping terms with customers which may affect the timing of revenue recognition. The Company's standard payment terms for its customers are generally 30 to 60 days after the Company transfers control of the product to its customer. The Company allows returns of defective disposable merchandise if the customer requests a return merchandise authorization from the Company.

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Variable Consideration

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Warranty

The Company generally provides one-year warranties against defects in materials and workmanship and will either repair the products or provide replacements at no charge to customers. As they are considered assurance-type warranties, the Company does not account for them as separate performance obligations. Warranty reserve requirements are based on a specific assessment of the products sold with warranties where a customer asserts a claim for warranty or a product defect.

Contract Balances

The Company records a receivable when it has an unconditional right to receive consideration after the performance obligations are satisfied. As of December 31, 2018, and December 31, 2017, accounts receivable totaled $232,602 and $137,499, respectively.

The Company deferred revenues related primarily to maintenance plans of $23,065 and $6,663 as of December 31, 2018 and December 31, 2017, respectively.

Practical Expedients

The Company has elected the practical expedient not to determine whether contracts with customers contain significant financing components.

NOTE 4 – STOCKHOLDERS' EQUITY (DEFICIT), STOCK OPTIONS AND WARRANTS

2017 Firm Commitment Public Offering

On January 19, 2017, the Company closed a firm commitment public offering for 1,750,000 Units at $2.25 per Unit. The Units comprised one share of common stock and 0.2 Series D Warrants with each whole Series D Warrant purchasing one share of the Company's common stock at an exercise price of $2.25 per share. The Company received gross proceeds of $3,937,500. Subsequently the underwriter exercised over-allotment for 175,000 shares of common stock and for Series D warrants to purchase 35,000 shares of common stock at $0.01 per warrant. The Company received net proceeds from the over-allotment of $358,312.

2017 Private Placement

On November 30, 2017, the Company closed a private placement of a newly created series of preferred stock designated as "Series C Convertible Preferred Stock" with a New York based Family Office. Pursuant to the Securities Purchase Agreement, the investor purchased 1,213,819 shares of Series C stock at a purchase price of $1.071 per Series C Share, together with a warrant to purchase up to 606,910 shares of common stock. The warrant has an exercise price of $1.26 per share, subject to adjustment, has a five- and one-half-year term and is exercisable commencing six months following the date of issuance. Total gross proceeds to the Company were $1,300,000 before deducting expenses and will be used for general working capital. In connection with the offering and pursuant to a registration rights agreement, the Company has agreed to file a "resale" registration statement covering all of the shares of common stock issuable upon conversion of the warrant. Pursuant to the Securities Purchase agreement, and as of this filing date, all the Preferred Series C shares were converted at a conversion rate of 1.167 to a maximum of 1,250,269 shares of common stock. The remaining 142,466 shares of Preferred Series C stock were cancelled with a redemption payment to the holder for $189,285.

2018 Firm Commitment Public Offering

In January 2018, the Company completed a firm commitment underwritten public offering of 2,900,000 Units at an offering price of $0.95 per Unit, with each Unit consisting of one share of the Company's common stock and 0.3 of a Series E Warrant, with each whole Series E Warrant purchasing one share of common stock at an exercise price of $1.00 per whole share. The shares of common stock and Series E Warrants were immediately separable and were issued separately. Gross proceeds were approximately $2,755,000, before deducting expenses. The Company granted the underwriter a 45-day option to purchase an additional (i) up to 290,000 additional shares of common stock at the public offering price per Unit less the price of the Series E Warrant included in the Units and less the underwriting discount and/or (ii) additional Series E Warrants to purchase up to 87,000 additional shares of common stock at a purchase price of $0.001 per Series E Warrant to cover over-allotments, if any. On February 21, 2018, the underwriter exercised on 215,247 shares of common stock, par value $0.01, at $0.9497 per share as described in the Underwriting Agreement. The Company received net proceeds of $188,066 after deductions of $16,354 representing the underwriter's discount of 8% of the purchase price of the shares.

Share Exchange Agreement with Helomics

On January 11, 2018, the Company entered into a share exchange agreement with Helomics Holding Corporation. Pursuant to the share exchange agreement, Helomics issued 2,500,000 shares of its Series A Preferred Stock in exchange for 1,100,000 shares of common stock. Under the share exchange agreement, in March 2018 the Company converted $500,000 in secured notes into another 5% of Helomics' outstanding shares, which resulted in the Company owning 25% of Helomics outstanding stock. The secured notes are related to the Company's previous loans of $500,000 to Helomics. The 1,100,000 shares are being held in escrow by Corporate Stock Transfer, Inc. as escrow agent. While the Company's shares are held in escrow, they will be voted as directed by the Company's board of directors and management. The Company shares will be released to Helomics following a determination that Helomics' revenues in any 12-month period have been equal or greater than $8,000,000. The Helomics Preferred Stock issued to the Company is convertible into an aggregate of 20% of the outstanding capital stock of Helomics. In addition, the terms of the Helomics Preferred Stock include certain protective provisions that require consent of the Company before Helomics may take certain actions, including issuing preferred stock senior to the Helomics Preferred Stock or entering into fundamental corporate transactions. The Company also has certain anti-dilution protections and the right to receive dividends.

