

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, 2019.
- 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

**PREDICTIVE ONCOLOGY INC.**

(Exact name of registrant as specified in its charter)

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

**33-1007393**  
(IRS Employer  
Identification No.)

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

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

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, \$0.01 par value	POAI	Nasdaq Capital Market

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

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

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

---

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

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.

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant’s most recently completed second fiscal quarter: \$19,734,292 as of June 30, 2019, based upon 2,640,039 shares at \$7.475 per share as reported on the Nasdaq Capital Market.

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 27, 2020, the registrant had 5,847,718 shares of common stock, par value \$.01 per share outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

---

	Page
<u>PART I</u>	
<u>ITEM 1. BUSINESS</u>	5
<u>EXECUTIVE OFFICERS OF THE REGISTRANT</u>	45
<u>ITEM 1A. RISK FACTORS</u>	14
<u>ITEM 1B. UNRESOLVED STAFF COMMENTS</u>	28
<u>ITEM 2. PROPERTIES</u>	29
<u>ITEM 3. LEGAL PROCEEDINGS</u>	29
<u>ITEM 4. MINE SAFETY DISCLOSURES</u>	29
<u>PART II</u>	
<u>ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	29
<u>ITEM 6. SELECTED FINANCIAL DATA</u>	31
<u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	31
<u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	42
<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	42
<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	42
<u>ITEM 9A. CONTROLS AND PROCEDURES.</u>	43
<u>ITEM 9B. OTHER INFORMATION</u>	44
<u>PART III</u>	
<u>ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	44
<u>ITEM 11. EXECUTIVE COMPENSATION</u>	50
<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	56
<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	57
<u>ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES</u>	58
<u>PART IV</u>	
<u>ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	59
<u>SIGNATURES</u>	60

---

## PART I

### ITEM 1. BUSINESS.

#### General

References in this annual report on Form 10-K to “Predictive”, “Company”, “we”, “us”, and “our” refer to the business of Predictive Oncology Inc. (NASDAQ: POAI) and its wholly-owned subsidiaries.

#### Cautionary Statement Concerning Forward-Looking Statements

*This Annual Report on Form 10-K contains various “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Forward-looking statements represent our expectations and beliefs concerning future results or events, based on information available to us on the date of the filing of this Form 10-K, and are subject to various risks and uncertainties. Factors that could cause actual results or events to differ materially from those referenced in the forward-looking statements are listed in Part I, Item 1A. Risk Factors and in Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations. We disclaim any intent or obligation to update or revise any of the forward-looking statements, whether in response to new information, unforeseen events, changed circumstances or otherwise, except as required by applicable law.*

#### Overview

We operate in two primary business areas: first, application of artificial intelligence (“AI”) in our precision medicine business, to provide AI-driven predictive models of tumor drug response to improve clinical outcomes for patients and to assist pharmaceutical, diagnostic, and biotech industries in the development of new personalized drugs and diagnostics; and second, production of the United States Food and Drug Administration (“FDA”)-cleared STREAMWAY® System for automated, direct-to-drain medical fluid disposal and associated products.

We have three operating segments: domestic, international, and Helomics. Domestic and international consist of the STREAMWAY System product sales. The Helomics segment consists of clinical testing and contract research. Our TumorGenesis subsidiary is included within corporate. Going forward, we have determined that we will focus our resources on the Helomics segment and our primary mission of applying AI to precision medicine and drug discovery.

#### Precision Medicine Business

Our precision medicine business, conducted in our Helomics division, is committed to improving the effectiveness of cancer therapy using our proprietary, multi-omic tumor profiling platform, one-of-a-kind database of historical tumor data, and the power of AI to build predictive models of tumor drug response.

Helomics’ mission is to improve clinical outcomes for patients by partnering with pharmaceutical, diagnostic, and academic organizations to bring innovative clinical products and technologies to the marketplace. In addition to our proprietary patient-derived (“PDx”) tumor profiling platform for oncology, Helomics offers: 1) data and AI driven contract research organization (“CRO”) services for clinical and translational research that leverage PDx tumor models, 2) a wide range of multi-omics assays (genomics, proteomics, and biochemical), and 3) AI driven predictive models to drive the discovery of targeted therapies.

## *Contract Research Organization (CRO) and AI-Driven Business*

We believe leveraging our unique, historical database of the drug responses of over 149,000 patient tumors to build AI and data-driven multi-omic predictive models of tumor drug response and outcome will provide actionable insights critical to both new drug development and individualizing patient treatment. Our large historical database of tumors and related data, plus our ability to obtain the associated patient outcome data is a significant competitive advantage. Cancer treatments require at least 5 years of testing to provide sufficient information on progression-free survival rates. While competitors must wait for this data, we can leverage it today. These AI-driven predictive models, coupled with the PDx platform will create a unique service to drive revenue generating projects with pharma, diagnostic and biotech companies in areas such as biomarker discovery, drug screening, drug repurposing, and clinical trials. The AI-driven models will, once validated, also provide clinical decision support to help oncologists individualize treatment.

Our CRO/AI business is committed to improving the process of targeted therapy discovery. Our proprietary, TruTumor multi-omic PDx profiling and AI platform coupled to our vast multi-omic database of biochemical and clinical information on patients with cancer, uses deep learning to understand the association between the mutational profile of a patient's tumor and the drug response profile of the tumor that is grown in the lab. This approach is used to build an AI-driven predictive model that offers actionable insights of which mutations in the tumor are associated with drugs to which the tumor is sensitive and which will lead to the optimal outcome for the patient.

Our CRO services business applies these AI-driven predictive models coupled with our unique proprietary TruTumor PDx model to address a range of needs from discovery through clinical and translational research, to clinical trials and diagnostic development and validation as noted below:

### Research

- Biomarker discovery
- Drug discovery
- Drug-repurposing

### Development

- Patient enrichment & selection for trials
- Clinical trial optimization
- Adaptive trials

### Clinical Decision Support

- Patient stratification
- Treatment selection

We believe this market segment has significant growth potential and we believe we are differentiated from traditional CRO's and other precision medicine and AI companies through these unique assets:

- clinically validated PDx platform;
- database of over 149,000 tumor cases;
- experienced AI team and AI platform;
- ability to access outcome data going back over ten years for over 120,000 of the tumor cases in our database.

## *Industry and Market Background and Analysis – Precision Medicine Business*

Precision medicine is an emerging approach for disease treatment and prevention that considers individual variability in genes, disease, environment, and lifestyle for each case to develop effective therapies. This approach allows doctors and researchers to predict more accurately which treatment, dose, and therapeutic regimen could provide the best possible outcome. The global precision medicine market is estimated to reach \$141.7 billion by 2026, up from \$43.6 billion in 2016. This growth is supported by the industry's investment in precision medicine, with leading biopharmaceutical companies doubling their investments in the technology over the last five years, with the potential to increase by an additional 33% over the next five years (Source: BIS Research's Global Precision Medicine Market to Reach \$141.70 Billion by 2026, December 2017).

Precision medicine, precisely targeting drugs based on the genomic profile of the patient, has become the aspiration for cancer therapy. Over the past several decades, researchers have identified molecular patterns that are useful in defining the prognosis of a given cancer, determining the appropriate treatments, and designing targeted treatments to address specific molecular alterations. The objective of precision oncology is to develop treatments tailored to the genetic changes in each person's cancer, intended to improve the effectiveness of the therapeutic regimen and minimize the treatment's effects on healthy cells. However, for a majority of patients the reality is that while many mutations in the patient's tumor can be identified most are not actionable with current protocols. As a result, the impact of targeted therapies is low, and uptake in clinical practice is inconsistent.

There is now a growing realization that genomics alone will not be enough to achieve the promise of personalized therapeutics, especially for cancer. A multi-omic approach (e.g. assessing the genome, transcriptome, epigenome, proteome, responseome, and microbiome) provides researchers and clinicians the comprehensive information necessary for new drug development and individualized therapy. Comparatively, the multi-omic approach provides a three-dimensional, 360-degree view of the cancer, while genomics alone is just a flat, one-dimensional view. However, multi-omic data is difficult to access quickly as it is both costly and time consuming to initiate prospective data collection, and few comprehensive, multi-omic datasets exist, especially specific to cancer.

### *Clinical Testing*

Via our Helomics subsidiary, we offer a group of clinically relevant, cancer-related tumor profiling and biomarker tests for gynecological cancers that determine how likely the patient is to respond to various types of chemotherapy and which therapies might be indicated by relevant tumor biomarkers.

Clinical testing is comprised of ChemoFx and BioSpeciFx tests. The ChemoFx test determines how a patient's tumor specimen responds to a panel of various chemotherapy drugs, while the BioSpeciFx test evaluates the expression of a specific genes, or biomarkers, in the patient's tumor. Our proprietary TruTumor™ PDx tumor platform provides us with the ability to work with actual live tumor cells to study the unique biology of the patient's tumor in order to understand how the patient responds to treatment.

Testing involves obtaining tumor tissue during biopsy or surgery which is then sent to our Clinical Laboratory Improvement Amendments ("CLIA") certified laboratory using a special collection kit. Two samples of the tumor tissue are obtained, fixed and live. The fixed tumor tissue is tested for a panel of biomarkers using a combination of Immunohistochemistry and Quantitative Polymerase Chain Reactions. The live tumor tissue is grown in the lab and used to test the drug response of the tumor to a panel of standard-of-care drugs. When testing is complete a report is provided back to the clinician with recommended therapies based on the drug response and biomarker profiles. Helomics integrates the drug response with other genomic and molecular data and compares it with historical data in our database to generate a roadmap that provides additional context to help the oncologist personalize patient treatment.

### *Business Strategy for Precision Medicine Business*

We are a data and AI-driven discovery services company that provides AI-driven predictive models of tumor drug response to improve clinical outcomes for patients by leveraging our two primary unique assets:

- A clinically validated PDx tumor profiling platform, TruTumor, that can generate drug response profiles and other multi-omic data. Over \$200 million has been invested in this platform and was clinically validated in ovarian cancer.
- Data on the drug response profiles of over 149,000 tumors across 137 cancer types tested using the PDx platform in over 10+ years of clinical testing. We call this database TumorSpace™.

Over 38,000 of the more than 149,000 clinically validated cases in our TumorSpace™ database are specific to ovarian cancer. The data in TumorSpace is highly differentiated, having both drug response data, biomarkers and access to historical outcome data from those patient samples. We intend to generate additional data (genomics and transcriptomics) from these tumor samples to deliver a multi-omic approach to the pharmaceutical industry.

Through our Helomics subsidiary, we will utilize both this historical data and the PDx platform to build AI-driven predictive models of tumor drug response and outcome through our CancerQuest 2020 ("CCQ2020") initiative. Once validated, we will commercialize these AI-driven predictive models in revenue generating service projects with pharmaceutical, biotech, and diagnostic companies.

A key part of our commercialization strategy for the CCQ2020 initiative is the understanding that our AI-driven models of tumor drug response serves a key unmet need of pharmaceutical, diagnostic, and biotech industries for actionable multi-omic insights on cancer. In collaboration with these companies, using the predictive models, we will accelerate the search for more individualized and effective cancer treatments, through revenue generating projects in biomarker discovery, drug screening, drug repurposing, and clinical trials.

Our commercial strategy has identified a portfolio of revenue generating project types that leverage the predictive models, our AI expertise, PDx tumor profiling, and CLIA laboratory to provide custom solutions utilizing our full array of assets and expertise.

The CCQ2020 initiative will focus initially on ovarian cancer, which is where we have the most expertise, samples, data, and access to outcomes. However, we intend to expand the initiative to include cancers of the lung, breast, colon, and prostate, and will actively seek partners to assist in that effort.

Within the clinical sector, we will utilize these predictive models (once validated) for new clinical decision support tools for individualizing therapy for patients with cancer. These clinical decision support tools are a longer revenue horizon than the research projects with pharmaceutical companies but, importantly, will provide a steady stream of additional data generation to refine the predictive models for both clinical and research applications.

### **Skyline Medical – The STREAMWAY System**

Sold through our subsidiary, Skyline Medical, Inc (“Skyline Medical”), the STREAMWAY System virtually eliminates staff exposure to blood, irrigation fluid and other potentially infectious fluids found in the healthcare environment. Antiquated manual fluid handling methods that require hand carrying and emptying filled fluid canisters present both an exposure risk and potential liability. Skyline Medical’s STREAMWAY System fully automates the collection, measurement, and disposal of waste fluids and is designed to: 1) reduce overhead costs to hospitals and surgical centers; 2) improve compliance with the Occupational Safety and Health Administration (“OSHA”) and other regulatory agency safety guidelines; 3) improve efficiency in the operating room and radiology and endoscopy departments, thereby leading to greater profitability; and 4) provide greater environmental stewardship by helping to eliminate the approximately 50 million potentially disease-infected canisters that go into landfills each year in the United States.

In December 2019, we announced that we had received indications of interest from several parties for the possible acquisition of our Skyline Medical division, and we reaffirmed that we are focusing our resources on our precision medicine business. We continue to operate the Skyline Medical business with a focus on maximizing our strategic opportunities with respect to this division.

#### *Industry and Market Background and 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. 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.

Most surgical 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. 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 (1) significantly reduces the risk of healthcare worker exposure to these infectious fluids by replacing canisters, (2) further reduces the risk of worker exposure when compared to powered canister technology that requires transport to and from the operating room, (3) reduces the cost per procedure for handling these fluids, and (4) enhances the surgical team's ability to collect data to accurately assess the patient's status during and after procedures. In addition to the traditional canister method of waste fluid disposal, several other powered medical devices have been developed that address some of the deficiencies described above. Most of these competing products continue to utilize some variation 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 with products already on the market have a clear competitive advantage over us in terms of brand recognition and market exposure. In addition, many of our competitors have extensive marketing and development budgets that could overpower an emerging growth company like ours.

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

#### *STREAMWAY System Product Sales*

Our domestic and international segments consist primarily of sales of the STREAMWAY System, as well as sales of the proprietary cleaning fluid and filters for use with the STREAMWAY System. 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 for the STREAMWAY System in the United States, Canada, and Europe. 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. In addition to simplifying the handling of these 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.

The STREAMWAY System is a wall-mounted fully automated system that disposes of 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 STREAMWAY System also provides an innovative way to dispose of ascites and pleural fluid with no evac bottles, suction canisters, transport, or risk of exposure. We also manufacture and sell two disposable products required for the operation of the STREAMWAY System: 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. The STREAMWAY disposables are a critical component of our business model. Recurring revenues from the sale of the disposables are expected to be significantly higher over time than the revenues from the initial sale of the unit. We have exclusive distribution rights to the disposable solution.

We sell our medical device products directly to hospitals and other medical facilities using employed sales representatives, independent contractors and distributors.

Our subsidiary, TumorGenesis, is pursuing 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. We have also 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).



## Competition and Competitive Advantages

*Precision Medicine Business.* We presently have the clinical information, including tumor drug response data and an in-house bioinformatics AI platform. Cancer treatments require at least 5 years of testing to see progression-free survival rates. While competitors must wait for this data, we can leverage that data today. Other companies within our market segment are spending significant investment dollars to generate this data which they cannot leverage until the future. We can leverage the data today by sequencing the tumors and gathering the outcome data which is measured in months instead of years. In addition, the following points detail the key differentiators in our model building approach.

- Models are built with real world data on how patient tumors responded to drugs, together with clinical outcome (progression-free survival/overall survival)
- We believe this patient-centric, highly standardized, and curated, multi-omic tumor model offers a better chance of generating serviceable predictive models of drug-response and outcomes than competitive approaches in the market today. The information embodied in the AI-driven predictive model provides insights into each tumor's response to different therapeutic options, resulting in the ability to provide actionable insights critical to both new drug development and individualizing patient treatment.

*Skyline Medical.* We further believe that the STREAMWAY System is unique to the industry in that it not only allows continuous suction but also provides for unlimited capacity, eliminating the need to interrupt a procedure to change canisters. To our knowledge, the STREAMWAY System is the only known fully automated direct-to-drain system that is wall-mounted and able to collect, measure, and dispose of an unlimited amount of waste fluid without interruption.

## Suppliers

We buy our raw materials from several suppliers and, except as set forth below, the loss of any one supplier would not materially adversely affect our business. We currently have a single supplier for certain materials and reagents that our Helomics subsidiary uses to perform its molecular diagnostic tests. While we have developed alternate sourcing strategies for these materials and vendors, we cannot be certain that these strategies will be effective or that the alternative sources will be available in a timely manner. If our current suppliers can no longer provide us with the materials it needs to perform molecular diagnostic tests, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, there could be an interruption in molecular diagnostic test processing. In the event of the loss of these suppliers, we could experience delays and interruptions that might adversely affect the financial performance of our business. We have existing and good relationships with our service vendors.

## Research and Development (“R&D”)

We spent \$422,964 and \$526,257 in 2019 and 2018, respectively, on R&D.

## 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 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 if a breach were to occur.

*Skyline Medical.* In general, our 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 that can be collected. We hold the following granted patents in the United States, and a pending application in the United States on our earlier STREAMWAY System models: US7469727, US8123731, and US Publication No. US20090216205 (collectively, the “Patents”). These Patents will begin to expire on August 8, 2023.

On January 25, 2014, we filed a non-provisional Patent Cooperation Treaty (“PCT”) Application No. PCT/US2014/013081 claiming priority from the U.S. Provisional Patent Application, number 61756763 which was filed on January 25, 2013. The 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. The United States Patent Office has assigned application #14/763,459 to our previously filed PCT application.

As of November 22, 2017, we were informed that the European Patent Office allowed all our claims for application #14743665.3-1651 and on as of July 11, 2018, we were 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 2014.

**Government Regulation**

Our businesses are subject to or impacted by extensive and frequently changing laws and regulations in the United States (at both the federal and state levels) and the other jurisdictions in which we conduct business, including some specific to our business, some specific to our industry, and others relating to conducting business generally (e.g., U.S. Foreign Corrupt Practices Act). We also are subject to inspections and audits by governmental agencies. The table below highlights key regulatory schemes applicable to our businesses:

<i>CLIA and State Clinical Laboratory Licensing</i>	<p>CLIA regulates the operations of virtually all clinical laboratories, requiring that they be certified by the federal government and that they comply with various technical, operational, personnel, and quality requirements intended to ensure that the services provided are accurate, reliable, and timely.</p> <p>State laws may require additional personnel qualifications or licenses, quality control, record maintenance, proficiency testing, or detailed review of our scientific method validations and technical procedures for certain tests.</p> <p>Violations of these laws and regulations may result in monetary fines, criminal and civil penalties and/or suspension or exclusion from participation in Medicare, Medicaid, and other federal or state healthcare programs.</p>
<i>Medicare and Medicaid; Fraud and Abuse</i>	<p>Diagnostic testing services provided under Medicare and Medicaid programs are subject to complex, evolving, stringent, and frequently ambiguous federal and state laws, and regulations, including those relating to billing, coverage, and reimbursement.</p> <p>Anti-kickback laws and regulations prohibit making payments or furnishing other benefits to influence the referral of tests billed to Medicare, Medicaid, or certain other federal or state healthcare programs.</p> <p>In addition, federal and state anti-self-referral laws generally prohibit Medicare and Medicaid payments for clinical tests referred by physicians who have an ownership or investment interest in, or a compensation arrangement with, the testing laboratory, unless specific exceptions are met.</p> <p>Federal substance abuse legislation enacted in 2018 contains anti-kickback provisions that are, by their terms, applicable to laboratory testing paid for by all payers. We are attempting to clarify the application of that legislation.</p> <p>Some states have similar laws that are not limited in applicability to only Medicare and Medicaid referrals and could also affect tests that are paid for by health plans and other non-governmental payers.</p> <p>Violations of these laws and regulations may result in monetary fines, criminal and civil penalties and/or suspension or exclusion from participation in Medicare, Medicaid, and other federal or state healthcare programs.</p>

<i>FDA</i>	The FDA has regulatory responsibility over, among other areas, instruments, software, test kits, reagents and other devices used by clinical laboratories to perform diagnostic testing in the United States.
<i>Environmental, Health and Safety</i>	<p>We are subject to laws and regulations related to the protection of the environment, the health and safety of employees, and the handling, transportation, and disposal of medical specimens, infectious and hazardous waste, radioactive materials, various aspects of pertinent technologies and methods of protection.</p> <p>Several organizations maintain oversight function including:</p> <ul style="list-style-type: none"> <li>• OSHA (Occupational Safety and Health Administration)</li> <li>• EPA (Environmental Protection Agency)</li> <li>• DOT (Department of Transportation)</li> <li>• USPS (US Postal Service)</li> <li>• US Public Health Service</li> <li>• JCAHO (Joint Commission on Accreditation of Healthcare Organizations)</li> <li>• NFPA (National Fire Protection Association)</li> <li>• AIA (American Institute of Architects)</li> <li>• AORN (Association of Operating Room Nurses)</li> </ul>
<i>Privacy and Security of Health and Personal Information</i>	<p>We are subject to laws and regulations regarding protecting the security and privacy of certain healthcare and personal information, including: (1) the federal Health Insurance Portability and Accountability Act and the regulations thereunder, which establish (a) a complex regulatory framework including requirements for safeguarding protected health information and (b) comprehensive federal standards regarding the uses and disclosures of protected health information; (2) state laws; and (3) the European Union's General Data Protection Regulation.</p> <p>A healthcare provider may be subject to penalties for non-compliance and may be required to notify individuals or state, federal, or county governments if the provider discovers certain breaches of personal information or protected health information.</p>

To date, no regulatory agency has established exclusive jurisdiction over the area of biohazardous and infectious waste in healthcare facilities.

***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.

We filed the 510(k) submission for clearance of the STREAMWAY 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.

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

### ***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 3<sup>rd</sup> edition certification for our STREAMWAY System is valid and enables us to continue to market and sell our product domestically and internationally.

We have contracted with TUV, a nationally recognized testing laboratory-NRTL, to certify our STREAMWAY System to the new 60601-1 3<sup>rd</sup> 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, we received a Medical Device Establishment License to sell the STREAMWAY System and related disposables in Canada.

### ***ISO Certification***

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

### **Employees**

We have 29 full-time employees and 3 part-time employees as of December 31, 2019.

### **Executive Offices**

Our principal executive offices are located at 2915 Commers Drive; Suite 900; Eagan, Minnesota 55121 and our telephone number is (651) 389-4800.

### **Corporate History**

We were originally incorporated on April 23, 2002 and reincorporated in Delaware in 2013. We changed our name from Skyline Medical, Inc. to Precision Therapeutics, Inc. on February 1, 2018 and to Predictive Oncology, Inc. on June 13, 2019.

### **Available Information**

Our website address is <http://www.predictive-oncology.com>. Information contained on our website is not incorporated by reference into this Annual Report on Form 10-K unless expressly noted.

We file reports with the Securities and Exchange Commission (“SEC”), which we make available on our website free of charge at <http://investors.predictive-oncology.com/financial-information>. These reports include Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, each of which is provided on our website as soon as reasonably practicable after we electronically file such materials with, or furnish them to, the SEC. We also make, or will make, available through our website other reports filed with or furnished to the SEC under the Securities Exchange Act of 1934, as amended, including our proxy statements and reports filed by officers and directors under Section 16(a) of that Act. You can also read and copy any materials we file with the SEC at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, DC 20549. You can obtain additional information about the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains a website (<http://www.sec.gov>) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

You can obtain copies of exhibits to our filings electronically at the SEC’s website at [www.sec.gov](http://www.sec.gov) or by mail from the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549 at prescribed rates. The exhibits are also available as part of the Annual Report on Form 10-K for the year ended December 31, 2019, which is available on our corporate website.

## 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. The risks described below are not the only ones that we may face. Additional risks that are not currently known to us or that we currently consider immaterial may also impair our business, financial condition or results of operations. 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.*

### **Risk Factors Relating to Our Business**

***We will require additional financing to finance operating expenses, repay our loan obligations and fulfill our business plan. Such financing, if available, will be dilutive.***

We have not achieved profitability and anticipate that we will continue to incur net losses at least through the remainder of 2020. We had cash of \$150,831 as of December 31, 2019 and will need to raise significant additional capital to meet our operating needs, support strategic investments, and pay debt obligations coming due.

As of December 31, 2019, we had outstanding debt, including accrued interest and penalties, totaling \$6,213,507, including secured convertible notes with remaining principal balances of \$1,989,104. Following certain extensions of some of our loans in 2020, we estimate that a total of \$7,733,281 in principal, interest and premiums will become payable on our debt between June and September 2020, unless portions of the debt are earlier converted or further extended. Any further extensions are likely to involve increases to the principal amounts and issuance of equity securities. Further, our accounts payable and accrued expenses as of December 31, 2019 were an aggregate \$5,397,274. Our inability to satisfy these liabilities would pose a significant risk to ongoing operations.

On October 24, 2019, we entered into an equity purchase agreement with Oasis Capital, LLC (“Oasis”) providing for a \$15,000,000 equity line. From time to time during the three-year commitment period, provided that the closing conditions are satisfied, we may provide Oasis with put notices to purchase a specified number of shares subject to certain limitations and conditions and at specified prices, which generally represent discounts to the market price of our common stock. During 2019, we issued 122,356 shares of common stock valued at \$319,196 pursuant to the equity line. As of December 31, 2019, there was \$14,680,805 remaining in available balance under the equity line. Additional needs to access this line will be dilutive.

We will require additional funding to finance operating expenses, invest in our sales organization and new product development, compete in the international marketplace, and develop the strategic assets of our Helomics businesses. 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.

We will attempt to raise these funds through equity or debt financing that may include public offerings, private placements, alternative offerings, further draws on the equity line, or other means. If we are successful in securing adequate funding, we plan to make significant capital or equipment investments, as well as 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. Further, if we are unable to generate adequate cash from operations, and if we are unable to find sources of funding, it may be necessary for us to sell one or more lines of business or all or a portion of our 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 our existing shareholders or that result in our existing shareholders losing part or all of their investment.

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 we will continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. 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. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources.”

***We may fail to prevent further defaults under the amended and restated secured note (the “L2 Note”) held by L2 Capital LLC (“L2”), which could result in material penalties and acceleration of the notes, and L2 could assert its rights as a secured creditor.***

Effective February 7, 2019, we entered into a forbearance agreement with L2. Under the forbearance agreement, we issued an aggregate of 11,667 shares to L2, and a total of \$242,386 was added to the principal amount of our indebtedness to L2. Interest on the L2 Note 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). As most recently extended, the L2 Note is due on June 28, 2020, and without a further default, the total amount payable would be \$2,420,220, including current principal, interest accruing through that date and premium payable upon repayment.

We believe that the default cure has been achieved. However, there can be no assurance that there will not be additional defaults under terms of the L2 Note. Upon a default, among other things, the L2 Note becomes immediately due and payable, we are 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 note plus default interest at 18%. Further, L2 has a security interest in substantially all of our assets. In the event of a default, we may attempt to refinance the payment of the balance of the L2 Note and applicable penalties; however, there is no assurance that such refinancing will be available. Therefore, defaults on the L2 Note would have a material adverse effect on our financial condition, including L2’s rights to seize our assets in the event we cannot satisfy our obligations under the note.

***Our ability to obtain and/or utilize financing to fund our ongoing operations may be limited by the terms of the L2 Note.***

Under two amendments, the maturity date of the L2 Note was extended from September 28, 2019 to December 31, 2019 and then extended again to March 31, 2020. In exchange for such extensions, the outstanding principal amount of the L2 Note was increased by a total of \$240,000, such that, as of the effective date of the second amendment, the outstanding principal amount owed under the L2 Note was \$1,989,104. Under the amendments, through March 31, 2020, L2 waived its rights under the L2 Note to have the L2 Note repaid from the proceeds of any financing consummated by us. In exchange for such waiver, we issued a total of 30,000 shares of common stock to L2.

