

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, 2020.
- 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

Non-accelerated filer

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 has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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: \$32,138,990 as of June 30, 2020, based upon 19,596,945 shares at \$1.64 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 10, 2021, the registrant had 48,794,320 shares of common stock, par value \$.01 per share outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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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 three 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; 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 and; third, contract services and research focused on solubility improvements, stability studies, and protein production.

We have three reportable segments: Helomics, Skyline, and Soluble. The Helomics segment includes clinical testing and contract research services that include the application of AI. Our Soluble segment provides services using a self-contained, automated system that conducts high-throughput, self-interaction chromatography screens, using additives and excipients commonly included in protein formulations resulting in soluble and physically stable formulations for biologics. Our Skyline segment consists of the STREAMWAY System product sales, and 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.

During the third quarter of 2020, there was a change in our reportable segments. As a result of the formation of the new Soluble subsidiary, we believe the Soluble business represents a reportable segment. Soluble signed its first contract during the third quarter of 2020. We also believe it is appropriate to combine our Skyline Medical and Skyline Europe entities into a single reportable segment based on the changes to our physical presence and intent to sign future contracts through the US entity. Finally, we believe the Helomics business continues to be a reportable segment of the business.

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. Our Patient-centric Drug Discovery using Active Learning asset (PeDAL™) is a unique technology that combines our proprietary, clinically validated patient tumor cell line assay (TruTumor™), a vast knowledgebase of proprietary and public data together (TumorSpace™) with active learning - the active learning allowing the efficient exploration of compound drug responses against a large diverse patient "space". PeDAL offers researchers the opportunity to efficiently and cost-effectively bring patient diversity much earlier in the drug discovery process. PeDAL works by iterative cycles of active-learning powered Learn-Predict-Test (L-P-T) to guide the testing of patient-specific compound responses using the TruTumor assay and patient cell lines to build a comprehensive predictive model of patient responses to compounds. This predictive model can then be used to rank compounds by the fraction of patients of certain profiles that respond as well as the set of compounds that provide the best coverage across patients. PeDAL will be used in fee-for-service projects with pharmaceutical companies.

Contract Research Organization ("CRO") and AI-Driven Business

We believe leveraging our unique, historical database of the drug responses of over 150,000 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. Through the course of over 15 years of clinical testing of the responses of patient tumors to drugs, Helomics has amassed a huge proprietary knowledgebase of 150,000 patient cases. This data has been rigorously de-identified and aggregated to build a unique, proprietary model of tumor drug response that we call TumorSpace. The TumorSpace model and its data provide *a priori* knowledge for the machine learning approaches we employ as part of the PeDAL approach.

TumorSpace model provides a significant competitive advantage to our business offerings. PeDAL's unique patient and tumor-centric AI-driven approach can rapidly and cost-effectively screen hundreds of compounds in thousands of tumor cell lines, and gain valuable information about off-target effects and deliver:

- A ranked list of drug candidates by responsiveness
- Sets of drug candidates that provide maximum patient coverage
- Biomarker profiles of patients that respond to specific drug candidates

PeDAL also can deliver drug candidates targeted at a specific patient profile as early as the hit-to-lead stage of discovery, significantly increasing the chance of clinical success, leading to a dramatic improvement in both the success, time, and cost of your oncology discovery programs. The AI-driven models will, once validated, also provide clinical decision support to help oncologists individualize treatment.

Our CRO/AI business leverages our core competence in profiling the drug response of patient tumors. Our large knowledgebase of tumor drug response and other data, together with proven AI, has created a unique capability for oncology drug discovery that allows for the highly efficient screening of drug responses from thousands of diverse, well-characterized patient primary tumor cell lines. This novel disruptive patient-centric approach is ideally suited to the early part of drug discovery (especially hit-to-lead, lead optimization, and pre-clinical), resulting in better prioritization of compounds and better coverage of patient diversity. This will dramatically improve the chances of successfully translating discoveries, resulting in lowered costs, shortened timelines, and most importantly enhanced "speed-to-patient" for new therapies.

Our CRO services business applies PeDAL 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 TruTumor platform;
- TumorSpace model of over 150,000 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 \$278.6 billion by 2030, up from \$43.6 billion in 2016. (Source: BIS Research's "Global Precision Medicine Market to Reach \$278.6 Billion by 2030", December 2030).

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 this 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, due to a lack of research regarding which mutations in a tumor confer a sensitivity to a particular drug. 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. Our Helomics TumorSpace database addresses this need.

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 Tumor Drug Response Testing (formerly ChemoFx) and Genomic Profiling (formerly BioSpeciFx) tests. The Tumor Drug Response Testing determines how a patient's tumor specimen responds to a panel of various chemotherapy drugs, while the Genomic Profiling evaluates the expression of specific genes, or biomarkers, in the patient's tumor. Our proprietary TruTumor 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. Tumor Drug Response Testing is a fresh tissue platform that uses the patient's own live tumor cells to help physicians identify effective treatment options for each gynecologic cancer patient.

Genomic Profiling offers a select group of clinically relevant protein expression and genetic mutation tests associated with drug response and disease prognosis. Physicians can select biomarkers for testing from carefully chosen panels of relevant tests, intuitively organized by cancer pathway and tumor type. Results for these tests are presented in a clear, easy to understand format, including summaries of the clinical relevance of each marker.

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:

- TruTumor - a clinically validated tumor-profiling platform 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.
- TumorSpace model contains data on the drug response profiles across 131 cancer types over 10+ years of clinical testing.

Over 38,000 of the more than 150,000 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 TumorSpace 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 serve 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, PeDAL tumor profiling, and CLIA laboratory to provide custom solutions utilizing our full array of assets and expertise.

The CCQ2020 initiative focused 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 fee-for-service 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.

Soluble Biotech

Our subsidiary, Soluble Biotech Inc. (“Soluble”), focuses on contract services and research focused on solubility improvements, stability studies, and protein production and operates the assets of Soluble Therapeutics and BioDtech, which the Company acquired in May 2020. Specifically, Soluble provides optimized FDA-approved formulations for vaccines, antibodies, and other protein therapeutics in a faster and lower cost basis to its customers. In addition, Soluble enables protein degradation studies, which is a new and, based on current projections, potentially substantial line of business for the Company.

The primary assets of Soluble are our automated High Throughput Self-Interaction Chromatography (HSC™). HSC is a self-contained, automated system that conducts high-throughput, self-interaction chromatography screens on FDA approved excipients for protein formulations. Our technology measures second virial coefficient (B22 value) of protein-protein interactions to identify excipients that promote protein solubility in solutions. The data generated from HSC screens are analyzed by a proprietary predictive algorithm to identify the optimal combination(s) of buffers, pH, and excipients, resulting in increased solubility and physical stability of proteins. Several of our clients have seen ten-fold and hundred-fold increases in their protein's solubility while maintaining physical stability. For biopharmaceutical clients this means faster development times and quicker progression of molecules into the clinic. For academic collaborators, this means further progression of biochemical & biology studies necessary to advance fundamental research in areas of unmet medical need.

In addition, Soluble provides comprehensive protein stability analysis. Analysis via time-dependent shelf-life studies and forced degradation studies designed to quickly determine which of the FDA approved additives that will improve the solubility and stability of proteins in solutions. Services include pre-formulation development, formulation stability assessment, and biophysical characterization which evaluate variables including pH, temperature, humidity, light, oxidizing agents, and mechanical stress to determine the most promising additives, formulation of B22 values and confirmation on conformation stability. We provide clients with a list of the most promising additives from a set of over 40 different additives that can increase the solubility and stability of protein formulations.

Soluble also offers protein solubility kits that allow rapid identification of soluble formulations. We provide four different kits to fulfill customer solubility requirements. The kits are in 96-well format and provide the tools and methods to compare relative solubility across 88 common formulations (with 8 controls). Soluble kits utilize a simple mix and spin protocol that quickly evaluates aggregation behavior as a function of pH, salt, and additives costing significantly less than if manually determined. In addition, we provide innovative technologies for bacterial detection and removal in therapeutic proteins that continue to be a significant issue in the pharmaceutical field.

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.

Skyline Medical operated with reduced personnel and associated operating costs in 2020. By streamlining our production, the Company maximized efficiency attaining similar revenue to 2019. Throughout the year we continued to receive indications of interest from several parties for the possible acquisition of the Skyline division, as well as other partnership initiatives. We continue to operate the Skyline Medical business by continually improving our strategic opportunities, while focusing our resources on our precision medicine business.

Industry and Market Background and Analysis - Infectious and Biohazardous Waste Management

There has long been recognition of the collective potential for ill effects to healthcare workers from exposure to infectious/biohazardous 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 Skyline Medical division consists primarily of sales of the STREAMWAY System, as well as sales of the proprietary cleaning fluid and filters for use with the STREAMWAY System. 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.

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. 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.

TumorGenesis

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 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.

Soluble. HSC Technology is a self-contained, automated system that conducts high-throughput, self-interaction chromatography screens on FDA approved excipients for protein formulations. The HSC Instrument and its technology has been validated over the past twelve years via industry and academic collaborations. The data generated from HSC screens are analyzed by a proprietary predictive algorithm to identify the optimal combination(s) of buffers, pH, and excipients, resulting in increased solubility and physical stability of proteins. Several of our clients have seen ten-fold and hundred-fold increases in their protein's solubility while maintaining physical stability. For biopharmaceutical clients this means faster development times and quicker progression of molecules into the clinic.

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 we need 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 \$372,710 and \$422,964 in 2020 and 2019, 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”). The 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:

CLIA and State Clinical Laboratory Licensing 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.

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.

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.

Medicare and Medicaid; Fraud and Abuse 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.

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.

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.

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. Upon full review of the legislation, we were in compliance at that time and continue to maintain compliance. We monitor regularly and reflect this in our annual compliance report.

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.

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.

FDA 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.

Environmental, Health and Safety 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.

Several organizations maintain oversight function including:

- OSHA (Occupational Safety and Health Administration)
- EPA (Environmental Protection Agency)
- DOT (Department of Transportation)
- USPS (US Postal Service)
- US Public Health Service
- JCAHO (Joint Commission on Accreditation of Healthcare Organizations)
- NFPA (National Fire Protection Association)
- AIA (American Institute of Architects)
- AORN (Association of Operating Room Nurses)

Privacy and Security of Health and Personal Information 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.

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.

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 in the past, 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 3rd 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 3rd Edition in late 2016. We attained certification to the new standard, and then submitted it to our Notified Body (BSI) for recommendation for our CE Mark, which we received in June 2017, allowing us to sell products outside of the United States.

Effective November 21, 2016, 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 22 full-time employees and 1 part-time employee as of December 31, 2020.

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 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, 2020, 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

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. Therefore, we could invest significant capital in 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 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 and commercialization efforts for our TruTumor and PeDAL 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 tumor platform and our PeDAL 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 additional 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 particularly services using our PeDAL, platform as these are new to the market, 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.

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, without limitation, 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 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 may require additional financing to finance operating expenses 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 2021. While we have received approximately \$34.4 million in new investment during the first quarter of 2021 and are attempting to curtail our expenses, we may need to raise additional capital 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, especially over the longer term. We would attempt to raise these funds through equity or debt financing that may include public offerings, private placements, alternative offerings, further draws on our equity line with Oasis Capital, LLC, or other means. Such additional financing would be dilutive to existing stockholders, and there is no assurance that such financing would be available upon acceptable terms. If such financing or adequate funds from operations are not available, we would be forced to limit our business activities, which would have a material adverse effect on our results of operations and financial condition. 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.

Our business and operations have been and will likely continue to be materially and adversely affected by the COVID-19 pandemic.