Merger Agreement with Helomics

On June 28, 2018, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Helomics and certain other entities. On October 26, 2018, the Merger Agreement was amended and restated. The Merger Agreement contemplated a reverse triangular merger with Helomics surviving the merger and becoming a wholly-owned operating subsidiary of the Company (the "Merger"). At the time of the Merger, all outstanding shares of Helomics stock not already held by the Company were to be converted into the right to receive a proportionate share of 7.5 million shares of newly issued common stock in the Company ("Merger Shares"), in addition to the 1.1 million shares of the Company's common stock already issued to Helomics for the Company's initial 20% ownership in Helomics. Additionally, 860,000 shares of the merger consideration were to be held in escrow for 18 months to satisfy indemnification claims. Helomics currently has outstanding $7.6 million in promissory notes and warrants to purchase 18.7 million shares at an exercise price of $1.00 per share of Helomics common stock held by the investors in the promissory notes. As a result of the Merger, the holders of said promissory notes and warrants would be entitled to additional warrants to purchase up to 5.0 million additional shares of Helomics common stock at an exercise price of $1.00 per share. Helomics agreed to use commercially reasonable efforts to cause the holder of each such promissory note to enter into an agreement whereby such holder agrees that, effective upon the closing of the Merger, (a) all or a certain portion of the indebtedness evidenced by such promissory note shall be converted into common stock in the Company, (b) all of such holder's Helomics' warrants shall be converted into warrants of the Company, and (c) the unconverted portion of said indebtedness shall be converted into a promissory note issued by the Company dated as of the closing of the Merger. The Merger is expressly conditioned on the holders of at least 75% of the $7.6 million in outstanding Helomics promissory notes agreeing to such an exchange (and the parties contemplate that each Helomics warrant will be exchanged for a Company warrant at a ratio of 0.6 Precision warrants for each Helomics warrant, with an exercise price of $1.00 per share. If all holders of such notes agreed to the exchange with respect to the full balance of the notes, such holders would receive an aggregate estimated 23.7 million shares of the Company's common stock and warrants to purchase an additional 14.2 million shares of the Company's common stock at $1.00 per share. In addition, Helomics currently has 995,000 warrants held by other parties at an exercise price of $0.01 per share of Helomics common stock. It is contemplated that these warrants will be exchanged at the time of the closing of the Merger for warrants to purchase 597,000 shares of Precision common stock at $0.01 per share.

Under the Merger Agreement, completion of the Merger is subject to customary closing conditions including the approval of the Merger by the stockholders of both companies and other conditions. The Merger Agreement likewise contains customary representations, warranties and covenants, including covenants obligating each of the Company and Helomics to continue to conduct their respective businesses in the ordinary course, and to provide reasonable access to each other's information. Finally, the Merger Agreement contains certain termination rights in favor of each of the Company and Helomics.

At a special meeting of stockholders on March 22, 2019, the Company's stockholders approved the Merger Agreement.

On July 10 and 11, 2018, the Company issued 250,000 shares of common stock, par value $0.01, at $1.18 per share for consulting fees pursuant to the TumorGenesis license fees contract, and 750,000 shares of common stock, par value $0.01, at $1.17 per share, in escrow, for TumorGenesis license fees pursuant to the TumorGenesis license fees contract.

Increases in Authorized Shares

At a special meeting of the stockholders on January 29, 2017, the stockholders approved a proposal to increase the number of authorized shares of common stock from 8,000,000 shares to 24,000,000 shares of common stock under the Company's certificate of incorporation.

At the annual meeting on December 28, 2017, the stockholders approved a proposal to increase the number of authorized shares of common stock from 24,000,000 to 50,000,000 shares of common stock, $0.01 par value. The amendment to the certificate of incorporation to affect this increase was filed on January 2, 2018.

At the special meeting of stockholders on March 22, 2019, the stockholders approved a proposal to increase the number of authorized shares of common stock from 50,000,000 to 100,000,000 shares of common stock, $0.01 par value. The amendment to the certificate of incorporation to affect this increase was filed on March 22, 2019.

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 market price on the date of issuance. 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

ASC 718 – *Compensation – Stock Compensation, ("ASC 718")* requires that a company that issues equity as compensation needs to record compensation expense on its statements of comprehensive loss that corresponds to the estimated cost of those equity grants. 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 policy is 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 has been on the NASDAQ Capital Market since 2015 and has had a volatile stock including reverse stock splits. 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.

On April 19, 2017, the Company terminated the Company's Partnership and Exclusive Reseller Agreement with GLG Pharma, LLC and thereby received 400,000 shares of common stock, par value $0.01, from escrow.

For grants of stock options and warrants in 2017 the Company used a 1.92% to 2.40% risk free interest rate, 0% dividend rate, 59% to 66% volatility and estimated terms of 5 to 10 years. Value computed using these assumptions ranged from $0.6541 to $1.5489 per share.

On January 15, 2018, the Company issued inducement stock options in accordance with NASDAQ listing rule for 50,000 shares of common stock, par value $0.01 at $0.97 per share to the Company's newly hired International Vice President of Sales. The options will vest in four equal increments: on the first, second, third and fourth quarters of the hiring date anniversary.

On March 12, 2018, the Company issued inducement stock options in accordance with NASDAQ rule for 111,112 shares of common stock, par value $0.01 at $1.35 per share to the Company's newly hired Vice President of Sales and Marketing. The options will vest in four equal increments: on the first, second, third and fourth quarters of the hiring date anniversary.

For grants of stock option and warrants in 2018 the Company used 2.33% to 3.07% risk free interest rate, 0% dividend rate, 59% to 66% volatility and estimated terms of 5 to 10 years. Value computed using these assumptions ranged from $0.3816 to $1.0044 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, 2016	165,643	$ 11.22	871,101	$ 52.22
Issued	2,612,070	1.45	1,082,946	1.49
Expired	(12,730)	10.39	(2,790)	281.46
Exercised	-	-	-	-
Outstanding at December 31, 2017	2,764,983	$ 2.00	1,951,257	$ 23.74
Issued	1,098,858	1.01	2,336,154	1.07
Expired	(194,564)	2.00	(10,706)	199.55
Exercised	-	-	(650,062)	1.00
Outstanding at December 31, 2018	3,669,277	$ 1.70	3,626,643	$ 4.17

At December 31, 2018, 2,946,488 stock options are fully vested and currently exercisable with a weighted average exercise price of $1.79 and a weighted average remaining term of 8.86 years. There are 2,247,489 warrants that are fully vested and exercisable. Stock-based compensation recognized in 2018 and 2017 was $1,124,928 and $2,298,680, respectively. The Company has $741,922 of unrecognized compensation expense related to non-vested stock options that are expected to be recognized over the next 20 months.