After March 31, 2020, if we receive cash proceeds from any source other than (1) sales of our products or (2) the first \$2,000,000 of proceeds from securities offering transactions, we are required to inform L2 of such receipt. L2 will have the right to require that we apply up to 50% of such proceeds to repay outstanding amounts owed under the L2 Note. As a result, proceeds from future securities offering transactions will likely be subject to L2’s repayment right. The aforementioned criteria will negatively impact our ability to obtain financing from securities offering transactions until repayment or conversion of the L2 Note. To the extent we are able to obtain such financing, this arrangement will limit our ability to use the proceeds thereof to fund our operations. If we are unable to obtain financing or use the proceeds to fund our operations, we will be forced to limit our business activities, which will have a material adverse effect on our results of operations and financial condition.

***The recent coronavirus (COVID-19) outbreak could adversely affect our financial condition and results of operation.***

In December 2019, a novel strain of coronavirus (“COVID-19”) was reported to have surfaced in Wuhan, China and has since spread to other parts of the world. The impact of the outbreak of COVID-19 on the business is unknown. State and local authorities in the United States, like their counterparts in many other countries, have since forced many businesses to temporarily shut down in an attempt to slow the spread of the virus, and Americans are being told by public officials to practice “social distancing”. Global stock markets have reacted very negatively, and many economists are projecting a sharp economic slowdown, at least in the near term, even if governments take emergency relief measures. Regardless of the extent of any economic slowdown, the outbreak could impact our ability to develop business, conduct operations, and obtain components used in our business in any region that is significantly impacted by the outbreak. The situation is constantly evolving, however, so the extent to which the COVID-19 outbreak will impact business and the economy is highly uncertain and cannot be predicted. Accordingly, we cannot predict the extent to which our financial condition and results of operations will be affected.

***Our limited operating history with respect to our precision medicine services makes evaluation of our business difficult.***

Our precision medicine services were launched with the initial investment in Helomics during the first quarter of 2018 and have not generated significant revenue to date. Our ability to implement a successful business plan with respect to precision medicine 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. Our prospects should be considered 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:

- Succeed 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.

***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 capital and management resources to new businesses. In addition, in August 2017, we entered into a merger agreement with InventaBioTech Inc., formerly known as CytoBioscience, which was subsequently terminated in November 2017. From July 2017 through November 2017, we advanced \$1,070,000 to InventaBioTech in the form of secured notes, which are still outstanding. We have concluded that it is probable that we will be unable to collect all amounts due according to the contractual terms of the receivable, and we have a full allowance on the note receivable. It is possible 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 future advances will be repaid. 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 using cash will deplete our capital resources, meaning 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 our stockholders' investments. Further, the energy and resources of our officers and personnel may be substantially diverted to 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.

***We face significant competition in the surgical fluid waste management industry, 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.***

The surgical fluid waste management industry is highly competitive with numerous competitors ranging from well-established manufacturers to innovative start-ups. Several 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.

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 with our STREAMWAY System 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.

***If our STREAMWAY System 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 Skyline Medical's 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 healthcare 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 STREAMWAY System or molecular diagnostic tests is unexpectedly high or if we experience problems in scaling our operations, there is no assurance that there will not be supply interruptions or delays that could limit the growth of our revenue.***

We are currently manufacturing the STREAMWAY System, following GMP compliance regulations of the FDA, at our own facility and anticipate having 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 higher than anticipated, there is no assurance that we or our manufacturing partners will be able to produce the product in sufficiently higher quantity to satisfy demands.

Likewise, as demand for our molecular diagnostic tests grow, we will need to continue to scale our testing capacity and processing technology to expand our customer service, billing, and systems processes and to enhance our internal quality assurance program. We will also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our molecular diagnostic tests. We 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 an inability to meet demand. There can be no assurance that we will be able to perform our testing on a timely basis at a level consistent with demand, or that our efforts to scale our operations will not negatively affect the quality of test results.

If we encounter difficulties in scaling our operations as a result of, among other things, quality control and quality assurance issues and availability of reagents and raw material supplies, we would likely experience reduced sales, increased repair or re-engineering costs, defects, and increased expenses due to switching to alternate suppliers. Any of these results would reduce our revenues and gross margins. Although we attempt to match our capabilities to estimates of marketplace demand, to the extent demand materially varies from our estimates, we may experience constraints in our operations and delivery capacity, which could adversely impact revenue in a given fiscal period. Any supply interruptions or inadequate supply would have a material adverse effect on our results of operations.



If we encounter difficulty meeting market demand or quality standards our reputation could be harmed, and our future prospects and business could suffer, causing a material adverse effect on our business, financial condition, and results of operations.

***We rely on sole suppliers for some of the materials used in our molecular diagnostic tests, and we may not be able to find replacements or transition to alternative suppliers in a timely manner.***

We rely on sole suppliers for certain materials used to perform our molecular diagnostic tests. We also purchase reagents used in our molecular diagnostic tests from sole-source suppliers. While we have developed alternate sourcing strategies for these materials and vendors, we 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 us with the materials needed to perform our molecular diagnostic tests, if the materials do not meet required quality specifications, or if we cannot obtain acceptable substitute materials, an interruption in molecular diagnostic test processing could occur. Any such interruption may directly impact our revenue and cause us to incur higher costs.

***If we are sued for product liability or errors and omissions liability, we could face substantial liabilities that exceed our resources.***

The marketing, sale, and use of our 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. We may also be subject to liability for errors in the results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. A product liability or errors and omissions liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain product liability and errors and omissions insurance, we cannot be certain that our insurance would fully protect us 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 us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation or cause us to suspend sales of our products and solutions. The occurrence of any of these events could have a material adverse effect on our business, financial condition, and results of operations.

***If our R&D efforts for our TruTumor and AI platforms take longer than expected, the commercial revenues from the service offerings that use these platforms could also be delayed.***

Our CRO business offers various services to pharma, diagnostics, and biotech companies. These services use our TruTumor PDx tumor platform and our AI platform. These platforms are the subject of active R&D to further improve and validate them for commercial use in order to help our clients in their drug discovery, biomarker, and clinical trial activities. We could face delays in this R&D, for example:

- we may not be able to secure access to and approval to use clinical data from academic hospital partners required to validate the platform in a timely manner;
- clinical testing volume (number of specimens coming to us for testing) may not grow sufficiently to drive data generation 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 R&D; and
- we may not be able to attract and retain the appropriately qualified staff to perform the necessary R&D.

We have a limited operating history with the CRO business which makes it difficult to forecast our future revenues. While we are committed to the buildout of the CRO services for the long term, we cannot predict at this time, with any certainty, the future viability of either business unit.

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

Our business requires that we collect and store sensitive data, including credit card information and proprietary business and financial information. We face a number of risks relative to the protection of, and the service providers' protection of, this critical information, including loss of access, inappropriate disclosure, and inappropriate access, as well as risks associated with our ability to identify and audit such events. The secure processing, storage, maintenance, and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our 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 we have not experienced any such attack or breach, if such event would occur and cause interruptions in our operations, our networks could be compromised and the information we store on those networks could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Unauthorized access, loss, or dissemination could disrupt our operations, including collecting, processing, and preparing company financial information, managing the administrative aspects of our business, and damaging our reputation, any of which could adversely affect our 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 our practices. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems, and compliance procedures in a manner adverse to our business.

***If our information technology and communications systems fail or we experience a significant interruption in our operation, our reputation, business, and results of operations could be materially and adversely affected.***

The efficient operation of our business is dependent on information technology and communications systems. The failure of these systems to operate as anticipated could disrupt our business and result in decreased revenue and increased overhead costs. In addition, we do not have complete redundancy for all of our systems and our disaster recovery planning cannot account for all eventualities. Our 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, and power loss or failure of computer systems, Internet, telecommunications or data networks. If these systems or services become unavailable or suffer a security breach, we may expend significant resources to address these problems, and our reputation, business, and results of operations could be materially and adversely affected.

***We are dependent on a few key executive officers for our success. Our inability to retain those officers would impede our business plan and growth strategies, which would have a negative impact on our business and the value of an investment.***

Our success depends on the skills, experience, and performance of key members of our management team. We heavily depend on our management team: Carl Schwartz, our Chief Executive Officer ("CEO"), and Bob Myers, our Chief Financial Officer ("CFO"). We have entered into employment agreements with the CEO and the CFO and may expand the relatively small number of executives. Were we to lose one or more of these key individuals, we would be forced to expend significant time and money in the pursuit of a replacement, which could result in both a delay in the implementation of our business plan and the diversion of our limited working capital. We can give no assurance that we would be able to find satisfactory replacements for these key individuals at all, or on terms that are not unduly expensive or burdensome to us.

***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 business, financial condition, and results of operations could be materially and adversely affected.

***Our 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 our 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 that 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 stock immediately before the ownership change.

***If we are required to further write down goodwill and other intangible assets, our financial condition and operating results would be negatively affected.***

When we acquire a business, a substantial portion of the purchase price of the acquisition is allocated to goodwill and other identifiable intangible assets. The amount of the purchase price which is allocated to goodwill and other intangible assets is determined by the excess of the purchase price over the net identifiable assets acquired. For example, when we acquired Helomics, we acquired \$3,725,000 in intangible assets and \$23,790,290 in goodwill, which represented the excess of the consideration transferred over the fair values of assets acquired and liabilities assumed and represents the future economic benefits arising from other assets acquired that could not be individually identified and separately recognized. We test intangible assets and goodwill for impairment at least annually. During the twelve months ended December 31, 2019, we recorded an impairment of goodwill of \$8,100,000. We also recorded an impairment of our intangible asset associated with our license agreements of \$770,250. Under current accounting standards, if we determine that intangible assets or goodwill are impaired in the future, we will be required to further write down these assets. Any write-downs that may be required to be recorded would adversely affect our financial condition and operating results.

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

We intend to make strategic acquisitions in the future. However, we may not be able to identify suitable acquisition opportunities, or we may be unable to obtain the consent of our stockholders and therefore, may not be able to complete such acquisitions. We may pay for acquisitions with our common stock or with convertible securities, which may dilute shareholders’ investment in our common stock, or we may decide to pursue acquisitions that our investors may not agree with. In connection with potential acquisitions, we may agree to substantial earn-out arrangements. To the extent we defer the payment of the purchase price for any acquisition through a cash earn-out arrangement, cash flows will be reduced in subsequent periods. In addition, acquisitions may expose us 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 our 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 we may need to assimilate widely dispersed operations with different corporate cultures. In addition, acquired companies may have liabilities that we failed to or were unable to discover in the course of performing due diligence investigations. We 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 we assume upon consummation of an acquisition. We may learn additional information about our acquired businesses that could have a material adverse effect on us, 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 our business. Failure to successfully manage the operational challenges and risks associated with, or resulting from, acquisitions could adversely affect our 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 our ability to service our debt within the scheduled repayment terms.

***We may fail to realize the anticipated benefits of the Helomics merger.***

The success of the Helomics merger will depend, in part, on our ability to realize the anticipated growth opportunities and synergies from combining our companies, Predictive and Helomics. The integration will be a time consuming and expensive process and may disrupt our operations if it is not completed in a timely and efficient manner. In addition, we may not achieve anticipated synergies or other benefits of the merger. Following the merger, we operate as a combined organization utilizing common information and communication systems, operating procedures, financial controls, and human resources practices. We 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 our services;
- difficulties in successfully integrating our management teams and employees;
- challenges encountered in managing larger operations;
- losses of key employees;
- failure to manage our growth and growth strategies;
- 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 our operations after the merger do not meet the expectations of our existing or prospective customers, then these customers and prospective customers may cease doing business with us altogether, which would harm our 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, we may not realize the anticipated benefits of the merger.

**Risks Related to Our Intellectual Property**

***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, contractual restrictions, and other 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.

If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. While we apply for patents covering our products and technologies and uses thereof, we may fail to apply for patents on important products and technologies in a timely fashion, or at all, or we may fail to apply for patents in relevant jurisdictions. Others could seek to design around our current or future patented technologies. 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.

Further, competitors could willfully infringe upon our intellectual property rights, design around our protected technology, or develop their own competitive technologies that arguably fall outside of our intellectual property rights. Others may independently develop similar or alternative products and technologies or replicate any of our products and technologies. 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 our intellectual property does not adequately protect us against competitors' products and methods, our competitive position could be adversely affected, as could our business and the results of our operations. To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of competition. If our intellectual property does not provide adequate coverage of our competitors' products, our competitive position could be adversely affected, as could our overall business.

***If we become subject to intellectual property actions, it 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. Litigation may be necessary for us to enforce our 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 us, and we might not be able to obtain licenses to technology that we require on acceptable terms, or at all. 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. 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 our business, financial condition, and operating results.

### **Risk Factors Relating to Regulation**

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

The production, marketing, and R&D 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 governs 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.

***Costs incurred because we are a public company may affect our profitability.***

As a public company, we incur significant legal, accounting, and other expenses and are subject to the SEC's rules and regulations relating to public disclosure that generally involve a substantial expenditure of financial resources. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC, require 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 our financial results. To the extent our earnings suffer as a result of the financial impact of our SEC reporting or compliance costs, our ability to develop an active trading market for our securities could be harmed.

***If the FDA begins to enforce regulation of our molecular diagnostic tests, we 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 our 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. As of the date of this filing, the FDA has not issued its final guidance. How the final guidance would affect our business is not yet known. We cannot provide any assurance that the FDA regulation will not be required in the future for our 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 us to continue to offer our molecular diagnostic tests or to develop and introduce new tests. We cannot predict the timing or content of future legislation enacted, regulations promulgated, or guidance issued regarding LDTs, or how it will affect our business.

If pre-market review is required by the FDA or if we decide to voluntarily pursue the FDA's pre-market review of our tests, there can be no assurance that our molecular diagnostic tests or any tests we 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 our current claims or adequate to support continued adoption of and reimbursement for our tests. If pre-market review is required, our 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 we are required to submit applications for our currently marketed tests, we may be required to conduct additional studies, which may be time-consuming and costly and could result in our currently marketed tests being withdrawn from the market. If our tests are allowed to remain on the market, but there is uncertainty in the marketplace about our tests, and if we are required by the FDA to label them investigational, or if labeling claims the FDA allows us 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 our business, and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements. We cannot predict the timing or form of any such guidance or regulation, or the potential effect on our existing molecular diagnostic tests or our tests in development, or the potential impact of such guidance or regulation on our business, financial condition, and results of operations.

***If we fail to comply with Federal, State, and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.***

We are subject to 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 our business to be eligible to bill Federal and State healthcare programs, as well as many private third-party payors, for our molecular diagnostic tests. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories. Pennsylvania laws also require that we maintain a license and establish standards for the day-to-day operation of our clinical reference laboratory in Pittsburgh, Pennsylvania. In addition, our Pittsburgh laboratory is required to be licensed on a test-specific basis by certain other states. If we were unable to obtain or lose our CLIA certificate or State licenses for our laboratories, whether as a result of revocation, suspension, or limitation, we would no longer be able to perform our molecular diagnostic tests, which could have a material adverse effect on our business, financial condition, and results of operations. If we were to lose our licenses issued by the States in which we are required to hold licenses, we would not be able to test specimens from those States. New molecular diagnostic tests we may develop may be subject to new approvals by governmental bodies, and we may not be able to offer our new molecular diagnostic tests to patients in such jurisdictions until such approvals are received.

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

We are subject to regulation by both the Federal government and the States in which we conduct our 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;
- 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 (“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.

We have implemented policies and procedures designed to comply with these laws and regulations. We periodically conduct internal reviews of our compliance with these laws. Our compliance is also subject to governmental review. The growth of our business may increase the potential of violating these laws, regulations, or our internal policies and procedures. The risk that we are 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 us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert managements' attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to civil and criminal penalties, damages, and fines, we could be required to refund payments received by it, we could face possible exclusion from Medicare, Medicaid and other Federal or State healthcare programs, and we could even be required to cease operations. Any of the foregoing consequences could have a material adverse effect on our business, financial condition, and results of operations.

***If we use hazardous materials in a manner that causes contamination or injury, we could be liable for resulting damages.***

We are subject to Federal, State, and local laws, rules and regulations governing the use, discharge, storage, handling, and disposal of biological material, chemicals, and waste. We 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, we could be held liable for any resulting damages, remediation costs, and any related penalties or fines. This liability could exceed our resources or any applicable insurance coverage we may have. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could have a significant impact on our operating results.

***The healthcare regulatory and political framework is uncertain and evolving.***

Healthcare laws and regulations are rapidly evolving and may change significantly in the future, which could adversely affect our financial condition and results of operations. For example, in March 2010, the Patient Protection and Affordable Care Act, ("ACA"), was adopted, which is a healthcare reform measure that provided healthcare insurance for approximately 30 million additional Americans. The ACA includes a variety of healthcare reform provisions and requirements that became effective at varying times through 2018 and substantially changed the way healthcare is financed by both governmental and private insurers, which may significantly impact our industry and our business. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are also invalid. While the Trump Administration and the Center for Medicare and Medicaid Services have both stated that the ruling will have no immediate effect, the U.S. Court of Appeals for the Fifth Circuit on December 18, 2019 ruled in a 2-1 decision that the individual mandate is unconstitutional, but did not invalidate the entire ACA. Several state attorneys general and the U.S. House of Representatives, which intervened in the case, subsequently asked the Supreme Court to hear the case, and on March 2, 2020, the Supreme Court agreed. The Supreme Court did not say when it will hear the case, but is likely to do so in the fall of 2020, with a decision to follow in the spring or summer of 2021. At this time, it is unclear how the Supreme Court's decision, subsequent proceedings, if any, and other efforts to repeal and replace the ACA will impact the ACA and our business.



The ACA 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 our relationship with our clients, we 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, we 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 the ACA, 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.

There is significant uncertainty about the future of the ACA in particular and healthcare laws in general in the United States. We are monitoring how any proposed changes could affect our business. We are unable to predict the likelihood of changes to the ACA. Depending on the nature of any repeal and replacement of the ACA, such actions could have a material adverse effect on our business, cash flow, results of operations, financial position, and prospects.

#### **Risks Related to the Securities Markets and Ownership of Our Common Stock**

***Our certificate of incorporation, as amended, provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the exclusive forum for certain legal actions between us and our stockholders, which could limit our stockholders’ ability to obtain a judicial forum viewed by the stockholders as more favorable for disputes with us or our directors, officers, or employees.***

Our certificate of incorporation, as amended, provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of the corporation, (2) any action asserting a claim of breach of a fiduciary duty owed by any director or officer of the corporation to the corporation or the corporation’s stockholders, (3) any action asserting a claim against the corporation arising pursuant to any provision of the General Corporation Law or the corporation’s Certificate of Incorporation or Bylaws, or (4) any action asserting a claim against the corporation governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, as amended, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rule and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These exclusive-forum provisions may limit a stockholder’s ability to bring a claim in a judicial forum of their choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees.

If a court were to find the choice of forum provision contained in our certificate of incorporation, as amended, to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

***Limitations on director and officer liability and indemnification of our officers and directors by us may discourage stockholders from bringing a 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, knowing violation of law, or unlawful payments of dividends. These provisions may discourage stockholders from bringing a 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 our 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 our common stock.

***Shares eligible for future sale may adversely affect the market.***

From time to time, certain stockholders may be eligible to sell some or all of their shares of common stock pursuant to Rule 144, promulgated under the Securities Act subject to certain limitations. In general, pursuant to Rule 144 as in effect as of the date of this filing, 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.***

The market for our common stock may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will be more volatile than a seasoned issuer for the indefinite future. In the past, plaintiffs have often initiated securities class action litigation against companies following periods of volatility in the market price of their 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, 2,300,000 shares have been designated as series B convertible preferred stock, 3,500,000 shares have been designated as series D convertible preferred stock, 350 shares have been designated as Series E convertible stock and the remaining authorized shares are undesignated preferred stock. Our Board of Directors has the power to issue any or all of the shares of undesignated preferred stock, including the authority to establish one or more series and to fix the powers, preferences, rights, and limitations of such class or series, without seeking stockholder approval. Further, as a Delaware corporation, we are subject to provisions of the Delaware General Corporation Law regarding business combinations. We may, in the future, consider adopting additional anti-takeover measures. The authority of our Board of Directors to issue undesignated stock and the anti-takeover provisions of Delaware law, as well as any future anti-takeover measures adopted by us, may, in certain circumstances, delay, deter, or prevent takeover attempts and other changes in control 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 exercised, further dilution will occur.

***Completion of the merger with Helomics on April 4, 2019, and the exchange offer resulted in the issuance of a large number of our shares and warrants, which significantly diluted and will significantly further dilute the percentage of stock held by existing holders of our common stock.***

On the effective date of the Helomics merger, we issued 400,000 shares of our common stock and 3,500,000 shares of series D preferred stock to holders of Helomics capital stock. This issuance is in addition to the 110,000 shares of our common stock previously issued to Helomics as consideration for the prior investment of a twenty percent ownership interest in Helomics; these 110,000 shares remained outstanding and were distributed to holders of Helomics capital stock. Each share of our series D preferred stock is convertible on a 10:1 basis of our common stock starting one year after issuance, subject to adjustment. Ultimately, we issued such holders of certain promissory notes of Helomics that were issued to investors (the "Helomics Notes Payable") and accompanying warrants : (1) 863,732 shares of our common stock, (2) 1,424,506 warrants to purchase shares of our common stock at an exercise price of \$10.00 per share and (3) 59,700 warrants to purchase shares of our common stock at an exercise price of \$0.10 per share. Conversion of the series D preferred stock and exercise of such warrants will further dilute the percentage of stock held by existing holders of our common stock.

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

Not applicable.

## **ITEM 2. PROPERTIES.**

Our corporate offices are located in Eagan, Minnesota. The lease as amended has a three-year term 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.

Skyline Medical Europe's offices are located in Belgium. We lease approximately 2,000 square feet at this location, 750 square feet of which is used for storage and 1,250 square feet for office space. The lease is effective through June 14, 2027.

The offices of our Helomics subsidiary are located in Pittsburgh, Pennsylvania. The lease, as amended, has a three-year term ending February 28, 2021. We lease 17,417 square feet at this location, of which approximately 1,000 square feet are used for office space and 16,417 square feet is used for laboratory operations.

We expect that the current space will be adequate for our current office and laboratory 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 STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

### **Market Information**

Effective June 13, 2019, our common stock was listed on the NASDAQ Capital Market under the symbol "POAI". Prior to this, effective February 2, 2018, our common stock was listed on the NASDAQ Capital Market under the symbol "AIPT". Prior to February 2, 2018 our common stock was listed on The NASDAQ Capital Market under the symbol "SKLN".

### **Holders**

As of March 27, 2020, there were approximately 141 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 12 below.

### **Recent Sales of Unregistered Securities**

The following is a summary of our transactions during 2019 involving sales of our securities that were not registered under the Securities Act:

In June 2019, we entered into a private placement securities purchase agreement with certain accredited investors for shares of series E convertible preferred stock. We issued 258 preferred shares. Each preferred share holder has the right to be converted into 0.056857% of the issued and outstanding shares of common stock immediately prior to conversion for each share of series E convertible preferred stock beginning six months after the initial close date of June 13, 2019. On June 13, 2020, we have the option to convert the preferred shares into common stock. The offering closed in September 2019, and Dawson James Securities, Inc. acted as the Placement Agent. The Company paid Dawson a commission of 8% of the gross proceeds and warrants that are convertible into common stock on a cashless basis based on 5% warrant coverage. The Company also reimbursed Dawson for legal fees equal to \$25,000 plus \$4,000 per closing, plus other reasonable out-of-pocket expenses under \$5,000 in the aggregate.

On September 27, 2019, the due date of the bridge loan was extended from September 28, 2019 to December 31, 2019. In exchange for the extension, the principal balance of the loan was increased by \$120,000 and we issued 15,000 shares to the investor.

On October 24, 2019, we entered into an equity purchase agreement with an investor, providing for an equity financing facility. Upon the terms and subject to the conditions in the purchase agreement, the investor is committed to purchase shares having an aggregate value of up to \$15,000,000 of our common stock for a period of up to three years. We issued to the investor 104,651 commitment shares for entering into the agreement. From the date of the agreement through December 31, 2019, we issued an aggregate 122,356 shares of common stock valued at \$319,196. From January 1, 2020 through March 12, 2020, we issued an aggregate 943,000 shares of common stock valued at \$1,869,899.

On November 12, 2019, we issued 10,356 shares of common stock valued at \$34,923 in payment for investor relations services and other.

On December 12, 2019, the due date of the bridge loan was extended from December 31, 2019 to March 31, 2020. In exchange for the extension, the principal balance of the loan was increased by \$120,000 and we issued 15,000 shares to the investor.

Unless otherwise specified above, we believe 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, many of which are beyond our control. 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:

- We may not be able to continue operating without additional financing;
- 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 2019 merger with Helomics including; 1) significant goodwill could result in further impairment; 2) possible failure to realize anticipated benefits of the merger; 3) costs associated with the merger may be higher than expected; 4) the merger may result in the disruption of our existing businesses; and 5) distraction of management and diversion of resources;
- 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;
- Risks related to the transaction with Quantitative Medicine including: 1) completion of the transaction; 2) possible failure to realize anticipated benefits of the merger; 3) costs associated with the merger may be higher than expected; 4) the merger may result in the disruption of our existing businesses; and 5) distraction of management and diversion of resources;
- Risk that we will be unable to complete the transaction with InventaBio Tech;
- 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;
- Acquisition and maintenance of any necessary regulatory clearances applicable to applications of our 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 our 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. We do 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 we believe that our plans, intentions, and expectations reflected in or suggested by the forward-looking statements in this report are reasonable, we cannot assure potential investors that these plans, intentions or expectations will be achieved. We disclose important factors that could cause actual results to differ materially from expectations in the “Risk Factors” section and elsewhere in this report. These cautionary statements qualify all forward-looking statements attributable to us or persons acting on our behalf.

Information regarding market and industry statistics contained in this report is included based on information available to us that we believe is accurate. It is generally based on academic and other publications that are not produced for purposes of securities offerings or economic analysis. We have not reviewed or included data from all sources, and we 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. We have no obligation to update forward-looking information to reflect actual results or changes in assumptions or other factors that could affect those statements.

## Overview

We operate in two primary business areas: first, application of artificial intelligence (“AI”) in our precision medicine business, to provide AI-driven predictive models of tumor drug response to improve clinical outcomes for patients and to assist pharmaceutical, diagnostic, and biotech industries in the development of new personalized drugs and diagnostics; and second, production of the United States Food and Drug Administration (“FDA”)-cleared STREAMWAY® System for automated, direct-to-drain medical fluid disposal and associated products.

We have three operating segments: domestic, international, and Helomics. Domestic and international consist of the STREAMWAY System product sales. The Helomics segment consists of clinical testing and contract research. Our CRO services business is committed to improving the effectiveness of cancer therapy using the power of AI applied to rich data diseases databases. Our operations in this segment expanded greatly in April 2019 with the acquisition of Helomics in a merger transaction that resulted in a significant issuance of equity securities and has greatly increased our capital needs. We have identified the CRO market as a burgeoning sector with significant growth potential. We also expect increased capital needs for our TumorGenesis subsidiary, which we formed to pursue a new rapid approach to growing tumors in the laboratory for precision cancer therapy and drug development. Going forward, we have determined that we will focus our resources on the Helomics segment and our primary mission of applying AI to precision medicine and drug discovery.

## **Merger Transaction with Helomics**

Effective April 4, 2019, we completed the merger with Helomics and, as of then, owned 100% of Helomics. The merger resulted in a significant issuance of equity securities and has greatly increased our capital needs. On the effective date of the Helomics merger, we issued to holders of Helomics capital stock (i) 400,000 shares of our common stock and (ii) 3,500,000 shares of series D preferred stock, which on April 4, 2020 will generally convert (subject to certain restrictions) into an aggregate 350,000 shares of common stock (a current exchange ratio of 1:10). Previously, we had issued 110,000 shares of our common stock to Helomics as consideration for the prior investment of a twenty percent ownership interest in Helomics; these 110,000 shares remained outstanding and were distributed to holders of Helomics capital stock. On the closing date of the merger, we also issued the following securities in exchange for certain promissory notes and warrants of Helomics: (1) 863,732 shares of our common stock, (2) 1,424,506 warrants to purchase common stock at an exercise price of \$10.00 per share and (3) 59,700 warrants to purchase common stock at an exercise price of \$0.10 per share. Conversion of the series D preferred stock and exercise of such warrants will further dilute the percentage of stock held by existing holders of our common stock.