In March 2020, the World Health Organization declared the recent spread of COVID-19 to be a global pandemic. In response to the crisis, emergency measures have been imposed by governments worldwide, including mandatory social distancing and the shutdown of non-essential businesses. These measures have adversely impacted the global economy, disrupted global supply chains and created significant volatility and disruption of financial markets, and our business and operations have been and will likely continue to be materially and adversely affected. For example, our contract manufacturer for the STREAMWAY® System has been forced to change locations, thereby delaying our order fulfillment for parts. We have also reduced on-site staff at several of our facilities, resulting in delayed production, less efficiency, and our sales staff is unable to visit with hospital administrators who are our customers and potential customers. In addition, COVID-19 has impacted the Company's capital and financial resources, including our overall liquidity position and outlook. For instance, our accounts receivable has slowed while our suppliers continue to ask for pre-delivery deposits. Ultimately, the extent of the impact of the COVID-19 pandemic on our future operational and financial performance will depend on, among other matters, the duration and intensity of the pandemic; the level of success of global vaccination efforts; governmental and private sector responses to the pandemic and the impact of such responses on us; and the impact of the pandemic on our employees, customers, suppliers, operations and sales, all of which are uncertain and cannot be predicted. These factors may remain prevalent for a significant period of time even after the pandemic subsides, including due to a continued or prolonged recession in the U.S. or other major economies. The impacts of the COVID-19 pandemic, as with any adverse public health developments, could have a material adverse effect on our business, results of operations, liquidity or financial condition and heighten or exacerbate risks described in this Annual Report on Form 10-K.

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.

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 year ended December 31, 2019, we recorded an impairment of goodwill of \$8,100,000 and during the year ended December 31, 2020 we recorded an impairment of goodwill of \$12,876,498. During 2019, 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.

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. In addition, 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.

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. In August 2020, however, the U.S. Department of Health and Human Services – the parent agency for FDA – announced that the FDA “will not require premarket review of LDTs absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances.” It is unclear at this time whether the Biden Administration will rescind or reverse this policy. It is also unclear at this time when, or if, the FDA will finalize its plans to end enforcement discretion (e.g., via notice and comment rulemaking or otherwise), and even then, the new regulatory requirements are expected to be phased-in over time. Nevertheless, the FDA may attempt to regulate certain LDTs on a case-by-case basis at any time.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals will be introduced from time-to-time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate certain LDTs as medical devices is difficult to predict at this time. If the FDA ultimately regulates certain LDTs, whether via final guidance, final regulation, or as instructed by Congress, our molecular diagnostic tests may be subject to certain additional regulatory 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.

Likewise, if we 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.

In sum, 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 and Medicaid 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. For instance, the ACA 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.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. The U.S. Supreme Court is currently reviewing the constitutionality of the ACA, although it is unclear when a decision will be made. Further, it is possible that additional governmental action will be taken in response to the COVID-19 pandemic.

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, if any, 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.

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 and 2,300,000 shares have been designated as series B convertible preferred stock and the remaining authorized shares are undesignated preferred stock. Our Board of Directors has the power to issue any or all of the shares of undesignated preferred stock, including the authority to establish one or more series and to fix the powers, preferences, rights, and limitations of such class or series, without seeking stockholder approval. Further, as a Delaware corporation, we are subject to provisions of the Delaware General Corporation Law regarding business combinations. We may, in the future, consider adopting additional anti-takeover measures. The authority of our Board of Directors to issue undesignated stock and the anti-takeover provisions of Delaware law, as well as any future anti-takeover measures adopted by us, may, in certain circumstances, delay, deter, or prevent takeover attempts and other changes in control 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.

General Risk Factors

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.

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.

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.

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

We may desire 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.

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 protected health and 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 2. PROPERTIES.

Our corporate offices are located in Eagan, Minnesota. 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. The lease as amended has a one-year term ending January 31, 2022.

The offices of our Helomics subsidiary are located in Pittsburgh, Pennsylvania. 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. The lease, as amended, has a two-year term ending February 28, 2023.

Soluble Biotech's offices are located in Birmingham, Alabama. We lease approximately 4,314 square feet at this location. The lease is effective through August 25, 2025.

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 10, 2021, there were approximately 236 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

Information regarding sales of unregistered securities during the periods covered hereby has been included in previous reports on Form 8-K or 10-Q. For additional information on such sales, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Financing Transactions.”

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;
- Our capital needs to accomplish our goals, including any further financing, which may be highly dilutive and may include onerous terms;
- Risks related to recent and future acquisitions, including the possibility of further impairment of goodwill and risks related to the benefits and costs of acquisition;
- Risks related to our partnerships with other companies, including the need to negotiate the definitive agreements; possible failure to realize anticipated benefits of these partnerships; and costs of providing funding to our partner companies, which may never be repaid or provide anticipated returns;
- Risk that we will be unable to protect our intellectual property or claims that we are infringing on others’ intellectual property;
- The impact of competition;

- 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 products and services are 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,
- Management of growth; and
- Risk that our business and operations will continue to be materially and adversely affected by the COVID-19 pandemic, which has impacted on a significant supplier; has resulted in delayed production and less efficiency; and has impacted on our sales efforts, accounts receivable, and terms demanded by suppliers; and may impact financing transactions.

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 three 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; second, a provider of soluble and stable formulations for proteins and third, 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 reportable segments: Helomics, Soluble, and Skyline. The Helomics segment includes clinical testing and contract research services that include the application of AI. Soluble segment consists of contract services and research focused on solubility improvements, stability studies, and protein production. Skyline consists of the STREAMWAY System product sales. The Helomics segment consists of clinical testing and contract research. Our TumorGenesis subsidiary specializes in media that help cancer cells grow and retain their DNA/RNA and proteomic signatures and 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.

Capital Requirements

Since inception, we have been unprofitable. We incurred net losses of \$25,884,397 and \$19,390,766 for the years ended December 31, 2020, and December 31, 2019, respectively. As of December 31, 2020, and December 31, 2019, we had an accumulated deficit of \$108,383,108 and \$82,498,711, respectively.

We have never generated sufficient revenues to fund our capital requirements. Since 2017, we have diversified our business by investing in ventures, including making significant loans and investments in early-stage companies. These activities led to the acquisition of Helomics in April 2019 and the purchase of the assets of two businesses in 2020 which have accelerated our capital needs further. We have funded our operations through a variety of debt and equity instruments. See “Liquidity and Capital Resources – Liquidity and Plan of Financing” 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; our ability to continue to sell our Skyline Medical products and to reach profitability in the Skyline Medical business, our ability to generate revenue from our Soluble reportable segment and the availability of future financing to fulfill our business plans. See “Liquidity and Capital Resources – Liquidity and Plan of Financing” below.

Our limited history of operations, especially in our precision medicine business, and our change in the emphasis of our business, starting in 2017, 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, 2020 with Year Ended December 31, 2019

	2020	2019	Difference
Revenue	\$ 1,252,272	\$ 1,411,565	\$ 159,293
Cost of goods sold	447,192	531,810	84,618
General and administrative expense	10,351,973	9,781,218	(570,755)
Operations expense	2,351,709	2,960,131	608,422
Sales and marketing expense	584,937	1,912,899	1,327,962

Revenue. We recorded revenue of \$1,252,272 in 2020, compared to \$1,411,565 in 2019. Our Skyline division was responsible for the majority of the revenue, with Helomics generating \$64,188 and \$48,447 in revenue in the years ended December 31, 2020 and 2019, respectively. We sold 25 STREAMWAY System units in 2020 and 41 STREAMWAY System units in 2019.

Cost of sales. Cost of sales was \$447,192 and \$531,810 in 2020 and 2019, respectively. The gross profit margin was 64% in 2020 compared to 62% in 2019. Our margins increased 2020 primarily due to decreased costs associated with supporting our maintenance contracts, offset by increased cost of sales related to sales in the Skyline Medical business in 2020 as a result of lower number of units, average cost increased slightly.

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 \$570,755 to \$10,351,973 in 2020 from \$9,781,218 in 2019. The increase is primarily due to increases in staff and related expenses due to additional headcount including new employees for our Soluble Biotech subsidiary, the assets of which we acquired in 2020, as well as certain one-time expenses related to severance incurred as part of our cost cutting measures. Also, increased depreciation is driven by newly added assets resulting from our asset purchase agreements for the assets of Soluble division and those of Quantitative Medicine LLC (“QM”), which we acquired in 2020.

Operations expense. Operations expense in our current stage primarily consists of expenses related to product development, prototyping and testing including staff related expenses for individuals performing this work.

Operations expense decreased by \$608,422 to \$2,351,709 in 2020 compared to \$2,960,131 in 2019. The decrease in operations expense in 2020 was primarily due to lower payroll costs and employee stock option vesting expenses, offset by increased costs associated with cloud computing.

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 \$1,327,962 to \$584,937 in 2020 compared to \$1,912,899 in 2019. Such expenses related almost exclusively to the Skyline Medical business. The decrease in 2020 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 payroll and bonus expense for sales staff as well as travel related costs, web development, public relations, and market research.

Impact of minority investment on net loss. The net loss for 2019 includes a loss on equity method investment of \$439,637. 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 in 2019 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 a loss on impairment of goodwill of \$12,876,498 during 2020. We incurred impairments charges of \$8,100,000 and \$770,250 on goodwill and intangibles, respectively during 2019.

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 and interim goodwill impairment tests in each 2020 and 2019, we concluded that goodwill was impaired as of the testing dates. 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 goodwill following the impairment was \$2,813,792 and \$15,690,290 at December 31, 2020 and December 31, 2019, respectively. We will continue to monitor our reporting unit in an effort to determine whether events and circumstances warrant further impairment testing in future periods, which may include interim periods. The cumulative losses on goodwill are \$20,976,498 as of December 31, 2020. Please see Note 11 to our audited financial statements included in this annual report for further information.

Other income. We earned other income of \$843,440 in 2020 compared to \$65,300 in 2019. Other income was comprised of gain on the forgiveness of the Paycheck Protection Program loan of \$541,867 and gains on settlement of outstanding payables during 2020. 2019 other income included gains on settlement of outstanding payables and dividend income.

Other expense. We incurred other expenses of \$2,427,026 in 2020 compared to \$3,466,696 in 2019. Other expenses consisted primarily of interest expense, payment penalties and amortization of original issue discounts.

Income Taxes. We have not recognized any income tax benefit in our statement of operations related to our U.S. operating losses, as all tax benefits are fully reserved.

Liquidity and Capital Resources

Cash Flows

Net cash used in operating activities was \$12,257,732 in 2020, compared with net cash used of \$8,732,451 in 2019. Cash used in operating activities increased in 2020 primarily due to increased operating losses as well as increased outflows related to payments on accounts payables and payments for accrued expenses, inventories and prepaid expenses.

Cash flows used in investing activities were \$167,456 in 2020 and \$599,087 in 2019. Cash flows used in investing activities in 2020 were primarily purchases of fixed assets, offset by disposals of fixed assets. 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.

Net cash provided by financing activities was \$12,952,689 in 2020 compared to net cash provided of \$9,320,217 in 2019. Cash flows provided by financing activities in 2020 were primarily due from proceeds of common stock issuances of \$4,891,348, proceeds from the issuance of common stock, prefunded warrants, warrants and the exchange of warrants of \$5,057,919 and the exercise of warrants of \$1,935,855. In 2019, we received 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.

Liquidity and Plan of Financing

Since our inception, we have incurred significant losses, and our accumulated deficit was \$108,383,108 as of December 31, 2020. 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 2021. We had revenues of \$1,252,272 and \$1,411,565 in 2020 and 2019, respectively, but we had negative operating cash flows of \$12,257,732 and \$8,732,451 in 2020 and 2019, respectively. Our cash balance was \$678,332 as of December 31, 2020, and our accounts payable and accrued expenses were an aggregate \$3,960,117. These matters are indicators of substantial doubt and were alleviated as noted below due to the registered direct offerings and private placement in January and February 2021. Additionally, all amounts payable related to outstanding debt agreements have been subsequently repaid. See "Financing Transactions" below.

Since January 2019, we have raised capital in a variety of private sales and public offerings of debt and equity securities. See "Financing Transactions" below. We have also issued equity securities in several acquisitions of other companies in 2019 and 2020. See "Issuances of Securities in Acquisitions" below. In January and February 2021, we received aggregate net proceeds of \$31,077,232 in a series of registered direct offerings and a private placement of equity securities. On March 1, 2021, we used \$5,906,802 of the net proceeds from the private placement to pay the remaining principal and interest on the loans originally issued in September 2018, September 2019 and February 2020 and to pay premium payable upon such repayment. The remaining net proceeds of the 2021 transactions have been or will be used for working capital.

We believe that our existing capital resources will be sufficient to support our operating plan at least through March 31, 2022. However, we may also seek to raise additional capital to support our growth through additional debt, equity or other alternatives or a combination thereof. We would raise such capital through equity or debt financing to fund our capital and equipment investments and our operations.