The following summarizes the status of options and warrants outstanding at December 31, 2018:

Range of Exercise Prices	Shares	Weighted Average Remaining Life
Options:		
$0.619	201,908	10.00
$0.82	60,000	9.91
$0.91	10,000	9.30
$0.965	3,000	9.38
$0.97	191,753	9.02
$1.01	149,110	9.12
$1.06	23,585	9.76
$1.10	86,958	9.46
$1.13	195,931	9.55
$1.15	21,740	9.59
$1.16	66,451	9.59
$1.18	30,000	9.61
$1.20	41,668	9.59
$1.21	30,000	9.61
$1.35	111,112	9.20
$1.454	17,200	8.75
$1.47	2,305,790	8.48
$2.10	14,286	8.25
$2.25	293	7.65
$2.42	20,640	7.64
$2.80	57,145	8.01
$3.75	4,000	7.50
$4.125	3,636	7.75
$4.1975	7,147	7.72
$4.25	3,529	7.25
$5.125	3,902	7.69
$65.75	190	6.81
$73.50	1,157	7.01
$77.50	2,323	6.50
$80.25	187	6.75
$86.25	232	6.25
$131.25	81	3.69
$148.125	928	4.21
$150.00	1,760	3.63
$162.50	123	6.01
$206.25	121	5.75
$248.4375	121	4.54
$262.50	130	4.54
$281.25	529	4.04
$318.75	3	4.35
$346.875	72	5.25
$431.25	306	5.19
$506.25	188	5.00
$596.25	42	4.75
Total	3,669,277	
Warrants:		
$0.836	221,292	4.92
$1.00	1,063,935	3.76
$1.07	697,946	3.85
$1.155	1,071,776	4.75
$1.3125	86,086	4.75
$2.25	385,000	3.06
$123.75	94,084	1.67
$243.75	2,529	0.59
$309.375	2,850	0.61
$309.50	222	0.85
$506.25	59	0.12
$609.375	862	0.09
Total	3,626,643	

Stock options and warrants expire on various dates from January 2019 to December 2028.

The Company's board of directors had determined that the Company would require additional authorized shares for anticipated equity financings, future equity offerings, strategic acquisition opportunities, and 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 called a special meeting of the stockholders that took place on January 29, 2017. The vote, a proposal to increase the number of authorized shares of common stock from 8,000,000 shares to 24,000,000 shares of common stock under the Company's certificate of incorporation passed. On December 28, 2017, the Company held its annual meeting. Pursuant to the meeting on January 2, 2018, the Certificate of Incorporation of the Company was amended to increase the number of authorized shares of common stock from 24,000,000 to 50,000,000 shares of common stock, $0.01 par value. Additionally, the stockholders approved an amendment to the Company's 2012 Plan to (i) increase the reserve of shares of common stock authorized for issuance thereunder to 5,000,000, (ii) to increase certain threshold limits for grants, and (iii) to re-approve the performance goals thereunder. Pursuant to the annual meeting and the aforementioned approvals, and as explained in the Company's definitive proxy statement filed with the SEC on December 4, 2017, amendments to the 2012 Plan were considered at the 2016 annual meeting but were not approved by the required vote. For options to purchase approximately 2.5 million shares granted after the 2016 annual meeting, the grantees agreed not to exercise the options prior to further stockholder approval of an increase in the reserve under the 2012 Plan. As a result of the stockholder approval of the amendments at the 2017 annual meeting, these restrictions on exercise were removed on December 28, 2017. Due to the removal of this restriction on exercise, the Company recognized a non-cash charge for compensation expense of approximately $1.9 million in the fourth quarter of 2017.

Stock Options and Warrants Granted by the Company

The following table is the listing of outstanding stock options and warrants as of December 31, 2018 by year of grant:

Stock Options:

Year	Shares	Price		
2011	173	281.25		
2012	1,841	131.25	–	150.00
2013	1,553	148.13	–	596.25
2014	836	162.50	–	431.25
2015	4,088	65.75	–	86.25
2016	100,294	2.25	–	5.13
2017	2,461,634	1.01	–	2.10
2018	1,098,858	0.62	–	1.35
Total	3,669,277	$0.62	–	596.25

Warrants:

Year	Shares	Price		
2014	6,455	243.75	–	609.38
2015	94,151	0.00	–	243.75
2016	252,333	1.00		
2017	1,082,946	1.07	–	2.25
2018	2,190,758	0.84	–	1.3125
Total	3,626,643	$0.00	–	609.38

NOTE 5– NOTES RECEIVABLE

In July 2017, the Company began to advance funds to CytoBioscience for working capital for CytoBioscience's business. All the notes receivable bear simple interest at 8% and were due in full on December 31, 2017. All the notes are covered by a security interest in all of CytoBioscience's accounts receivable and related rights in connection with all of the advances. The principal amount of the secured promissory notes receivable from CytoBioscience totaled $1,070,000 as of December 31, 2017. In March 2018, the Company executed a new note replacing all previous CytoBioscience notes for $1,112,524, plus interest paid monthly at the per annum rate of (8%) on the principal amount. The secured note has a term of two years with the unpaid principal and unpaid accrued interest due and payable on February 28, 2020. CytoBioscience was current in its payments to the Company through and including July 2018. The Company had not received the scheduled interest payments from CytoBioscience for August through yearend. On September 27 and 28, 2018 CytoBioscience, through its parent company (WestMountain; now named InventaBioTech, OTC symbol INVB), made public filings indicating that their notes payable was in default. In October 2018, CytoBioscience communicated to the Company that CytoBioscience is raising capital that it believes will allow it to resume debt service payments, and that CytoBioscience wishes to negotiate an extension to the note. The Company has reached agreement with CytoBioscience on repayment and in February and March 2019 received payments towards the interest due and a portion of the principal. As of December 31, 2018, the Company does not believe a reserve is needed.