## **Capital Requirements**

Since inception, we have been unprofitable. We incurred net losses of \$19,390,766 and \$10,086,477 for the years ended December 31, 2019, and December 31, 2018, respectively. As of December 31, 2019, and December 31, 2018, we had an accumulated deficit of \$82,498,711 and \$63,107,945, respectively.

We have never generated sufficient revenues to fund our capital requirements. From 2009 through 2018, we built the Skyline Medical business and sold a total of 41 STREAMWAY System during 2019, building a national sales network and international sales. However, the Skyline Medical business has never reached profitability. In 2017, we determined to diversify our business by investing in ventures in the precision medicine business, including making significant loans and investments in early stage companies. These activities led to the acquisition of Helomics in April 2019, which has accelerated our capital needs further. 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 generate revenues from our Helomics segment; to continue to sell our Skyline Medical products and attempt to reach profitability in the Skyline Medical business and the availability of future financing to fulfill our business plans. See “Plan of Financing; Going Concern Qualification” below.

Our limited history of operations, especially in our precision medicine business, and our change in the emphasis of our business, 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, 2019 with Year Ended December 31, 2018

	2019	2018	Difference
Revenue	\$ 1,411,565	\$ 1,411,655	\$ (90)
Cost of goods sold	531,810	415,764	116,046
General and administrative expense	9,781,218	4,626,997	5,154,221
Operations expense	2,960,131	1,861,121	1,099,010
Sales and marketing expense	1,912,899	2,369,152	(456,253)

*Revenue.* We recorded revenue of \$1,411,565 in 2019, compared to \$1,411,655 in 2018. All revenue was derived from the Skyline Medical business except for \$48,447 in Helomics revenues in 2019. We sold 41 STREAMWAY System units in each of 2019 and 2018.

*Cost of sales.* Cost of sales was \$531,810 and \$415,764 in 2019 and 2018, respectively. The gross profit margin was 62% in 2019 compared to 71% in 2018. Our margins decreased 2019 primarily due to Helomics costs surpassing the revenue earned in the same period. Exclusive of Helomics, cost of sales related to sales in the Skyline Medical business in 2019 was comparable to 2018.

*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 by \$5,154,221 to \$9,781,218 in 2019 from \$4,626,997 in 2018. The increase is primarily due to a combination of initial costs of the Helomics merger and increased expenses of the combined company due to increase in the size of operations. As a result, salaries, taxes and benefits, rent and depreciation and amortization all increased substantially. There were also additional legal and audit expenditures related to the merger. Additionally, we issued all employees and directors stock options upon completion of the Helomics merger, resulting in increased vesting expenses. We also recognized a one-time credit loss of \$1,037,524 in 2019 on notes receivable from CytoBioscience which resulted from loans we made to CytoBioscience in 2017 in anticipation of a potential acquisition that was not completed.

*Operations expense.* Operations expense primarily consists of expenses related to product development and prototyping and testing in our current stage.

Operations expense increased by \$1,099,010 to \$2,960,131 in 2019 compared to \$1,861,121 in 2018. The increase in operations expense in 2019 was primarily due to higher payroll costs and employee stock option vesting expenses.

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

Sales and marketing expenses decreased by \$456,253 to \$1,912,899 in 2019 compared to \$2,369,152 in 2018. Such expenses related almost exclusively to the Skyline Medical business. The decrease in 2019 was a direct result of the strategic decision focus on the precision medicine business and reduce the emphasis on expenditures in the Skyline Medical business. These factors decreased our expenses for web development, public relations, and market research as well as decreases in travel and bonus expense for sales staff.

*Impact of minority investment on net loss.* The net loss for 2019 includes a loss on equity method investment of \$439,637 compared to \$2,293,580 in 2018. The 2019 loss represented a portion of Helomics’ net loss from continuing operations of \$1,555,542 prior to the merger on April 4, 2019 and resulted from our ownership of 25% of Helomics’ capital stock before the merger. This net loss was offset by the gain of \$6,164,260 on revaluation upon the initial acquisition of Helomics. Commencing with the merger effective April 4, 2019, we own 100% of the Helomics business, which is included in the consolidated financial statements.

*Loss on goodwill and intangible impairment.* We incurred impairment charges of \$8,100,000 and \$770,250 on goodwill and intangibles, respectively during 2019. No impairment charges were incurred during 2018.

Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the fair value of net assets acquired in the Helomics acquisition and represents the future economic benefits that we expect to achieve as a result of the acquisition that are not individually identified and separately recognized. Goodwill is tested for impairment annually at the reporting unit level, or whenever events or circumstances present an indication of impairment. The primary items that generate goodwill include the value of the synergies between the acquired company and the Company and the acquired assembled workforce, neither of which qualifies for recognition as an intangible asset.

Based upon our annual goodwill impairment test, we concluded that goodwill was impaired as of the testing date. Pursuant to Accounting Standards Update No. 2017-04, *Simplifying the Test for Goodwill Impairment*, the single step is to determine the estimated fair value of our reporting unit and compare it to the carrying value of the reporting unit, including goodwill. To the extent the carrying amount of goodwill exceeds the implied goodwill, the difference is the amount of the goodwill impairment. Our annual impairment test as of December 31, 2019 resulted in \$8,100,000 of impairment charges related to our goodwill. Please see Note 1 to our audited financial statements included in this annual report for further information. Our goodwill at December 31, 2019 following the impairment was \$15,690,290. We will continue to monitor our reporting unit in an effort to determine whether events and circumstances warrant further impairment testing which may include interim periods.

*Other income.* We earned other income of \$287,056 in 2019 compared to \$510,254 in 2018. Other income was comprised of unrealized gains related to the derivative liability incurred from the warrants on the bridge loan and interest and dividend income.

*Other expense.* We incurred other expenses of \$3,979,946 in 2019 compared to \$441,772 in 2018. Other expenses consisted primarily of interest expense, payment penalties, amortization of original issue discounts, and loss on debt extinguishment related to our notes payable.

## **Liquidity and Capital Resources**

### **Cash Flows**

Net cash used in operating activities was \$8,732,451 in 2019, compared with net cash used of \$5,287,956 in 2018. Cash used in operating activities increased in 2019 primarily because of the increase in total operating expenses primarily due to additional costs related to the newly acquired Helomics business, which was partially offset by increased accounts payables and accrued expenses due to extending payment terms with vendors.

Cash flows used in investing activities were \$599,087 in 2019 and \$1,110,651 in 2018. Cash flows used in investing activities in 2019 were primarily for loans made to Helomics, partially offset by cash received from Helomics on the acquisition date. Cash flows used in investing activities in 2018 were primarily for notes receivable pertaining to the secured loan to Helomics.

Net cash provided by financing activities was \$9,320,217 in 2019 compared to net cash provided of \$5,794,570 in 2018. Cash flows provided by financing activities in 2019 were primarily due to proceeds from debt issuance of \$2,690,000, including \$1,920,000 from our CEO, proceeds from the issuance of preferred stock due to a private placement of \$2,338,840, and proceeds of common stock issuances of \$5,323,018. In 2018, we received \$650,061 due to the exercise of warrants issued from previous financings, \$2,185,000 from debt issuance due to the sale of convertible notes to two investors netting us \$1,815,000 and a loan from our CEO for \$370,000 and net proceeds of \$2,755,087 from a public stock offering.

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

Since our inception, we have incurred significant losses, and our accumulated deficit was \$82,498,711 as of December 31, 2019. We have committed significant capital and management resources to develop our CRO business and other new business areas and intend to continue to devote significant resources to the Helomics business and other new businesses in this market. To fund this, we have significantly decreased our salary and benefits expenses, particularly in our Skyline Medical business unit, through reductions in personnel and other measures. We continue to focus on reducing expenses. Our businesses will need to generate significantly more revenue to sufficiently fund our operations without external financing. Our operations from inception have been funded with private placements of convertible debt securities and equity securities, public offerings, and loan agreements. We have not achieved profitability and anticipate that we will continue to incur net losses at least through the remainder of 2020. We had revenues of \$1,411,565 and \$1,411,655 in 2019 and 2018, respectively, but we had negative operating cash flows of \$8,732,451 and \$5,287,956 in 2019 and 2018, respectively. Our cash balance was \$150,831 as of December 31, 2019, and our accounts payable and accrued expenses were an aggregate \$5,527,274. Additionally, all amounts payable related to outstanding debt agreements are all due within one year. We have raised capital in the following transactions since January 1, 2018:

*2018.* In January 2018, we received \$2,755,087 net proceeds from a firm commitment underwritten public offering. We sold secured convertible notes to two investors in September 2018 netting \$1,815,000 in cash proceeds. We borrowed \$370,000 from our CEO in November 2018.

*2019.* In February 2019, we received loans for \$1,250,000 from our CEO. On March 1, 2019 we closed on a public offering receiving \$1,111,880 in net proceeds. On March 29, 2019 we closed on a public offering receiving \$1,053,360 in net proceeds. In June through September 2019 we raised \$2,338,840 in net proceeds from a private placement of convertible preferred stock. In September 2019, we received \$700,000 in proceeds of debt financing from a private investor. In October 2019, we raised \$2,811,309 in net proceeds from a public offering of our common stock. In October 2019, we entered into an equity purchase agreement with an investor, providing for an “equity line” financing facility. Upon the terms and subject to the conditions in the purchase agreement, upon demands by the Company subject to certain limitations, the investor is committed to purchase common stock having an aggregate value of up to \$15,000,000 for a period of up to three years.

2020. In February 2020, we received loans for \$1,450,000 from the sale of a secured promissory note to a private investor. In March 2020, we received gross proceeds of \$3,500,000 from the sale of common stock, common stock equivalents and warrants.

As a result of the March 2020 extensions of the secured investor notes and the January 2020 restructuring of the notes issued to Carl Schwartz described under “Financing Transactions” below, the following are the mandatory repayment dates of our indebtedness (unless portions of certain notes are earlier converted or unless notes are further extended) (amounts shown include assumed interest accruing through the due date): (1) secured notes due on June 28, 2020, with a total amount payable on that date of \$3,608,089 (including current principal and assumed interest), (2) a secured note due on August 5, 2020 with a total amount payable on that date of \$1,819,668, (including current principal, assumed interest and a 20% premium payable upon repayment) and (3) notes due on September 30, 2020 with a total amount payable on that date of \$2,305,524 (including current principal and assumed interest).

As a result of our capital needs for operations and debt repayment, we need to raise significant capital. There is no assurance that we will be successful in raising sufficient capital. 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 in addition to payment of cash, which may have the result of diluting the investment of our stockholders.

We will attempt to raise these funds through equity or debt financing. We will attempt to raise funds from other sources that may include public offerings, private placements, 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 in Helomics. 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 we 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 2018 Public Offering of Common Stock and Warrants*

In January 2018, we completed a firm commitment underwritten public offering of 290,000 units at an offering price of \$9.50 per unit, with each unit consisting of one share of our common stock and 0.3 of a warrant, with each whole warrant purchasing ten shares of common stock at an exercise price of \$10.00 per whole share. The shares of common stock and warrants were immediately separable and were issued separately. Gross proceeds were \$2,755,087, before deducting expenses. On February 21, 2018, the underwriter exercised on 21,525 shares of common stock, par value \$0.01, at \$9.5 per share. We 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 related to this exercise.

#### *September 2018 Senior Secured Promissory Notes*

On September 28, 2018, we 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”). Pursuant to the agreements, we issued a convertible promissory note to each of the Investors in the original principal amount of an aggregate \$2,297,728 in exchange for cash proceeds of \$2,000,000, less commissions, with net proceeds of \$1,815,000. Pursuant to a security agreement between us and each of the Investors, we have granted to each of the Investors a security interest in our assets to secure repayment of the notes. We loaned one-half of the net proceeds to Helomics.

As additional consideration for the loan, we issued an aggregate 65,000 shares of our common stock to the Investors or their affiliates plus warrants to acquire up to an aggregate 107,178 shares of our common stock at an exercise price of \$11.55 per share. Upon the closing of the second tranche loan, the Warrants would be increased to cover an aggregate total of 133,681 shares. Each Warrant is exercisable by the Investor beginning on the sixth month anniversary of the Effective Date through the fifth-year anniversary thereof.

Effective September 27, 2019, the bridge loan of one investor was paid in full. Also, effective September 27, 2019, the due date of the bridge loan of the other investor was extended to December 31, 2019 in exchange for \$120,000 increase in the principal balance and 15,000 shares of common stock. Effective December 12, 2019, the due date of the remaining bridge loan was extended to March 31, 2020 in exchange for \$120,000 increase in principal balance and 15,000 shares of common stock.

The bridge loan accrues interest at a rate of 8% per annum. Upon the earlier to occur of an event of default 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 bridge loan into shares of common stock at a conversion factor that is the lesser of a discounted 20-day average price or a set price floor. 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 267,833 shares.

#### *Loans by Carl Schwartz*

In November 2018, Dr. Schwartz made a loan to us with a principal balance of \$370,000. As of December 31, 2018, one promissory note was held with a principal balance of \$370,000 and an unamortized discount of \$63,028. From November 30, 2018 through July 15, 2019, Dr. Schwartz made numerous loans to us in the total amount of \$1,920,000 under two promissory notes. As consideration for these amounts, Dr. Schwartz received promissory notes and warrants to purchase 22,129 shares of our common stock at \$8.36 per share. Further, beginning on February 1, 2019 and the first day of each calendar month thereafter while the note remained outstanding, a number of additional warrants were issued.

As of January 2020, we were in default under one of the notes which was due on December 31, 2019 and determined that we would not be able to pay remaining outstanding note when it became due on February 8, 2020. During January 2020, we entered into an exchange agreement with our CEO, Dr. Schwartz. Under the exchange agreement, the two outstanding promissory notes due to Dr. Schwartz totaling \$1,935,000 were cancelled and in exchange a new promissory note was issued in the amount of \$2,115,000 bearing 12% interest per annum and maturing on September 30, 2020. In addition to the promissory note, Dr. Schwartz received 50,000 shares of our common stock. No rights and obligations remain under the cancelled notes.

As of December 31, 2019, the outstanding principal balance was \$2,115,000. The notes accrued interest at a rate of 8% per annum through December 31, 2019 and 12% per annum after December 31, 2019.

#### *March 1, 2019 Registered Sale of Common Stock and Warrants*

On February 27, 2019, we entered into a placement agency agreement for a registered direct offering in which we sold 138,500 shares of common stock and warrants to purchase up to 69,250 shares of common stock. The common stock and warrants were sold in units, with each unit consisting of 0.1 share of common stock and a Warrant to purchase 0.05 of a share of our common stock at an exercise price of \$10.00 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 \$9.00 per unit, resulting in gross proceeds of \$1,246,608 and net offering proceeds, after deducting the placement agent's fees and other estimated offering expenses, were \$1,111,888. The closing of this offering occurred on March 1, 2019. We granted the placement agency or its assigns the right to purchase up to an aggregate of 6,925 units at an exercise price of \$11.25 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 for a registered direct offering in which we sold 147,875 shares of common stock and warrants to purchase up to 73,938 shares of common stock. The common stock and warrants were sold in units, with each unit consisting of 0.1 share of common stock and a warrant to purchase 0.05 shares of our common stock at an exercise price of \$10.00 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 \$8.00 per unit, resulting in gross proceeds of \$1,183,101, before deducting placement agent fees and estimated offering expenses. The net offering proceeds were \$1,053,460. The closing of this offering occurred on March 29, 2019. Pursuant to the placement agency agreement, we granted the placement agency or its assigns the right to purchase up to an aggregate of 73,938 units at an exercise price of \$10.00 per unit. The unit purchase options shall expire on March 29, 2024.

#### *June 2019 Series E Convertible Preferred Stock*

In June 2019, we entered into a private placement securities purchase agreement with investors for shares of Series E convertible preferred stock. We issued 258 preferred shares. Each preferred share holder shall have the right to convert each Series E preferred share into 0.056857% of the issued and outstanding shares of common stock immediately prior to conversion for each share of Series E convertible preferred stock beginning six months after the initial close date of June 13, 2019. On the date that is 12 months after the initial closing date, we have the option to convert the preferred shares into common stock upon the same terms and limitations as the above optional conversion. The preferred shares include a contingent beneficial conversion amount of \$289,936, representing the intrinsic value of the shares at the time of issuance. We determined the Series E convertible preferred stock should be classified as permanent equity and we are accreting the beneficial conversion feature amount to the earliest redemption date of six months after the initial closing of the Series E convertible preferred stock. This offering closed in September 2019.

#### *October 1, 2019 Registered Sale of Common Stock and Warrants*

On October 1, 2019, we entered into a placement agency agreement for a public offering in which we sold 633,554 shares of our common stock. The common stock was sold at a price of \$5.00 per share, resulting in gross proceeds to the Company of \$3,167,769 and net offering proceeds, after deducting the Placement Agents' fees and other estimated offering expenses, were \$2,811,309. The closing of the offering occurred on October 4, 2019. Pursuant to the placement agency agreement, we granted warrants to the placement agents to purchase up to 63,355 shares of common stock, at an exercise price of \$6.25 per share. The warrants include a cashless exercise provision and will have piggy-back registration rights.

#### *October 24, 2019 Equity Line Agreement*

On October 24, 2019, we entered into an equity purchase agreement with an investor, providing for an equity financing facility. Upon the terms and subject to the conditions in the purchase agreement, the investor is committed to purchase shares having an aggregate value of up to \$15,000,000 of our common stock for a period of up to three years. We issued to the investor 104,651 commitment shares for entering into the agreement. From time to time during the three-year commitment period, provided that the closing conditions are satisfied, we may provide the investor with put notices to purchase a specified number of shares subject to certain limitations and conditions and at specified prices, which generally represent discounts to the market price of the common stock.

From the date of the agreement through December 31, 2019, we issued an aggregate 122,356 shares of common stock valued at \$319,196. From January 1, 2020 through March 12, 2020, we issued an aggregate 943,000 shares of common stock valued at \$1,869,899.

#### *February 5, 2020 Sale of Convertible Note*

On February 5, 2020, we entered into a securities purchase agreement with an investor, pursuant to which we issued a convertible promissory note to the investor in the principal amount of \$1,450,000 in exchange for cash proceeds of \$1,200,000. \$240,000 of the note's principal represents an original issue discount ("OID") and the remaining \$10,000 represents a credit for the investor's transaction expenses. We granted to the investor a security interest in our assets to secure repayment of the note. The principal amount of the note accrues interest at a rate of 8% per annum (with six months of interest guaranteed). Unless previously converted, the note will mature and become due and payable on August 5, 2020. We will incur a 20% repayment charge in connection with any repayment of principal under the note. Subject to certain limitations, the outstanding principal amount of the note and interest thereon are convertible at the election of the investor into shares of our common stock at a conversion price equal to \$2.589. Advances under the note will be made in three tranches. The principal amount of the first tranche, which was advanced on February 5, 2020, was \$490,000 (including a \$400,000 cash advance, a pro rata \$80,000 OID and the \$10,000 transaction expense credit). The second and third tranches, each with principal amounts of \$480,000 (including a \$400,000 cash advance and a pro rata \$80,000 OID), will be advanced 30 and 60 days after the effective date, respectively. We issued to the investor five-year warrants to purchase 94,631 shares of our common stock at the closing of the first tranche, and will issue warrants to purchase 92,700 shares at the closing of each of the second and third tranches. The warrants are exercisable beginning on the sixth month anniversary of the issuance date at an exercise price equal \$2.992 per share. As additional consideration for the investment, we issued 46,875 shares of our common stock as inducement shares to the investor at the closing of the first tranche. The investor will have piggyback registration rights with respect to the inducement shares and the shares issuable upon conversion of the Note.

#### *March 19, 2020 Private Placement of Common Stock and Warrants*

On March 19, 2020, we sold and issued (i) 260,000 shares of common stock, at a sale price of \$2.121 per share; (ii) prefunded warrants to acquire 1,390,166 shares of common stock, sold at \$2.12 per share and exercisable at an exercise price of \$0.001 per share; (iii) warrants to acquire 1,650,166 shares of common stock at \$1.88 per share, exercisable immediately and terminating five and one-half years after the date of issuance; and (iv) warrants to acquire 1,650,166 shares of common stock at \$1.88 per share, exercisable immediately and terminating two years after the date of issuance. The gross proceeds were \$3,498,611.92. In the securities purchase agreement with the investors dated March 13, 2020, until 90 days after the initial registration statement required by the Registration Rights Agreement is declared effective by the SEC, neither us nor any of our subsidiaries will issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of common stock or common stock equivalents. Notwithstanding the foregoing, if, at any time following 30 days after the effective date of such registration statement, the last closing sale price for the common stock on the Nasdaq Capital Market is at least \$6.30 (subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the Purchase Agreement) for three consecutive trading days, then these issuance restrictions no longer apply.



### *March 19, 2020 Amendments to and Extensions of Promissory Notes*

On March 19, 2020, we entered into a third amendment to the Amended and Restated Senior Secured Promissory Note dated September 28, 2018 and amended and restated as of February 7, 2019 issued to L2 Capital, LLC (as amended by that certain First Amendment dated September 27, 2019 and that certain Second Amendment dated December 12, 2019, the “L2 Note”). Under the third amendment, the maturity date of the L2 Note was extended from March 28, 2020 to June 28, 2020.

On March 19, 2020, we entered into an amendment to the Senior Secured Promissory Note dated September 27, 2019 issued to Oasis Capital, LLC (the “Oasis Note”). Under the amendment, the maturity date of the Oasis Note was extended from March 27, 2020 to June 27, 2020. In exchange for such extension, the outstanding principal amount of the Oasis Note was increased by \$300,000, such that, as of the effective date of the amendment, the outstanding principal amount owed under the Oasis Note was \$980,833.33. Under the amendment, through March 26, 2020, the holder waived its rights under the Oasis Note to have the Oasis Note repaid from the proceeds of any financing consummated by the Company. In exchange for such waiver, we issued 30,000 shares of common stock (the “Waiver Shares”) to the holder.

### **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 (“U.S. 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 fixed assets, 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 we choose 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.** We recognize revenue in accordance with the SEC’s Staff Account Bulletin Revenue Recognition and ASC 606 – *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.

*Revenue from Product Sales.* We have medical device revenue consisting primarily of sales of the STREAMWAY System, as well as sales of the proprietary cleaning fluid and filters for use with the STREAMWAY System. This revenue stream is reported within both the domestic and international revenue segments. We sell our medical device 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. Our sales agreement, Terms and Conditions, is a dually executed contract providing explicit criteria supporting the sale of the STREAMWAY System. We consider the combination of a purchase order and acceptance of our Terms and Conditions to be a customer’s contract in all cases.

Product sales for medical devices consist of a single performance obligation that we satisfy at a point in time. We recognize product revenue when the following events have occurred: (1) we have transferred physical possession of the products, (2) we have a present right to payment, (3) 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 our facilities (“FOB origin,” which is our 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. Our standard payment terms for customers are generally 30 to 60 days after we transfer control of the product to the customer. We allow returns of defective disposable merchandise if the customer requests a return merchandise authorization from us.

Customers may also purchase a maintenance plan for the medical devices from us, which requires us 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 earned and 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.

All amounts billed to a customer in a sales transaction for medical devices 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.

*Revenue from Clinical Testing.* The Precision Oncology Insights are clinic diagnostic testing comprised of our ChemoFx and BioSpeciFx tests. The ChemoFx test determines how a patient’s tumor specimen reacts to a panel of various chemotherapy drugs, while the BioSpeciFx test evaluates the expression of a particular gene related to a patient’s tumor specimen. Revenues are recognized when control of the promised goods or services is transferred to customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. The estimated uncollectible amounts are generally considered implicit price concessions that are a reduction in revenue. Payments terms vary for contracts and services sold by our Helomics subsidiary. Our performance obligations are satisfied at one point in time when test reports are delivered and studies are completed.

For service revenues, we estimate the transaction price which is the amount of consideration we expect to be entitled to receive in exchange for providing services based on our historical collection experience using a portfolio approach as a practical expedient to account for patient contracts as collective groups rather than individually. We monitor our estimates of transaction price to depict conditions that exist at each reporting date. If we subsequently determine that we will collect more consideration than we originally estimated for a contract with a patient, we will account for the change as an increase to the estimate of the transaction price, provided that such downward adjustment does not result in a significant reversal of cumulative revenue recognized.

We recognize revenue from these patients when contracts as defined in ASC 606, *Revenue from Contracts with Customers* are established at the amount of consideration to which we expect to be entitled or when we receive substantially all of the consideration subsequent to the performance obligations being satisfied.

*CRO Revenue.* Contract revenues are generally derived from studies conducted with biopharmaceutical and pharmaceutical companies. The specific methodology for revenue recognition is determined on a case-by-case basis according to the facts and circumstances applicable to a given contract. We typically use an input method that recognizes revenue based on our efforts to satisfy the performance obligation relative to the total expected inputs to the satisfaction of that performance obligation. For contracts with multiple performance obligations, we allocate the contract’s transaction price to each performance obligation on the basis of the standalone selling price of each distinct good or service in the contract. Advance payments received in excess of revenues recognized are classified as deferred revenue until such time as the revenue recognition criteria have been met. Payment terms are net 30 from the invoice date, which is sent to the customer as we satisfy the performance obligation relative to the total expected inputs to the satisfaction of that performance obligation.



*Variable Consideration.* We record revenue from distributors and direct end customers in an amount that reflects the transaction price we expect to be entitled to after transferring control of those goods or services. Our current contracts do not contain any features that create variability in the amount or timing of revenue to be earned.

*Warranty.* We generally provide one-year warranties against defects in materials and workmanship on product sales and will either repair the products or provide replacements at no charge to customers. As they are considered assurance-type warranties, we do 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.* We record a receivable when we have an unconditional right to receive consideration after the performance obligations are satisfied. Our deferred revenues

*Practical Expedients.* We have elected the practical expedient not to determine whether contracts with customers contain significant financing components as well as the practical expedient to recognize shipping and handling costs at point of sale.

**Stock-Based Compensation.** We account for share-based compensation expense in accordance with ASC 718, Compensation—Stock Compensation, which requires us to measure and recognize compensation expense in our financial statements based on the fair value at the date of grant for our share-based awards. We recognize compensation expense for these equity-classified awards over their requisite service period and adjust for forfeitures as they occur.

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.

Prior to 2019, we did not have significant historical trading data on our common stock and therefore 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 5 – Stockholders' Equity, 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. We have 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.

**Business Combination.** We accounted for the Helomics merger as a business combination, using the acquisition method of accounting. This method requires, among other things, that assets acquired and liabilities assumed be recognized at fair value as of the acquisition date. The fair value for the assets acquired and the liabilities assumed are based on information knowable and determined by management as of the date of this filing. We allocate the purchase price to tangible and intangible assets acquired and liabilities assumed, based on their estimated fair values. The excess of the purchase price, if any, over the aggregate fair value of assets acquired and liabilities assumed is allocated to goodwill.

## **Goodwill and Other Intangible Impairment.**

In accordance with ASC 350 - *Intangibles – Goodwill and Other*, goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the fair value of net assets acquired and represents the future economic benefits that we expect to achieve as a result of the acquisition that are not individually identified and separately recognized. Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination. Goodwill is an indefinite-lived asset and is not amortized. Goodwill is tested for impairment annually at the reporting unit level, or whenever events or circumstances present an indication of impairment. We may assess qualitative factors to determine if it is more likely than not that the carrying value of a reporting unit exceeds its estimated fair value. We believe a qualitative testing approach was not appropriate and, therefore, proceeded to the quantitative testing. When performing quantitative testing, we first estimate the fair value of the Helomics reporting unit using discounted cash flows. To determine fair values, we must make assumptions about a wide variety of internal and external factors. Significant assumptions used in the impairment analysis include financial projections of free cash flow (including significant assumptions about operations, capital requirements and income taxes), long-term growth rates for determining terminal value, and discount rates for the Helomics reporting unit. Comparative market multiples are also used to corroborate the results of the discounted cash flow test. These assumptions require significant judgment and actual results may differ from assumed and estimated amounts.