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. Since late 2018, these financing transactions have consisted of (1) secured convertible notes to private investors starting in late 2018, the remaining amount of which was repaid on March 1, 2021; (2) a series of loans from Dr. Carl Schwartz, our CEO, starting in late 2018, which were exchanged for common stock in 2020; and (3) a number of public offerings, registered direct offerings and private placements, including an equity line arrangement (offerings), since 2019.

Secured Notes and Repayment in Full

In September 2018, the Company issued convertible secured promissory notes to two private investors in the original principal amount of an aggregate \$2,297,727 (together, the “2018 Investor Note”) in exchange for cash proceeds of \$2,000,000. As additional consideration for the 2018 Investor Note, 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 2018 Investor Note accrued interest at a rate of 8% per annum. In February 2019, the Company entered into a forbearance agreement with the 2018 Investor Note investors pursuant to which, among other things, the investors agreed to forbear on their rights to accelerate the 2018 Investor Note 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. In September 2019, the 2018 Investor Note of one investor was paid in full. On March 19, 2020, the Company and the L2 Capital, LLC (“L2”) agreed to extend the note maturity to June 28, 2020. The Company and L2 further agreed to extend the due date to July 15, 2020 and then in July 2020 agreed to extend to September 30, 2020. Effective September 30, 2020, L2 and the Company agreed to extend to March 31, 2021.

No payment penalties were paid in relation to payments on the 2018 Investor Note during the year ended December 31, 2020 and \$525,926 in payment penalties were accrued but not paid as of December 31, 2020. The outstanding principal balance of the 2018 Investor Note as of December 31, 2020 was \$1,721,776, with an unamortized discount of \$0.

Each investor received the right to convert all or any part of its portion of the 2018 Promissory Note into shares of the Company’s common stock at a discounted price, subject to certain limitations. During the year ended December 31, 2020 and 2019, L2 converted \$267,328 and \$140,000 of the principal balance, respectively and received 170,000 and 47,556 shares of the Company’s common stock, respectively.

During September 2019, the Company issued a secured promissory note with a principal amount of \$847,500 (the “2019 Investor Note”) to Oasis Capital, LLC (“Oasis”), an affiliate of L2, in exchange for cash proceeds of \$700,000. As additional consideration for the loan, the Company issued an aggregate 8,857 shares of its common stock to Oasis 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 2019 Investor Note accrued interest at a rate of 8% per annum. On March 19, 2020, the Company entered into an agreement to extend the due date the 2019 Investor Note from March 2020 to June 27, 2020. The Company increased the principal amount due on the 2019 Investor Note by \$300,000 and issued 30,000 shares of its common stock as consideration for the extension. The change in value resulting from the extension exceeded 10% and as a result the extension was accounted for as an extinguishment under ASC 470, *Debt*. During the first quarter of 2020, the Company incurred a \$300,000 loss on debt extinguishment related to the extension of the note. The Company and Oasis further agreed to extend the due date of the note to July 15, 2020 and then agreed to extend to September 30, 2020. The change in value resulting from the extension to September 30, 2020 exceeded 10% and as a result the extension was accounted for as an extinguishment under ASC 470, *Debt*. During the third quarter of 2020, the Company incurred a \$345,000 loss on debt extinguishment related to the extension of the 2019 Investor Note to September 30, 2020. Effective September 30, 2020, Oasis and the Company agreed to further extend the maturity date of the 2019 Investor Note to March 31, 2021. The change in value resulting from the extension to March 31, 2021 exceeded 10% and as a result the extension was accounted for as an extinguishment under ASC 470, *Debt*. During the third quarter of 2020, the Company incurred a \$690,000 loss on debt extinguishment related to the extension of the note to March 31, 2021. Further, the parties agreed that the note shall be convertible into shares of the Company’s common stock, at a conversion price equal to the lesser of (i) \$1.00 and (ii) 70% of the lowest VWAP (as defined in the note) of the Company’s common stock during the twenty (20) Trading Day (as defined) period ending on either (i) the last complete Trading Day prior to the conversion date or (ii) the conversion date, as determined by the holder in its sole discretion upon such conversion (subject to adjustment). During the fourth quarter of 2020, Oasis converted \$525,000 in outstanding principal of the 2019 Investor Note in exchange for 1,136,448 shares of the Company’s common stock. No payment penalties were paid in relation to payments on this promissory note during the year ended December 31, 2020 and \$320,542 in payment penalties were accrued but not paid as of December 31, 2020. As of December 31, 2020, the remaining balance on the promissory note was \$1,490,833 with \$244,830 unamortized discount.

On February 5, 2020, the Company issued a secured promissory note with a principal amount of \$1,450,000 (the “2020 Investor Note”) to Oasis. Net proceeds of \$400,000 were received for each of the first, second, and third tranches on February 5, 2020, March 5, 2020, and April 5, 2020, respectively. The Company granted to Oasis a security interest in its assets to secure repayment of the note. The 2020 Investor Note accrued interest at a rate of 8% per annum. Subject to certain limitations, the outstanding principal amount of the note and interest thereon were convertible at the election of the investor into shares of the Company’s common stock at a conversion price equal to \$2.589. The conversion price was amended effective September 30, 2020 to a variable price equal to 70% of the lowest volume weighted average price (“VWAP”) (as defined in the note) of Company’s common stock during the twenty (20) Trading Day (as defined in the note) period ending on either (i) the last complete Trading Day prior to the conversion date or (ii) the conversion date, as determined by the holder in its sole discretion upon such conversion (subject to adjustment). The note contains a conversion feature and a put which were determined to be derivatives and are discussed further below. Effective July 15, 2020, the Company and Oasis agreed to amend the maturity date of the note to September 30, 2020. The change in value resulting from the amendment to maturity to September 30, 2020 exceeded 10% and as a result the amendment was accounted for as an extinguishment under ASC 470, *Debt*. During the third quarter of 2020, the Company incurred a \$172,500 loss on debt extinguishment related to the amendment of the note to September 30, 2020. Effective September 30, 2020, the investor and the Company agreed to further extend the maturity date of the 2020 Investor Note to March 31, 2021. The change in value resulting from the extension to March 31, 2021 exceeded 10% and as a result the extension was accounted for as an extinguishment under ASC 470, *Debt*. During the third quarter of 2020, the Company incurred a \$345,000 loss on debt extinguishment related to the extension of the note to March 31, 2021. As additional consideration, the Company issued to Oasis warrants to purchase 94,631, 92,700 and 92,700 shares of the Company’s common stock at the closing of the first, second and third tranches, respectively. 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 Oasis at the closing of the first tranche. During the fourth quarter of 2020, Oasis converted \$503,354 in outstanding principal in exchange for 1,075,911 shares of the Company’s common stock. No payment penalties were paid in relation to payments on this promissory note during the year ended December 31, 2020 and \$314,011 in payment penalties were accrued but not paid as of December 31, 2020. As of December 31, 2020, the outstanding balance on the promissory note was \$1,464,146 with no remaining unamortized discount.

On March 1, 2021, the Company used \$5,906,802 of the proceeds of the private placement on February 23, 2021, described below under “2021 Offerings”, to repay in full the outstanding principal and interest and applicable premium amounts under the 2018 Investor Note, the 2019 Investor Note and the 2020 Investor Note.

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.

During January 2020, the Company entered into an exchange agreement with Dr. Schwartz. Under the exchange agreement, the two outstanding notes were cancelled and in exchange a new combined promissory note in the amount of \$2,115,000 (the “2020 Schwartz Note”) bearing 12% interest per annum and maturing on September 30, 2020 was issued. In addition to the 2020 Schwartz 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. The Company determined that the exchange agreement had, in substance, occurred at December 31, 2019.

Effective as of April 21, 2020, the Company and Dr. Schwartz, entered into an exchange agreement relating to the 2020 Schwartz Note. The 2020 Schwartz Note bore twelve percent (12%) interest per annum and had a maturity date of September 30, 2020. The accrued interest on the note through April 21, 2020 was \$77,878, resulting in a total balance of \$2,192,878 in principal and accrued interest on the 2020 Schwartz Note as of such date. Dr. Schwartz and the Company agreed to exchange the 2020 Schwartz Note for newly issued shares of common stock of the Company at market value. Pursuant to the exchange agreement, Dr. Schwartz was issued 1,533,481 shares of newly issued common stock at an exchange rate of \$1.43 per share, equal to the closing price of the common stock on April 21, 2020. Dr. Schwartz agreed (1) not to sell or otherwise transfer 766,740 shares for three months after the date of the exchange agreement, and (2) not to sell or otherwise transfer the remaining 766,741 shares for six months after the date of the exchange agreement. In 2021, the Company determined that due to a calculation error, the balance of the 2020 Schwartz Note should have been higher by \$143,574 at the time of the exchange agreement, and on February 24, 2021, the Company issued an additional 100,401 shares to Dr. Schwartz.

2019 Offerings

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 agent 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, 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 agent 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.

In June through September 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 shareholder had 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 included a contingent beneficial conversion amount of \$289,935, 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 was accreted through the earliest redemption date of December 13, 2019.

In May 2020, we notified the holders of our Series E Convertible Preferred Stock of our election to convert the outstanding shares of Series E Stock into common stock effective on June 13, 2020 pursuant to the terms of the Series E Stock. Prior to the conversion, there were 207.7 shares of Series E Stock outstanding. Each share of Series E Stock converted into 0.056857% of the issued and outstanding shares of common stock immediately prior to conversion; therefore, the 207.7 outstanding shares of Series E Stock on June 13, 2020 converted into 1,257,416 shares of common stock equal to 11.8% of the outstanding shares of common stock as of June 12, 2020.

On October 4, 2019, we sold 633,554 shares of our common stock in a public offering. 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.

On October 24, 2019, we entered into an equity purchase agreement with Oasis, providing for an equity line 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 Oasis 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 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 the common stock.

From the date of the agreement through December 31, 2019, we sold an aggregate 122,356 shares of common stock to Oasis for proceeds of \$319,195.

2020 Paycheck Protection Program Loan and Forgiveness

On April 20, 2020, the Company entered into a promissory note with Park State Bank, which provides for an unsecured loan of \$541,867 pursuant to the Paycheck Protection Program (the "PPP") under the Coronavirus Aid, Relief, and Economic Security Act and applicable regulations (the "CARES Act"). The promissory note has a term of 2 years with a 1% per annum interest rate. Payments are deferred for 6 months from the date of the promissory note and the Company can apply for forgiveness of all or a portion of the promissory note after 60 days for covered use of funds.

Pursuant to the terms of the PPP, the promissory note, or a portion thereof, may be forgiven if proceeds are used for qualifying expenses as described in the CARES Act, such as payroll costs, costs used to continue group health care benefits, mortgage interest payments, rent and utilities. The Company has used all proceeds for qualifying expenses. The Company received forgiveness for the loan under the Paycheck Protection Program and recognized a gain in other income for the full amount of the loan during the fourth quarter of 2020.

2020 Offerings

On March 19, 2020, in a private placement we sold and issued (1) 260,000 shares of common stock, at a sale price of \$2.121 per share; (2) 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; (3) 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 (4) 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 sale resulted in gross proceeds of \$3,498,612 and net proceeds of \$3,127,112. The Company paid the Placement Agent an aggregate fee equal to 7.5% of the aggregate gross proceeds received by the Company in the offering. The Company also paid the Placement Agent a management fee equal to 1% of the aggregate gross proceeds received by the Company in the offering and reimbursed the Placement Agent for \$25,000 in non-accountable expenses and up to \$40,000 in legal and other out-of-pocket expenses. In addition, the Company granted to the Placement Agent or its assigns warrants to purchase up to an aggregate of 123,762 shares of its common stock (which represents 7.5% of the Shares sold to investors in the private placement) at an exercise price equal to 125% of the price of the Shares in the private placement, or \$2.65125. These placement agent warrants will expire on March 18, 2025.

During May 2020, the Company sold 1,396,826 shares of common stock in a registered direct offering under its shelf registration statement. In a concurrent private placement, the Company also issued such investors warrants to purchase up to an aggregate of 1,396,826 shares of our common stock. The Shares and the Warrants were sold at a combined offering price of \$1.575 per Share and associated Warrant. Each Warrant is exercisable immediately upon issuance at an exercise price of \$1.45 per share and will expire five and one-half years from the issue date. The sale of the offering shares and associated warrants resulted in gross proceeds of \$2,200,001 and net proceeds of \$1,930,100 after deducting the placement agent fees and estimated offering expenses payable by the Company. The Company granted to the placement agent or its assigns warrants to purchase up to an aggregate of 104,762 shares of its common stock at an exercise price of \$1.9688.