In October 2017, the Company advanced $600,000 for working capital for Helomics' business. Additionally, in December 2017, the Company advanced $67,512 to De Lage Landen, a vendor of Helomics, as a fifty percent (50%) down payment for a lease to purchase certain equipment. The note is covered by a security interest in certain equipment of Helomics. In March 2018, the Company converted $500,000 of the note receivable into 833,333 shares of common stock for an additional 5% interest in Helomics. The Company now has an equity stake in Helomics totaling 25%.

In September 2018, the Company advanced an additional $60,000 for working capital for Helomics' business. The balance due to the Company is $163,468, plus interest as of September 30, 2018. Subsequently in October 2018, the Company advanced $907,500 for working capital for Helomics' business. In December 2018, the Company advanced $30,000 to Helomics under the same note. The balance due to the Company at December 31, 2018, is $1,165,013 in principal, plus interest of $29,215. On the balance sheet there is a reduction to the loan of $751,330 due to the equity method accounting losses incurred from Helomics ownership; see Note 2. In January and February 2019, the Company also advanced Helomics $305,000. In March 2019, the Company advanced an additional $420,000 to Helomics from the Form S-3 public offering that netted the Company approximately $1.1M. The balance to date owed by Helomics is $1,890,013 plus interest. The Company expects that additional advances will be required before the merger is complete. All additional advances are covered by the security interest in certain equipment of Helomics. In addition, Helomics pledged all of its assets as security for the Company's convertible secured note financing. Upon completion of the merger with Helomics all intercompany notes would be eliminated in their entirety.

NOTE 6 – CONVERTIBLE DEBT AND DERIVATIVE LIABILITY

Effective September 28, 2018 (the "Effective Date"), the Company issued convertible secured promissory notes to two private investors in the original principal amount of an aggregate $2,297,727 (the "bridge loan"). The Company and Helomics have granted to each of the investors a security interest in their assets to secure repayment of the notes. The securities purchase agreements with the investors also provide for a second investment of an aggregate of $500,000 by the investors at the consummation of the Merger transaction with Helomics, at which point the aggregate principal amounts of the notes will become $2,865,909. As additional consideration for the investment, the Company issued an aggregate 650,000 shares of its common stock (the "Inducement Shares") to the investors or their affiliates plus warrants to acquire up to an aggregate 1,071,776 shares of the Company's common stock at an exercise price of $1.155 per share. Upon the closing of the second tranche investment, the warrants would be increased to cover an aggregate total of 1,336,805 shares. Each warrant is exercisable by the investor beginning on the sixth month anniversary of the effective date through the fifth-year anniversary thereof.

The notes accrue interest at a rate of 8% per annum (with twelve months of interest guaranteed). The maturity date of the notes is twelve months from the Effective Date. Upon the earlier to occur of an event of default (as defined in the notes) or the filing of certain registration statements, each investor will have the right at any time thereafter to convert all or any part of its Note into shares of the Company's common stock at a conversion price which is equal to the lesser of: (i) $1.00 and (ii) 70% of the lowest volume-weighted average price (the "VWAP") of the Company's common stock during the 20-trading day period ending on either the last complete trading day prior to the conversion date, or the conversion date ("Conversion Shares"). The number of Conversion Shares that may be issued is subject to an exchange cap such that the sum of (a) the total number of Conversion Shares plus (b) the number of Inducement Shares is limited to an aggregate 2,678,328 shares.

Management has concluded the conversion feature is an embedded derivative that is required to be bifurcated and separately presented as a liability on the balance sheet. The embedded derivative's value was determined using 70% of the VWAP for the 20 trading days preceding the balance sheet date, and assuming conversion on that date as management believed it is probable that the notes will be convertible based on management's expectation that additional financing will be required.

The Company accounted for the warrants by deriving the Black-Scholes value ascertained with a discount rate of 2.94% over five years with a 59% volatility rate pursuant to the Company's established warrant volatility and a calculated value per warrant of .5361 resulting in a fair value of $574,631. Management concluded that the warrants and Inducement Shares qualify for equity classification. The proceeds from the bridge loan were allocated between the convertible note, warrants, and inducement shares based on the relative fair value of the individual elements. In December 2018, the derivative liability was adjusted for the change in the 70% of the VWAP for the 20 days preceding the balance sheet date and assuming conversion on that date as management believed it is probable that the notes will be convertible based on management's expectation that additional financing will be required. The derivative liability recorded in September 2018 was $645,008. The fair value of the derivative liability as of December 31, 2018 is $272,745. An unrealized gain for the corresponding change in fair value was recorded to other income in 2018.

The value of the embedded derivative was based upon level 3 inputs – see the Fair Value Caption in Note 1.

NOTE 7 - LOSS PER SHARE

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

	Year Ended December 31,	
	2018	**2017**
Numerator:		
Net loss available in basic and diluted	$ (10,086,477)	$ (6,003,017)
Denominator:		
Weighted average common shares outstanding-basic	12,816,289	6,362,989
Effect of dilutive stock options warrants and preferred stock (1)	-	-
Weighted average common shares outstanding-diluted	12,816,289	6,362,989
Loss per common share-basic and diluted	$ (0.79)	$ (0.94)

(1) The number of shares underlying options and warrants outstanding as of December 31, 2018 and December 31, 2017 are 7,295,921 and 4,716,240, respectively. The number of shares underlying the preferred stock as of December 31, 2018 is 79,246 for Series B Convertible. The number of shares underlying the convertible debt is 3,294,087. The effect of the shares that would be issued upon exercise of such options, warrants, convertible debt and preferred stock has been excluded from the calculation of diluted loss per share because those shares are anti-dilutive.