In testing goodwill for impairment as of December 31, 2019, the Company performed a quantitative impairment test, including computing the fair value of the Helomics reporting unit and comparing that value to its carrying value. Based upon the Company's annual goodwill impairment test, the Company concluded that goodwill was impaired as of the testing date of December 31, 2019. Pursuant to ASU 2017-04 – Simplifying the Test for Goodwill Impairment, the single step is to determine the estimated fair value of the reporting unit and compare it to the carrying value of the reporting unit, including goodwill. To the extent the carrying amount of goodwill exceeds the implied goodwill, the difference is the amount of the goodwill impairment. The Company's annual impairment test as of December 31, 2019 resulted in \$8,100,000 of impairment expense related to goodwill. There was no impairment expense recorded in the twelve months ended December 31, 2018.

When evaluating the fair value of Helomics reporting unit the Company used a discounted cash flow model. Key assumptions used to determine the estimated fair value included: (a) expected cash flow for the 20-year period following the testing date (including net revenues, costs of revenues, and operating expenses as well as estimated working capital needs and capital expenditures); (b) an estimated terminal value using a terminal year growth rate of 3.0% determined based on the growth prospects of the reporting unit; and (c) a discount rate of 18.3% based on management's best estimate of the after-tax weighted average cost of capital. The discount rate included a company specific risk premium of 7% for risks related to the term of the forecasts. The majority of the inputs used in the discounted cash flow model are unobservable and thus are considered to be Level 3 inputs.

A decrease in the growth rate of 1% or an increase of 1% to the discount rate would reduce the fair value of Helomics reporting unit by approximately an additional \$400,000 and \$3,400,000, respectively.

The Company will continue to monitor its reporting units to determine whether events and circumstances warrant further interim impairment testing. Goodwill is not expected to be deductible for tax purposes.

We also review identifiable intangible assets for impairment in accordance with ASC 350 – *Intangibles – Goodwill and Other*, whenever events or changes in circumstances indicate the carrying amount may not be recoverable. Our intangible assets are definite lived and currently solely of 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 we operate.

**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 beginning on pages F-1 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

Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), defines the term “disclosure controls and procedures” as those controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our 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, 2019. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were not effective as of December 31, 2019 due to the material weakness in internal controls regarding adequate accounting resources, as described below:

### 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, 2019 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 not effective as of December 31, 2019 due to the following material weakness.

*Material Weakness in Internal Controls.* Management has determined that we have not maintained adequate accounting resources with a sufficient understanding of U.S. GAAP to allow us to properly identify and account for new complex transactions. Management has determined that this represents a material weakness in our internal control over financial reporting. Notwithstanding the material weakness in our internal control over financial reporting, we have concluded that the consolidated financial statements and other financial information included in our annual and quarterly filings fairly present in all material respects our financial condition, results of operations and cash flows as of, and for, the periods presented.

*Material Weakness Remediation Activities.* To remediate the material weakness in our internal control over financial reporting described above, we have reevaluated our overall staffing levels within the accounting department and have hired additional resources with qualifications that include a high level of experience with complex technical accounting transactions and application of U.S. GAAP. We have also engaged an external accounting firm to assist with the assessment of new complex transactions. We also plan to re-evaluate the trainings and ongoing professional education that is provided to, and required of, our accounting personnel. Once these processes have been in operation for a sufficient period of time for our management to conclude that the material weakness has been fully remediated and our internal controls over financial reporting are effective, we will consider this material weakness fully addressed.

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 were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the three months ended December 31, 2019 that has materially affected, or are 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. Our Board presently consists of seven 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 executive officers and directors for the year ended December 31, 2019:

Name		Age	Position Held
Carl Schwartz	(4)	79	Chief Executive Officer and Director
Bob Myers		65	Chief Financial Officer
Thomas J. McGoldrick	(2) (3) (4) (5)	78	Director
Andrew P. Reding	(1)	50	Director
J. Melville Engle	(1) (2) (3)	70	Director
Timothy A. Krochuk	(1) (3) (4) (6)	50	Director
Richard L. Gabriel	(4)	71	Director
Gerald J. Vardzel, Jr.		54	Director
Pamela S. Prior	(1)(7)	58	Director
Daniel E. Handley	(8)	59	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

(5) Mr. McGoldrick resigned his position in January 2020.

(6) Mr. Krochuk did not run for re-election in 2019. His term ended on December 31, 2019.

(7) Ms. Prior was appointed as a Director in January 2020.

(8) Dr. Handley was appointed as a Director in February 2020.

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, our stockholders approved amendments to the Certificate of Incorporation and Bylaws to establish a classified Board of Directors, and we filed the Amended and Restated Certificate of Incorporation. The amendments to our Certificate of Incorporation and Bylaws provide for the division of the members of our shareholders into three classes, with the term of each class expiring in different years. As a result of this stockholder approval, three classes of directors were created: Class I continuing for a term expiring in 2022, Class II for a term expiring in 2020, and Class III for a term, expiring in 2021. Beginning with the 2019 annual meeting of stockholders, the class of directors up for election or reelection will be elected to three-year terms. The current directors are divided into classes as follows:

**CLASS I**  
(term expiring in 2022)  
Pam S. Prior  
Daniel E. Handley

**CLASS II**  
(term expiring in 2020)  
Andy Reding  
J. Melville Engle  
Gerald J. Vardzel, Jr.

**CLASS III**  
(term expiring in 2021)  
Dr. Carl Schwartz  
Richard Gabriel

Mr. Krochuk did not run for an additional term, and therefore, as of December 31, 2019, he was no longer a Director. In January 2020, Thomas McGoldrick resigned his position and Ms. Prior was appointed as a Director. Daniel Handley was appointed as a director in February 2020.

## 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 our Chief Financial Officer. Mr. Myers was our Acting Chief Financial Officer and Corporate Secretary since December 2011. He has over 40 years' experience in multiple industries focusing on medical device, service and manufacturing and prior to joining the Company was a financial contractor represented by 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.

**Andrew P. Reding, Director.** Mr. Reding has served as director since 2006. He is an executive with extensive experience in sales and marketing of capital equipment for the acute care markets. 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 has served as a director since 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.

**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.

**Pamela S. Prior, Director.** Ms. Prior was appointed to the Board of Directors on 1, 2020 and is the founder and CEO of Priorities Group, Inc., a provider of CFO services to small and mid-sized businesses. Her previous experience includes approximately 35 years in accounting, predominantly in management as a Chief Financial Officer and Controller. Most recently, Ms. Prior was CFO at Schiller Grounds Care, a privately held lawn equipment manufacturing company; CFO at Global Specimen Solutions, a privately held technology and services company for specimen and consent management, subsequently purchased by Covance; CFO at Gentriss Corp., a privately held pharmacogenomics company subsequently purchased by Cancer Genetics, Inc.; and CFO at Greatwide Truckload Management, a \$300 million subsidiary of a \$1 billion private equity owned logistics company. Ms. Prior also served as Controller and Director of Internal Control for Tasty Baking Company, a publicly traded (NYSE) regional baking company, and Controller of PCI Services, a subsidiary of publicly held Cardinal Health. Ms. Prior received her MBA and her Bachelor's Degrees at the University of Delaware and is a licensed CPA in the Commonwealth of Pennsylvania. Ms. Prior also serves as Treasurer on the boards of two non-profit organizations: The Crossing Choir, a professional choir under the direction of Donald Nally, dedicated to new choral music and the possessor of two Grammy Awards and seven Grammy nominations; and, A Soldier's Hands, a grass roots organization founded in 2008 dedicated to delivering care packages to whole units of deployed United States military personnel. Ms. Prior also chairs the Company's Audit Committee.

**Gerald J. Vardzel, Jr., Director.** Mr. Vardzel was appointed to the Board on April 4, 2019. He is currently President of Helomics, our wholly owned subsidiary. Prior to the merger with Helomics, he was president and Chief Executive Officer of Helomics. He has over 25 years of healthcare executive management experience developing and implementing commercialization strategies and models for technology launches. His Go-To-Market expertise includes equity financing, strategic planning, market intelligence, M&A, and new market development in both start-up and established settings including fortune 500 market leaders. He has developed innovative solutions for both CLIA and FDA regulatory paths defining the delivery chains from discovery to clinical acceptance. Mr. Vardzel also has significant experience designing and implementing sales and marketing programs tailored not only to expand market share, but to empirically assess client satisfaction, strengthen business processes, and maximize profitability. Mr. Vardzel was previously Vice President of Corporate Development and Strategic Initiatives at Global Specimen Solutions. Furthermore, as an executive affiliate to the healthcare industry, he routinely consults for several small-to-mid sized private equity firms advising on, in part, the feasibility of acquisition targets. Mr. Vardzel graduated from the University of Pittsburgh.

**Daniel E. Handley M.S., Ph.D., Director.** Dr. Handley was appointed to the Board on February 19, 2020. He serves as a Professor and the Director of the Clinical and Translational Genome Research Institute of Southern California University of Health Sciences. Previously, he was the Chief Scientific Officer of the Clinical and Translational Genome Research Institute, a Florida 501(c)3 non-profit corporation. During that time, he also held a courtesy faculty appointment in the Department of Biological Sciences at Florida Gulf Coast University. He previously served as the Chief Scientific Officer for Advanced Healthcare Technology Solutions, Inc., Life-Seq, LLC, as a senior researcher at the Procter & Gamble Co., a senior administrator, researcher, and laboratory manager at the David Geffen UCLA School of Medicine, and as a founding biotechnology inventor for the National Genetics Institute. He holds a B.A. in Biophysics from Johns Hopkins University, an M.S. in Logic and Computation from Carnegie Mellon University, a Ph.D. in Human Genetics from the University of Pittsburgh. He completed his post-doctoral training at Magee-Women's Research Institute researching advanced genomic technologies applied to fetal and maternal health. He is a decorated veteran of the U.S. Navy, having served as a nuclear propulsion instructor and a submarine nuclear reactor operator.

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 us.

### **Audit Committee**

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

All members of the Audit Committee are independent directors. Pursuant to its charter and the authority delegated to it by the Board of Directors, the Audit Committee has sole authority for oversight of our independent registered public accounting firm. In addition, the Audit Committee reviews the results and scope of the audit and other services provided by our independent registered public accounting firm, and also reviews our accounting and control procedures and policies. The Audit Committee meets as often as it determines necessary but not less frequently than once every fiscal quarter.

Our Audit Committee currently consists of Ms. Prior, as the chairperson, Mr. Reding and Mr. Engle. During 2019, the Audit Committee chairperson was Mr. Krochuk, who was replaced on the committee and as chairperson by Ms. Prior in January 2020. Each Audit Committee member is a non-employee director of the Board. The Board of Directors has determined that all current members of our Audit Committee are independent. The Audit Committee met six times in fiscal 2019.

### **Audit Committee Financial Expert**

The Board has determined that Ms. Prior 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. As noted above, Ms. Prior, Mr. Reding, and Mr. Engle are independent within the meaning of NASDAQ’s listing standards.

### **Compensation Committee**

The Compensation Committee of the Board of Directors currently consists of two directors, Mr. Engle, as the chairperson, and Ms. Prior. 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, “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 Ms. Prior. 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. Engle, as the chairperson. The Board of Directors is currently considering replacements for Mr. Krochuk and Mr. McGoldrick both of whom were on the Governance/Nominating Committee prior to their departure. Mr. Engle 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 or as recommended by our stockholders. Annually, the Committee recommends a slate of nominees to the Board for consideration at our annual stockholders' meeting;
- 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 us, 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 (1) committee member qualifications, (2) appointments, removals and rotation of committee members, (3) committee structure and operations (including authority to delegate to subcommittees), and (4) committee reporting to the Board. Finally, the Committee performs any other activities consistent with this Charter, our 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. Schwartz, as the chairperson, and Mr. Gabriel. The Board of Directors is currently considering replacements for Mr. Krochuk and Mr. McGoldrick both of whom were on the Merger & Acquisition Committee prior to their departure and were "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 advises the Company with respect to 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 our officers and directors, and persons who own more than ten percent of a registered class of our 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 us 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 us during the fiscal year ended December 31, 2019 and Forms 5 and amendments thereto furnished to us with respect to such fiscal year, or written representations that no Forms 5 were required, we believe that the following is the list of our 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, 2019: Andrew Reding 3 late reports covering 3 transactions; Thomas J. McGoldrick 3 late reports covering 3 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 5 late reports covering 16 transactions.

### **Code of Ethics**

We have adopted a Code of Ethics that applies to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions) and directors. Our Code of Ethics satisfies the requirements of Item 406(b) of Regulation S-K and is included as an exhibit to this Form 10-K.

## **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 Chief Financial Officer, collectively referred to as the "Named Executive Officers." We did not have any other executive officers, as determined in accordance with SEC rules, during 2019.

## Summary Compensation Table for Fiscal 2019 and 2018

The following table provides information regarding the compensation earned during the fiscal years ended December 31, 2019 and December 31, 2018 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 <sup>(2)</sup>	2019	\$ 100,000	\$ -	\$ -	\$ 376,600	\$ -	\$ 476,600
	2018	\$ -	\$ -	\$ -	\$ 242,636	\$ -	\$ 242,636
Bob Myers, CFO <sup>(3)</sup>	2019	\$ 270,833	\$ -	\$ -	\$ 100,597	\$ -	\$ 371,430
	2018	\$ 198,467	\$ 19,250	\$ -	\$ -	\$ -	\$ 217,717

(1) Represents the actual compensation cost granted during 2019 and 2018 as determined pursuant to FASB ASC 718 – Stock Compensation utilizing the assumptions discussed in Note 5, “Stockholder’s Equity, Stock Options, and Warrants,” in the notes to the financial statements included in this report.

(2) On December 1, 2016, Dr. Schwartz was appointed Chief Executive Officer. Dr. Schwartz received a salary increase to \$400,000 annually on August 1, 2018. Dr. Schwartz opted to take nine months of his 2019-year salary as stock options in lieu of cash. Dr. Schwartz received options to purchase 47,702 and 30,833 shares of common stock in lieu of a cash salary in 2019 and 2018, respectively. The shares all vest at the time of grant and range in price from \$5.51 per share to \$7.90 per share for 2019 grants and \$9.70 per share to \$11.60 per share for 2018 grants.

(3) Mr. Myers received salary increases on August 1, 2018 and August 1, 2019 to annualized amounts of \$250,000 and \$300,000, respectively. Mr. Myers received \$19,250 paid in 2019 for 2018 accrued bonus.

## Outstanding Equity Awards at Fiscal Year-end for Fiscal 2019

The following table sets forth certain information regarding outstanding equity awards held by the named executive officers as of December 31, 2019:

	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	7		\$ 2,812.50	7/19/2023
	6/30/2015	52		\$ 775.00	6/30/2025
	3/31/2016	59		\$ 42.50	3/31/2026
	6/30/2016	133		\$ 37.50	6/30/2026
	9/30/2016	121		\$ 41.25	9/30/2026
	12/31/2016	893		\$ 28.00	12/31/2026
	3/31/2017	238		\$ 21.00	3/31/2027
	6/22/2017	37,689		\$ 14.70	6/22/2027
	11/10/2017	2,834		\$ 14.70	11/10/2027
	1/2/2018	14,175		\$ 9.70	1/2/2028
	6/30/2018	12,168		\$ 11.30	6/30/2028
	8/1/2018	4,490		\$ 11.60	8/1/2028
	1/2/2019	32,305		\$ 6.19	1/2/2029
	4/4/2019	20,000		\$ 7.48	4/4/2029
	7/1/2019	4,219		\$ 7.90	7/1/2029
8/1/2019	5,128		\$ 6.50	8/1/2029	
9/1/2019	6,050		\$ 5.51	9/1/2029	
Bob Myers	8/13/2012	53		\$ 1,500.00	8/13/2022
	3/18/2013	42		\$ 1,481.25	3/18/2023
	3/6/2014	14		\$ 4,312.50	3/6/2024
	9/16/2016	357		\$ 41.98	9/16/2026
	6/22/2017	30,411		\$ 14.70	6/22/2027
	4/4/2019	16,600		\$ 7.48	4/4/2029

## Executive Compensation Components for Fiscal 2019

*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.

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 received 20% contractual cash bonuses. Any other bonus for the CFO, 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 signed an amended contract whereby the contractual bonuses were removed subsequent to August 1, 2018. All bonuses subsequent to 2018 are 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 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, our stockholders approved amendments to the 2012 Plan to: (1) increase the share reserve under the 2012 Plan by an aggregate 500,000 shares from the most recent reserve of 500,000 shares to an aggregate 1,000,000 shares, and (2) increase in certain thresholds for limitations on grants under the 2012 Plan. As of December 31, 2019, options to purchase 766,424 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 Board took into account its intention to grant further equity awards to current and future executive officers and key employees and directors.

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

On July 1, 2019, we entered into an amended employment agreement with Dr. Schwartz. The annualized base salary for Dr. Schwartz was \$400,000 for both 2019 and 2018. Such base salary may be adjusted by us 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 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 (1) will be granted on the first business day of such Compensation Period, (2) will have an exercise price per share equal to the closing sale price of our common stock on the date of grant, (3) will have an aggregate exercise price equal to the dollar amount of base salary to be received in options, (4) will have a term of ten years, and (5) will vest pro rata on a monthly basis over the period of time during which the base salary would have been earned. Dr. Schwartz opted to take nine months of his 2019-year salary as stock options in lieu of cash.

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 2018 and subsequent years, the bonus is 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.

Dr. Schwartz is 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.

If we terminate Dr. Schwartz's employment without cause or if he terminates his employment for "good reason," he shall be entitled to receive us 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 any earned 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: 1) 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; 2) Dr. Schwartz embezzles or misappropriates any assets from us or any of our subsidiaries; 3) Dr. Schwartz's violation of any of his obligations in the agreement, if such conduct is not cured within 30 days after notice; 4) breach of any agreement between Dr. Schwartz and us or to which we and Dr. Schwartz are parties, or a breach of his fiduciary responsibility to us; 5) commission by Dr. Schwartz of fraud or other willful conduct that adversely affects our business or reputation; or, 6) we have a reasonable belief he engaged in some form of harassment or other improper conduct prohibited by our policy or the law. "Good reason" is defined as (1) a material diminution in employee's position, duties, base salary, and responsibilities; or (2) our notice to him that his position will be relocated to an office which is greater than 100 miles from his prior office location. In all cases of Good Reason, he must have given notice to us that an alleged Good Reason event has occurred and the circumstances must remain uncorrected by us after the expiration of 30 days after receipt by us of such notice.

During Dr. Schwartz's employment 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 us or solicit our clients or prospective clients with whom he worked, solicited, marketed, or obtained confidential information about during his employment with us, regarding services or products that are competitive with any of our services or products.

#### *Employment Agreement with Chief Financial Officer.*

On August 13, 2012, we entered into an employment agreement with Bob Myers, who has served as Chief Financial Officer since July 1, 2012. Under the agreement the employment of Mr. Myers is at will.

On August 20, 2018, we entered into an amendment to employment agreement with Mr. Myers. Effective August 1, 2018, Mr. Myers received an annualized base salary of \$250,000. Effective August 1, 2019, Mr. Myers received an annualized base salary of \$300,000.

Mr. Myers is 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.

Base salaries for Mr. Myers may be adjusted by us but may not be reduced except in connection with a reduction imposed on substantially all employees as part of a general reduction. He will also each be eligible to receive an annual incentive bonus for each calendar year at the end of which he remains employed by us, subject to the attainment of certain objectives.

If we terminate his employment without cause or if he terminates his employment for "good reason," he shall be entitled to receive us severance pay in an amount equal to:(1) before the first anniversary of the date of the agreement, three months of base salary, or (2) 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: 1) that he 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; 2) he embezzles or misappropriates assets from us or any of our subsidiaries; 3) his violation of his obligations in the agreement, if such conduct is not cured within 30 days after notice; 4) breach of any agreement between him and us or to which we and Mr. Myers are parties, or a breach of his fiduciary responsibility to us; 5) commission by Mr. Myers of fraud or other willful conduct that adversely affects our business or reputation; or, 6) we have a reasonable belief he engaged in some form of harassment or other improper conduct prohibited by Company policy or the law. "Good reason" is defined as (1) a material diminution in his position, duties, base salary, and responsibilities; or (2) our notice to Mr. Myers that his position will be relocated to an office which is greater than 100 miles from his prior office location. In all cases of Good Reason, he must have given notice to us that an alleged Good Reason event has occurred and the circumstances must remain uncorrected by us after the expiration of 30 days after receipt by us of such notice.

During Mr. Myers employment and for twelve months thereafter, regardless of the reason for the termination, he may not engage in a competing business, as defined in the agreement and will not solicit any person to leave employment with us or solicit our clients or prospective clients with whom he worked, solicited, marketed, or obtained confidential information about during his employment with us, regarding services or products that are competitive with any of our 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 if the remaining period of the option is less than five years after such termination). 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. 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 2019

The following table summarizes the compensation paid to each non-employee director in the fiscal year ended December 31, 2019:

	Fees Paid or Earned in		Stock Awards	Option Awards (1)	Total
	Cash				
Thomas McGoldrick	\$ -	\$ -	-	\$ 116,866 (2)	\$ 116,866
Andrew Reding	\$ -	\$ -	-	\$ 100,361 (3)	\$ 100,361
Richard Gabriel	\$ -	\$ -	-	\$ 100,361 (4)	\$ 100,361
Tim Krochuk	\$ -	\$ -	-	\$ 116,866 (5)	\$ 116,866
J. Melville Engle	\$ -	\$ -	-	\$ 116,866 (6)	\$ 116,866

- (1) Represents the actual compensation cost granted during 2019 as determined pursuant to FASB ASC 718 – Stock Compensation utilizing the assumptions discussed in Note 5, "Stockholder's Equity, Stock Options, and Warrants," in the notes to the financial statements included in this report.
- (2) Mr. McGoldrick was awarded options to purchase 15,736 shares of common stock both for serving on the Board and for participating on the Compensation, Corporate Governance, and Merger & Acquisition Committees. Mr. McGoldrick was awarded options to purchase 12,500 shares of common stock related to the closing of the Helomics merger.
- (3) Mr. Reding was awarded options to purchase 8,073 shares of common stock both for serving on the Board and for participating on the Audit Committee. Mr. Reding was awarded options to purchase 12,500 shares of common stock related to the closing of the Helomics merger.
- (4) Mr. Gabriel was awarded options to purchase 8,073 shares of common stock for serving on the Board and for participating on the Merger & Acquisition Committee. Mr. Gabriel was awarded options to purchase 12,500 shares of common stock related to the closing of the Helomics merger.
- (5) Mr. Krochuk was awarded options to purchase 15,736 shares of common stock for serving on the Board and for participating on the Audit, Governance and Merger & Acquisition Committees. Mr. Krochuk was awarded options to purchase 12,500 shares of common stock related to the closing of the Helomics merger.
- (6) Mr. Engle was awarded options to purchase 15,736 shares of common stock for serving on the Board and the Audit and Compensation Committees. Mr. Engle was awarded options to purchase 12,500 shares of common stock related to the closing of the Helomics merger.

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

**Equity Compensation Plan Information**

The following table presents the equity compensation plan information as of December 31, 2019:

	<b>Number of securities to be issued upon exercise of outstanding restricted stock, warrants and options (a)</b>	<b>Weighted- average exercise price of outstanding options, warrants (b)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (C)</b>
Equity compensation plans approved by security holders (1)	766,424	\$ 11.34	233,576
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 March 22, 2019, our shareholders approved 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 1,000,000.

**Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth as of December 31, 2019 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 5,847,718 shares of our common stock outstanding on March 27, 2020. Unless otherwise noted below, the address for each person or entity listed in the table is c/o Predictive Oncology Inc., 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121.



Name of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
<b>Officers and Directors</b>		
Carl Schwartz <sup>(2)</sup>	324,436	7.53%
Gerald J. Vardzel, Jr. <sup>(3)</sup>	116,711	2.86%
Bob Myers <sup>(4)</sup>	38,255	0.96%
Thomas J. McGoldrick <sup>(5)</sup>	61,342	1.49%
Andrew Reding <sup>(6)</sup>	46,422	1.13%
Timothy Krochuk <sup>(7)</sup>	52,324	1.27%
J. Melville Engle <sup>(8)</sup>	49,719	1.21%
Richard L. Gabriel <sup>(9)</sup>	40,480	0.99%
<b>All directors and executive officers as a group (8 persons)</b>	730,689	15.76%
Douglas Armstrong <sup>(10)</sup>	216,432	5.33%
Robert Keyser Jr. <sup>(10)</sup>	216,432	5.33%

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: (1) voting power, which includes the power to vote, or to direct the voting of shares; and (2) 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 number 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) 74,432 shares owned directly, and (ii) 130,562 shares issuable upon exercise of options held by Dr. Schwartz that are exercisable within 60 days of December 31, 2019, and (iii) 119,442 shares issuable upon exercise of warrants held by Dr. Schwartz that are exercisable within 60 days of December 31, 2019.
3. Includes options to purchase 25,138 shares that are exercisable within 60 days of December 31, 2019.
4. Includes options to purchase 39,178 shares that are exercisable within 60 days of December 31, 2019.
5. Includes options to purchase 61,335 shares that are exercisable within 60 days of December 31, 2019.
6. Includes options to purchase 46,416 shares that are exercisable within 60 days of December 31, 2019.
7. Includes options to purchase 52,324 shares that are exercisable within 60 days of December 31, 2019.
8. Includes options to purchase 39,480 shares that are exercisable within 60 days of December 31, 2019.
9. Includes options to purchase 130,562 shares that are exercisable within 60 days of December 31, 2019.
10. Based on amendment to Schedule 13D filed October 16, 2019.

### 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 we may be a party prior to their implementation, to assess whether such transactions meet applicable legal requirements.

One of our directors, Richard L. Gabriel, is the Chief Operating Officer and serves as a director of GLG Pharma (“GLG”). Tim Krochuk, a Company director until December 2019, is on the supervisory board for GLG.

GLG and we 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 our wholly-owned subsidiary. As of May 1, 2019, Mr. Gabriel executed a one-year contract with renewable three-month periods to continue as the Chief Operating Officer for TumorGenesis. Mr. Gabriel receives \$13,500 in monthly cash payments.

On November 30, 2018, Dr. Carl Schwartz, our CEO, made a loan of \$370,000 to us and received a note and a common stock purchase warrant for 22,129 warrant shares at \$8.36 per share. Effective as of January 8, 2019, Dr. Schwartz made an additional loan 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 74,219 warrant shares at an exercise price of \$7.04. Each tranche is exercisable beginning on the sixth month anniversary of the date of the related loan through the fifth-year anniversary of the date of the related loan. On January 8, 2019, Dr. Schwartz also purchased 7,813 shares of our common stock in a private investment for \$50,000, representing a price of \$6.40 per share, pursuant to a subscription agreement. On February 6, 2019, Dr. Schwartz made an additional loan of \$300,000 in us and received an amended and restated note in the original principal amount of \$1,620,000 due on February 8, 2020, and an amended and restated warrant, which added a third tranche of 13,889 warrant shares at an exercise price of \$11.88 per share. On May 21, 2019, we issued a third and restated common stock purchase warrant to Dr. Schwartz for value received in connection with the funding of all or a portion of the purchase price of his second amended and restated promissory note in the principal amount of \$1,620,000. We have accounted for the liability to issue more warrants as a derivative liability as the exact number of warrants that will be issued was uncertain at the time of the agreement. We issued 5,753 warrants to Dr. Schwartz under the agreement in 2019, which reduced the value of the derivative liability by \$38,413. As of December 31, 2019, the recorded derivative liability related to the agreement was \$22,644.

During 2019, Dr. Schwartz advanced \$300,000 to us. The loan earns 8% interest per annum. The due date of the loan was amended and the loan is now due December 31, 2019. An additional consideration of \$15,000 was given for this extension. The loan is not connected to the previous note payable due to Dr. Schwartz.