On June 25, 2020, the Company entered into agreements with the holders of an aggregate of 1,396,826 of the warrants issued in connection with the May 2020 registered direct offering, under which the investors exercised the warrants and received the same number new warrants. The investors paid an exercise price of \$1.45 per share plus an additional \$0.125 for each new warrant. The Company issued 1,396,826 shares and issued new warrants which are exercisable immediately and have a term of five and one-half years and an exercise price per share equal to \$1.80. The Company received \$2,130,701 in gross proceeds and net proceeds of \$1,865,800 after deducting the placement agent fees and estimated offering expenses payable by the Company. Before deducting placement agent fees and expenses, the Company received approximately \$2,200,000 from the transactions. Pursuant to an engagement letter, the Company agreed to pay the Placement Agent a cash fee equal to 7.5% of the gross proceeds received from the exercise and the sale of the New Warrants. The Company also paid the Placement Agent a management fee equal to 1% of the aggregate gross aggregate gross proceeds received by the Company in the offering and reimbursed the Placement Agent for \$25,000 in non-accountable expenses and up to \$40,000 in legal and other out-of-pocket expenses. In addition, the Company granted to the Placement Agent or its assigns warrants to purchase up to an aggregate of 104,763 shares of its common stock (which represents 7.5% of the shares sold to investors in the exercise transaction) at an exercise price equal to 125% of the exercise price of the New Warrants, or \$2.25.

In connection with the equity line arrangement entered into with Oasis in October 2019, during the year ended December 31, 2020, we issued an aggregate 4,231,073 shares of common stock to Oasis for net proceeds of \$4,891,348.

2021 Offerings

In January and February 2021, the Company completed a series of five offerings, all of which were priced at-the-market under applicable NASDAQ rules. The first four offerings were registered direct offerings of common stock under its shelf registration statement, and in each such case, in a concurrent private placement, the Company also issued such investors one warrant to purchase common stock for each two shares purchased in the transaction. Following those four offerings, the Company completed a private placement of common stock, with each investor receiving one warrant to purchase common stock for each two shares purchased in the transaction. In each case, each such investor warrant is exercisable immediately upon issuance and will expire five and one-half years from the issue date. In each case, the Company paid to the placement agent an aggregate fee equal to 7.5% of the aggregate gross proceeds received by the Company in the offering and a management fee equal to 1% of the aggregate gross proceeds received by the Company in the offering and reimbursed the placement agent for certain non-accountable and out-of-pocket expenses. In addition, the Company granted to the placement agent or its assigns warrants to purchase 7.5% of the shares sold to investors in the offering at an exercise price equal to 125% of the price of the shares in the transaction, with a term of five years for the registered direct offerings or five and one-half years for the private placement. These offerings were as follows:

Offering Closing Date	Shares	Sale Price per Share*	Investor Warrants	Exercise Price per Share – investor Warrants	Placement Agent Warrants	Exercise Price per Share – Placement Agent Warrants	Gross Proceeds of Offering	Net Proceeds of Offering
January 12, 2021 (registered direct)	3,655,840	\$0.842	1,825,420	\$0.80	273,813	\$1.0525	\$3,074,007	\$2,731,767
January 21, 2021 (registered direct)	2,200,000	\$1.00	1,100,000	\$1.00	165,000	\$1.25	\$2,200,000	\$1,932,050

January 26, 2021 (registered direct)	3,414,970	\$1.20	1,707,485	\$1.20	256,123	\$1.50	\$4,097,964	\$3,668,687
February 16, 2021 (registered direct)	4,222,288	\$1.75	2,111,144	\$2.00	316,672	\$2.1875	\$7,389,004	\$6,679,989
February 23, 2021 (private placement)	9,043,766	\$1.95	4,521,883	\$2.00	678,282	\$2.4375	\$17,635,344	\$16,064,739
Total	22,536,864		11,265,932		1,689,890		\$34,396,319	\$31,077,232

* Sale price includes one share and a warrant to purchase one-half share.

2021 Warrant Exercises

During the period January 1, 2021 through February 25, 2021, the holders of outstanding investor warrants have exercised such warrants for the total purchase of 4,964,994 shares at a weighted average exercise price of \$0.63 per share, for total proceeds of \$ 4,269,617.

Issuances of Securities in Acquisitions

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 not already held by the Company. 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. On April 4, 2020, the 3,500,000 shares of Series D convertible preferred stock were converted into 350,004 shares of common stock. Also, on April 4, 2019, the Company completed an exchange offer with the holders of certain notes and warrants of Helomics, in which the Company issued 863,732 shares of common stock to the noteholders in exchange for their notes and issued warrants to purchase up to 1,425,506 warrants of the Company at an exercise price of \$10.00 per share in exchange for the Helomics warrants held by the noteholders. An additional 59,700 Company warrants at an exercise price of \$0.10 per share were exchanged for Helomics warrants held by other parties. On September 14, 2020, the Company agreed to amend the Company warrants at \$10.00 per share to allow the holders to exercise the warrants at an exercise price of \$0.845 per share, equal to the then-current market value of the common stock. See Notes 2 and 5 to the Consolidated Financial Statements.

On May 27, 2020, the Company entered into an Asset Purchase Agreement with InventaBioTech, Inc. (“InventaBioTech”) and two of its subsidiaries, Soluble Therapeutics, Inc. (“Soluble”), and BioDtech, Inc. (“BioDtech”), and simultaneously completed the acquisition of substantially all of Soluble’s and BioDtech’s assets. In exchange, the Company issued 125,000 shares of common stock and waived all existing claims that the Company has or may have against InventaBioTech (f/k/a CytoBioscience, Inc.), including the nonpayment of \$1,290,000 owed by InventaBioTech to the Company. See Note 5 to the Consolidated Financial Statements.

On July 1, 2020, the Company entered into an Asset Purchase Agreement with Quantitative Medicine LLC (“Seller”), a Delaware limited liability company and its owners and simultaneously completed the acquisition of substantially all of the assets owned by Seller. Quantitative Medicine is a biomedical analytics and computational biology company that 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. In exchange for Seller’s assets, including CoRE, the Company provided consideration in the form of 954,719 shares of common stock, which, when issued, had a fair value of \$1,470,267. One half of the shares issued, or 477,359 shares were deposited and held in escrow upon issuance, while 207,144 of the remaining shares were issued to Carnegie Mellon University (“CMU”) in satisfaction of all pre-closing amounts owed to CMU under a technology licensing agreement that was assumed by the Company on the closing date. Half of the shares held in escrow will be released on the six-month anniversary of the closing date, and the other half will be released on the one-year anniversary of the closing date; provided, however, that all or some of the escrow shares may be released and returned to the Company for reimbursement in the event that the Company suffers a loss against which the Selling Parties have indemnified the Company pursuant to the Agreement. See Note 5 to the Consolidated Financial Statements.

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 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 Tumor Drug Response Testing (formerly ChemoFx) and Genomic Profiling (formerly BioSpeciFx) tests. The Tumor Drug Response Testing test determines how a patient’s tumor specimen reacts to a panel of various chemotherapy drugs, while the Genomic Profiling 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 relate primarily to maintenance plans and CRO revenue.

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.

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.

Fixed Assets. We account for assets acquired at fair value as of the acquisition date. The fair value for assets acquired are based on their estimated fair values. 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.

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. 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.

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. During the third quarter of 2020, the Company's share price experienced a sustained reduction in trading values. This was also reflective of broader difficulties in the general economic conditions due to the COVID pandemic. Based on our examination of these and other qualitative factors at September 30, 2020, the Company concluded that that potential impairment indicators were present and that an impairment assessment was warranted for goodwill.

In testing goodwill for impairment as of September 30, 2020, 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 quantitative goodwill impairment test, the Company concluded that goodwill was impaired as of the testing date of September 30, 2020. The quantitative review as of September 30, 2020 resulted in \$2,997,000 of impairment expense related to goodwill.

When evaluating the fair value of Helomics reporting unit the Company used a discounted cash flow model and market comparisons. 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 25% 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 10% for risks related to the term of the forecasts.

In testing goodwill for impairment as of December 31, 2020, 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, 2020. 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, 2020 resulted in \$9,879,458 of impairment expense related to goodwill. A decrease in the growth rate of 0.5% or an increase of 0.5% to the discount rate would reduce the fair value of Helomics reporting unit by approximately an additional \$588,000 and \$988,000, respectively. As of December 31, 2020, the cumulative impairment recorded was \$20,976,498.

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 in 2020 included: (a) expected cash flow for the 10-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 5.0% determined based on the growth prospects of the reporting unit; and (c) a discount rate of 14.0% 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 1.0% for risks related to the term of the forecasts. The Company further used a probability weighting of various forecasts to address forecast risk.

Long-lived Assets

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.

Because evaluation of other long-lived assets is necessary based on a triggering event, the Company prepared the undiscounted cash flows per ASC 360. The Company concluded that the undiscounted cash flows of the long-lived assets exceeded the carrying values. The Company concluded there was no impairment of its finite lived assets as of December 31, 2020.

Income Taxes. Deferred income taxes are provided on a liability method, whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences, which are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment. The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

Recent Accounting Developments

See "Note 1 - Summary of Significant Accounting Policies - Recently Adopted Accounting Standards" 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, 2020. 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, 2020 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, 2020 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, 2020 due to the following material weakness identified first identified during the second quarter of 2019.

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 during the fourth quarter of 2019 hired additional resources with qualifications that include a high level of experience with complex technical accounting transactions and application of U.S. GAAP. In the first quarter of 2020, we also engaged an external accounting consultant to assist with the assessment of new complex transactions, which has been ongoing to date. We have completed internal control remediation testing utilizing an external consulting company. We have also re-evaluated the training and ongoing professional education that is provided to, and required of, our accounting personnel.

Once the above actions and 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 Baker Tilly US, 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, 2020 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, 2020:

Name		Age	Position Held
Carl Schwartz	(4) (5)	80	Chief Executive Officer and Director
Bob Myers		66	Chief Financial Officer
J. Melville Engle	(1) (2) (3)	71	Director
Nancy Chung-Welch, Ph.D.	(2) (4) (7)	60	Director
Richard L. Gabriel	(4)	72	Director
Daniel E. Handley, Ph.D.	(3) (6)	61	Director
Chuck Nuzum	(1) (2) (8)	72	Director
Gregory S. St.Clair	(1) (9)	55	Director
Thomas J. McGoldrick	(2) (3) (4) (10)	79	Director
Gerald J. Vardzel, Jr.	(11)	55	Director
Pamela S. Prior	(1) (12)	59	Director
Andrew P. Reding	(1) (13)	51	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) Member of the Finance Committee
- (6) Dr. Handley was appointed as a Director in February 2020.
- (7) Dr. Chung-Welch was appointed as a Director in July 2020.
- (8) Mr. Nuzum was appointed as a Director in July 2020.
- (9) Mr. St. Clair was appointed as a Director in July 2020.
- (10) Mr. McGoldrick resigned his position in January 2020.
- (11) Mr. Vardzel resigned his position in July 2020.
- (12) Ms. Prior was appointed as a Director in January 2020 and resigned her position in July 2020.
- (13) Mr. Reding resigned his position in July 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)	CLASS II (term expiring in 2023)	CLASS III (term expiring in 2021)
Chuck Nuzum Daniel E. Handley	J. Melville Engle Nancy Chung-Welch Gregory S. St. Clair	Dr. Carl Schwartz Richard Gabriel

Business Experience

Carl Schwartz, Chief Executive Officer and Director. Dr. Schwartz was the owner manager of dental groups in Burton, Michigan and Grand Blanc, Michigan. Dr. Schwartz previously served on the Board of Delta Dental Corporation of Michigan, was a member of the Michigan Advisory Board for Liberty Mutual Insurance and was a member of the Board of Trustees of the Museum of Contemporary Art in Florida. In 1988, Dr. Schwartz joined a family business becoming chief executive officer of Plastics Research Corporation, a Flint, Michigan, manufacturer of structural foam molding, a low-pressure injection molding process. While there he led its growth from \$2 million in revenues and 20 employees, to it becoming the largest manufacturer of structural foam molding products under one roof in the U.S. with more than \$60 million in revenues and 300 employees when he retired in 2001. He holds B.A. and D.D.S. degrees from the University of Detroit.