NOTE 8– 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.

The Tax Reform Act was enacted December 22, 2017. Effective January 1, 2018 the Tax Reform Act reduced corporate income tax rates from 34% to 21%. Other changes effect operating loss carry-forwards and carrybacks, as well as a repeal of the corporate alternative minimum tax. As a result of the Tax Reform Act, deferred tax assets and liabilities were re-measured to account for the lower tax rates. There was no income tax impact from the re-measurement due to the 100% valuation allowance on the Company’s deferred tax assets.

There is no federal or state income tax provision in the accompanying statements of comprehensive loss due to the cumulative operating losses incurred and 100% valuation allowance for the deferred tax assets.

Actual income tax benefit (expense) differs from statutory federal income tax benefit (expense) as follows for the years ended December 31:

	2018	**2017**
Statutory federal income tax benefit	$ 2,118,160	$ 2,633,841
State tax benefit, net of federal taxes	66,117	76,922
Foreign tax benefit	132,931	-
Foreign operations tax rate differential	(94,373)	-
State rate adjustment	15,355	(77,556)
R&D tax credit	22,532	-
Nondeductible/nontaxable items	(118,905)	(757,149)
State NOL adjustment	746,479	-
OID and derivatives	(159,037)	-
NQSO adjustment	-	537,884
New federal rate adjustment	-	(4,974,121)
Other	47,868	(8,336)
Valuation allowance decrease (increase)	(2,777,127)	2,568,515
Total income tax benefit (expense)	$ -	$ -

Deferred taxes consist of the following as of December 31:

	2018	2017
Deferred tax assets:		
Noncurrent:		
Depreciation	$ 4,488	$ 3,251
Inventory	6,991	6,950
Compensation accruals	60,905	50,436
Accruals and reserves	77,777	64,732
Charitable contribution carryover	3,972	4,068
Derivatives	57,276	-
Related party investments	481,652	-
Intangibles	2,020	-
NQSO compensation	1,019,139	766,648
NOL and credits	9,655,388	7,479,505
Total deferred tax assets	11,369,608	8,375,590
Deferred tax liabilities:		
Noncurrent:		
Original issue discount	(216,891)	-
Total deferred tax liabilities	(216,891)	-
Net deferred tax assets	11,152,717	8,375,590
Less: valuation allowance	(11,152,717)	(8,375,590)
Total	$ -	$ -

The Company has determined, based upon its history, that it is probable that future taxable income may be insufficient to fully realize the benefits of the net operating loss carryforwards and other deferred tax assets. As such, the Company has determined that a full valuation allowance is warranted. Future events and changes in circumstances could cause this valuation allowance to change.

During December 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 Company may have experienced additional “ownership change(s)” since December 2013, but a formal study has not yet been performed. 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, 2017, the Company had approximately $34,529,255 of gross NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2018, subject to the Section 382 limitation described above. The federal NOLs will expire beginning in 2022 if unused. The Company also had approximately $12,261,799 of gross NOLs to reduce future state taxable income at December 31, 2017. The state NOL’s will expire beginning in 2022 if unused. The Company's net deferred tax assets, which include the NOLs, are subject to a full valuation allowance. At December 31, 2017, the federal and state valuation allowances were $8,129,778 and $245,812, respectively.

At December 31, 2018, the Company had approximately $40,094,472 of gross NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2019, subject to the Section 382 limitation described above. The federal NOLs will expire beginning in 2022 if unused. The Company also had approximately $12,940,458 of gross NOLs to reduce future state taxable income at December 31, 2018. The state NOL’s will expire beginning in 2022 if unused. The Company also had approximately $421,782 in gross foreign NOLs to reduce future Belgian taxable income at December 31, 2018. The Company's net deferred tax assets, which include the NOLs, are subject to a full valuation allowance. At December 31, 2018, the federal, state and foreign valuation allowances were $9,603,237, $1,416,758 and $132,722, respectively.

Tax years subsequent to 2014 remain open to examination by federal and state tax authorities. 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.

The Company recognizes interest and penalties on unrecognized tax benefits as well as interest received from favorable tax settlements within income tax expense. At December 31, 2018 and 2017, the Company recorded no accrued interest or penalties related to uncertain tax positions.

NOTE 9– RENT OBLIGATION

Precision's corporate offices are located at 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121. On November 22, 2017, the Company signed a second amendment to its lease last amended on January 28, 2013. The lease as amended has a three-year term effective February 1, 2018 ending January 31, 2021. The Company leases 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. The Company expects that this space will be adequate for our current office and manufacturing needs.

Skyline Medical Europe's offices are located at 9 Chemin de la Fraite – 1380 Ohain, Belgium. The lease agreement was signed April 24, 2018 and started on June 15, 2018. The Company leases around 2,000 square feet at this location, 300 of which is used for storage and 1,250 for office space. The lease is effective through June 14, 2027. We expect that this space will be adequate for our current office and storage needs. Rent expense is 3,000 Euros Per month.

Rent expense was $69,013 and $66,122 for 2018 and 2017, respectively.

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

2019	$	80,320
2020		82,320
2021		43,320
2022		40,320
2023		40,320
Thereafter		161,280

NOTE 10 - 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.

One of the Company's directors, Richard L. Gabriel, is the Chief Operating Officer and serves as a director of GLG Pharma ("GLG"). Another Company director, Tim Krochuk, is on the supervisory board for GLG. The Company and GLG have a partnership agreement with Helomics for the purpose of bringing together their proprietary technologies to build out personalized medicine platform for the diagnosis and treatment of women's cancer. There has been no revenue or expenses generated by this partnership to date.