As of January 2020, we were in default under the \$315,000 note payable to Dr. Schwartz which was due on December 31, 2019 and determined that we would not be able to pay the \$1,620,000 note payable to Dr. Schwartz when it became due on February 8, 2020. In January 2020, an exchange agreement was entered into with Dr. Schwartz to cancel both of these notes and issue a new promissory note. See Note 13 - Subsequent Events for further discussion.

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

In connection with the audit of the fiscal 2019 and 2018 financial statements, we entered into an engagement agreement with Deloitte & Touche LLP, which sets forth the terms by which they will perform audit services for us.

The following table represents aggregate fees billed to us for the fiscal years ended December 31, 2019 and December 31, 2018, by Deloitte & Touche LLP, our principal accountants. All fees described below were approved by the Audit Committee. None of the hours expended on the audit of the 2019 and 2018 financial statements were attributed to work performed by persons who were not employed full time on a permanent basis by Deloitte & Touche LLP.

	2019	2018
Audit Fees (1)	\$ 530,128	\$ 401,000
Audit-Related Fees (2)	-	-
Tax Fees (3)	34,719	25,000
All Other Fees (4)	-	-
	<u>\$ 564,847</u>	<u>\$ 426,000</u>

(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 2019 and 2018.

(3) Tax Fees consist of fees billed in the indicated year for professional services performed by Deloitte & Touche LLP with respect to tax compliance.

(4) There were no Other Fees in 2019 and 2018.

#### PART IV

#### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

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

##### (1) Financial Statements

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

- [Report of Independent Registered Public Accounting Firm dated March 31, 2020;](#)
- [Consolidated Balance Sheets as of December 31, 2019 and December 31, 2018;](#)
- [Consolidated Statements of Net Loss for the Years Ended December 31, 2019 and December 31, 2018;](#)
- [Consolidated Statements of Stockholders' Equity \(Deficit\) from December 31, 2017 to December 31, 2019;](#)
- [Consolidated Statements of Cash Flows for the Years Ended December 31, 2019 and December 31, 2018; and](#)
- [Notes to Consolidated Financial Statements.](#)

##### (2) Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the SEC have been omitted because the information required to be shown in the schedules is not applicable or is included elsewhere in the financial statements and Notes to Financial Statements.

##### (3) Exhibits

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

## SIGNATURES

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

Dated: March 31, 2020

Predictive Oncology 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	
<u>/s/ Carl Schwartz</u> Carl Schwartz	Chief Executive Officer and Director (principal executive officer)	March 31, 2020
<u>/s/ Bob Myers</u> Bob Myers	Chief Financial Officer (principal financial and accounting officer)	March 31, 2020
<u>/s/ Andrew P. Reding</u> Andrew P. Reding	Director	March 31, 2020
<u>/s/ Gerald J Vardzel, Jr.</u> Gerald J Vardzel, Jr	Director	March 31, 2020
<u>/s/ Richard L. Gabriel</u> Richard L. Gabriel	Director	March 31, 2020
<u>/s/ Pamela S. Prior</u> Pamela S. Prior	Director	March 31, 2020
<u>/s/ J. Melville Engle</u> J. Melville Engle	Director	March 31, 2020
<u>/s/ Daniel E. Handley</u> Daniel E. Handley	Director	March 31, 2020

EXHIBIT INDEX  
PREDICTIVE ONCOLOGY INC.  
FORM 10-K

Exhibit Number	Description
2.1	Amended and Restated Agreement and Plan of Merger dated October 22, 2018 (18) <a href="#">Exhibit 2.1</a>
3.1	Certificate of Incorporation (1) <a href="#">Exhibit 3.1</a>
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 (6) <a href="#">Exhibit 3.2</a>
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 (7) <a href="#">Exhibit 3.3</a>
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 (11) <a href="#">Exhibit 3.4</a>
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 (12) <a href="#">Exhibit 3.5</a>
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 (13) <a href="#">Exhibit 3.6</a>
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 (21) <a href="#">Exhibit 3.7</a>
3.8	Certificate of Amendment to Certificate of Incorporation to effect name change, filed with the Delaware Secretary of State on February 1, 2018 (8) <a href="#">Exhibit 3.8</a>
3.9	Certificate of Amendment to Certificate of Incorporation to increase authorized share capital and establish a classified Board of Directors (23) <a href="#">Exhibit 3.9</a>
3.10	Second Amended and Restated Bylaws as of June 10, 2019 (34) <a href="#">Exhibit 3.10</a>
3.11	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (9) <a href="#">Exhibit 3.11</a>
3.12	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (20) <a href="#">Exhibit 3.12</a>
3.13	Certificate of Amendment to Certificate of Incorporation dated March 22, 2019 (24) <a href="#">Exhibit 3.13</a>
<a href="#">3.14*</a>	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock</a>
3.15	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock Effective June 13, 2019 (35) <a href="#">Exhibit 3.15</a>
3.16	Certificate of Amendment of Certificate of Incorporation (34) <a href="#">Exhibit 3.16</a>
3.17	Certificate of Amendment of Certificate of Incorporation (41) <a href="#">Exhibit 3.17</a>
4.1	Form of specimen certificate evidencing shares of Series B Convertible Preferred Stock (10) <a href="#">Exhibit 4.1</a>
4.2	Form of New Warrant Agency Agreement by and between Skyline Medical Inc. and Form of Warrant Certificate for Series B Warrant (14) <a href="#">Exhibit 4.2</a>
4.3	Form of Series B Warrant Certificate (included as part of Exhibit 4.2) (14) <a href="#">Exhibit 4.3</a>
4.4	Form of Series C Warrant (15) <a href="#">Exhibit 4.4</a>
4.5	Form of Unit Purchase Option (15) <a href="#">Exhibit 4.5</a>
4.6	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 (16) <a href="#">Exhibit 4.6</a>
4.7	Form of Series D Warrant Certificate (included as part of Exhibit 4.6) (16) <a href="#">Exhibit 4.78</a>
4.8	Form of Amendment to Warrant (8) <a href="#">Exhibit 4.8</a>

- 4.9 Investor Warrant (20) [Exhibit 4.9](#)
- 4.10 Series E Warrant Agency Agreement by and between Skyline Medical Inc. and Corporate Stock Transfer, Inc. dated January 9, 2018 (22) [Exhibit 4.10](#)
- 4.11 Form of Series E Warrant Certificate (22) [Exhibit 4.11](#)
- 4.12 Common Stock Purchase Warrant issued to L2 Capital, LLC dated September 28, 2018 (23) [Exhibit 4.12](#)
- 4.13 Common Stock Purchase Warrant issued to Peak One Opportunity Fund, LP dated September 28, 2018 (23) [Exhibit 4.13](#)
- 4.14 Second Amended and Restated Common Stock Purchase Warrant issued to Carl Schwartz dated February 6, 2019 (25) [Exhibit 4.14](#)
- 4.15 Form of Warrant (Initial Issue Date: March 1, 2019) (26) [Exhibit 4.15](#)
- 4.16 Form of Unit Purchase Option (26) [Exhibit 4.16](#)
- 4.17 Common Stock Purchase Warrant issued to Carl Schwartz dated November 30, 2018 (27) [Exhibit 4.17](#)
- 4.18 Amended and Restated Common Stock Purchase Warrant issued to Carl Schwartz dated January 8, 2019 (28) [Exhibit 4.18](#)
- 4.19 Form of Common Stock Purchase Warrant issued March 29, 2019 (31) [Exhibit 4.19](#)
- 4.20 Form of Unit Purchase Option for the Purchase of Units (31) [Exhibit 4.20](#)
- 4.21 Common Stock Purchase Warrant Issued to Oasis Capital, LLC dated September 27, 2019 (37) [Exhibit 4.21](#)
- 4.22 Form of Specimen Common Stock Certificate (38) [Exhibit 4.22](#)
- 4.23 Form of Common Stock Purchase Warrant Issued on or about October 1, 2019 (39) [Exhibit 4.23](#)
- 4.24 Common Stock Purchase Warrant issued to Oasis Capital, LLC dated February 5, 2020 (45) [Exhibit 4.24](#)
- 4.25 Form of Series A Warrant (46) [Exhibit 4.25](#)
- 4.26 Form of Series B Warrant (46) [Exhibit 4.26](#)
- 4.27 Form of Prefunded Warrant (46) [Exhibit 4.27](#)
- 4.28 Form of Prefunded Common Stock Purchase Warrant (47) [Exhibit 4.28](#)
- [4.29\\*](#) [Description of Registrant's Securities](#)
- 10.1 Office Lease Agreement between the registrant and Roseville Properties Management Company, as agent for Lexington Business Park, LLC (2) [Exhibit 10.1](#)
- 10.2 Form of Non-Qualified Stock Option Agreement under the 2012 Stock Incentive Plan (3)\*\* [Exhibit 10.2](#)
- 10.3 Employment Agreement with Robert Myers dated August 11, 2012 (3)\*\* [Exhibit 10.3](#)
- 10.4 Amended Lease with Roseville Properties Management Company, Inc. dated January 29, 2013 (4) [Exhibit 10.4](#)
- 10.5 Amended and Restated 2012 Stock Incentive Plan (24) [Exhibit 10.5](#)
- 10.6 Form of Stock Option Agreement effective as of July 1, 2016 (17) [Exhibit 10.6](#)
- 10.7 Form of Stock Option Agreement for Executive Officers (19) [Exhibit 10.7](#)
- 10.8 Form of Stock Option Agreement for Directors (19) [Exhibit 10.8](#)
- 10.9 Employment Agreement by and between Carl Schwartz and Issuer dated November 10, 2017 (29)\*\* [Exhibit 10.9](#)

- 10.10 Securities Purchase Agreement by and between the Company and L2 Capital, LLC dated September 28, 2018 (23) [Exhibit 10.10](#)
- 10.11 Senior Secured Promissory Note issued to L2 Capital, LLC dated September 28, 2018 (23) [Exhibit 10.11](#)
- 10.12 Registration Rights Agreement by and between the Company and L2 Capital, LLC dated September 28, 2018 (23) [Exhibit 10.12](#)
- 10.13 Security Agreement by and between the Company and L2 Capital, LLC dated September 28, 2018 (23) [Exhibit 10.13](#)
- 10.14 Securities Purchase Agreement by and between the Company and Peak One Opportunity Fund, LP dated September 28, 2018 (23) [Exhibit 10.14](#)
- 10.15 Senior Secured Promissory Note issued to Peak One Opportunity Fund, LP dated September 28, 2018 (23) [Exhibit 10.15](#)
- 10.16 Registration Rights Agreement by and between the Company and Peak One Opportunity Fund, LP dated September 28, 2018 (23) [Exhibit 10.16](#)
- 10.17 Security Agreement by and between the Company and Peak One Opportunity Fund, LP dated September 28, 2018 (23) [Exhibit 10.17](#)
- 10.18 Promissory Note issued to Carl Schwartz dated November 30, 2018 (27) [Exhibit 10.18](#)
- 10.19 Forbearance Agreement by and between L2 Capital, LLC and the Company dated February 7, 2019 (25) [Exhibit 10.19](#)
- 10.20 Forbearance Agreement by and between Peak One Opportunity Fund, LP and the Company dated February 7, 2019 (25) [Exhibit 10.20](#)
- 10.21 Amended and Restated Promissory Note issued to L2 Capital, LLC dated February 7, 2019 (25) [Exhibit 10.21](#)
- 10.22 Amended and Restated Promissory Note issued to Peak One Opportunity Fund, LP dated February 7, 2019 (25) [Exhibit 10.22](#)
- 10.23 Amended and Restated Promissory Note issued to Carl Schwartz dated January 8, 2019 (28) [Exhibit 10.23](#)
- 10.24 Subscription Agreement by and between Carl Schwartz and the Company dated January 8, 2019 (28) [Exhibit 10.24](#)
- 10.25 Amendment to Employment Agreement by and between the Issuer and Carl Schwartz dated August 20, 2018 (29)\*\* [Exhibit 10.25](#)
- 10.26 Amendment to Employment Agreement by and between the Issuer and Bob Myers dated August 20, 2018\*\* (30) [Exhibit 10.26](#)
- 10.27 Consulting Agreement by and between the Issuer and Richard Gabriel dated May 1, 2019 (32) [Exhibit 10.27](#)
- 10.28 Securities Purchase Agreement (Series E) (36) [Exhibit 10.28](#)

- 10.29 Second Amendment to Employment Agreement by and between the Issuer and Carl Schwartz dated July 1, 2019\*\* (33) [Exhibit 10.29](#)
- 10.30 Securities Purchase Agreement by and between the Issuer and Oasis Capital, LLC dated September 27, 2019 (37) [Exhibit 10.30](#)
- 10.31 Senior Secured Promissory Note Issued to Oasis Capital, LLC dated September 27, 2019 (37) [Exhibit 10.31](#)
- 10.32 Security Agreement by and between the Issuer and Oasis Capital, LLC dated September 27, 2019 (37) [Exhibit 10.32](#)
- 10.33 Amendment #1 to the Amended and Restated senior Secured Promissory Note Originally Issued to L2 Capital, LLC on September 18, 2018 (37) [Exhibit 10.33](#)
- 10.34 Equity Purchase Agreement by and between the Issuer and Oasis Capital, LLC dated October 24, 2019 (40) [Exhibit 10.34](#)
- 10.35 Registration Rights Agreement by and between the Issuer and Oasis Capital, LLC dated October 24, 2019 (40) [Exhibit 10.35](#)
- 10.36 Amendment #2 to the Amended and Restated senior Secured Promissory Note Originally Issued to L2 Capital, LLC on September 18, 2018 (42) [Exhibit 10.36](#)
- 10.37 Promissory Note Issued to Oasis Capital, LLC dated November 26, 2019 (43) [Exhibit 10.37](#)
- 10.38 Exchange Agreement by and between the Issuer and Carl Schwartz dated January 31, 2020 (44) [Exhibit 10.38](#)
- 10.39 Promissory Note issued to Carl Schwartz dated January 31, 2020 (44) [Exhibit 10.39](#)
- 10.40 Securities Purchase Agreement by and between the Issuer and Oasis Capital, LLC dated February 5, 2020 (45) [Exhibit 10.40](#)
- 10.41 Senior Secured Promissory Note Issued to Oasis Capital, LLC dated February 5, 2020 (45) [Exhibit 10.41](#)
- 10.42 Security Agreement by and between the Issuer and Oasis Capital, LLC dated February 5, 2020 (45) [Exhibit 10.42](#)
- 10.43 Securities Purchase Agreement by and among the Company and the Investors dated March 15, 2020 (46) [Exhibit 10.43](#)
- 10.44 Registration Rights Agreement by and among the Company and the Investors dated March 15, 2020 (46) [Exhibit 10.44](#)
- 10.45 Amendment #3 to the Amended and Restated Senior Secured Promissory Note Originally Issued on September 28, 2018 (47) [Exhibit 10.45](#)
- 10.46 Amendment #1 to the Senior Secured Promissory Note Originally Issued on September 27, 2019 (47) [Exhibit 10.46](#)
- 14.1 Code of Ethics (5) [Exhibit 14.1](#)
- [23.1\\*](#) [Consent of Independent Registered Public Accounting Firm: Deloitte & Touche LLP](#)
- [31.1\\*](#) [Certification of principal executive officer required by Rule 13a-14\(a\)](#)
- [31.2\\*](#) [Certification of principal financial officer required by Rule 13a-14\(a\)](#)
- [32.1\\*](#) [Section 1350 Certification](#)



101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

\*Filed herewith.

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

- (1) Filed on December 19, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (2) Filed on November 12, 2008 as an exhibit to our Registration Statement on Form S-1 and incorporated herein by reference.
- (3) Filed on November 5, 2012 as an exhibit to our Registration Statement on Form S-1 and incorporated herein by reference.
- (4) 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.
- (5) Filed on April 16, 2012 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference.
- (6) Filed on October 24, 2014 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (7) Filed on June 30, 2015 as an appendix to our Information Statement on Schedule 14C and incorporated herein by reference.
- (8) Filed on February 6, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (9) 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.
- (10) 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.
- (11) Filed on September 16, 2016 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (12) Filed on October 27, 2016 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (13) Filed on January 27, 2017 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (14) 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.
- (15) Filed on November 30, 2016 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (16) 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.

- (17) Filed on March 15, 2017 as an exhibit to our Registration Statement on Form S-8 and incorporated herein by reference.
- (18) Filed on October 30, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (19) Filed on August 14, 2017 as an exhibit to our Quarterly Report on Form 10-Q and incorporated herein by reference.
- (20) Filed on November 29, 2017 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (21) Filed on January 2, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (22) Filed on January 10, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (23) Filed on October 4, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (24) Filed on March 22, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (25) Filed on February 12, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (26) Filed on March 1, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (27) Filed on December 7, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (28) Filed on January 14, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (29) Filed on January 25, 2019 as an exhibit to the Schedule 13D report filed by Carl Schwartz and incorporated herein by reference.
- (30) Filed on April 1, 2019 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference.
- (31) Filed on April 2, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (32) Filed on May 8, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (33) Filed on August 19, 2019 as an exhibit to our Quarterly Report on Form 10-Q and incorporated herein by reference
- (34) Filed on June 13, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (35) Filed on June 19, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference

- (36) Filed on July 11, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (37) Filed on September 30, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (38) Filed on October 3, 2019 as an exhibit to our Registration Statement on Form S-3 (File No. 333-234073) and incorporated herein by reference
- (39) Filed on October 10, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (40) Filed on October 25, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (41) Filed on October 28, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (42) Filed on December 17, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (43) Filed on December 19, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (44) Filed on February 4, 2020 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (45) Filed on February 7, 2020 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (46) Filed on March 16, 2020 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (47) Filed on March 23, 2020 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference

The audited financial statements for the periods ended December 31, 2019 and December 31, 2018 are included on the following pages:

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
Financial Statements:	
<a href="#">Report of Independent Registered Public Accounting Firm</a>	<a href="#">F-1</a>
<a href="#">Consolidated Balance Sheets</a>	<a href="#">F-2</a>
<a href="#">Consolidated Statements of Net Loss</a>	<a href="#">F-3</a>
<a href="#">Consolidated Statements of Stockholders' Equity</a>	<a href="#">F-4</a>
<a href="#">Consolidated Statements of Cash Flows</a>	<a href="#">F-6</a>
<a href="#">Notes to Consolidated Financial Statements</a>	<a href="#">F-7</a>

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Predictive Oncology Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Predictive Oncology Inc. (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of net loss, stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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 audits. 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 audits 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 audits, 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, Minnesota

March 31, 2020

We have served as the Company's auditor since 2018.

**PREDICTIVE ONCOLOGY INC.**  
**CONSOLIDATED BALANCE SHEETS**

	December 31, 2019	December 31, 2018
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents	\$ 150,831	\$ 162,152
Accounts Receivable	297,055	232,602
Notes Receivable (inclusive of \$0 and \$452,775 in advances to Helomics; net of \$1,037,524 and \$0 in allowances for credit losses)	-	497,276
Inventories	190,156	241,066
Prepaid Expense and Other Assets	160,222	318,431
<b>Total Current Assets</b>	<b>798,264</b>	<b>1,451,527</b>
Notes Receivable	-	1,112,524
Fixed Assets, net	1,507,799	180,453
Intangibles, net	3,649,412	964,495
Lease Right-of-Use Assets	729,745	-
Goodwill	15,690,290	-
<b>Total Assets</b>	<b>\$ 22,375,510</b>	<b>\$ 3,708,999</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$ 3,155,641	\$ 445,689
Notes Payable – Net of Discounts of \$350,426 and \$1,032,813	4,795,800	1,634,914
Accrued Expenses	2,371,633	1,279,114
Derivative Liability	50,989	272,745
Deferred Revenue	40,384	23,065
Lease Liability – Net of Long-Term Portion	459,481	-
<b>Total Current Liabilities</b>	<b>10,873,928</b>	<b>3,655,527</b>
Lease Liability	270,264	-
<b>Total Liabilities</b>	<b>11,144,192</b>	<b>3,655,527</b>
Stockholders' Equity:		
Preferred Stock, 20,000,000 authorized inclusive of designated below		
Series B Convertible Preferred Stock, \$.01 par value, 2,300,000 authorized, 79,246 and 79,246 shares outstanding	792	792
Series D Convertible Preferred Stock, \$.01 par value, 3,500,000 authorized, 3,500,000 and 0 shares outstanding	35,000	-
Series E Convertible Preferred Stock, \$.01 par value, 350 authorized, 258 and 0 shares outstanding	3	-
Common Stock, \$.01 par value, 100,000,000 and 50,000,000 authorized, 4,056,652 and 1,409,175 outstanding	40,567	14,092
Additional Paid-in Capital	93,653,667	63,146,533
Accumulated Deficit	(82,498,711)	(63,107,945)
<b>Total Stockholders' Equity</b>	<b>11,231,318</b>	<b>53,472</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 22,375,510</b>	<b>\$ 3,708,999</b>

See Notes to Consolidated Financial Statements

**PREDICTIVE ONCOLOGY INC.**  
**CONSOLIDATED STATEMENTS OF NET LOSS**

	<b>Year Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
Revenue	\$ 1,411,565	\$ 1,411,655
Cost of goods sold	531,810	415,764
Gross margin	879,755	995,891
General and administrative expense	9,781,218	4,626,997
Operations expense	2,960,131	1,861,121
Sales and marketing expense	1,912,899	2,369,152
Total operating loss	(13,774,493)	(7,861,379)
Gain on revaluation of cash advances to Helomics	1,222,244	-
Other income	287,056	510,254
Other expense	(3,979,946)	(441,772)
Loss on goodwill impairment	(8,100,000)	-
Loss on intangible impairment	(770,250)	-
Loss on equity method investment	(439,637)	(2,293,580)
Gain on revaluation of equity method investment	6,164,260	-
Net loss	\$ (19,390,766)	\$ (10,086,477)
Deemed dividend on Series E Convertible Preferred Stock	289,935	-
Net loss attributable to common shareholders	\$ (19,680,701)	\$ (10,086,477)
Loss per common share - basic and diluted	\$ (6.86)	\$ (7.87)
Weighted average shares used in computation - basic and diluted	2,870,132	1,281,629

See Notes to Consolidated Financial Statements

**PREDICTIVE ONCOLOGY INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**FOR THE YEARS ENDED**  
**DECEMBER 31, 2019 and 2018**

	Year Ended December 31, 2018								
	Series B Preferred		Series C Preferred		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	
Balance at 12/31/2017	79,246	\$ 792	647,819	\$ 6,479	694,328	\$ 6,943	\$ 55,699,169	\$ (53,021,469)	\$ 2,691,914
Preferred conversion to common shares pursuant to private placement agreement			(647,819)	(6,479)	58,975	590	5,889		-
Shares issued pursuant to S-3 public offering					290,000	2,900	2,752,187		2,755,087
Investment in Subsidiary pursuant to Helomics 20% acquisition					110,000	1,100	1,041,150		1,042,250
E Warrant exercises pursuant to S-3 public offering at \$10.00 exercise price per share					14,539	145	145,251		145,396
Shares issued pursuant to S-3 public offering over-allotment option at \$9.497 exercise price per share					21,525	215	204,206	1	204,422
Re-priced warrant exercise pursuant to 2016 private investment					50,467	505	504,160		504,665
Shares issued pursuant to a consultant contract @ 11.80 per share					25,000	250	294,750		295,000
Shares issued in escrow pursuant to a contract with TumorGenesis @ 11.70 per share					75,000	750	876,750		877,500
Stock issuable for bridge loan					65,000	650	205,955		206,605
Warrants issued per bridge loan							183,187		183,187
Shares issued to employee in lieu of bonus					4,341	44	40,194		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	79,246	\$ 792	-	-	1,409,175	\$ 14,092	\$ 63,146,533	\$ (63,107,945)	\$ 53,472



	Year Ended December 31, 2019										
	Series B Preferred		Series D Preferred		Series E Preferred		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at 12/31/2018	79,246	\$ 792	-	-	-	-	1,409,175	\$ 14,092	\$ 63,146,533	\$ (63,107,945)	\$ 53,472
Investment by CEO							7,813	78	49,922		50,000
Shares issued in forbearance agreement							16,667	166	158,183		158,349
Shares issued pursuant to S-3 public offering							919,929	9,200	5,263,818		5,273,018
Shares issued pursuant to note conversions - bridge loan							103,415	1,034	377,539		378,573
Shares issued pursuant to bridge loan agreement							30,000	300	127,200		127,500
Shares issued pursuant to promissory notes							8,857	89	130,129		130,218
Warrants issued pursuant to promissory note									180,640		180,640
Warrants issued pursuant to CEO note payable									356,471		356,471
Stock issued for Helomics acquisition			3,500,000	35,000			400,000	4,000	5,573,250		5,612,250
Stock issued to extinguish debt as part of Helomics purchase consideration							863,732	8,637	6,454,672		6,463,309
Issuance of warrants as Helomics purchase consideration									6,261,590		6,261,590
Exercise of warrants							59,700	597	5,373		5,970
Issuance of Series E preferred shares					258	3			2,338,837		2,338,840
Issuance of noteholders warrants									177,343		177,343
Inducement shares issued pursuant to equity line							104,652	1,047	448,953		450,000
Shares issued pursuant to equity line							122,356	1,224	317,972		319,196
Vesting expense									2,250,422		2,250,422
Share issuance to investor relations consultant and other							10,356	103	34,820		34,923
Net loss										(19,390,766)	(19,390,766)
Balance at 12/31/2019	79,246	\$ 792	3,500,000	\$ 35,000	258	\$ 3	4,056,652	\$ 40,567	\$ 93,653,667	\$ (82,498,711)	\$ 11,231,318

See Notes to Consolidated Financial Statements

**PREDICTIVE ONCOLOGY INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Year Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
<b>Cash flow from operating activities:</b>		
Net loss	\$ (19,390,766)	\$ (10,086,477)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Recognition of credit loss on notes receivable	1,037,524	-
Loss on equity method investment	439,637	2,293,580
Gain on revaluation of equity method investment	(6,164,260)	-
Depreciation and amortization	704,883	147,628
Vesting expense	2,250,422	1,124,928
Equity instruments issued for management, consulting, and other	484,923	335,238
Amortization of debt discount	2,023,315	385,111
Gain on valuation of equity-linked instruments	(221,756)	(372,263)
Gain on revaluation of cash advances to Helomics	(1,222,244)	-
Debt extinguishment costs	581,073	-
Loss on goodwill and intangible impairment	8,870,250	-
Loss on fixed asset disposal	1,096	-
<b>Changes in assets and liabilities:</b>		
Accounts receivable	143,316	(95,103)
Inventories	91,114	23,979
Prepaid expense and other assets	(29,747)	139,895
Accounts payable	365,772	305,227
Accrued expenses	1,285,678	493,899
Deferred revenue	17,319	16,402
<b>Net cash used in operating activities:</b>	<b>(8,732,451)</b>	<b>(5,287,956)</b>
<b>Cash flow from investing activities:</b>		
Redemption of certificates of deposit	-	244,971
Advances on notes receivable	(975,000)	(1,123,619)
Cash received from notes receivable	154,418	-
Cash received from Helomics acquisition	248,102	-
Purchase of fixed assets	(5,888)	(177,732)
Acquisition of intangibles	(20,719)	(54,271)
<b>Net cash used in investing activities</b>	<b>(599,087)</b>	<b>(1,110,651)</b>
<b>Cash flow from financing activities:</b>		
Proceeds from debt issuance	2,690,000	2,185,000
Repayment of debt	(1,154,513)	-
Payment penalties	(202,294)	-
Proceeds from issuance of stock pursuant to equity line	319,196	-
Proceeds from exercise of warrants into common stock	5,970	650,061
Proceeds from issuance of Series E convertible preferred stock	2,338,840	-
Issuance of common stock	5,323,018	2,959,509
<b>Net cash provided by financing activities</b>	<b>9,320,217</b>	<b>5,794,570</b>
<b>Net decrease in cash</b>	<b>(11,321)</b>	<b>(604,037)</b>
Cash at beginning of period	162,152	766,189
Cash at end of period	<u>\$ 150,831</u>	<u>\$ 162,152</u>
<b>Non-cash transactions</b>		
Bridge loan conversion into common stock	378,573	-
Forbearance settlement bridge loan	503,009	-
Additional warrants issued pursuant to CEO note payable	47,078	-
Warrants issued pursuant to debt issuance	180,640	-
Consideration given for acquisition of Helomics	26,711,790	-
Debt modification costs	162,750	-
Conversion of preferred stock to common stock	-	6,479
Equity method investment – Helomics	-	1,542,250
Licensing fee for TumorGenesis	-	877,500
<b>Cash paid during the period for:</b>		
Interest paid on debt	146,064	-

See Notes to Consolidated Financial Statements



**PREDICTIVE ONCOLOGY INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

**Nature of Operations and Continuance of Operations**

Predictive Oncology Inc., (the “Company” or “Predictive”) 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 its Certificate of Incorporation to change the corporate name from Skyline Medical Inc. to Precision Therapeutics Inc., effective February 1, 2018. Because of this change, the Company’s common stock traded under the ticker symbol “AIPT,” effective February 2, 2018. On June 10, 2019, the Company filed with the Secretary of State of Delaware a Certificate of Amendment to its Certificate of Incorporation to change the corporate name from Precision Therapeutics Inc. to Predictive Oncology Inc., trading under the new ticker symbol “POAI,” effective June 13, 2019. Skyline Medical Inc. remains as an incorporated division of Predictive Oncology Inc. On October 28, 2019, the Company completed a one-for-ten reverse stock split that was effective for trading purposes on October 29, 2019. All numbers of shares and per-share amounts have been adjusted to reflect the reverse stock split.