Bob Myers, Chief Financial Officer. Effective July 1, 2012, Mr. Myers was appointed as 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.

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 director 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.

Nancy Chung-Welch, Ph.D. Dr. Chung-Welch was appointed to the Board on July 9, 2020. Dr. Chung-Welch is currently an independent consultant advising life science companies and their institutional investors on life science companies, technologies and industries with an emphasis on the research product/tools market. Previously she was a Director, Business Development at Cell Signaling Technology and was Director, Business Development at Thermo Fisher Scientific and Technical Marketing Manager for Fisher Scientific. She has over 25 years of marketing and business development experience in the life sciences market. Dr. Chung-Welch has a balanced blend of business and technical/analytical strengths to provide sound foundation for technology/IP assessments and external partnerships. She has a strong record of domestic and international experience in business and customer needs analysis, technology assessment, licensing, distribution deals, partnerships, strategic alliances, strategic customer relationships, mergers/acquisitions. She previously served as Instructor in Surgery and Assistant in Physiology at Harvard Medical School and the Massachusetts General Hospital with expertise in basic science research, including cell biology, tissue culture, vascular physiology, genomics, proteomics, and lab automation applications. She is also a hands-on marketing executive and has conceptualized, launched, and managed products and services in the laboratory, medical, biotech/pharma, academic and government markets. She received her Ph.D. in Vascular Physiology and Cell Biology from Boston University.

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.

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.

Chuck Nuzum. Mr. Nuzum was appointed to the Board on July 9, 2020. Mr. Nuzum has extensive experience as a CFO that ranges from private start-ups to large publicly-traded companies. Mr. Nuzum presently provides financial consulting services on a project basis to companies such as McKesson, BioMarin, AutoDesk and Squire Patton Boggs, mentors start-up companies and serves on the Board of Directors of several companies. Previously he was co-founder and CFO of the Tyburn Group, a financial services company that creates and delivers prepaid payroll and general purpose card programs for customers. For the four years prior, Mr. Nuzum served as the Controller of Dey, L.P., a large pharmaceutical manufacturing subsidiary of Merck KGaA. Prior to that he was co-founder, Executive Vice President and CFO of SVC Financials Services, one of the first companies in the field to integrate a mobile money solution for global distribution, Vice President of Finance and Administration at Tiburon, Inc., a leader in public safety and justice information systems, and CFO of Winebid.com the world's leading e-commerce wine auction company. For more than two decades, Mr. Nuzum was CFO of Loomis Fargo & Co., the well-known international provider of ATM systems, armored cars and other security services. Mr. Nuzum, a Certified Public Accountant, earned his BA at the University of Washington at Seattle.

Gregory S. St. Clair. Mr. St. Clair was appointed to the Board on July 9, 2020. Mr. St. Clair is the Founder and Managing Member of SunStone Consulting, LLC, a healthcare consulting firm that serves healthcare providers throughout the United States since 2002. As frequently sought experts on issues related to compliance, reimbursement and revenue integrity, Mr. St. Clair and his team are constantly on-call to assist clients as they address financial challenges through creative solutions to the nation's health systems. Previously, Mr. St. Clair worked as a national vice president for CGI, ImrGlobal, and Orion Consulting and as national director for Coopers & Lybrand. He holds a B.S. in both Accounting and Finance from Juniata College in Huntingdon, Pennsylvania. Below is a description of each committee of the Board of Directors as such committees are presently constituted.

Board Committee Structures

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 Mr. Nuzum, as the chairperson, Mr. St. Clair and Mr. Engle. During 2020, the Audit Committee chairperson was Ms. Prior, who was replaced on the committee and as chairperson by Mr. Nuzum in July 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 2020.

Audit Committee Financial Expert

The Board has determined that Mr. Nuzum 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, Mr. Nuzum, Mr. St. Clair, 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 three directors, Mr. Engle, as the chairperson, Dr. Chung-Welch and Mr. Nuzum. 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 2020, the Compensation Committee met eight 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, Dr. Chung-Welch and Mr. Nuzum. 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 Dr. Handley, as the chairperson and Mr. Engle. Dr. Handley and Mr. Engle are “independent directors,” 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, develops and recommends to the Board a set of corporate governance principles applicable to the Company, and reviews and reassesses the adequacy of such guidelines annually and recommends 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, Mr. Gabriel, as the chairperson, and Dr. Schwartz and Dr. Chung-Welch. Dr. Chung-Welch is an “independent director” 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 currently has 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, 2020 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, 2020: J. Melville Engle 1 late report covering 1 transaction; Carl Schwartz 1 late report covering 1 transaction; and Gerald Vardzel 1 late report covering 1 transaction; and Pamela Prior with a late Form 3.

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 2020.

Summary Compensation Table for Fiscal 2020 and 2019

The following table provides information regarding the compensation earned during the fiscal years ended December 31, 2020 and December 31, 2019 by each of the Named Executive Officers:

Name and Principal Position	Year	Salary	Bonus	(1) Stock Awards	(1) Option Awards	All Other Compensation	Total Compensation
Carl Schwartz, CEO ⁽²⁾	2020	\$ 430,000	\$ -	\$ 46,002	\$ -	\$ -	\$ 476,002
	2019	\$ 100,000	\$ -	\$ -	\$ 376,600	\$ -	\$ 476,600
Bob Myers, CFO ⁽³⁾	2020	\$ 327,838	\$ -	\$ 15,334	\$ -	\$ -	\$ 343,172
	2019	\$ 270,833	\$ -	\$ -	\$ 100,597	\$ -	\$ 371,430

(1) Represents the actual compensation cost granted during 2020 and 2019 as determined pursuant to FASB ASC 718, *Stock Compensation*.

(2) On December 1, 2016, Dr. Schwartz was appointed Chief Executive Officer. Dr. Schwartz received a salary increase to \$460,000 annually on September 23, 2020 retroactively effective to July 1, 2020. Dr. Schwartz received 300,000 restricted stock units on September 23, 2020, payable in shares of common stock and vesting in equal annual installments over three years. 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 shares of common stock in lieu of a cash salary in 2019. The shares all vest at the time of grant and range in price from \$1.54 per share to \$7.90 per share for 2019 grants.

(3) Mr. Myers received a salary increase to \$345,000 annually on September 23, 2020 retroactively effective to July 1, 2020. Mr. Myers received 100,000 restricted stock units on September 23, 2020, payable in shares of common stock and vesting in equal annual installments over three years. Mr. Myers received a salary increase on August 1, 2019 to an annualized amount of \$300,000. Mr. Myers received \$19,250 paid in 2019 for 2018 accrued bonus. Mr. Myers received options to purchase 16,600 shares of common stock vesting over two (2) years in eight (8) equal installments priced at \$1.54 per share.

Outstanding Equity Awards at Fiscal Year-end for Fiscal 2020

The following table sets forth certain information regarding outstanding equity awards held by the named executive officers as of December 31, 2020:

	Options				Restricted Stock Units	
	Grant Date	Number of Securities Underlying Options Exercisable	Option Exercise Price	Option Expiration Date	Number of Units of Stock That Have Not Vested	Market Value
						Of Units of Stock That Have Not Vested
Carl Schwartz	7/19/2013	7	\$ 1.54	7/19/2023	—	—
	6/30/2015	26	\$ 1.54	6/30/2025	—	—
	6/30/2015	26	\$ 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	179	\$ 1.54	12/31/2026	—	—
	12/31/2016	714	\$ 28.00	12/31/2026	—	—
	3/31/2017	238	\$ 21.00	3/31/2027	—	—
	6/22/2017	37,689	\$ 1.54	6/22/2027	—	—
	11/10/2017	2,834	\$ 1.54	11/10/2027	—	—
	1/2/2018	14,175	\$ 1.54	1/2/2028	—	—
	6/30/2018	12,168	\$ 1.54	6/30/2028	—	—
	8/1/2018	4,490	\$ 1.54	8/1/2028	—	—
	1/2/2019	32,305	\$ 1.54	1/2/2029	—	—
	4/4/2019	20,000	\$ 1.54	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	—	—
	3/31/2020	3,174	\$ 1.58	3/31/2030	—	—
	6/30/2020	3,049	\$ 1.64	6/30/2030	—	—
	9/23/2020	—	—	—	300,000	\$ 253,710
	9/30/2020	6,142	\$ 0.81	9/30/2030	—	—
	12/31/2020	20,481	\$ 0.73	12/31/2030	—	—
Bob Myers	8/13/2012	53	\$ 1.54	8/13/2022	—	—
	3/18/2013	42	\$ 1.54	3/18/2023	—	—
	3/6/2014	14	\$ 1.54	3/6/2024	—	—
	9/16/2016	357	\$ 1.54	9/16/2026	—	—
	6/22/2017	30,411	\$ 1.54	6/22/2027	—	—
	4/4/2019	16,600	\$ 1.54	4/4/2029	—	—
	9/23/2020	—	—	—	100,000	\$ 84,570

Executive Compensation Components for Fiscal 2020

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 September 3, 2020, our stockholders approved amendments to the 2012 Plan to increase the share reserve under the 2012 Plan by an aggregate 750,000 shares from the most recent reserve of 1,000,000 shares to an aggregate 1,750,000 shares. As of December 31, 2020, options to purchase 1,027,214 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.

Restricted Stock Units. 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 restricted stock units to our executive officers.

Restricted stock units provide executive officers with stock that is not fully transferable until certain conditions are met. Upon satisfaction of the conditions, the stock is no longer restricted, and becomes transferable to the officer.

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.

On September 23, 2020, the Compensation Committee of the Board of Directors of the Company approved the elements of a compensation program for the executive officers of the Company. The base salaries of the executive officers were increased by 15%, effective as of July 1, 2020, resulting in annualized base salaries of \$460,000 for Dr. Schwartz. In addition, Dr. Schwartz was awarded a one-time, special interim grant of retention equity awards for 2020 on September 23, 2020 of 300,000 restricted stock units payable in shares of common stock and vesting in equal annual installments over three years, subject to continued employment, with accelerated vesting upon certain events, including involuntary termination without cause, voluntary termination for good reason or retirement after at least eighteen months upon at least six months' notice.

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.

In addition, as a part of the compensation program approved in September 2020, Dr. Schwartz will be eligible for an annual bonus and a long-term incentive program effective January 1, 2021. Based on Company and personal performance vs. annual objectives to be established by the officers and the Committee and to be evaluated by the Committee, the officers will be granted an annual bonus opportunity ranging from 0% to 50% of base salary, or at the Board's discretion, a higher percentage based on performance. In addition, under the long-term incentive program, the officer will receive annual grants of restricted stock units on January 1 of each calendar year starting in 2021. Each grant will consist of 100,000 restricted stock units with vesting of each grant over three years based on performance and continued employment.

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 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 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.

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.

On September 23, 2020, the Compensation Committee of the Board of Directors of the Company approved the elements of a compensation program for the executive officers of the Company. The base salaries of the executive officers were increased by 15%, effective as of July 1, 2020, resulting in annualized base salaries of \$345,000 for Mr. Myers. In addition, Mr. Myers was awarded a one-time, special interim grant of retention equity awards for 2020 on September 23, 2020 of 100,000 restricted stock units payable in shares of common stock and vesting in equal annual installments over three years, subject to continued employment, with accelerated vesting upon certain events, including involuntary termination without cause, voluntary termination for good reason or retirement after at least eighteen months upon at least six months' notice.

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.

In addition, as a part of the compensation program approved in September 2020, Mr. Myers will be eligible for an annual bonus and a long-term incentive program effective January 1, 2021. Based on Company and personal performance vs. annual objectives to be established by the officers and the Committee and to be evaluated by the Committee, the officers will be granted an annual bonus opportunity ranging from 0% to 50% of base salary, or at the Board's discretion, a higher percentage based on performance. Also, under the long-term incentive program, the officer will receive annual grants of restricted stock units on January 1 of each calendar year starting in 2021. Each grant will consist of 50,000 restricted stock units with vesting of each grant over three years based on performance and continued employment.