Richard L. Gabriel is also contracted as the Chief Operating Officer for TumorGenesis the 100% wholly-owned subsidiary of the Company. Mr. Gabriel receives $12,000 per month pursuant to a renewable six-month contract. The contract extends to March 31, 2019.

On November 30, 2018, our CEO, Carl Schwartz, made an investment of $370,000 in the Company and received a note and a common stock purchase warrant for 221,292 warrant shares at $0.836 per share. Effective as of January 8, 2019, Dr. Schwartz made an additional investment of $950,000 and received an amended and restated note in the original principal amount of $1,320,000 and an amended and restated warrant, which added a second tranche of 742,188 warrant shares at an exercise price of $0.704. Each tranche is exercisable beginning on the sixth month anniversary of the date of the related investment through the fifth-year anniversary of the date of the related investment. On January 8, 2019, Dr. Schwartz also purchased 78,125 shares of the Company's common stock in a private investment for $50,000, representing a price of $0.64 per share, pursuant to a subscription agreement. On February 6, 2019, Dr. Schwartz made an additional investment of $300,000 in the Company and received an amended and restated note in the original principal amount of $1,620,000 and an amended and restated warrant, which added a third tranche of 138,889 warrant shares at an exercise price of $1.188 per share. On February 1, 2019 and the first day of each calendar month thereafter while the note and the warrant remain outstanding, a number of additional shares will be added to the second tranche and the third tranche equal to (1) one-half percent (1/2%) of the outstanding principal balance of the Note on such date, divided by (2) the closing price of the Company's common stock on that date. The number of warrant shares will be subject to a share limit such that the total of (a) the 78,128 shares of common stock purchased by Dr. Schwartz on January 8, 2019, and (b) the total number of warrant shares (1,108,596 warrant shares as of February 6, 2019) may not exceed 2,818,350 shares (equal to 19.9% of the outstanding shares of common stock on January 8, 2019). If the second tranche and/or third tranche cannot be increased as required herein due to the share limit, then in lieu of any such increase, the Company shall pay to Dr. Schwartz a cash amount equal to one-half percent (1/2%) of the principal balance of the Schwartz note in lieu of such increase.

NOTE 11 – RETIREMENT SAVINGS PLANS

The Company has 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 2017, and again in 2018, the Company matched 100%, of the employee's contribution up to 4.0% of their earnings. The employer contribution was $51,647 and $29,952 in 2018 and 2017, respectively. There were no discretionary contributions to the plan in 2018 and 2017.

NOTE 12 – CORRECTION OF IMMATERIAL MISSTATEMENT TO PRIOR PERIOD FINANCIAL STATEMENTS

During fiscal 2018, the Company identified certain warrants issued in 2016 and 2017, which were incorrectly recognized as expense in 2017 when the warrants vested. As a result, investors stock compensation expense and additional paid-in capital were overstated by $2,150,097 for the year ended December 31, 2017.

Also during fiscal 2018, the Company identified that employee stock compensation expense was incorrectly recognized in 2017. As a result, employee stock compensation expenses and additional paid-in capital were understated by $406,522 for the year ended December 31, 2017.

Lastly during fiscal 2018, the Company identified that certain nonqualified stock options were excluded from the Company's tax provision calculation in 2017. As a result, deferred tax assets and the valuation allowance on these assets were understated by $767,000 as of December 31, 2017.

Based on an analysis of Accounting Standards Codification ("ASC") 250 – "Accounting Changes and Error Corrections" (ASC 250"), Staff Accounting Bulletin 99 – "Materiality" ("SAB 99") and Staff Accounting Bulletin 108 – Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements ("SAB 108"), the Company determined that these costs were immaterial to the previously-issued financial statements. The Company analyzed and considered all relevant quantitative and qualitative factors and determined that the prior fiscal year financial statements should be corrected, even though such revision previously was and continues to be immaterial to the prior year financial statements. Management also determined that such correction to prior fiscal year financial statement for immaterial misstatements would not require previously filed reports to be amended and that such corrections may be made the next time the Company files the prior year financial statements.

Accordingly, the Company restated its presentation of general and administrative, sales and marketing, and operating expenses as well as retained earnings and additional paid-in capital in the consolidated financial statements for the year ended December 31, 2018 to reflect such corrections as if they had been recorded in the appropriate fiscal period as of December 31, 2017. Specifically, the adjustments were reflected and corrected in the last quarter of 2017 for the period ended December 31, 2017, by reducing investors stock compensation expense under general and administrative expenses and reducing additional paid-in capital by $2,150,097; and, by increasing employee stock compensation expenses under general and administrative, selling and operating expense and increasing additional paid-in capital by a total of $406,522 on the comparative balance sheet for the period ended December 31, 2017. In addition, the Company restated Note 4 – Stockholders' Equity (Deficit), Stock Options and Warrants, and Note 8 – Income Taxes, to reflect the impact of these restatements on the footnote disclosures as of and for the year ended December 31, 2017.

NOTE 13 – SUBSEQUENT EVENTS

Registered Offering of Common Stock and Warrants

On February 27, 2019, Precision Therapeutics Inc., entered into a Placement Agency Agreement (the "Placement Agency Agreement") pursuant to which Dawson James Securities, Inc. served as placement agent on a "best efforts" basis (the "Placement Agent") for a registered direct offering in which the Company sold 1,385,000 shares of the Company's common stock ("Common Stock") and warrants to purchase up to 692,500 shares of Common Stock (the "Warrants") (the "Offering"). The Common Stock and warrants were sold in units (the "Units"), with each Unit consisting of one share of Common Stock and a warrant to purchase 0.5 of a share of the Company's Common Stock at an exercise price of $1.00 per whole share. The warrants are exercisable at any time on or after the date of issuance and expire on the fifth anniversary of issuance.

The Units were sold at a price of $0.90 per Unit, resulting in gross proceeds to the Company of approximately $1.25 million, before deducting placement agent fees and estimated offering expenses. The net offering proceeds to the Company, after deducting the placement agent's fees and other estimated offering expenses payable by the Company, are expected to be approximately $1.08 million.