The Company is a healthcare company that provides personalized medicine solution and medical devices in two main areas: (1) precision medicine, which aims to apply artificial intelligence (“AI”) to personalized medicine and drug discovery; and (2) 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 proprietary cleaning fluid and filters to users of its systems.

In addition, the Company’s wholly-owned subsidiary, TumorGenesis Inc. (“TumorGenesis”), is developing the next generation, patient-derived tumor models for precision cancer therapy and drug development. TumorGenesis Inc., formed during the first quarter of 2018, is presented as part of the consolidated financial statements (“financial statements”) and is included in corporate in the Company’s segment reporting.

During the first quarter of 2018, the Company acquired 25% of the capital stock of Helomics Holding Corporation (“Helomics”). On April 4, 2019, the Company completed a forward triangular merger with Helomics Acquisition Inc., a wholly-owned subsidiary of the Company and Helomics, acquiring the remaining 75% of the capital stock of Helomics (“Helomics Acquisition”).

The Company has incurred recurring losses from operations and has an accumulated deficit of \$82,498,711. The Company does not expect to generate sufficient operating revenue to sustain its operations in the near-term. During fiscal year 2019, the Company incurred negative cash flows from operations. 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. These conditions raise substantial doubts about the Company’s ability to continue as a going concern. The Company had cash and cash equivalents of \$150,831 as of December 31, 2019 and needs to raise significant additional capital to meet its operating needs and pay debt obligations coming due. Outstanding debt, including accrued interest and penalties, totaled \$6,213,507 as of December 31, 2019, all of which is due within six months. Debt is secured by all assets of the Company and its subsidiaries. The Company intends to raise these funds through equity or debt financing that may include public offerings, private placements, alternative offerings, or other means. In October 2019, the Company entered into a purchase agreement for an equity line under which it can raise up to \$15,000,000 over a three-year period, subject to market conditions including trading volume and stock price. Given the limitations in place there is no guarantee that the Company will be able to raise the full amount available under the equity line over the course of the three-year period. During 2019, the Company issued 122,356 shares of its common stock valued at \$319,196 pursuant to the equity line. In 2020, the Company completed various debt and equity financings and raised net proceeds of \$6,159,906, that is net of repayments. See Note 13 – Subsequent Events for more information. Despite these sources of funding, it is not probable the Company will be able to obtain additional financing in order to fund operations. 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 accompanying financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

The Company has no commitments or contingencies.

### Recently Adopted Accounting Standards

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“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. 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. Upon adoption, the Company recognized \$353,007 of lease right-of-use (ROU) assets and liabilities for operating leases on its consolidated balance sheet, of which, \$79,252 were classified as current liabilities. The adoption of ASU 2016-02 did not have a material impact on the Company’s consolidated results of operations or cash flows.

The Company leases facilities under long-term operating leases that are non-cancelable and expire on various dates. At the lease commencement date, lease ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term, which includes all fixed obligations arising from the lease contract. If an interest rate is not explicit in a lease, the Company utilizes its incremental borrowing rate for a period that closely matches the lease term. See Note 10 – Leases.

### Accounting Policies and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent assets and liabilities at the date of the financial statements and during the reporting period. Actual results could materially differ from those estimates.

### Cash and Cash Equivalents

Cash and cash equivalents consist of cash on hand. The company has no cash equivalents during the years ended December 31, 2018 and December 31, 2019.

### 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 allowance based on management’s assessment of the current status of individual accounts. During 2019, the Company recorded a valuation allowance of \$1,037,524 related to the notes receivable balance. See Note 6 – Notes Receivable.

### Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. Inventory balances consist of the following:

	<u>December 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Finished goods	\$ 91,410	\$ 58,701
Raw materials	69,821	127,003
Work-In-Process	28,925	55,362
Total	<u>\$ 190,156</u>	<u>\$ 241,066</u>

## Fixed Assets

Fixed assets are stated at cost less accumulated depreciation. Depreciation of fixed assets is computed using the straight-line method over the estimated useful lives of the respective assets. Accumulated depreciation is included in fixed assets, net on the accompanying consolidated balance sheets. Estimated useful life by asset classification is as follows:

	Years
Computers and office equipment	3 - 7
Leasehold improvements <sup>(1)</sup>	5
Manufacturing and laboratory equipment	3 - 7
Demonstration equipment	3
Laboratory equipment	4

(1) Leasehold improvements are depreciated over the shorter of the useful life or the remaining lease term.

The Company's fixed assets consist of the following:

	December 31, 2019	December 31, 2018
Computers and office equipment	\$ 508,143	\$ 204,903
Leasehold improvements	188,014	140,114
Manufacturing tooling	1,510,165	108,955
Demo equipment	73,051	85,246
Total	2,279,373	539,218
Less: Accumulated depreciation	771,574	358,765
Total fixed assets, net	\$ 1,507,799	\$ 180,453

Upon retirement or sale of fixed assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations expense. Maintenance and repairs are expensed as incurred.

Depreciation expense was \$414,331 and \$84,995 in 2019 and 2018, respectively.

## Intangible Assets

Finite-lived intangible assets consist of patents and trademarks, licensing fees, developed technology, and customer relationships, and are amortized over their estimated useful life. The tradename is an indefinite-lived intangible asset and is not amortized. Amortization expense was \$290,552 and \$62,633 in 2019 and 2018, respectively. Accumulated amortization is included in intangibles, net in the accompanying consolidated balance sheets. The Company reviews finite-lived identifiable intangible assets for impairment in accordance with ASC 360 — *Property, Plant and Equipment*, whenever events or changes in circumstances indicate the carrying amount may not be recoverable. 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. The Company reviews its other intangible assets in accordance with ASC 350—*Intangibles—Goodwill and Other*. Under this topic, intangible assets determined to have an indefinite useful life are not amortized but are tested for impairment annually or more often if an event or circumstances indicate that an impairment loss has been incurred.

As of December 31, 2019, there were \$3,649,412 in net intangibles, representing a large fluctuation due to the Helomics acquisition as compared to \$964,495 in net intangibles as of December 31, 2018.

The components of intangible assets were as follows:

	December 31, 2019			December 31, 2018		
	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount
Patents & Trademarks	\$ 339,023	\$ (195,286)	\$ 143,737	\$ 318,304	\$ (182,559)	\$ 135,745
Licensing Fees	-	-	-	877,500	(48,750)	828,750
Developed Technology	2,882,000	(108,075)	2,773,925	-	-	-
Customer Relationships	445,000	(111,250)	333,750	-	-	-
Tradename	398,000	-	398,000	-	-	-
Total	\$ 4,064,023	\$ (414,611)	\$ 3,649,412	\$ 1,195,804	\$ (231,309)	\$ 964,495

The following table outlines the estimated future amortization expense related to intangible assets held as of December 31, 2019:

Year ending December 31,	Expense
2020	\$ 305,785
2021	305,785
2022	194,535
2023	157,452
2024	157,452
Thereafter	2,130,403
Total	\$ 3,251,412

### Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment and intangible assets with estimable useful lives, for impairment whenever events or changes in circumstances indicate that the carrying amount of such an asset may not be recoverable.

The recoverability of an asset to be held and used is determined by comparing the carrying amount to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of the asset exceeded its estimated undiscounted future cash flows, the Company recorded an impairment charge in the amount by which the carrying amount of the asset exceeds its fair value, which is determined by either a quoted market price, if any, or a value determined by utilizing discounted cash flow techniques.

During 2019, the Company recognized \$58,500 of amortization expense related to license fees. The Company also determined that due to lower than anticipated revenues from the Company's TumorGenesis subsidiary, the licensing fee intangible asset may not be recoverable. The Company incurred impairment charges of \$770,250 related to the full remaining value of the TumorGenesis licensing fees asset, which was included in corporate in the Company's segment reporting. No impairment charges were incurred during 2018.

### Goodwill

In accordance with ASC 350 – *Intangibles – Goodwill and Other*, goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the fair value of net assets acquired. Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination. Goodwill is an indefinite-lived asset and is not amortized. Goodwill is tested for impairment annually at the reporting unit level, or whenever events or circumstances present an indication of impairment.

In the Helomics acquisition, the Company recorded goodwill of \$23,790,290. The goodwill was recorded to the Helomics segment which represents a single reporting unit. As a part of the annual impairment testing, the Company had the option to assess qualitative factors to determine if it was more likely than not that the carrying value of a reporting unit exceeded its estimated fair value. The Company believed a qualitative testing approach was not appropriate and, therefore, proceeded to the quantitative testing. When performing quantitative testing, the Company first estimated the fair value of the Helomics reporting unit using discounted cash flows. To determine fair values, the Company was required to make assumptions about a wide variety of internal and external factors. Significant assumptions used in the impairment analysis included financial projections of free cash flow (including significant assumptions about operations including the rate of future revenue growth, capital requirements, and income taxes), long-term growth rates for determining terminal value, and discount rates for the Helomics reporting unit. Comparative market multiples were also used to corroborate the results of the discounted cash flow test. These assumptions required significant judgment and actual results may differ from assumed and estimated amounts.

In testing goodwill for impairment as of December 31, 2019, the Company performed a quantitative impairment test, including computing the fair value of the Helomics reporting unit and comparing that value to its carrying value. Based upon the Company's annual goodwill impairment test, the Company concluded that goodwill was impaired as of the testing date of December 31, 2019. Pursuant to ASU 2017-04 – *Simplifying the Test for Goodwill Impairment*, the single step is to determine the estimated fair value of the reporting unit and compare it to the carrying value of the reporting unit, including goodwill. To the extent the carrying amount of goodwill exceeds the implied goodwill, the difference is the amount of the goodwill impairment. The Company's annual impairment test as of December 31, 2019 resulted in \$8,100,000 of impairment expense related to goodwill. There was no impairment expense recorded in the twelve months ended December 31, 2018.

Goodwill balance at December 31, 2018	\$	<u>-</u>
Acquired		23,790,290
Impairment		<u>(8,100,000)</u>
Goodwill balance at December 31, 2019	\$	<u>15,690,290</u>

When evaluating the fair value of Helomics reporting unit the Company used a discounted cash flow model. Key assumptions used to determine the estimated fair value included: (a) expected cash flow for the 20-year period following the testing date (including net revenues, costs of revenues, and operating expenses as well as estimated working capital needs and capital expenditures); (b) an estimated terminal value using a terminal year growth rate of 3.0% determined based on the growth prospects of the reporting unit; and (c) a discount rate of 18.3% based on management's best estimate of the after-tax weighted average cost of capital. The discount rate included a company specific risk premium of 7% for risks related to the term of the forecasts.

The majority of the inputs used in the discounted cash flow model are unobservable and thus are considered to be Level 3 inputs.

The Company will continue to monitor its reporting units to determine whether events and circumstances warrant further interim impairment testing. Goodwill is not expected to be deductible for tax purposes.

### Fair Value Measurements

As outlined in ASC – 820, *Fair Value Measurement*, 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 consist of cash and cash equivalents, was determined based on Level 1 inputs. The fair value of the Company's derivative liabilities related to the bridge loan and the note payable agreement with the Company's CEO was determined based on Level 3 inputs.

### **Revenue Recognition**

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. Sales taxes are excluded from revenue and expenses. See Note 4 – Revenue Recognition.

### **Income Taxes**

The Company accounts for income taxes in accordance with ASC 740 - *Income Taxes* ("ASC 740"). Under ASC 740, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to impact taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

There is no income tax provision in the accompanying consolidated statements of net loss due to the cumulative operating losses that indicate a 100% valuation allowance for the deferred tax assets and state income taxes is appropriate.

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.

Under Internal Revenue Code Section 382, certain stock transactions which significantly change ownership could limit the amount of net operating carryforwards that may be utilized on an annual basis to offset taxable income in future periods. The Company has not yet performed an analysis of the annual net operating loss carryforwards and limitations that are available to be used against taxable income. Consequently, the limitation, if any, could result in the expiration of the Company's loss carryforwards before they can be utilized. The Company has not analyzed net operating loss carryforwards under Section 382 to date. As a result of the Helomics acquisition, there may be significant limitation to the net operating loss. The Company intends to complete a Section 382 analysis in 2020.

Tax years subsequent to 2015 remain open to examination by federal and state tax authorities.

### **Advertising**

Advertising costs are expensed as incurred. Advertising expenses were \$21,166 in 2019 and \$43,548 in 2018.

### **Research and Development**

Research and development costs are charged to operations as incurred. Research and development costs were \$422,964 and \$526,257 during 2019 and 2018, respectively.

### **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. During 2019, the Company capitalized offering costs of \$324,459 that were deemed to be significant.

## 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 for cash amounts held in a single institution that are in excess of amounts insured by the Federal Deposit Insurance Corporation.

## Product Warranty Costs

In 2019 and in 2018, the Company incurred \$15,717 and \$10,682, respectively in product warranty costs.

## Other Expense

Other expense consisted primarily of interest expense, payment penalties, amortization of original issue discounts, and loss on debt extinguishment associated to the Company's notes payable.

## Segments

The Company has determined its operating segments in accordance with ASC 280 – *Segment Reporting*. Factors used to determine the Company's reportable segments include the availability of separate financial statements, the existence of locally based leadership across geographic regions, the economic factors affecting each segment, and the evaluation of operating results at the segment level. The Chief Operating Decision Maker ("CODM") allocates the Company's resources for each of the operating segments and evaluates their relative performance. Each operating segment listed below has separate financial statements and locally based leadership that are evaluated based on the results of their respective segments. It should be noted that the operating segments below have different products and services. The financial information is consolidated and evaluated regularly by the CODM in assessing performance and allocating resources.

During the fourth quarter of 2019, the CODM made changes to the internal organization of the Company which resulted in a change in the Company's operating segments. The CODM determined that clinical testing revenue, CRO revenue and D-CHIP should be consolidated into one operating segment, Helomics. The Company concluded the change in operating segments did not require restatement of prior period amounts as in 2018, substantially all of the Company's revenues and expenses were located or derived from operations within the Domestic operating segment. The Company has three operating segments: domestic, international, and Helomics. See Note 4 – Revenue Recognition for a description of the products and services recognized in each segment. The segment revenues and segment net losses for the year ended December 31, 2019 are included in the table below. All revenues are earned from external customers. All interest income and interest expense are recognized under corporate. There are significant changes in the Company's assets relating to the Helomics acquisition specifically for intangibles, tangible fixed assets, and goodwill; see Note 2 – Helomics Acquisition for further discussion. Expenditures for long-lived assets exclusive of the Helomics acquisition were not significant.

	Year Ended December 31, 2019				
	Domestic	International	Helomics	Corporate	Total
Revenue	\$ 1,275,048	\$ 88,070	\$ 48,447	-	\$ 1,411,565
Depreciation and Amortization	(43,728)	(4,692)	(556,538)	(99,925)	(704,883)
Impairment expense	-	-	(8,100,000)	(770,250)	(8,870,250)
Loss on equity method investment	-	-	-	(439,637)	(439,637)
Segment Loss	\$ (2,783,531)	\$ (351,759)	\$ (12,354,108)	\$ (3,901,368)	\$ (19,390,766)

	December 31, 2019				
	Domestic	International	Helomics	Corporate	Total
Assets	\$ 670,841	\$ 298,952	\$ 21,275,306	\$ 130,411	\$ 22,375,510

In 2018, substantially all the Company revenues and expenses were located or derived from operations in the United States and recorded under the domestic segment.

	December 31, 2018				
	Domestic	International	Helomics	Corporate	Total
Assets	\$ 932,367	\$ 41,377	-	\$ 2,735,255	\$ 3,708,999

## **Risks and Uncertainties**

The Company is subject to risks common to companies in the medical device and biopharmaceutical industries, 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 Food and Drug Administration, Clinical Laboratory Improvement Amendments, and other governmental agencies.

### **NOTE 2 – HELOMICS ACQUISITION**

On April 4, 2019, the Company completed a forward triangular merger with Helomics Acquisition Inc., a wholly-owned subsidiary of the Company and Helomics, acquiring the remaining 75% of the capital stock of Helomics.

Helomics' precision medicine services are designed to use AI and a comprehensive disease database to improve the effectiveness of cancer therapy. 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 AI 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.

The acquisition of Helomics was accounted for as a business combination using the acquisition method of accounting. This method requires, among other things, that assets acquired and liabilities assumed be recognized at fair value as of the acquisition date. The fair value for the assets acquired and the liabilities assumed are based on information knowable and determined by management as of the date of this filing. The Company incurred \$656,615 in acquisition costs predominantly in legal and audit expenses.

The fair value of the consideration transferred in the acquisition has five components totaling \$26,711,790. The following table summarizes the acquisition date fair values of assets acquired and liabilities assumed, and the consideration transferred:

Value of shares to Helomics shareholders (i)	\$ 5,612,250
Value of Helomics notes receivable forgiven (ii)	2,210,381
Value of shares to extinguish debt (iii)	6,463,309
Value of warrants issued (iv)	6,261,590
Gain on revaluation of equity method investment (v)	6,164,260
Fair value of the consideration	<u>\$ 26,711,790</u>
Less assets acquired:	
Cash and cash equivalents	248,102
Accounts receivable	207,769
Inventory	17,727
Prepaid expenses	15,321
Fixed assets, net	1,749,080
Intangible assets	3,725,000
Lease right of use assets	780,594
Plus liabilities assumed:	
Accounts payable	2,374,596
Note Payable	303,333
Accrued expenses	363,569
Lease Liability – Net of Long-term Portion	422,126
Lease liability	358,468
Total assets acquired and liabilities assumed	<u>(2,921,501)</u>
Goodwill	<u>\$ 23,790,290</u>

(i) Upon the acquisition, all outstanding shares of Helomics stock not already held by the Company were converted into the right to receive a proportionate share of 400,000 shares of common stock and 3,500,000 shares of Series D convertible preferred stock of the Company. The fair value of these shares on the date of issuance was \$5,612,250; (ii) the Company forgave notes and interest due from Helomics relating to previous cash advances equaling \$2,210,381; (iii) the Company eliminated debt owed by Helomics to noteholders by issuing 863,732 shares of common stock to the noteholders, the value of the shares was \$6,463,309; (iv) the Company issued 1,425,506 warrants in exchange for warrants to purchase 23,741,772 shares of Helomics common stock to the Helomics noteholders agreeing to extinguish or extend their notes. An additional 59,700 warrants were exchanged for warrants held by other parties; the total consideration of all the exchanged warrants was valued by using the Black Scholes method and equaled \$6,261,590; and, (v) as the Company's acquisition of Helomics was a business combination achieved in stages, the initial 25% purchase of Helomics in 2018 was required to be revalued at current fair value on the acquisition date. Immediately prior to the acquisition date the recorded value of the equity method investment was zero. On the acquisition date the Company determined the fair value of the previous equity method investment was \$6,164,260 and recorded a gain for the same amount in order to recognize the investment at its fair value. The gain was calculated as the difference between the implied fair value of the Company's previous equity method investment in Helomics and the recorded book value immediately prior to the acquisition date. The implied fair value was calculated based on the purchase consideration exchanged to acquire the remaining 75% of Helomics and factoring a 10% discount for lack of control.

The fair values of all common and preferred shares issued as consideration in the transaction was determined using the closing bid price of the Company's common stock on April 4, 2019.

The Company did not legally assume the debt extinguished on the day of the acquisition, however three noteholders did not exchange their notes for shares representing \$303,333 in principal. The holders agreed to extend their notes, with the last extension due on October 11, 2019. This portion of the debt was assumed by the Company and paid during the fourth quarter of 2019. In order to receive the extension, the Company agreed to issue 58,300 warrants to the noteholders at an exercise price of \$1.00 per share. The warrants were valued using the Black Scholes method. See Note 7 – Notes Payable for further discussion.

#### *Identifiable Intangible Assets*

The Company acquired intangible assets related to trademarks for the acquired Helomics trade name with an estimated fair market value of \$398,000. The Company expects to employ the Helomics trade name for the foreseeable future. The fair values of the assets were determined by the relief-from-royalty method under the income approach.

The Company acquired intangible assets with a useful life of three years and an estimated value of \$445,000 related to customer relationships stemming from stable and predictable cash flow streams associated with customers. Helomics' customer base includes contract research partnerships with pharmaceutical, diagnostic, biotechnology, and research companies. Helomics' existing customers are all within its CRO services business line. The customer relationships were valued using the with and without method under the income approach.

The Company acquired intangible assets with a useful life of 20 years and an estimated value of \$2,882,000 related to developed technology stemming from the D-CHIP diagnostic platform and underlying tumor database. Since the D-CHIP platform and underlying database was identified as the primary asset, this technology was valued using the multi-period excess earnings method under the income approach.

The acquisition costs related to the intangible assets are presented in legal and accounting expenses within general and administrative expenses in the accompanying consolidated statements of net loss.

#### Goodwill

Goodwill of \$23,790,290 recognized in the Helomics acquisition represents the excess of the consideration transferred over the fair values of assets acquired and liabilities assumed and represents the future economic benefits and synergies arising from the transaction. None of the goodwill is deductible for income tax purposes.

#### Financial Results

The financial results of Helomics since the acquisition date have been included in the Company's accompanying consolidated statements of net loss.

#### Pro Forma

The following pro forma information presents the combined results of operations of the Company and Helomics as if the acquisition of Helomics had been completed on January 1, 2018, with adjustments to give effect to pro forma events that are directly attributable to the acquisition.

	Year Ended December 31,	
	2019	2018
	Unaudited	
Revenue	\$ 1,457,625	\$ 1,812,433
Net loss attributable to common shareholders	\$ (20,947,033)	(12,419,423)

The primary adjustments include the deduction of the original depreciation and amortization and the inclusion of the revalued depreciation and amortization for Helomics tangible and intangible assets. The unaudited pro forma results do not reflect any operating efficiencies or potential cost savings which may result from the consolidation of operations. Accordingly, these unaudited pro forma results are presented for informational purposes only and are not necessarily indicative of what the actual results of operations of the combined company would have been if the acquisition had occurred at the beginning of those respective time periods, nor are they indicative of future results of operations.

There are certain portions of purchase accounting, specifically Section 382 for *Tax Loss Carryforwards*, which take place after a company has undergone a shift in ownership, that the Company has not completed yet and may have a significant impact on the financial statements.

#### NOTE 3 – EQUITY METHOD INVESTMENT

The Company acquired 25% of the capital stock of Helomics, in transactions in the first quarter of 2018. Prior to the merger on April 4, 2019, the Helomics investment was accounted for using the equity method. Helomics losses reduced the equity method investment asset on the balance sheet until it was reduced to zero with subsequent losses reducing the note receivable due from Helomics. The Company recognized a loss on equity method investment totaling \$439,637 and \$2,293,580 in 2019 and 2018, respectively, related to its investment in Helomics.

Summarized financial information for Helomics for the year ended December 31, 2019 is not presented as the results are consolidated within the Company's financial results. The results for Helomics as of December 31, 2018 are presented below:

	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

	<b>Period January 1, 2019 to April 4, 2019</b>	<b>Year Ended December 31, 2018</b>
Revenue	\$ 45,835	\$ 523,546
Gross margin	7,348	214,426
Net loss on Operations	(1,555,542)	(9,452,835)
Net Loss	(1,166,656) <sup>1</sup>	(7,159,255) <sup>1</sup>

<sup>1</sup>The loss to investee was calculated at 80% for the initial period of ownership, January 11, 2018 – February 27, 2018, and at 75% for the period of February 28, 2018 – April 4, 2019 at the current equity investment percentage owned by the Company.

The Helomics losses reduced 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 was reduced to zero. Subsequent losses reduced the note receivable due from Helomics. Note receivable on the balance sheet as of December 31, 2018 was \$413,683. The actual note due to the Company was \$1,165,013 reflecting a reduction to the loan of \$751,330 due to the equity method accounting losses incurred from Helomics ownership.

#### **NOTE 4 – REVENUE RECOGNITION**

##### *Revenue from Product Sales*

The Company has medical device revenue consisting primarily of sales of the STREAMWAY System, as well as sales of the proprietary cleaning fluid and filters for use with the STREAMWAY System. This revenue stream is reported within both the domestic and international revenue segments. The Company sells its medical device 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, and 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 acceptance of its Terms and Conditions to be a customer’s contract in all cases.

Product sales for medical devices 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: (1) the Company has transferred physical possession of the products, (2) the Company has a present right to payment, (3) the customer has legal title to the products, and (4) 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 for the medical devices 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 for medical devices 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. This revenue stream is reported under the domestic and international sales segments.

### *Revenue from Clinical Testing*

The Precision Oncology Insights are clinic diagnostic testing comprised of the Company's ChemoFx and BioSpeciFx tests. The ChemoFx test determines how a patient's tumor specimen reacts to a panel of various chemotherapy drugs, while the BioSpeciFx test evaluates the expression of a particular gene related to a patient's tumor specimen. Revenues are recognized when control of the promised goods or services is transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. The estimated uncollectible amounts are generally considered implicit price concessions that are a reduction in revenue. Helomics payments terms vary by the agreements reached with insurance carriers and Medicare. The Company's performance obligations are satisfied at one point in time when test reports are delivered.

For service revenues, the Company estimates the transaction price which is the amount of consideration it expects to be entitled to receive in exchange for providing services based on its historical collection experience using a portfolio approach as a practical expedient to account for patient contracts as collective groups rather than individually. The Company monitors its estimates of transaction price to depict conditions that exist at each reporting date. If the Company subsequently determines that it will collect more consideration than it originally estimated for a contract with a patient, it will account for the change as an increase to the estimate of the transaction price, provided that such downward adjustment does not result in a significant reversal of cumulative revenue recognized.

The Company recognizes revenue from these patients when contracts as defined in ASC 606, *Revenue from Contracts with Customers* are established at the amount of consideration to which it expects to be entitled or when the Company receives substantially all of the consideration subsequent to the performance obligations being satisfied. The Company's standard payment terms for hospital and patient direct bill is 30 days after invoice date. This revenue stream is reported under the Helomics segment.

### *CRO Revenue*

Contract revenues are generally derived from studies conducted with biopharmaceutical and pharmaceutical companies. The specific methodology for revenue recognition is determined on a case-by-case basis according to the facts and circumstances applicable to a given contract. The Company typically uses an input method that recognizes revenue based on the Company's efforts to satisfy the performance obligation relative to the total expected inputs to the satisfaction of that performance obligation. For contracts with multiple performance obligations, the Company allocates the contract's transaction price to each performance obligation on the basis of the standalone selling price of each distinct good or service in the contract. Advance payments received in excess of revenues recognized are classified as deferred revenue until such time as the revenue recognition criteria have been met. Payment terms are net 30 from the invoice date, which is sent to the customer as the Company satisfies the performance obligation relative to the total expected inputs to the satisfaction of that performance obligation. This revenue stream is reported under the Helomics segment.