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.

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 on June 16, 2020 the Board instituted an annual common stock award for all the directors under which they will receive \$7,000 in value of newly issued shares of common stock, par value \$0.01 per year annually for three years, as long as they are serving as a director at the annual appointment date. Additionally, the directors will receive a \$3,000 cash payment per year annually for three years, as long as they are serving as a director at the annual appointment date.

Effective on April 3, 2020 the Board instituted an annual stock options award program for the Chairman of the Board under which he/she will be awarded options to purchase \$20,000 worth of shares of common stock, par value \$0.01 at an exercise price determined by the close on April 2 or the last trading day prior to April 3.

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 2020

The following table summarizes the compensation paid to each non-employee director in the fiscal year ended December 31, 2020:

	Fees Paid or Earned in Cash	Stock Awards (2)	Option Awards (1)	Total
J. Melville Engle	\$ 3,000	\$ 7,000	\$ 60,542(3)	\$ 70,542
Carl Schwartz	\$ 3,000	\$ 7,000	\$ 27,136(4)	\$ 37,136
Charles Nuzum Sr.	\$ -	\$ 10,000	\$ 25,061(5)	\$ 35,061
Daniel Handley	\$ 3,000	\$ 7,000	\$ 27,136(6)	\$ 37,136
Greg St. Clair Sr.	\$ 3,000	\$ 7,000	\$ 16,710(7)	\$ 26,710
Nancy Chung-Welch	\$ 3,000	\$ 7,000	\$ 25,061(8)	\$ 35,061
Richard Gabriel	\$ 3,000	\$ 7,000	\$ 27,136(9)	\$ 37,136
Andrew Reding	\$ -	\$ -	\$ 10,246(10)	\$ 10,246
Gerald John Vardzel Jr.	\$ 3,000	\$ 7,000	\$ 6,248(11)	\$ 16,248
Pamela Prior	\$ -	\$ -	\$ 6,248(12)	\$ 6,248

- (1) Represents the actual compensation cost granted during 2020 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) Represents the actual compensation cost granted during 2020 as determined pursuant to FASB ASC 718, *Stock Compensation*.
- (3) Mr. Engle was awarded options to purchase 60,153 shares of common stock both for serving on the Board and for participating on the Audit, Compensation and Governance Committees. Mr. Engle was awarded options to purchase 15,267 shares of common stock for serving as Chairman of the Board. Mr. Engle was awarded common stock equaling \$7,000 in value based on the closing price on the day before issuance.
- (4) Dr. Schwartz was awarded options to purchase 32,846 shares of common stock both for serving on the Board and participating on the Merger & Acquisition Committee. Dr. Schwartz was awarded common stock equaling \$7,000 in value based on the closing price on the day before issuance.
- (5) Mr. Nuzum was awarded options to purchase 40,277 shares of common stock both for serving on the Board and for participating on the Audit and Compensation Committees. Mr. Nuzum was awarded common stock equaling \$10,000 in value based on the closing price on the day before issuance.
- (6) Dr. Handley was awarded options to purchase 32,846 shares of common stock both for serving on the Board and for participating on the Governance Committee. Dr. Handley was awarded common stock equaling \$7,000 in value based on the closing price on the day before issuance.
- (7) Mr. St. Clair was awarded options to purchase 26,623 shares of common stock both for serving on the Board and for participating on the Audit Committee. Mr. St. Clair was awarded common stock equaling \$7,000 in value based on the closing price on the day before issuance.
- (8) Dr. Chung-Welch was awarded options to purchase 40,277 shares of common stock both for serving on the Board and for participating on the Compensation and Merger & Acquisition Committees. Dr. Chung-Welch was awarded common stock equaling \$7,000 in value based on the closing price on the day before issuance.
- (9) Mr. Richard Gabriel was awarded options to purchase 32,846 shares of common stock both for serving on the Board and for participating on the Merger & Acquisition Committee. Mr. Gabriel was awarded common stock equaling \$7,000 in value based on the closing price on the day before issuance.
- (10) Mr. Reding resigned from the Board effective July 8, 2020. Mr. Reding was awarded options to purchase 6,223 shares of common stock for serving on the Board.
- (11) Mr. Vardzel resigned from the Board effective June 8, 2020. Mr. Vardzel was awarded options to purchase 3,174 shares of common stock for serving on the Board.
- (11) Ms. Prior resigned from the Board effective June 16, 2020. Ms. Prior was awarded options to purchase 3,174 shares of common stock for serving on the Board.

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, 2020:

	Number of securities to be issued upon exercise of outstanding restricted stock, warrants and options (a)	Weighted- average exercise price of outstanding options, warrants (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (C)
Equity compensation plans approved by security holders (1)	1,413,547	\$ 4.16	204,654
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. On September 3, 2020, 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 1,750,000.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth as of December 31, 2020 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 48,094,049 shares of our common stock outstanding on February 24, 2021. 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
Officers and Directors		
Carl Schwartz ⁽²⁾	1,885,146	3.91%
Bob Myers ⁽³⁾	47,555	0.10%
Chuck Nuzum ⁽⁴⁾	46,989	0.10%
Gregory St. Clair ⁽⁵⁾	31,321	0.07%
Daniel Handley ⁽⁶⁾	36,916	0.08%
J. Melville Engle ⁽⁷⁾	129,209	0.27%
Richard L. Gabriel ⁽⁸⁾	84,396	0.18%
Nancy Chung-Welch ⁽⁹⁾	44,975	0.09%
All directors and executive officers as a group (8 persons)	2,306,507	4.74%
Certain Beneficial Owners		
Intracoastal Capital LLC ⁽¹⁰⁾	3,476,948	7.23%

- 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.
- Includes (i) 1,711,742 shares owned directly, and (ii) 173,404 shares issuable upon exercise of options held by Dr. Schwartz that are exercisable within 60 days of December 31, 2020.
- Includes options to purchase 47,478 shares that are exercisable within 60 days of December 31, 2020.
- Includes options to purchase 40,277 shares that are exercisable within 60 days of December 31, 2020.
- Includes options to purchase 26,623 shares that are exercisable within 60 days of December 31, 2020.
- Includes options to purchase 32,846 shares that are exercisable within 60 days of December 31, 2020.
- Includes options to purchase 125,139 shares that are exercisable within 60 days of December 31, 2020.
- Includes options to purchase 72,326 shares that are exercisable within 60 days of December 31, 2020.
- Includes options to purchase 40,277 shares that are exercisable within 60 days of December 31, 2020.
- Includes warrants to purchase 1,425,664 shares that are exercisable within 60 days of December 31, 2020.

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”).

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. During January 2020, the Company entered into an exchange agreement with 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. On April 21, 2020, the Company and Dr. Schwartz entered into an exchange agreement relating to the promissory note of the Company dated January 21, 2020 issued by the Company in the principal amount of \$2,115,000 (“the Note”). The Note was cancelled in exchange for 1,533,481 shares of newly issued Common Stock at an exchange rate of \$1.43 per share.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

In connection with the audit of the fiscal 2020 and 2019 financial statements, we entered into an engagement agreement with Baker Tilly US, LLP (2020) and Deloitte & Touche LLP (2019), 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, 2020 and December 31, 2019, by Baker Tilly US, LLP and Deloitte & Touche LLP, respectively, our principal accountants. All fees described below were approved by the Audit Committee. None of the hours expended on the audit of the 2020 and 2019 financial statements were attributed to work performed by persons who were not employed full time on a permanent basis by Baker Tilly US, LLP or Deloitte & Touche LLP.

	2020	2019
Audit Fees (1)	\$ 306,235	\$ 530,128
Audit-Related Fees (2)	27,461	-
Tax Fees (3)	22,250	34,719
All Other Fees (4)	37,415	-
	<u>\$ 393,361</u>	<u>\$ 564,847</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) Audit-Related Fees in 2020 consisted of fees related to providing predecessor auditor with required representations related to registration statements filed in 2020, and there were no audit-related fees in 2019.
- (3) Tax Fees consist of fees billed in the indicated year for professional services performed by Baker Tilly US, LLP with respect to tax compliance during 2020 and Deloitte & Touche LLP with respect to tax compliance during 2019.
- (4) Other Fees consist of fees related to consulting services performed by Baker Tilly US, LLP provided prior to Baker Tilly US, LLP's engagement as the Company's independent registered public accounting firm. All services were provided prior to April 1, 2020 and were related to the audit closing process for the year ended December 31, 2019 as further described in the Company's Form 8-K filing on April 30, 2020. There were no other fees in 2019.

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 15, 2021;
- Report of Independent Registered Public Accounting Firm dated March 31, 2020;
- Consolidated Balance Sheets as of December 31, 2020 and December 31, 2019;
- Consolidated Statements of Net Loss for the Years Ended December 31, 2020 and December 31, 2019;
- Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2020 to December 31, 2019;
- Consolidated Statements of Cash Flows for the Years Ended December 31, 2020 and December 31, 2019; 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 15, 2021

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 15, 2021
<u>/s/ Bob Myers</u> Bob Myers	Chief Financial Officer (principal financial and accounting officer)	March 15, 2021
<u>/s/ J. Melville Engle</u> J. Melville Engle	Director	March 15, 2021
<u>/s/ Nancy Chung-Welch</u> Nancy Chung-Welch	Director	March 15, 2021
<u>/s/ Richard L. Gabriel</u> Richard L. Gabriel	Director	March 15, 2021
<u>/s/ Daniel E. Handley</u> Daniel E. Handley	Director	March 15, 2021
<u>/s/ Chuck Nuzum</u> Chuck Nuzum	Director	March 15, 2021
<u>/s/ Gregory St. Clair Sr.</u> Gregory St. Clair Sr.	Director	March 15, 2021

EXHIBIT INDEX
PREDICTIVE ONCOLOGY INC.
FORM 10-K

Exhibit Number	Description
1.1	Amended and Restated Letter Agreement dated March 15, 2020 by and between the Company and H.C. Wainwright & Co., LLC (46) Exhibit 1.1
1.2	Engagement Letter with H.C. Wainwright & Co. dated January 7, 2021 (49) Exhibit 1.2
2.1	Amended and Restated Agreement and Plan of Merger dated October 22, 2018 (18) Exhibit 2.1
3.1	Certificate of Incorporation (1) Exhibit 3.1
3.2	Certificate of Amendment to Certificate of Incorporation to effect reverse stock split and reduction in authorized share capital filed with the Delaware Secretary of State on October 20, 2014 (6) Exhibit 3.2
3.3	Certificate of Amendment to Certificate of Incorporation regarding increase in share capital, filed with the Delaware Secretary of State on July 24, 2015 (7) Exhibit 3.3
3.4	Certificate of Amendment to Certificate of Incorporation to increase authorized share capital, filed with the Delaware Secretary of State on September 16, 2016 (11) Exhibit 3.4
3.5	Certificate of Amendment to Certificate of Incorporation to effect reverse stock split and reduction in authorized share capital, fled with the Delaware Secretary of State on October 26, 2016 (12) Exhibit 3.5
3.6	Certificate of Amendment to Certificate of Incorporation regarding increase in share capital, filed with the Delaware Secretary of State on January 26, 2017 (13) Exhibit 3.6
3.7	Certificate of Amendment to Certificate of Incorporation to effect reverse stock split, filed with the Delaware Secretary of State on January 2, 2018 (21) Exhibit 3.7
3.8	Certificate of Amendment to Certificate of Incorporation to effect name change, filed with the Delaware Secretary of State on February 1, 2018 (8) Exhibit 3.8
3.9	Certificate of Amendment to Certificate of Incorporation to increase authorized share capital and establish a classified Board of Directors (23) Exhibit 3.9
3.10	Second Amended and Restated Bylaws as of June 10, 2019 (34) Exhibit 3.10
3.11	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (9) Exhibit 3.11
3.12	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (20) Exhibit 3.12
3.13	Certificate of Amendment to Certificate of Incorporation dated March 22, 2019 (24) Exhibit 3.13
3.14	Certificate of Designation Of Preferences, Rights And Limitations of Series D Convertible Preferred Stock (48) Exhibit 3.14