The closing of the Offering occurred on March 1, 2019.

Pursuant to the Placement Agency Agreement, the Company agreed to pay the Placement Agent a cash fee equal to 8% of the aggregate purchase price of the Units sold. The Company also agreed to reimburse the Placement Agent for its expenses in connection with this offering, up to $30,000, and agreed to reimburse the placement agent for its reasonable "blue sky" fees and expenses, of $5,000. The Placement Agency Agreement contains indemnification, representations, warranties, conditions precedent to closing and other provisions customary for transactions of this nature.

Also pursuant to the Placement Agency Agreement, the Company, in connection with the offering, entered into Unit Purchase Option agreements, dated as of March 1, 2019 (the "Unit Purchase Options"), pursuant to which the Company granted the Placement Agent or its assignees the right to purchase from the Company up to an aggregate of 69,250 Units (which represents 5% of the Units sold to investors in the offering) at an exercise price equal to 125% of the public offering price of the Units in the offering, or $1.125 per Unit. The Unit Purchase Options shall expire on February 27, 2024.

On March 12, 2019, Peak One, one of the noteholders from the bridge loan, converted 71,046 shares of stock reducing the principal of the loan by $44,475. The value was computed, pursuant to the agreement, by calculating the average VWAP for the prior 20 days and multiplying that average by 70%.

Dr. Carl Schwartz, the Company's CEO made an additional loan to the Company and made a private investment in the Company's common stock, which in total, generated an additional $1,300,000, see Note 10 – Related party Transactions.

The Company entered into a forbearance agreement with L2 Capital, LLC and Peak One Opportunity Fund, LP. AS part of the agreement the Company added 15% to the principal of the note and issued inducement shares of common stock. The Company accrued approximately $503,000 in penalty expenses as a result as of December 31, 2018. This penalty expense is recorded in accrued expenses on the balance sheet.

On March 26, 2019, Precision Therapeutics Inc., entered into a Placement Agency Agreement (the "Placement Agency Agreement") pursuant to which Dawson James Securities, Inc. served as placement agent on a "best efforts" basis (the "Placement Agent") for a registered direct offering in which the Company sold 1,478,750 shares of the Company's common stock ("Common Stock") and warrants to purchase up to 739,375 shares of Common Stock (the "Warrants") (the "Offering"). The Common Stock and warrants were sold in units (the "Units"), with each Unit consisting of one share of Common Stock and a warrant to purchase 0.5 of a share of the Company's Common Stock at an exercise price of $1.00 per whole share. The warrants are exercisable at any time on or after the date of issuance and expire on the fifth anniversary of issuance.

The Units were sold at a price of $0.80 per Unit, resulting in gross proceeds to the Company of approximately $1.18 million, before deducting placement agent fees and estimated offering expenses. The net offering proceeds to the Company, after deducting the placement agent's fees and other estimated offering expenses payable by the Company, are expected to be approximately $1.05 million.

The closing of the Offering occurred on March 29, 2019.

Pursuant to the Placement Agency Agreement, the Company agreed to pay the Placement Agent a cash fee equal to 8% of the aggregate purchase price of the Units sold. The Company also agreed to reimburse the Placement Agent for its expenses in connection with this offering, up to $30,000, and agreed to reimburse the placement agent for its reasonable "blue sky" fees and expenses, of $5,000. The Placement Agency Agreement contains indemnification, representations, warranties, conditions precedent to closing and other provisions customary for transactions of this nature.

Also pursuant to the Placement Agency Agreement, the Company, in connection with the offering, entered into Unit Purchase Option agreements, dated as of March 29, 2019 (the "Unit Purchase Options"), pursuant to which the Company granted the Placement Agent or its assignees the right to purchase from the Company up to an aggregate of 73,938 Units (which represents 5% of the Units sold to investors in the offering) at an exercise price equal to 125% of the public offering price of the Units in the offering, or $1.00 per Unit. The Unit Purchase Options shall expire on March 29, 2024.

The securities in the Offerings were offered and sold pursuant to the Company's "shelf" registration statement (File No. 333-213766), which was declared effective by the United States Securities and Exchange Commission on October 4, 2016.

Exhibit 10.56

AMENDMENT TO EMPLOYMENT AGREEMENT

This Amendment to Employment Agreement ("Amendment") is made by and between Precision Therapeutics Inc. ("Precision") and Robert Myers ("Myers"), collectively referred to as the "Parties."

1. **Background Facts.** The Parties agree with the following facts that are incorporated by reference into this Amendment.

a. Myers is currently employed as the Chief Financial Officer of Precision, formerly known as BioDrain Medical, Inc.

b. Myers entered into the Employment Agreement with BioDrain Medical, Inc. effective August 11, 2012 (the "Employment Agreement" attached hereto as Exhibit A).

c. Section 18 of the Employment Agreement permits the Parties to modify the Employment Agreement in writing and signed by both Parties.

d. The Parties agree to amend the Employment Agreement by mutual consent by entering into this Amendment.

e. NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree to amend the Employment Agreement as follows.