### *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.

### *Warranty*

The Company generally provides one-year warranties against defects in materials and workmanship on product sales 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, 2019 and 2018, accounts receivable totaled \$297,055 and \$232,602, respectively.

The Company's deferred revenues related primarily to maintenance plans of \$40,384 and \$23,065 as of December 31, 2019 and 2018, respectively.

### *Practical Expedients*

The Company has elected the practical expedient not to determine whether contracts with customers contain significant financing components as well as the practical expedient to recognize shipping and handling costs at point of sale.

## **NOTE 5 – STOCKHOLDERS' EQUITY, STOCK OPTIONS AND WARRANTS**

### *Authorized Shares*

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.

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.

### *2018 Firm Commitment Public Offering*

In January 2018, the Company completed a firm commitment underwritten public offering of 290,000 units at an offering price of \$9.50 per unit, with each unit consisting of one share of the Company's common stock and 0.3 of a warrant, with each whole warrant purchasing one share of common stock at an exercise price of \$1.00 per whole share. The shares of common stock and warrants were immediately separable and were issued separately. Gross proceeds were \$2,755,087, before deducting expenses. On February 21, 2018, the underwriter exercised on 21,525 shares of common stock, par value \$0.01, at \$9.50 per share as described in the underwriting agreement. The Company received net proceeds of \$188,066 after underwriting expenses of \$16,354 related to this exercise.

### *Share Exchange Agreement with Helomics*

On January 11, 2018, the Company entered into a share exchange agreement with Helomics. Pursuant to the share exchange agreement, Helomics issued 2,500,000 shares of its series A preferred stock in exchange for 110,000 shares of common stock. The Helomics preferred stock issued to the Company was convertible into an aggregate of 20% of the outstanding capital stock of Helomics. 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.



### *Share Issuance for Consulting*

On July 10 and 11, 2018, the Company issued 25,000 shares of common stock, par value \$0.01, at \$11.80 per share for consulting fees pursuant to the TumorGenesis license fees contract, and 75,000 shares of common stock, par value \$0.01, at \$11.70 per share, in escrow, for TumorGenesis license fees pursuant to the TumorGenesis license fees contract.

### *2019 Registered Sales of Common Stock and Warrants*

On February 27, 2019, the Company entered into a placement agency agreement for a registered direct offering in which the Company sold 138,500 shares of common stock and warrants to purchase up to 69,250 shares of common stock. The common stock and warrants were sold in units, with each unit consisting of 0.1 share of common stock and a warrant to purchase 0.05 of a share of the Company's common stock at an exercise price of \$10.00 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 \$9.00 per unit, resulting in gross proceeds of \$1,246,608 and net offering proceeds, after deducting the placement agent's fees and other estimated offering expenses of \$1,111,888. The closing of this offering occurred on March 1, 2019. The Company granted the placement agents or its assigns the right to purchase up to an aggregate of 6,925 units at an exercise price of \$11.25 per unit. The unit purchase options shall expire on February 27, 2024.

On March 26, 2019, the Company entered into a placement agency agreement for a registered direct offering in which the Company sold 147,875 shares of common stock and warrants to purchase up to 73,938 shares of common stock. The common stock and warrants were sold in units, with each unit consisting of 0.1 share of common stock and a warrant to purchase 0.05 of a share of the Company's common stock at an exercise price of \$10.00 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 \$8.00 per unit, resulting in gross proceeds of \$1,183,101 and net offering proceeds, after deducting the placement agent's fees and other estimated offering expenses of \$1,053,460. The closing of this offering occurred on March 29, 2019. The Company granted the placement agents or its assigns the right to purchase up to an aggregate of 73,937 units at an exercise price of \$1.00 per unit. The unit purchase options shall expire on March 29, 2024.

On October 1, 2019, the Company entered into a placement agency agreement for a public offering in which the Company sold 633,554 shares of the Company's common stock. The common stock was sold at a price of \$5.00 per share, resulting in gross proceeds to the Company of \$3,167,769 and net offering proceeds, after deducting the placement agents' fees and other estimated offering expenses of \$2,811,309. The closing of the offering occurred on October 4, 2019. In addition, the Company granted warrants to the placement agents to purchase up to 63,355 shares of common stock. The warrants have an exercise price of \$6.25 and include a cashless exercise.

### *Series E Convertible Preferred Stock*

In June 2019, the Company entered into a private placement securities purchase agreement with investors for shares of Series E convertible preferred stock. The Company issued 258 preferred shares. Each preferred share holder shall have the right to convert each Series E convertible preferred share into 0.056857% of the issued and outstanding shares of common stock immediately prior to conversion for each share of Series E convertible stock beginning six months after the initial close date of June 13, 2019. On the date that is 12 months after the initial closing date, the Company has the option to convert the preferred shares into common stock upon the same terms and limitations as the above optional conversion. The preferred shares include a contingent beneficial conversion amount of \$289,936, representing the intrinsic value of the shares at the time of issuance. The Company determined the Series E convertible preferred stock should be classified as permanent equity and the beneficial conversion feature amount is being accreted to the earliest redemption date of six months after the initial closing of the Series E convertible preferred stock. This offering was closed in September 2019.

## Equity Line

On October 24, 2019, the Company entered into an equity purchase agreement with an investor, providing for an equity financing facility. Upon the terms and subject to the conditions in the purchase agreement, the investor is committed to purchase shares having an aggregate value of up to \$15,000,000 of the Company's common stock for a period of up to three years. The Company issued to the investor 104,651 commitment shares at a fair market value of \$450,000 for entering into the agreement. From time to time during the three-year commitment period, provided that the closing conditions are satisfied, the Company may provide the investor with put notices to purchase a specified number of shares subject to certain limitations and conditions and at specified prices, which generally represent discounts to the market price of the common stock. During 2019, the Company issued 122,356 shares of common stock valued at \$319,196 pursuant to the equity line. As of December 31, 2019, there was \$14,680,805 remaining available balance under the equity line.

## 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 outstanding under this plan have a contractual life of ten years.

## Valuation and Accounting for Options and Warrants

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 net 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.

The Company determines the grant date fair value of options and warrants using a Black-Scholes option valuation model based upon assumptions regarding risk-free interest rate, expected dividend rate, volatility and estimated term. Beginning in 2019, the Company began calculating the estimated volatility used in the Black-Scholes option valuation model based on the trading history of the Company's own stock. Given the limited trading history of the Company's common stock, the Company had previously used the volatility of comparable companies in order to value options and warrants granted in years prior to 2019.

The fair value of each option grant is estimated on the grant date using the Black-Scholes option valuation model with the following assumptions:

	Year Ended December 31,				
	2019		2018		
	Stock Options				
Expected dividend yield	0.0%		0.0%		
Expected stock price volatility	78.6%	-	82.4%	66.0%	
Risk-free interest rate	1.50%	-	2.76%	2.46%	- 3.07%
Expected life of options (in years)	10		10		
	Warrants				
Expected dividend yield	0.0%		0.0%		
Expected stock price volatility	78.6%	-	82.4%	59.0%	
Risk-free interest rate	1.39%	-	2.58%	2.33%	- 2.96%
Expected life of options (in years)	5		5		

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, 2017	276,498	\$ 19.95	195,126	\$ 237.40
Issued	109,886	10.13	233,615	10.67
Forfeited	(19,456)	20.00	(1,071)	1,995.53
Exercised	-	-	(65,006)	10.00
Outstanding at December 31, 2018	366,928	\$ 17.03	362,664	\$ 41.67
Issued	423,295	6.53	1,869,299	9.25
Forfeited	(23,799)	13.30	(653)	3,249.28
Exercised	-	-	(59,700)	0.10
Outstanding at December 31, 2019	766,424	\$ 11.34	2,171,610	\$ 15.26

At December 31, 2019, 669,050 stock options are fully vested and currently exercisable with a weighted average exercise price of \$11.93 and a weighted average remaining term of 8.38 years. There are 2,171,610 warrants that are fully vested and exercisable. Stock-based compensation recognized in 2019 and 2018 was \$2,250,422 and \$1,124,928, respectively. The Company has \$201,628 of unrecognized compensation expense related to non-vested stock options that are expected to be recognized over the next 21 months.

The following summarizes the status of options and warrants outstanding at December 31, 2019:

Range of Exercise Prices	Shares	Weighted Average Remaining Life
<b>Options:</b>		
\$2.61 – 6.50	157,848	9.53
\$7.324 – 8.491	285,826	9.07
\$9.00 – 14.70	310,882	7.50
\$21.00 – 51.25	11,045	6.90
\$657.50 – 5,962.50	823	4.39
<b>Total</b>	<b>766,424</b>	
<b>Warrants:</b>		
\$0.10 – 8.36	250,145	4.56
\$10.00	1,674,088	4.22
\$10.71 – 22.50	237,970	3.23
\$1,237.50	9,407	0.67
<b>Total</b>	<b>2,171,610</b>	

Stock options and warrants expire on various dates from January 2020 to December 2029.

## Stock Options and Warrants Granted by the Company

The following table is the listing of outstanding stock options and warrants as of December 31, 2019 by year of grant:

### Stock Options:

Year	Shares	Price		
2011	17	\$2,812.50		
2012	171	1,312.50	–	1,500.00
2013	150	1,481.25	–	5,962.50
2014	84	1,625.00	–	4,312.50
2015	401	657.50	–	862.50
2016	9,617	22.50	–	51.25
2017	235,053	10.10	–	21.00
2018	97,636	6.19	–	13.50
2019	423,295	2.61	–	9.00
Total	766,424	\$0.45	–	5962.50

### Warrants:

Year	Shares	Price		
2015	9,407	\$1,237.50		
2016	25,233	10.00		
2017	108,295	10.71	–	22.50
2018	219,076	8.36	–	13.125
2019	1,809,599	2.50	–	11.88
Total	2,171,610	\$2.50	–	3,095.00

## NOTE 6– NOTES RECEIVABLE

The Company has a secured promissory note receivable from CytoBioscience for \$1,112,524, plus interest paid monthly at the per annum rate of (8%) on the principal amount. Unpaid principal and unpaid accrued interest on the note were due and payable on February 28, 2020. In 2019, CytoBioscience and its parent company, InventaBioTech, paid interest in the first quarter due through April 2019. The Company has not received any payments from CytoBioscience since the first quarter of 2019. The Company has evaluated the feasibility of repayment, including direct conversations with the CEO and former CEO of CytoBioscience, and has concluded that recovery of the note is in doubt and that it is probable that the Company will be unable to collect all amounts due according to the contractual terms of the receivable. The Company does not anticipate any cash recovery through the sale of this equipment and has recorded a reserve for the full value of the note receivable. The Company obtained a judgment against CytoBioscience and has proceeded with court proceedings to claim the collateral equipment and to attempt to recover the original balance plus interest due under the note. On March 2, 2020, the Company signed a term sheet with InventaBio Tech and its subsidiary Soluble Therapeutics, LLC (“Soluble”) to acquire certain assets in exchange for termination and waiver of all remaining amounts due and payable under the CytoBioscience Note. See Note 13 - Subsequent Events for further discussion.

During 2018, the Company converted \$500,000 of its note receivable from Helomics into 833,333 shares of Helomics common stock for an additional 5% interest in Helomics, giving the Company an equity stake in Helomics totaling 25%.

Also, during 2018, the Company advanced an additional \$997,500 to Helomics under the same note. The balance due to the Company at December 31, 2018 was \$1,165,013 in principal, plus interest of \$29,215.

During 2019, the Company advanced Helomics \$975,000. As of April 3, 2019, the Company had a principal balance of \$2,140,013, plus interest of \$70,369 due from Helomics. On the Company's balance sheet there was a reduction to the loan of \$1,190,967 due to the cumulative equity method investments losses incurred from Helomics ownership; see Note 1. There were no further advances to Helomics prior to the completion of the merger. Upon completion of the merger with Helomics all intercompany notes were eliminated; see Note 2 – Helomics Acquisition.

#### NOTE 7 – NOTES PAYABLE

The balances of notes payable were as follows:

	Due Date	December 31, 2019	December 31, 2018
Bridge loan	March 31, 2020	\$ 1,989,104	\$ 2,297,727
Promissory note	March 27, 2020	680,833	-
Equity line borrowing	May 26, 2020	18,563	-
Equity line borrowing	June 10, 2020	147,783	-
Equity line borrowing	June 20, 2020	194,943	-
	September 30,		
Dr. Schwartz note	2020	2,115,000	370,000
Total Notes Payable, gross		5,146,226	2,667,727
Less: Unamortized discount		350,426	1,032,813
Total Notes Payable, net		\$ 4,795,800	\$ 1,634,914

#### Bridge Loan

During September 2018, 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") in exchange for cash proceeds of \$2,000,000. As additional consideration for the loan, the Company issued an aggregate 65,000 shares of its common stock as inducement shares plus warrants to acquire up to an aggregate 107,178 shares of common stock at an exercise price of \$11.55 per share. Pursuant to a security agreement between the Company and the investors, the Company granted to the investors a security interest in its assets to secure repayment of the note. The bridge loan accrues interest at a rate of 8% per annum. During February 2019, the Company entered into a forbearance agreement with the bridge loan investors pursuant to which, among other things, the investors agreed to forbear on their rights to accelerate the bridge loan based on an event of default and a claimed event of default. In connection with such forbearance, an additional \$344,659 in principal and an additional 16,667 common shares were issued to the investors. During September 2019, the bridge loan of one investor was paid in full. Payment penalties of \$144,378 were paid in relation to payments on the bridge loan during 2019 and an additional \$497,276 in payment penalties were accrued but not paid as of December 31, 2019. No payments on the bridge loan were made during 2018. The outstanding principal balance of the remaining bridge loan as of December 31, 2019 was \$1,989,104 with an unamortized discount of \$133,839.

Each investor has the right to convert all or any part of its bridge loan into shares of the Company's common stock at a conversion factor that is the lesser of a discounted 20-day average price or a set price floor. 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 267,833 shares. During 2019, the investors converted \$378,573 of the principal balance and received 103,415 shares of the Company's common stock. No conversions took place during 2018.

#### *Dr. Schwartz Notes*

In November 2018, Dr. Schwartz made a loan to the Company with a principal balance of \$370,000. As of December 31, 2018, one promissory note was held with a principal balance of \$370,000 and an unamortized discount of \$63,028. From November 30, 2018 through July 15, 2019, Dr. Schwartz made numerous loans to the Company in the total amount of \$1,920,000 under two promissory notes. As consideration for these amounts, Dr. Schwartz received promissory notes and warrants to purchase 22,129 shares of the Company's common stock at \$8.36 per share. Further, beginning on February 1, 2019 and the first day of each calendar month thereafter while the note remained outstanding, a number of additional warrants were issued. Beginning in October 2019, the Company and Dr. Schwartz began to renegotiate the note. Due to the negotiations, the company did not issue any additional warrants because they would be cancelled under the new deal.

As of January 2020, the Company was in default under one of the notes which was due on December 31, 2019 and determined that it would not be able to pay remaining outstanding note when it became due on February 8, 2020. In January 2020, an exchange agreement was entered into between Dr. Schwartz and the Company which cancelled the two outstanding notes and issued a new promissory note. See Note 13 - Subsequent Events for further discussion.

As of December 31, 2019, the outstanding principal balance was \$2,115,000. The notes accrued interest at a rate of 8% per annum through December 31, 2019 and 12% per annum after December 31, 2019.

#### *Helomics Investor Notes*

As disclosed in Note 2 – Helomics Acquisition, the Company assumed notes totaling \$303,333 as part of the Helomics acquisition. The total outstanding principal and interest balances related to these notes was paid in full by the Company in October 2019. The payments included \$18,216 in payment penalties.

#### *Promissory Note*

During September 2019, the Company issued a promissory note with a principal amount of \$847,500 in exchange for cash proceeds of \$700,000. Pursuant to a security agreement between the Company and the investor, the Company has granted to the investor a security interest in its assets to secure repayment of the note. As additional consideration for the loan, the Company issued an aggregate 8,857 shares of its common stock to the investor plus warrants to acquire up to 68,237 shares of the Company's common stock at an exercise price of \$6.21 per share. The warrants are exercisable beginning on the sixth month anniversary of the effective date through the fifth-year anniversary thereof. The note accrues interest at a rate of 8% per annum. During 2019, the Company made one payment in the amount of \$166,667. Payment penalties of \$33,333 were paid in relation to payments on this promissory note during 2019 and an additional \$136,167 in payment penalties were accrued but not paid as of December 31, 2019. As of December 31, 2019, the remaining balance on the promissory note was \$680,833 with an unamortized discount of \$216,587.

#### *Short Term Borrowings*

During 2019, the Company entered into short-term borrowings with an investor. The maturity date of the notes is six months after the dates of issuance with interest rates of 8% payable at maturity. Repayment of such notes is subject to a premium. During 2019, the Company issued short term notes for a total of \$478,159 for cash proceeds of \$440,000 and repaid \$118,527 of principal using a portion of proceeds from the equity financing facility. Payment penalties of \$6,367 were paid in relation to payments on these short-term borrowings during 2019 and an additional \$35,468 in payment penalties were accrued but not paid as of December 31, 2019. The total amount outstanding under the short-term loans as of December 31, 2019 was \$361,289.

#### *Extension of Notes Payable*

Throughout 2019, the Company entered into a number of extensions related to its various outstanding notes payable. During 2019, the Company incurred a \$581,073 loss on debt extinguishment and recognized \$162,750 as debt discount related to extensions of notes payable. The Company issued a total of 30,000 shares of its common stock and warrants to acquire 13,000 shares of the Company's common stock as additional consideration for these extensions.

## Derivative Liability

Management has concluded the September 2018 bridge loan contains a conversion feature which is an embedded derivative that is required to be bifurcated and separately presented as a liability on the consolidated balance sheets. The embedded derivative's value was determined using discounted stock price 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 recognized an unrealized gain in other income on the statements of net loss for the corresponding change in fair value of \$221,756 and \$372,263 in 2019 and 2018, respectively. The fair value of the derivative liability related to the bridge loan as of December 31, 2019 was \$50,989.

On May 21, 2019, the Company issued a common stock purchase warrant to Dr. Schwartz for value received in connection with the First Note. Beginning on February 1, 2019 and the first day of each calendar month thereafter while the First Note and associated warrants remained outstanding, a number of additional shares were added to the warrant. The Company accounted for the liability to issue more warrants as a derivative liability as the exact number of warrants to be issued was uncertain at the time of the agreement. The Company issued 5,753 warrants to Dr. Schwartz under the agreement in 2019. The remaining derivative liability of \$22,644 was reduced to zero as of December 31, 2019 due to the exchange agreement in January 2020, which eliminated the issuance of any future warrants related to these notes. See Note 13 – Subsequent Events for further discussion.

The table below discloses changes in value of the Company's embedded derivative liabilities related to the bridge loan and the derivative included in the note payable agreements with Dr. Schwartz during the years ended December 31, 2019 and December 31, 2018.

Derivative liability balance at December 31, 2017	\$	-
Derivative instruments recognized		645,008
Gain recognized to revalue derivative instrument at fair value		(372,263)
Derivative liability balance at December 31, 2018	\$	272,745
Derivative instrument recognized		69,722
Gain recognized to revalue derivative instrument at fair value		(221,756)
Adjustments to derivative liability for warrants issued		(47,078)
Reduction of derivative liability		(22,644)
Derivative liability balance at December 31, 2019	\$	50,989

## NOTE 8 - LOSS PER SHARE

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

	Year Ended December 31,	
	2019	2018
Numerator:		
Net loss attributable to common shareholders per common share: basic and diluted calculation	\$ (19,680,701)	\$ (10,086,477)
Denominator:		
Weighted average common shares outstanding-basic	2,870,132	1,281,629
Effect of diluted stock options, warrants and preferred stock (1)	-	-
Weighted average common shares outstanding-diluted	2,870,132	1,281,629
Loss per common share-basic and diluted	\$ (6.86)	\$ (7.87)

(1) The following is a summary of the number of underlying shares outstanding at the end of the respective periods that have been excluded from the diluted calculations because the effect on loss per common share would have been anti-dilutive:

	<b>Year Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
Options	766,424	366,928
Warrants	2,171,610	362,664
Convertible debt	82,751	329,409
Preferred stock: Series B	7,925	7,925
Preferred stock: Series D	350,000	-
Preferred stock: Series E	594,383	-

#### **NOTE 9– 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 carryforwards 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 net loss due to the cumulative operating losses incurred and 100% valuation allowance for the deferred tax assets.

Actual income tax benefit differs from statutory federal income tax benefit as follows:

	<b>Year Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
Statutory federal income tax benefit	\$ 3,977,561	\$ 2,118,160
State tax benefit, net of federal taxes	368,635	66,117
Foreign tax benefit	104,050	132,931
Foreign operations tax rate differential	(73,869)	(94,373)
State rate adjustment	(17,585)	15,355
R&D tax credit	51,143	22,532
Nondeductible/nontaxable items	(517,465)	(118,905)
State NOL adjustment	(1,054,778)	746,479
OID and derivatives	141,908	(159,037)
Helomics purchase adjustment	66,394,188	-
Other	115,896	47,868
Valuation allowance increase	(69,489,684)	(2,777,127)
<b>Total income tax benefit</b>	<b>\$ -</b>	<b>\$ -</b>



Deferred taxes consist of the following:

	December 31, 2019	December 31, 2018
<b>Deferred tax assets:</b>		
<b>Noncurrent:</b>		
Depreciation	\$ -	\$ 4,488
Inventory	6,891	6,991
Compensation accruals	56,670	60,905
Accruals and reserves		77,777
Deferred revenue	7,480	
Charitable contribution carryover	3,740	3,972
Derivatives	10,708	57,276
Related party investments	657,633	481,652
Intangibles	295,941	2,020
NSQO compensation	1,589,430	1,019,139
NOL and credits	78,417,618	9,655,388
Total deferred tax assets	81,046,111	11,369,608
<b>Deferred tax liabilities:</b>		
<b>Noncurrent:</b>		
Original issue discount	(14,021)	(216,891)
Depreciation	(389,689)	
Total deferred tax liabilities	(403,710)	(216,891)
Net deferred tax assets	80,642,401	11,152,717
Less: valuation allowance	(80,642,401)	(11,152,717)
Total	-	-

As a result of the Helomics merger on April 4, 2019, the Company's deferred assets and liabilities at December 31, 2019 are presented on a consolidated basis. The Company intends to file federal consolidated returns post merger. 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 ("NOL") 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.

The acquired NOL carryforwards from Helomics experienced an ownership change as defined in Section 382 of the Internal Revenue Code as a result of the merger. In addition, the Company experienced an ownership change in December 2013. As a result, the ability to utilize the Company's NOLs is limited. The Company may have experienced additional ownership changes 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, 2018, the Company had \$40,444,754 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. \$34,529,255 of the federal NOLs will expire beginning in 2022 if unused and \$5,915,499 will carryforward indefinitely. The Company also had \$13,114,182 of gross NOLs to reduce future state taxable income at December 31, 2018. The state NOL's will expire beginning in 2019 if unused. The Company also had \$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.

At December 31, 2019, the Company had \$291,476,788 of gross NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2020, subject to the Section 382 limitation described above. The federal NOL's of \$264,379,011 expire beginning in 2021 if unused and \$27,097,777 will carryforward indefinitely. The Company also had \$213,762,905 of gross NOLs to reduce future state taxable income at December 31, 2019. The state NOL's will expire beginning in 2020 if unused. The Company also had \$773,455 in gross foreign NOLs to reduce future Belgian taxable income at December 31, 2019. The Company's net deferred tax assets, which include the NOLs, are subject to a full valuation allowance. At December 31, 2019, the federal, state, and foreign valuation allowances were \$58,991,353, \$21,414,302, and \$236,746, respectively.

Tax years subsequent to 2015 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, 2019 and 2018, the Company recorded no accrued interest or penalties related to uncertain tax positions.

#### NOTE 10 - LEASES

The Company's corporate offices are located in Eagan, Minnesota. The lease as amended has a three-year term 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 square feet is used for manufacturing.

Skyline Medical Europe's offices are located in Belgium. The Company leases around 2,000 square feet at this location, 750 square feet of which is used for storage and 1,250 square feet is used for office space. The lease is effective through June 14, 2027.

Helomics' offices are located in Pittsburgh, Pennsylvania. The lease, as amended, has a three-year term ending February 28, 2021. The Company leases 17,417 square feet at this location, of which approximately 1,000 square feet is used for office space and 16,417 square feet is used for laboratory operations. The Company expects that this space will be adequate for its current office and laboratory needs.

Lease expense under operating lease arrangements was \$431,170 and \$69,013 for 2019 and 2018, respectively.

The following table summarizes other information related to the Company's operating leases:

	December 31, 2019
Weighted average remaining lease term – operating leases in years	3.28
Weighted average discount rate – operating leases	8%

The Company's lease obligation as of December 31, 2019 is as follows:

2020	\$	476,468
2021		111,353
2022		43,154
2023		44,017
2024		44,897
2025 and thereafter		112,271
Total lease payments		<u>832,160</u>
Less interest		102,415
Present value of lease liabilities	\$	<u>729,745</u>

#### NOTE 11 - 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"). Tim Krochuk, a Company director until December 31, 2019, is on the supervisory board for GLG. The Company and GLG have a partnership agreement 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. During 2018 and through April 1, 2019, Mr. Gabriel received \$12,000 per month pursuant to a renewable six-month contract. On May 1, 2019, Mr. Gabriel executed a one-year contract with renewable three-month periods to continue as the Chief Operating Officer for TumorGenesis, receiving \$13,500 in monthly cash payments.

Dr. Carl Schwartz, the Company's CEO, had made investments in the Company in exchange for promissory notes and common stock. See Note 7 – Notes Payable for detailed description of these arrangements.

#### **NOTE 12 – 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. During 2019 and 2018, the Company matched 100%, of the employee's contribution up to 4.0% of their earnings. The employer contribution was \$110,714 and \$51,647 in 2019 and 2018, respectively. There were no discretionary contributions to the plan in 2019 and 2018.

#### **NOTE 13 – SUBSEQUENT EVENTS**

##### *Equity Line Agreement*

During the first quarter of 2020, the Company issued 943,000 shares of its common stock valued at \$1,869,899 pursuant to the equity line.

##### *Short Term Borrowings*

During the first quarter of 2020, the Company issued additional short-term notes for a total of \$1,098,684 for cash proceeds of \$1,020,000 and repaid \$657,105 of principal using a portion of proceeds from the equity financing facility.

##### *Promissory Note*

On February 5, 2020, the Company issued a promissory note with a principal amount of \$1,450,000 in exchange for cash proceeds of \$1,200,000. Distributions of proceeds under the note will be made in three tranches. The principal amount of the first tranche was \$490,000 resulting in cash proceeds to the Company of \$400,000. The principal amount of the second tranche received on March 5, 2020, was \$480,000 resulting in cash proceeds to the Company of \$400,000. The third tranche, with a principal amount of \$480,000, will be distributed 60 days after February 5, 2020. The note is due in full on July 5, 2020. Pursuant to a security agreement between the Company and the investor, the Company has granted to the investor a security interest in its assets to secure repayment of the note. The note accrues interest at a rate of 8% per annum.

As additional consideration, the Company issued to the investor warrants to purchase 94,631 shares of the Company's common stock at the closing of the first tranche and will issue additional warrants to purchase 92,700 shares at the distribution of each of the second and third tranches. The warrants are exercisable beginning on the sixth month anniversary of the issuance date at an exercise price equal \$2.992 per share. The Company also issued 46,875 shares of its common stock to the investor at the closing of the first tranche.