- 3.15 Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock Effective June 13, 2019 (35) [Exhibit 3.15](#)
- 3.16 Certificate of Amendment of Certificate of Incorporation (34) [Exhibit 3.16](#)
- 3.17 Certificate of Amendment of Certificate of Incorporation (41) [Exhibit 3.17](#)
- 4.1 Form of specimen certificate evidencing shares of Series B Convertible Preferred Stock (10) [Exhibit 4.1](#)
- 4.2 Form of New Warrant Agency Agreement by and between Skyline Medical Inc. and Form of Warrant Certificate for Series B Warrant (14) [Exhibit 4.2](#)
- 4.3 Form of Series B Warrant Certificate (included as part of Exhibit 4.2) (14) [Exhibit 4.3](#)
- 4.4 Form of Series C Warrant (15) [Exhibit 4.4](#)
- 4.5 Form of Unit Purchase Option (15) [Exhibit 4.5](#)
- 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) [Exhibit 4.6](#)
- 4.7 Form of Series D Warrant Certificate (included as part of Exhibit 4.6) (16) [Exhibit 4.7](#)
- 4.8 Form of Amendment to Warrant (8) [Exhibit 4.8](#)
- 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 [Exhibit 4.29](#)
- 4.30 Common Stock Purchase Warrant issued to Oasis Capital, LLC dated March 6, 2020 (50) [Exhibit 4.30](#)
- 4.31 Common Stock Purchase Warrant issued to Oasis Capital, LLC dated April 5, 2020 (50) [Exhibit 4.31](#)
- 4.32 Form of Common Stock Purchase Warrant (53) [Exhibit 4.32](#)
- 4.33 Form of Common Stock Purchase Warrant (54) [Exhibit 4.33](#)
- 4.34 Form of Common Stock Purchase Warrant (39) [Exhibit 4.34](#)
- 4.35 Form of Common Stock Purchase Warrant (49) [Exhibit 4.35](#)
- 4.36 Form of Common Stock Purchase Warrant (51) [Exhibit 4.36](#)
- 4.37 Form of Common Stock Purchase Warrant (52) [Exhibit 4.37](#)
- 4.38 Form of Placement Agent Warrant to H.C. Wainwright & Co., LLC or its designees in connection with certain financing transactions in 2020 and 2021 (56) [Exhibit 4.38](#)
- 4.39 Form of Common Stock Purchase Warrant dated February 16, 2021 (57) [Exhibit 4.39](#)
- 4.40 Form of Common Stock Purchase Warrant dated February 22, 2021 (58) [Exhibit 4.40](#)
- 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](#)
- 10.47 Form of Securities Purchase Agreement dated January 8, 2021, by and between Predictive Oncology Inc. and certain Purchasers (49) [Exhibit 10.47](#)
- 10.48 Form of Securities Purchase Agreement dated January 19, 2021, by and between Predictive Oncology Inc. and certain Purchasers (50) [Exhibit 10.48](#)
- 10.49 Form of Securities Purchase Agreement dated January 21, 2021, by and between Predictive Oncology Inc. and certain Purchasers (51) [Exhibit 10.49](#)
- 10.50 Form of Securities Purchase Agreement dated February 10, 2021, by and between Predictive Oncology Inc. and certain Purchasers (57) [Exhibit 10.50](#)
- 10.51 Form of Securities Purchase Agreement dated February 18, 2021, by and between Predictive Oncology Inc. and certain Purchasers (58) [Exhibit 10.51](#)
- 10.52 Form of Registration Rights Agreement dated February 18, 2021, by and between Predictive Oncology Inc. and certain Purchasers (58) [Exhibit 10.52](#)
- 14.1 Code of Ethics (5) [Exhibit 14.1](#)
- [21.1*](#) [Subsidiaries of the Registrant](#)
- [23.1*](#) [Consent of Independent Registered Public Accounting Firm: Baker Tilly US, LLP](#)
- [23.2*](#) [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

*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
- (48) Filed on April 1, 2020 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference
- (49) Filed on January 12, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (50) Filed on April 6, 2020 as an exhibit to our Registration Statement on Form S-3 (File No. 333-237581) and incorporated herein by reference
- (51) Filed on January 21, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (52) Filed on January 26, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (53) Filed on May 8, 2020 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (54) Filed on June 26, 2020 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (55) Filed on October 25, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (56) Filed on January 29, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (57) Filed on February 12, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (58) Filed on February 22, 2021 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, 2020 and December 31, 2019 are included on the following pages:

INDEX TO FINANCIAL STATEMENTS

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Financial Statements:	
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Consolidated Balance Sheets	F-5
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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, 2020, the related consolidated statements of net loss, stockholders' equity, and cash flows for the year ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020, and the results of its operations and its cash flows for the year ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

We have also audited the adjustments made to segment information presented as of and for the year ended December 31, 2019 to retroactively apply the change in the Company's reportable segments as discussed in Note 14 – Segments. In our opinion, such adjustments were appropriate and have been properly applied. We were not engaged to audit, review or apply any procedures to the 2019 consolidated financial statements of the Company other than with respect to the adjustments to Note 14 and, accordingly, we do not express an opinion or any other form of assurance on the 2019 consolidated financial statements taken as a whole.

Basis for Opinion

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

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

Our audit included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Critical Audit Matter Description

Valuation and classification of warrants issued as either a liability or permanent equity

As described in Note 5 to the consolidated financial statements, the Company completed several equity offerings during the year and each included the issuance of warrants. The terms and conditions included in the warrant agreements varied for each offering as discussed in Notes 5 and 8. Management determined the proper classification of the warrants by reviewing the terms and conditions of each warrant and applying the applicable accounting guidance, including Accounting Standards Codification (ASC) 480 Distinguishing Liabilities from Equity and ASC 815 Derivatives and Hedging. The terms and conditions of the warrants that were issued during the first and second quarters of 2020 contained certain settlement provisions in which the holder could obtain the Black Scholes value upon the occurrence of a fundamental transaction and, as a result, the Company concluded the warrants should be classified as liabilities and be recorded at fair value on a recurring basis determined using the Black Scholes pricing model. Effective September 23, 2020, the Company amended the terms and conditions of substantially all of its warrant agreements. The Company modified the settlement provisions such that the warrant holder would only obtain the same form and type of consideration as other shareholders upon the occurrence of a fundamental transaction. As a result of the amendment, the warrants met the criteria for classification as permanent equity and therefore, the fair value of these warrants on the date of modification, totaling approximately \$2,669,000, was reclassified to permanent equity.

The accounting guidance for determining the proper classification of warrants is highly complex and is subject to interpretation. A slight variation in the terms and conditions of the warrant could result in the warrant being classified as a liability, which would also impact the consolidated statement of operations and comprehensive loss, as the subsequent accounting for warrants treated as liabilities is significantly different from those classified as permanent equity. Due to the complexity in the accounting guidance, the need for management judgment in applying the accounting guidance, and the fact that a slight change in terms can result in significant changes in both the initial accounting and subsequent accounting for the warrants, we identified the evaluation of the classification and valuation of the warrants issued and modified during the year as a critical audit matter.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included the following:

- As part of our risk assessment procedures, we evaluated the design and implementation of the Company's controls over the evaluation and application of the relevant accounting guidance to the specific terms and conditions within the warrant agreements, as well as over the selection of the inputs used for the Black Scholes pricing model.
- We obtained the Company's accounting analysis for each offering. We compared the terms described in the Company's analysis to the terms of the respective agreement to determine the completeness and accuracy of the analysis performed. With the assistance of firm personnel having expertise in the accounting for complex equity instruments, we performed a detailed examination of the warrant agreements for each offering as initially granted and as modified, with a primary focus on the key terms and conditions regarding the treatment of the warrants upon the occurrence of a fundamental transaction, as well as other unique terms and conditions, depending on the specific agreement. Based on the original terms and conditions, warrant holders could have received a different form of consideration than holders of equally and more subordinated equity instruments upon the occurrence of a fundamental transaction. As a result, the warrants were classified as liabilities and recorded at fair value initially and subsequently at each reporting period.
- We evaluated the appropriateness of the Black Scholes model for valuing the warrants and tested the relevant inputs for the Black Scholes model with the most significant input being the expected stock volatility. We recalculated the Company's volatility based on changes in its historical stock price over the expected term in order to test the reasonableness of this input. We also tested the clerical accuracy of the Black Scholes calculations for each warrant grant.
- We evaluated the September 23, 2020, amendment based on the Company's accounting analysis, noting that, as a result of the modification of terms and conditions of the warrants, they met the requirements for classification as permanent equity, as the potential for warrant holders to receive consideration based upon the Black Scholes model was removed from the terms and conditions. We also discussed with the Company's legal counsel the impact of the change in these terms and conditions on warrant holders upon the occurrence of a fundamental transaction.

Critical Audit Matter Description

Evaluation of goodwill for impairment

As discussed in Notes 1 and 11 to the consolidated financial statements, goodwill is tested for impairment for the Helomics reporting unit at least annually, or more frequently, as events occur or circumstances change based on the applicable accounting guidance within ASC 350 Intangibles – Goodwill and other. In the third quarter of fiscal year 2020, the Company assessed relevant events and circumstances and determined it was appropriate to perform a quantitative impairment test and recorded an impairment charge of \$2,997,000. At December 31, 2020, the Company performed its annual quantitative impairment test and recorded an additional impairment charge of approximately \$9,879,000. In performing the impairment tests, management used both a discounted cash flow approach and a market capitalization approach to determine the estimated fair value of the Helomics reporting unit.

Auditing management's goodwill impairment test as of December 31, 2020, was complex and highly judgmental due to the significant estimation required to determine the estimated fair value of the Helomics reporting unit. In particular, the fair value estimate was sensitive to changes in significant assumptions, such as the Company's financial forecast and its assumptions regarding potential revenue contracts and expected relationships between revenue and expenses over the forecast period given the limited historical results, the discount rate and the terminal growth rate, which are both affected by expectations about future market or economic conditions, including uncertainty resulting from the COVID-19 pandemic.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included substantively testing, with the assistance of firm personnel with expertise in the application of fair value and valuation methodologies, the appropriateness of the judgments and assumptions used in management's estimation process for determining the fair value of the Company's Helomics reporting unit which included the following procedures:

- Testing the mathematical accuracy of the calculations performed along with completeness of the information used in the calculation.
- Assessing the accuracy and reasonableness of management's financial forecasts by comparing prior year forecasts to actual results, as well as comparing the forecasts prepared for the current year's goodwill impairment evaluation to current year's results. We obtained and evaluated supporting documentation for any significant changes in future operating costs as compared to actual results. We assessed the Company's probability weighted forecast approach which was used to analyze a range of outcomes for the Helomics reporting unit given the uncertainties surrounding the timing of revenue and related margins.
- Performing inquiries of personnel at the Helomics reporting unit that were highly involved in the development of the forecasts to evaluate the reasonableness of revenue and margin forecasts and compared the forecasts to comparable companies' performance in Helomic's industry.
- Evaluating the appropriateness of the valuation methodologies used, as well as the discount rate, terminal growth rate, market comparable entities and overall reasonableness of the fair value calculation.
- Comparing the significant assumptions used by management to current industry and economic trends.
- Testing management's reconciliation of the fair value of the reporting unit to the market capitalization of the Company.
- Considering the adequacy of the impairment recorded based on the subsequent equity financings and warrant exercises totaling approximately \$35 million in 2021.

/s/ Baker Tilly US, LLP (formerly known as Baker Tilly Virchow Krause, LLP)

We have served as the Company's auditor since 2020.

Minneapolis, Minnesota
March 15, 2021

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, before the effects of the retrospective adjustments to the disclosures for a change in the composition of reportable segments discussed in Note 14 to the consolidated financial statements, the consolidated balance sheet of Predictive Oncology Inc. (the "Company") as of December 31, 2019, the related consolidated statements of net loss, stockholders' equity, and cash flows, for the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements") (the 2019 consolidated financial statements before the effects of the retrospective adjustments discussed in Note 14 to the financial statements are not presented herein). In our opinion, the 2019 financial statements, before the effects of the retrospective adjustments to the disclosures for a change in the composition of reportable segments discussed in Note 14 to the financial statements, present fairly, in all material respects, the financial position of the Company as of December 31, 2019, and the results of its operations and its cash flows for the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

We were not engaged to audit, review, or apply any procedures to the retrospective adjustments to the disclosures for a change in the composition of reportable segments discussed in Note 14 to the consolidated financial statements, and accordingly, we do not express an opinion or any other form of assurance about whether such retrospective adjustments are appropriate and have been properly applied. Those retrospective adjustments were audited by other auditors.