2. **Amendment to the Employment Agreement.** The Parties agree to amend the Employment Agreement with all of the changes in this Section 2:

a. **Increase in Base Salary.** The following sentences are added in Section 4a (entitled "Base Salary") of the Employment Agreement after the first sentence in Section 4a:

> Effective August 1, 2018, Employee will receive an annualized base salary of $250,000 (gross, less applicable legally required withholdings and such other deductions as Employee voluntarily authorizes in writing). Effective August 1, 2019, Employee will receive an annualized base salary of $300,000 (gross, less applicable legally required withholdings and such other deductions as Employee voluntarily authorizes in writing).

b. **Increase in Vacation.** The following sentence is added in Section 5c (entitled "Vacation") of the Employment Agreement after the second sentence in Section 5c:

> Effective August 1, 2018, Employee shall be entitled to five (5) weeks of paid vacation per each calendar year earned ratably over each calendar year, to be taken at such times as Employee and Company shall determine and provided that no vacation time shall unreasonably interfere with the duties required to be rendered by Employee hereunder.

c. **No Guaranteed Minimum Annual Incentive Bonus.**

i. The third sentence in Section 4c (entitled "Bonus") of the Employment Agreement set forth below is deleted in its entirety:

The minimum bonus that may be earned by Employee for any year will be not less than 20% of Employee's then-current base salary.

ii. The following sentence is added in Section 4(c) of the Employment Agreement and replaces the third sentence above:

Employee is eligible to receive a pro-rata annual incentive bonus for 2018 for the period January 1, 2018 through July 31, 2018 that will be not less than 20% of Employee's then-current base salary.

3. **No Other Changes.** Except as modified by this Amendment, there are no changes to the Employment Agreement. The Parties acknowledge and agree the Employment Agreement as modified by this Amendment remains in full force and effect. Myers acknowledges and agrees that the changes in this Amendment do not impact the other terms and conditions as outlined in the Employment Agreement, including but not limited to Section 6 (entitled "Non-Competition"), Section 7 (entitled "Intellectual Property") and Section 8 (entitled "Nondisclosure of Confidential Information").

4. **Severability.** If any provision of the Amendment is unenforceable for any reason, such provision or portion shall be considered separate from the remainder of the Amendment, and the rest of the Employment Agreement as modified by this Amendment shall remain in full force and effect. In the event that any provision of this Amendment is unenforceable because it is overly broad or vague as written, or if any provision violates any applicable law at the time of its enforcement, such provision shall be deemed modified to narrow or clarify its application to the extent necessary to make the provision enforceable, if possible, to the fullest extent allowable. The provisions of this Amendment will be interpreted, where possible, to sustain their legality and enforceability.

5. **Complete Agreement.** Any modification of, or addition to, this Amendment must be in writing and signed by both Parties. This Amendment and the Employment Agreement constitute the entire understanding between the Parties and supersede all prior discussions, representations, and/or agreements between the Parties with respect to the matters herein.

6. **Myers' Agreement and Understanding.** Myers has read this Amendment carefully and understand all of its terms. Myers has had the opportunity to discuss this Amendment with Myers' own attorney prior to signing it and to make certain that Myers fully understands the content and effect of this Amendment. Myers entered into this Amendment voluntarily.

/s/ Robert Myers	8/20/18
Robert Myers	Date

Precision Therapeutics Inc.

By	/s/ Carl Schwartz	8/20/18
		Date
Title	CEO	

Exhibit A

See attached Employment Agreement.

Exhibit 23.1

Deloitte & Touche LLP
50 South 6th Street
Suite 2800
Minneapolis, MN 55402-1538
USA

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CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-169556, 333-175565, 333-186464, 333-188510, 333-198378, 333-213742, and 333-216711 on Form S-8; and in Registration Statement Nos. 333-213766, 333-221966, 333-228908, and 333-229664 on Form S-3 of our report dated April 1, 2019, relating to the consolidated financial statements of Precision Therapeutics Inc. (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the financial statements) appearing in this Annual Report on Form 10-K of Precision Therapeutics Inc. for the year ended December 31, 2018.

Deloitte & Touche LLP

Minneapolis, Minnesota
April 1, 2019

Exhibit 23.2

Olsen Thielen & Co., Ltd.
CPAS AND ADVISORS

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements of our report dated April 2, 2018, except for Note 12 as to which the date is April 1, 2019, which expresses an unqualified opinion and includes an explanatory paragraph relating to the Company's ability to continue as a going concern for the year ended December 31, 2017, appearing in this Annual Report on Form 10-K of Skyline Medical, Inc. for the year ended December 31, 2018.

Registration Statement on Form S-8 Nos. 333-169556 relating to the 2008 Equity Incentive Plan, as amended; 333-175565 relating to 2008 Equity Incentive Plan, as amended; 333-186464 relating to the 2012 Stock Incentive Plan; 333-188510 relating to the Amended and Restated 2012 Stock Incentive Plan; 333-198378 relating to the Amended and Restated 2012 Stock Incentive Plan; 333- 213742 related to the Amended and Restated 2012 Stock Incentive Plan, and 333-216711 related to inducement option.

Registration Statement on Form S-3 Nos. 333-213766, 333-221966, 333-228908, and 333-229664.

Olsen Thielen & Co., Ltd.

Olsen Thielen + Co., Ltd

Roseville, Minnesota
April 1, 2019

2675 Long Lake Road | Roseville, Minnesota | 55113-1117 | 651-483-4521 | 651-483-2467 FAX
300 Prairie Center Drive, Suite 300 | Eden Prairie, Minnesota | 55344-7908 | 952-941-9242 | 952-941-0577 FAX
otcpas.com

EXHIBIT 31.1

CERTIFICATION

I, Carl Schwartz, certify that:

1. I have reviewed this annual report on Form 10-K of Precision Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15-d-15 (e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 1, 2019

/s/ Carl Schwartz
Carl Schwartz
Chief Executive Officer (Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Bob Myers, certify that:

1. I have reviewed this annual report on Form 10-K of Precision Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15-d-15 (e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 1, 2019

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

Exhibit 32.1

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

In connection with the Annual Report of Form 10-K of Precision Therapeutics Inc. (the "Company") for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Carl Schwartz, Chief Executive Officer, and I, Bob Myers, Chief Financial Officer, of the Company, certify, pursuant to § 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1350, that to our knowledge:

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

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

Date: April 1, 2019

/s/ Carl Schwartz
Carl Schwartz
Chief Executive Officer
(Principal Executive Officer)

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