##### *Letter of Intent*

On January 24, 2020, the Company announced that it has signed a letter of intent to acquire Quantitative Medicine ("QM"). QM is a biomedical analytics and computational biology company that has developed a novel, computational drug discovery platform called CoRE. CoRE is designed to dramatically reduce the time, cost, and financial risk of discovering new therapeutic drugs by predicting the main effects of drugs on target molecules that mediate disease.

Completion of the transaction, which is expected to be completed in the second quarter of 2020, is subject to the negotiation of a definitive agreement and other terms and conditions.

#### *Term Sheet with InventaBio Tech*

On March 2, 2020, the Company signed a term sheet with InventaBio Tech and its subsidiary Soluble to purchase certain assets including but not limited to certain intellectual property relating to CRO services and technology, certain equipment useful in such services and technology and all other assets held by Soluble relating to CRO as well as all intellectual property and other assets held by BioDtech, Inc., a related party to InventaBio, in exchange for termination and waiver of all remaining amounts due and payable under the note receivable from CytoBioscience and 125,000 shares of the Company's common stock. Completion of the transaction is subject to certain closing conditions including the execution and delivery of the agreements for each, the Soluble and the BioDtech, Inc assets and other conditions customary for transactions of this type.

#### *CEO Promissory Note Exchange Agreement*

During January 2020, the Company entered into an exchange agreement with its CEO, Dr. Schwartz. Under the exchange agreement, the two outstanding notes were cancelled and in exchange a new promissory note in the amount of \$2,115,000 bearing 12% interest per annum and maturing on September 30, 2020 was issued. In addition to the promissory note, Dr. Schwartz received 50,000 shares of the Company's common stock. All warrants issued under the prior promissory notes were cancelled under the exchange agreement; no rights and obligations remain under the cancelled notes. Beginning in October 2019, the Company and Dr Schwartz began to renegotiate the note. Due to the negotiations, the company did not issue any additional warrants because they would be cancelled under the new deal. The Company determined that the exchange agreement had in substance occurred at December 31, 2019 and is therefore included within the financial statements as of and for the year ended December 31, 2019 and a related loss on debt extinguishment of \$310,000 was recognized in 2019.

#### *Shares Issued to Vendor*

On March 4, 2020, the Company issued 150,000 shares of common stock in payment for public relations services.

#### *March 2020 Private Placement*

On March 15, 2020, the Company entered into a securities purchase agreement with certain accredited investors for the sale in a private placement of 260,000 shares of the Company's common stock at \$2.12 per share. For each offering share an investor purchases, the investor received: (1) a warrant to purchase one share of common stock, exercisable immediately and terminating five and one-half years after the date of issuance and (2) a warrant to purchase one share of common stock, exercisable immediately and terminating two years after the date of issuance. All such warrants issued are exercisable at a price of \$1.88 per share.

In addition, and in lieu of common shares, certain investors purchased prefunded warrants to purchase 1,390,166 shares of common stock at a purchase price of \$2.12 per prefunded warrant, which represents the per share offering price, minus the \$0.0001 per share exercise price of each such prefunded warrant.

The sale of the offering shares and prefunded warrants resulted in gross proceeds of \$3,498,612 and net proceeds of \$3,127,112 after deducting the placement agent fees and estimated offering expenses payable by the Company. The Company agreed to use the net proceeds from the offering for general corporate purposes. The offering closed on March 18, 2020, subject to the satisfaction of customary closing conditions.

#### *Extension of Notes Payable*

On March 19, 2020, the Company entered into an agreement to extend the due date of its outstanding notes payable from March 27, 2020 and March 31, 2020 to June 27, 2020. The Company increased the principal amount due on the notes payable by \$300,000 and issued 30,000 shares of its common stock as consideration for these extensions. The Company has not determined if the extension will be accounted for as a modification or an extinguishment under ASC 470-50 *Debt, Modifications and extinguishments*.

#### *2019 Coronavirus Outbreak*

In December 2019, a novel strain of coronavirus ("COVID-19") was reported to have surfaced in Wuhan, China and has since spread to other parts of the world. The impact of the outbreak of COVID-19 on the business is unknown. State and local authorities in the United States, like their counterparts in many other countries, have since forced many businesses to temporarily shut down in an attempt to slow the spread of the virus, and Americans are being told by public officials to practice "social distancing". Global stock markets have reacted very negatively, and many economists are projecting a sharp economic slowdown, at least in the near term, even if governments take emergency relief measures. Regardless of the extent of any economic slowdown, the outbreak could impact the Company's ability to develop business, conduct operations, and obtain components used in its business in any region that is significantly impacted by the outbreak. The situation is constantly evolving, however, so the extent to which the COVID-19 outbreak will impact business and the economy is highly uncertain and cannot be predicted. Accordingly, the Company cannot predict the extent to which its financial condition and results of operations will be affected.

## PRECISION THERAPEUTICS INC.

CERTIFICATE OF DESIGNATION OF PREFERENCES,  
RIGHTS AND LIMITATIONS OF  
SERIES D CONVERTIBLE PREFERRED STOCKPURSUANT TO SECTION 151 OF THE  
DELAWARE GENERAL CORPORATION LAW

Effective April 3, 2019

Pursuant to Section 151 of the General Corporation Law of the State of Delaware, Precision Therapeutics Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware, in accordance with the provisions of Section 103 thereof, does hereby submit the following:

The undersigned, Carl Schwartz and Bob Myers, do hereby certify that:

1. They are the Chief Executive Officer and Chief Financial Officer, respectively, of Precision Therapeutics Inc., a Delaware corporation (the “**Corporation**”).
2. The following resolutions were duly adopted by the board of directors of the Corporation (the “**Board**”):

WHEREAS, the Certificate of Incorporation of the Corporation, as amended, authorizes the issuance of up to 20,000,000 shares of preferred stock, par value \$0.01 per share, of the Corporation (“**Preferred Stock**”) in one or more series, and expressly authorizes the Board, subject to limitations prescribed by law, to provide, out of the unissued shares of Preferred Stock, for series of Preferred Stock, and, with respect to each such series, to establish and fix the number of shares to be included in any series of Preferred Stock and the designation, rights, preferences, powers, restrictions and limitations of the shares of such series; and

WHEREAS, it is the desire of the Board to establish and fix the number of shares to be included in a new series of Preferred Stock and the designation, rights, preferences and limitations of the shares of such new series.

NOW, THEREFORE, BE IT RESOLVED, that the Board does hereby provide for the issue of a series of Preferred Stock and does hereby in this Certificate of Designation (the “**Certificate of Designation**”) establish and fix and herein state and express the designation, rights, preferences, powers, restrictions and limitations of such series of Preferred Stock as follows:

1. Designation. There shall be a series of Preferred Stock that shall be designated as “Series D Convertible Preferred Stock” (the “**Series D Preferred Stock**”) and the number of authorized shares constituting such series shall be 3,500,000. The rights, preferences, powers, restrictions and limitations of the Series D Preferred Stock shall be as set forth herein.
-

2. Defined Terms. For purposes hereof, the following terms shall have the following meanings:

“**Automatic Conversion Date**” has the meaning set forth in Section 4.1 hereof.

“**Beneficial Ownership Limitation**” has the meaning set forth in Section 5.

“**Board**” has the meaning set forth in the Recitals.

“**Business Day**” means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed.

“**Certificate of Designation**” has the meaning set forth in the Recitals.

“**Commission**” means the United States Securities and Exchange Commission.

“**Common Stock**” means the common stock, par value \$0.01 per share, of the Corporation.

“**Conversion Shares**” means, collectively, the shares of Common Stock issuable upon conversion of the Shares of Series D Preferred Stock in accordance with the terms hereof.

“**Conversion Rate**” means 1.0, subject to adjustment in accordance with Section 7 hereto.

“**Corporation**” has the meaning set forth in the Preamble.

“**Date of Issuance**” means the date on which the Corporation consummates the Merger.

“**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

“**Fundamental Transaction**” means that (i) the Corporation shall, directly or indirectly, in one or more related transactions, (1) consolidate or merge with or into (whether or not the Corporation is the surviving corporation) any other Person unless the shareholders of the Corporation immediately prior to such consolidation or merger continue to hold more than 50% of the outstanding shares of Voting Stock after such consolidation or merger, or (2) sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of the properties and assets of the Company and its subsidiaries, taken as a whole, to any other Person, or (3) allow any other Person to make a purchase, tender or exchange offer that is accepted by the holders of more than 50% of the outstanding shares of Voting Stock of the Corporation (not including any shares of Voting Stock of the Corporation held by the Person or Persons making or party to, or associated or affiliated with the Persons making or party to, such purchase, tender or exchange offer), or (4) consummate a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with any other Person whereby such other Person acquires more than 50% of the outstanding shares of Voting Stock of the Corporation (not including any shares of Voting Stock of the Corporation held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination), or (ii) any “person” or “group” (as these terms are used for purposes of Sections 13(d) and 14(d) of the Exchange Act and the rules and regulations promulgated thereunder), is or shall become the “beneficial owner” (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of 50% of the aggregate ordinary voting power represented by issued and outstanding Voting Stock of the Corporation. For clarity, the Merger does not constitute a Fundamental Transaction.

---

“**Merger**” means that certain merger contemplated by the Agreement and Plan of Merger, as amended, by and among the Corporation, Helomics Acquisition, Inc., Helomics Holding Corporation and Gerald J. Vardzel, as Stockholder Representative.

“**Person**” means an individual, corporation, partnership, joint venture, limited liability company, governmental authority, unincorporated organization, trust, association or other entity.

“**Preferred Stock**” has the meaning set forth in the Recitals.

“**Securities Act**” means the Securities Act of 1933, as amended.

“**Series D Preferred Stock**” has the meaning set forth in Section 1.

“**Share**” means a share of Series D Preferred Stock.

“**Transfer Agent**” means the registrar and transfer agent for the Common Stock and the Series D Preferred Stock, as appointed by the Corporation from time to time. Corporate Stock Transfer, Inc. shall serve as the initial Transfer Agent.

“**Voting Stock**” of a Person means capital stock of such Person of the class or classes pursuant to which the holders thereof have the general voting power to elect, or the general power to appoint, at least a majority of the board of directors, managers or trustees of such Person (irrespective of whether or not at the time capital stock of any other class or classes shall have or might have voting power by reason of the happening of any contingency).

3. Voting.

3.1 The Series D Preferred Stock shall have no voting rights, except as expressly set forth in this Section 3.

3.2 So long as any shares of Series D Preferred Stock are outstanding, the affirmative vote of the holders of a majority of the Series D Preferred Stock at the time outstanding, given in person or by proxy, either in writing without a meeting or by vote at any meeting called for the purpose, shall be necessary for effecting or validating any amendment, alteration or repeal of any of the provisions of this Certificate of Designation that materially and adversely affects the powers, preferences or special rights of the Series D Preferred Stock, whether by merger or consolidation or otherwise; *provided, however*, (i) that in the event of an amendment to terms of the Series D Preferred Stock, including by merger or consolidation, so long as the Series D Preferred Stock remains outstanding with the terms thereof materially unchanged, or the Series D Preferred Stock is converted into, preference securities of the surviving entity, or its ultimate parent, with such powers, preferences or special rights that are, in the good faith determination of the Board of the Corporation, taken as a whole, not materially less favorable to the holders of the Series D Preferred Stock than the powers, preferences or special rights of the Series D Preferred Stock in effect prior to such amendment or the occurrence of such event, taken as a whole, then such amendment or the occurrence of such event shall not be deemed to materially and adversely affect such powers, preferences or special rights of the Series D Preferred Stock, and (ii) the authorization, establishment or issuance by the Corporation of any other series of Preferred Stock with powers, preferences or special rights that are senior to or on a parity with the Series D Preferred Stock, including, but not limited to, powers, preferences or special rights with respect to dividends, distributions or liquidation preferences, shall not be deemed to materially and adversely affect the power, preferences or special rights of the Series D Preferred Stock, and in the case of either clause (i) or (ii), the holders of Series D Preferred Stock shall not have any voting rights with respect thereto.

---

3.3 For purposes of Section 3.2, each Share of Series D Preferred Stock shall have one vote per share. Except as set forth herein, the Series D Preferred Stock shall not have any relative, participating, optional or other special voting rights and powers other than as set forth herein, and the consent of the holders thereof shall not be required for the taking of any corporate action.

3.4 No amendment to these terms of the Series D Preferred Stock shall require the vote of the holders of Common Stock (except as required by law) or any series of Preferred Stock other than the Series D Preferred Stock.

3.5 Without the consent of the holders of the Series D Preferred Stock, so long as such action does not materially and adversely affect the powers, preferences or special rights of the Series D Preferred Stock, taken as a whole, and to the extent permitted by law, the Corporation may amend, alter, supplement, or repeal any terms of this Certificate of Designation for the following purposes:

(a) to cure any ambiguity, or to cure, correct, or supplement any provision that may be ambiguous, defective, or inconsistent; or

(b) to make any provision with respect to matters or questions relating to the Series D Preferred Stock that is not inconsistent with the provisions of this Certificate of Designation.

#### 4. Conversion.

4.1 Automatic Conversion. Subject to the provisions of this Section 4 and Section 5, each Share of Series D Preferred Stock convert automatically into a number of shares of Common Stock determined below, upon the earlier of (i) the consummation of any Fundamental Transaction, or (ii) the one-year anniversary of the Issuance Date (the date of such automatic conversion, the “**Automatic Conversion Date**”). Upon the Automatic Conversion Date, each Share of Series D Preferred Stock shall convert automatically into a number of shares of Common Stock equal to the Conversion Rate in effect on the one-year anniversary of the Issuance Date or immediately prior to consummation of such Fundamental Transaction, as applicable.

---



4.2 Procedures for Conversion; Effect of Conversion

(a) Procedures. In order to effectuate an automatic conversion of Shares of Series D Preferred Stock pursuant to Section 4.1, all holders of record of Shares of Series D Preferred Stock shall be given written notice of the Automatic Conversion Date. Such notice need not be given in advance of the occurrence of the Automatic Conversion Date. Such notice shall be sent by first class or registered mail, postage prepaid, or given by electronic communication in compliance with the provisions of the Delaware General Corporation Law, to each record holder Series D Preferred Stock. On the Automatic Conversion Date, all outstanding Shares of Series D Preferred Stock shall be deemed to have been converted into Conversion Shares, which shall be deemed to be outstanding of record, and all rights with respect to the Series D Preferred Stock so converted, including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate, except only the rights of the holders thereof to receive the number of Conversion Shares into which their Shares have been converted, upon surrender of their Shares of Series D Preferred Stock (or if the certificate or certificates representing such Shares have been lost or destroyed, by delivering an affidavit of loss or destruction and, if requested by the Corporation or the Transfer Agent, an indemnity bond (or other indemnity arrangement) that is sufficient in the judgment of the Corporation and the Transfer Agent to protect the Corporation and the Transfer Agent from any loss that they may suffer if any Share is replaced). Not later than three Business Days after the Transfer Agent has received Shares from a holder of Series D Preferred Stock, the Corporation shall deliver, or cause the Transfer Agent to deliver, to such holder the number of Conversion Shares that were issued upon the automatic conversion of such surrendered Shares either (x) by delivering a certificate or certificates representing the number of such Conversion Shares or (y) electronically through the applicable procedures of The Depository Trust Company (“**DTC**”) (or such other clearing corporation) that are satisfactory to the Transfer Agent, as instructed by the holder.

(b) All shares of Common Stock issued upon conversion of Shares of Series D Preferred Stock shall be duly and validly issued, fully paid and nonassessable, free and clear of all taxes, liens, charges and encumbrances with respect to the issuance thereof.

(c) Effect of Conversion. All Shares of Series D Preferred Stock converted as provided in this Section 4 shall no longer be deemed outstanding as of the Automatic Conversion Date (excluding any Series D Preferred Stock that is not converted as a result of Section 5, which shall remain outstanding after the Automatic Conversion Date until such time as such Section does not prohibit the conversion thereof) and all rights with respect to such Shares shall immediately cease and terminate as of such time, other than the right of the holder to receive shares of Common Stock in exchange therefor.

4.3 Reservation of Stock. The Corporation shall at all times when any Shares of Series D Preferred Stock are outstanding reserve and keep available out of its authorized but unissued shares of capital stock, solely for the purpose of issuance upon the conversion of the Series D Preferred Stock, such number of shares of Common Stock issuable upon the conversion of all outstanding Shares of Series D Preferred Stock pursuant to this Section 4. The Corporation shall take all such actions as may be necessary to ensure that all such shares of Common Stock may be so issued without violation of any applicable law or governmental regulation or any requirements of any domestic securities exchange upon which shares of Common Stock may be listed (except for official notice of issuance which shall be immediately delivered by the Corporation upon each such issuance).

---

5. Beneficial Ownership Limitations. Notwithstanding Section 4.1, the Corporation shall not effect any conversion of the Series D Preferred Stock into shares of Common Stock to the extent that, after giving effect to the conversion, the holder of Series D Preferred Stock (together with such Holder's "affiliates," as such term is defined in Rule 405 under the Securities Act, and any Persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own in excess of the Beneficial Ownership Limitation, as defined below. For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by such holder and its affiliates shall include the number of shares of Common Stock issuable upon conversion of the Series D Preferred Stock with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which are issuable upon exercise or conversion of the unexercised or unconverted portion of any other securities of the Corporation that are subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by such holder or any of its affiliates. Except as set forth in the preceding sentence, for purposes of this Section, beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act.

For purposes of this Section, in determining the number of outstanding shares of Common Stock, a holder of Series D Preferred Stock may rely on the number of outstanding shares of Common Stock as stated in the most recent of the following: (i) the Corporation's most recent periodic or annual report filed with the Commission, as the case may be, (ii) a more recent public announcement by the Corporation or (iii) a more recent written notice by the Corporation or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a holder, the Corporation shall within three Business Days confirm to such holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Corporation, including the Series D Preferred Stock, by such holder or its affiliates since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of Conversion Shares upon conversion of Series D Preferred Stock by the applicable holder. Upon no fewer than 61 days' prior written notice to the Corporation, a holder may increase or decrease the Beneficial Ownership Limitation provisions of this Section applicable to its Series D Preferred Stock, provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of Conversion Shares upon conversion of this Series D Preferred Stock held by such holder and the provisions of this Section shall continue to apply. Any such increase or decrease will not be effective until the 61st day after such notice is delivered to the Corporation and shall only apply to such holder and no other holder. The limitations contained in this paragraph shall apply to a successor holder of Series D Preferred Stock.

6. Status of Converted or Acquired Shares. All shares of Series D Preferred Stock (i) converted into shares of Common Stock in accordance with Section 4 herein or (ii) acquired by the Corporation shall be restored to the status of authorized but unissued shares of undesignated Preferred Stock of the Corporation.

---

7. Certain Adjustments upon Stock Splits, Combinations, Etc. If the Corporation, at any time while any Preferred Stock is outstanding: (i) pays a stock dividend or otherwise makes a distribution payable in shares of Common Stock, (ii) subdivides outstanding shares of Common Stock into a larger number of shares or (iii) combines (including by way of a reverse stock split) outstanding shares of Common Stock into a smaller number of shares, then the Conversion Rate shall be adjusted to equal an amount equal to such Conversion Rate immediately before such adjustment multiplied by a fraction of which the numerator shall be the number of shares of Common Stock outstanding immediately after giving effect to such event, and of which the denominator shall be the number of shares of Common Stock outstanding immediately before giving effect to such event.

8. Maturity. The Series D Preferred Stock has no maturity date, no sinking fund has been established for the retirement or redemption of Series D Preferred Stock, and the Series D Preferred Stock has no redemption provisions.

9. Rank. With respect to payment of dividends and distribution of assets upon liquidation or dissolution or winding up of the Corporation, whether voluntary or involuntary, the Series D Preferred Stock shall rank equal to the Common Stock on an as converted basis.

10. Notices. Except as otherwise provided herein, all notices, requests, consents, claims, demands, waivers and other communications hereunder shall be in writing and shall be deemed to have been given: (a) when delivered by hand (with written confirmation of receipt); (b) when received by the addressee if sent by a nationally recognized overnight courier (receipt requested); (c) on the date sent by facsimile or e-mail of a PDF document (with confirmation of transmission) if sent during normal business hours of the recipient, and on the next Business Day if sent after normal business hours of the recipient; or (d) on the third day after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. Such communications must be sent (a) to the Corporation, at its principal executive offices and (b) to any stockholder, at such holder's address as it appears in the stock records of the Corporation (or at such other address for a stockholder as shall be specified in a notice given in accordance with this Section 10).

11. Amendment and Waiver. Subject to Section 3 hereof, no provision of this Certificate of Designation may be amended, modified or waived except by an instrument in writing executed by the Corporation, and any such written amendment, modification or waiver will be binding upon the Corporation and each holder of Series D Preferred Stock.

12. Effective Date. The Certificate of Designation shall be effective on April 3, 2019 upon the filing of the Certificate of Designation with the Secretary of State of Delaware.

---

RESOLVED, FURTHER, that the Chairman of the Board, the president or any vice-president, and the secretary or any assistant secretary, of the Corporation be and they hereby are authorized and directed to prepare and file this Certificate of Designation of Preferences, Rights and Limitations in accordance with the foregoing resolution and the provisions of Delaware law.

[Signature page follows]

---

IN WITNESS WHEREOF, the undersigned have executed this Certificate of Designation effective as of the date set forth above.

/s/ Carl Schwartz  
Carl Schwartz, Chief Executive Officer of Precision Therapeutics Inc.

/s/ Bob Myers  
Bob Myers, Chief Financial Officer of Precision Therapeutics Inc.

[Signature page to Certificate of Designation]

---

### **Description of Registrant's Securities**

As of March 27, 2020, Predictive Oncology Inc. (the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), namely, our common stock, par value \$0.01 per share ("Common Stock").

#### **Description of Common Stock**

The following description of our Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Certificate of Incorporation, as amended (the "Certificate of Incorporation"), our Second Amended and Restated Bylaws, as amended (the "Bylaws"), and the Certificate of Designation of Preferences, Rights and Limitations applicable to each series of our Preferred Stock (as defined below) (collectively, the "Certificates of Designation"), each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.1 is a part. We encourage you to read the Certificate of Incorporation, the Bylaws, the Certificates of Designation, and the applicable provisions of the General Corporation Law of the State of Delaware (the "DGCL") for additional information.

**Authorized Capital Stock.** Our authorized capital stock consists of 100,000,000 shares of Common Stock, and 50,000,000 shares of preferred stock, \$0.01 par value per share ("Preferred Stock"). Out of the Preferred Stock, as of December 31, 2019, (i) 300,000 shares have been designated Series B Convertible Preferred Stock, of which 79,246 shares were outstanding, (ii) 3,500,000 shares have been designated Series D Convertible Preferred Stock, of which 3,500,000 shares were outstanding, and (iii) 350 shares have been designated Series E Convertible Preferred Stock, of which 258 shares were outstanding.

The outstanding shares of our Common Stock and Preferred Stock are fully paid and nonassessable.

The Series B Convertible Preferred Stock is convertible into Common Stock at the option of its holders on a 1:1 basis, subject to a 4.99% beneficial ownership blocker. The Series D Convertible Preferred Stock converts on a 1:10 basis on April 4, 2020, subject to a 4.99% beneficial ownership blocker. Each share of Series E Convertible Preferred Stock is convertible at the option of its holder into 0.056857% of the shares of Common Stock issued and outstanding immediately prior to giving effect to such conversion, subject to a 19.99% beneficial ownership blocker, and on June 13, 2020, the Company may at its option convert all outstanding shares of Series E Convertible Preferred Stock into shares of Common Stock.

**Blank Check Preferred Stock.** Our Board of Directors is authorized, subject to any limitations prescribed by law, to provide for the issuance of the shares of Preferred Stock in series and, by filing a certificate pursuant to the applicable law of the State of Delaware, to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and any qualifications, limitations or restrictions thereon. The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the outstanding shares of Common Stock without a vote of the holders of the Preferred Stock, or of any series thereof, unless a vote of any such holders is required pursuant to the certificate or certificates establishing the series of Preferred Stock.

---

Voting Rights. The holders of our Common Stock are entitled to one vote for each outstanding share of Common Stock owned by that shareholder on every matter properly submitted to the shareholders for their vote. Shareholders are not entitled to vote cumulatively for the election of directors.

Dividend Rights. Subject to the dividend rights of the holders of any outstanding series of preferred stock, holders of our Common Stock are entitled to receive ratably such dividends and other distributions of cash or any other right or property as may be declared by our Board of Directors out of our assets or funds legally available for such dividends or distributions.

Liquidation Rights. In the event of any voluntary or involuntary liquidation, dissolution or winding up of our affairs, holders of our Common Stock would be entitled to share ratably in our assets that are legally available for distribution to shareholders after payment of liabilities and after the satisfaction of any liquidation preference owed to the holders of any Preferred Stock.

Conversion, Redemption and Preemptive Rights. Holders of our Common Stock have no conversion, redemption, preemptive, subscription or similar rights.

Bylaws. Certain provisions of our Bylaws could have anti-takeover effects. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our corporate policies formulated by our Board of Directors. In addition, these provisions also are intended to ensure that our Board of Directors will have sufficient time to act in what our Board of Directors believes to be in the best interests of our Company and our shareholders. Nevertheless, these provisions could delay or frustrate the removal of incumbent directors or the assumption of control of us by the holder of a large block of Common Stock, and could also discourage or make more difficult a merger, tender offer, or proxy contest, even if such event would be favorable to the interest of our shareholders. These provisions are summarized below.

*Advance Notice Provisions for Raising Business or Nominating Directors.* Sections 2.09 and 2.10 of our Bylaws contain advance-notice provisions relating to the ability of shareholders to raise business at a shareholder meeting and make nominations for directors to serve on our Board of Directors. These advance-notice provisions generally require shareholders to raise business within a specified period of time prior to a meeting in order for the business to be properly brought before the meeting.

*Number of Directors and Vacancies.* Our Bylaws provide that the exact number of directors shall be determined from time to time solely by resolution adopted by the affirmative vote of a majority of the entire Board of Directors. The Board of Directors is divided into three classes, as nearly equal in number as possible, designated: Class I, Class II and Class III (each, a “Class”). In the case of any increase or decrease, from time to time, in the number of directors, the number of directors in each class shall be apportioned as nearly equal as possible. Except as otherwise provided in the Certificate of Incorporation, each director serves for a term ending on the date of the third annual meeting of the Company’s stockholders following the annual meeting at which such director was elected; provided, that the term of each director shall continue until the election and qualification of a successor and be subject to such director’s earlier death, resignation or removal. Vacancies on the Board of Directors resulting from death, resignation, removal or otherwise and newly created directorships resulting from any increase in the number of directors may be filled solely by a majority of the directors then in office (although less than a quorum) or by the sole remaining director.

Listing. Our Common Stock is traded on the Nasdaq Capital Market under the trading symbol “POAI”.



**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, 333-216711, and 333-230704 on Form S-8; and in Registration Statement Nos. 333-213766, 333-221966, 333-228908, 333-234073, and 333-235441 on Form S-3; and in Registration Statement No. 333-234366 on Form S-1 of our report dated March 31, 2020, relating to the financial statements of Predictive Oncology Inc. appearing in this Annual Report on Form 10-K of Predictive Oncology Inc. for the year ended December 31, 2019.

*/s/ DELOITTE & TOUCHE LLP*

Minneapolis, Minnesota  
March 31, 2020

---

## CERTIFICATION

I, Carl Schwartz, certify that:

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

Date: March 31, 2020

/s/ Carl Schwartz

Carl Schwartz

Chief Executive Officer (Principal Executive Officer)

---

## CERTIFICATION

I, Bob Myers, certify that:

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

Date: March 31, 2020

/s/ Bob Myers

Bob Myers

Chief Financial Officer (Principal Financial Officer)

---

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

In connection with the Annual Report of Form 10-K of Predictive Oncology Inc. (the "Company") for the year ended December 31, 2019 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: March 31, 2020

/s/ Carl Schwartz

Carl Schwartz

Chief Executive Officer

(Principal Executive Officer)

/s/ Bob Myers

Bob Myers

Chief Financial Officer

(Principal Financial Officer)

---