Going Concern

The 2019 financial statements were prepared assuming that the Company would continue as a going concern. As of December 31, 2019, the Company did not expect to generate sufficient operating cashflows to sustain its operations in the near-term and needed to raise significant additional capital to meet its operating needs, and pay debt obligations coming due, which raised substantial doubt about its ability to continue as a going concern. The 2019 financial statements did not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ DELOITTE & TOUCHE LLP

Minneapolis, Minnesota

March 31, 2020 (March 15, 2021 as to the effects of the correction to the 2019 financial statements discussed in Note 11)

We began serving as the Company's auditor in 2018. In 2020 we became the predecessor auditor.

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash	\$ 678,332	\$ 150,831
Accounts Receivable	256,878	297,055
Inventories	289,535	190,156
Prepaid Expense and Other Assets	289,490	160,222
Total Current Assets	1,514,235	798,264
Fixed Assets, net	3,822,700	1,507,799
Intangibles, net	3,398,101	3,649,412
Lease Right-of-Use Assets	1,395,351	729,745
Other Long-Term Assets	116,257	-
Goodwill	2,813,792	15,690,290
Total Assets	\$ 13,060,436	\$ 22,375,510
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	\$ 1,372,070	\$ 3,155,641
Notes Payable – Net of Discounts of \$244,830 and \$350,426	4,431,925	4,795,800
Accrued Expenses and other liabilities	2,588,047	2,371,633
Derivative Liability	294,382	50,989
Deferred Revenue	53,028	40,384
Lease Liability – Net of Long-Term Portion	597,469	459,481
Total Current Liabilities	9,336,921	10,873,928
Other Long Term Liabilities	235,705	-
Lease Liability, long-term portion	845,129	270,264
Total Liabilities	10,417,755	11,144,192
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, 0 and 3,500,000 shares outstanding	-	35,000
Series E Convertible Preferred Stock, \$.01 par value, 350 authorized, 0 and 258 shares outstanding	-	3
Common Stock, \$.01 par value, 100,000,000 authorized, 19,804,787 and 4,056,652 outstanding	198,048	40,567
Additional Paid-in Capital	110,826,949	93,653,667
Accumulated Deficit	(108,383,108)	(82,498,711)
Total Stockholders' Equity	2,642,681	11,231,318
Total Liabilities and Stockholders' Equity	\$ 13,060,436	\$ 22,375,510

See Notes to Consolidated Financial Statements

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF NET LOSS

	Year Ended December 31,	
	2020	2019
Revenue	\$ 1,252,272	\$ 1,411,565
Cost of goods sold	447,192	531,810
Gross profit	805,080	879,755
General and administrative expense	10,351,973	9,781,218
Operations expense	2,351,709	2,960,131
Sales and marketing expense	584,937	1,912,899
Loss on goodwill impairment	12,876,498	8,100,000
Loss on intangible impairment	-	770,250
Total operating loss	(25,360,037)	(22,644,743)
Gain on revaluation of cash advances to Helomics	-	1,222,244
Other income	843,440	65,300
Other expense	(2,427,026)	(3,466,696)
Loss on early extinguishment of debt	(1,996,681)	(513,250)
Gain on derivative instruments	1,765,907	221,756
Gain on notes receivables associated with asset purchase	1,290,000	-
Loss on equity method investment	-	(439,637)
Gain on revaluation of equity method investment	-	6,164,260
Net loss	\$ (25,884,397)	\$ (19,390,766)
Deemed dividend	554,287	289,935
Net loss attributable to common shareholders	\$ (26,438,684)	\$ (19,680,701)
Loss per common share - basic and diluted	\$ (2.21)	\$ (6.86)
Weighted average shares used in computation - basic and diluted	11,950,154	2,870,132

See Notes to Consolidated Financial Statements

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Series B Preferred		Series D Preferred		Series E Preferred		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Paid-In Capital	Deficit	
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							10,356	103	34,820		34,923

consultant and other																
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

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Series B Preferred		Series D Preferred		Series E Preferred		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares		Shares	Amount	Paid-In Capital	Deficit	
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
Shares issued pursuant to CEO note conversion and accrued interest and exchange agreement							1,583,481	15,835	2,307,043		2,322,878
Inducement shares issued pursuant to promissory note extension							30,000	300	40,950		41,250
Issuance of shares and prefunded warrants pursuant to March 2020 private placement							260,000	2,600	455,223		457,823
Inducement shares issued pursuant to 2020 convertible debt and warrants							46,875	468	119,532		120,000
Warrants issued pursuant to 2020 convertible debt									116,951		116,951
Shares issued pursuant to note conversions - bridge loan							170,000	1,700	265,628		267,328
Shares issued pursuant to series E preferred stock conversions					(258)	(3)	1,398,607	13,986	(13,983)		-
Warrants issued pursuant to 2020 convertible debt									62,373		62,373
Shares issued pursuant to series D preferred stock conversions			(3,500,000)	(35,000)			350,004	3,500	31,500		-
Issuance of shares from prefunded warrant exercises							1,390,166	13,902	(13,149)		753
Issuance of shares pursuant to May 2020 offering, net							1,396,826	13,968	591,949		605,917
Shares issued in connection with asset purchase agreement							1,079,719	10,797	1,661,970		1,672,767
Exercise of warrants and							1,274,826	12,748	1,682,237		1,694,985

issuance of new
warrants June
2020, net

Repricing and
Reclassification
of warrants
issued pursuant
to convertible
debt

1,865,953

1,865,953

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)

	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			
Repricing and Reclassification of June 2020 warrants									803,455		803,455
Exercise of warrants							122,000	1,220	190,930		192,150
Shares issued pursuant to Equity Line							4,231,073	42,311	4,849,037		4,891,348
Shares issued pursuant to convertible debt							212,359	22,124	1,006,230		1,028,354
Share issuance to consultant and other							202,199	2,022	428,184		430,206
Vesting expense and option repricing									721,269		721,269
Net loss										(25,884,397)	(25,884,397)
Balance at 12/31/20	79,246	\$ 792	-	\$ -	-	\$ -	17,804,787	\$ 198,048	\$ 110,826,949	\$ (108,383,108)	\$ 2,642,681

See Notes to Consolidated Financial Statements

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2020	2019
Cash flow from operating activities:		
Net loss	\$ (25,884,397)	\$ (19,390,766)
Adjustments to reconcile net loss to net cash used in operating activities:		
Recognition of credit loss on notes receivable	-	1,037,524
Loss on equity method investment	-	439,637
Gain on revaluation of equity method investment	-	(6,164,260)
Depreciation and amortization	1,024,848	704,883
Vesting expense	721,269	2,250,422
Equity instruments issued for management, consulting, and other	450,901	484,923
Amortization of debt discount	1,246,541	2,023,315
Gain on valuation of equity-linked instruments	(1,765,907)	(221,756)
Gain on revaluation of cash advances to Helomics	-	(1,222,244)
Gain on note receivable associated with asset purchase agreement	(1,290,000)	-
Gain on extinguishment of PPP loan	(541,867)	-
Debt extinguishment costs	1,996,681	581,073
Loss on goodwill and intangible impairment	12,876,498	8,870,250
Loss on fixed asset disposal	120,577	1,096
Changes in assets and liabilities:		
Accounts receivable	69,913	143,316
Inventories	(94,715)	91,114
Prepaid expense and other assets	(245,526)	(29,747)
Accounts payable	(1,656,158)	365,772
Accrued expenses	700,966	1,285,678
Deferred revenue	12,644	17,319
Net cash used in operating activities:	(12,257,732)	(8,732,451)
Cash flow from investing activities:		
Advances on notes receivable	-	(975,000)
Cash received from notes receivable	-	154,418
Cash received from Helomics acquisition	-	248,102
Purchase of fixed assets	(298,379)	(5,888)
Proceeds from sale of fixed assets	193,321	-
Acquisition of intangibles	(62,398)	(20,719)
Net cash used in investing activities:	(167,456)	(599,087)
Cash flow from financing activities:		
Proceeds from debt issuance	2,761,867	2,690,000
Repayment of debt	(1,472,389)	(1,154,513)
Payment penalties	(247,327)	(202,294)
Proceeds from issuance of stock pursuant to equity line	4,891,348	319,196
Proceeds from exercise of warrants into common stock	1,935,855	5,970
Proceeds from issuance of Series E convertible preferred stock	-	2,338,840
Issuance of common stock, prefunded warrants, warrants and exchange of warrants, net	5,057,919	5,323,018
Other liabilities	25,416	-
Net cash provided by financing activities:	12,952,689	9,320,217
Net decrease in cash	527,501	(11,321)
Cash at beginning of year	150,831	162,152
Cash at end of year	\$ 678,332	\$ 150,831
Non-cash transactions		
Bridge loan conversion into common stock	267,328	378,873
Forbearance settlement bridge loan	-	503,009
Additional warrants issued pursuant to CEO note payable	-	47,078
Warrants issued pursuant to debt issuance	179,324	180,640
Consideration given for acquisition of Helomics	-	26,711,790
Debt modification costs	-	162,750
Shares issued pursuant to CEO note conversion and accrued interest and exchange agreement	2,322,878	-
Shares issued pursuant to convertible debt	1,028,354	-
Fixed assets acquired for notes receivable and common stock	2,962,767	-
Increase to operating lease right of use asset and lease liability due to new and modified leases	1,417,077	-
Put and conversion derivative from debt issuance and modification	636,563	-
Shares issued pursuant to debt	140,555	-
Series D preferred stock conversions	35,000	-
Fixed assets acquired for financing arrangements	113,192	-
Series E preferred stock conversion	13,983	-
Cash paid during the period for:		
Interest paid on debt	\$ 145,831	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” or “we”) 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 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 \$108,383,108. The Company does not expect to generate sufficient operating revenue to sustain its operations in the near-term. During fiscal year 2020, the Company incurred negative cash flows from operations. These matters are indicators of substantial doubt and were alleviated as noted below due to the registered direct offerings and private placement in January and February 2021.

On October 24, 2019, the Company 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, the Company 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. The Company has issued 4,353,429 shares of common stock valued at \$5,210,581 pursuant to the equity line. As of December 31, 2020, there was \$9,789,419 remaining in available balance under the equity line. Additional needs to access this line will be dilutive.

In January and February 2021, we received aggregate net proceeds of \$31,077,232 in a series of registered direct offerings and a private placement of equity securities. On March 1, 2021, we used \$5,906,802 of the net proceeds from the private placement to pay the remaining principal and interest on the loans originally issued in September 2018, September 2019 and February 2020 and to pay premium payable upon such repayment. The remaining net proceeds of the 2021 transactions have been or will be used for working capital. See *Note 17 – Subsequent Events* for more information.

We believe that our existing capital resources will be sufficient to support our operating plan at least through March 31, 2022. However, we may also seek to raise additional capital to support our growth through additional debt, equity or other alternatives or a combination thereof. We would raise such capital through equity or debt financing to fund our capital and equipment investments and our operations.

We currently expect to use cash on hand, cash flows from operations and capital expenditures, in the next twelve months and beyond, and expect such sources to be sufficient to fund our requirements over that time.

Coronavirus Outbreak

In March 2020, the World Health Organization declared the recent spread of COVID-19 to be a global pandemic. In response to the crisis, emergency measures have been imposed by governments worldwide, including mandatory social distancing and the shutdown of non-essential businesses. These measures have adversely impacted the global economy, disrupted global supply chains and created significant volatility and disruption of financial markets. While it is not currently possible to estimate the duration and severity of the COVID-19 pandemic or the adverse economic impact resulting therefrom, our business and operations have been and will likely continue to be materially and adversely affected. For example, our contract manufacturer for the STREAMWAY® System has been forced to change locations, thereby delaying our order fulfillment for parts. We have also reduced on-site staff at several of our facilities, resulting in delayed production, less efficiency, and our sales staff is unable to visit with hospital administrators who are our customers and potential customers. In addition, COVID-19 has impacted the Company's capital and financial resources, including our overall liquidity position and outlook. For instance, our accounts receivable has slowed while our suppliers continue to ask for pre-delivery deposits. Although we have received a Paycheck Protection Program ("PPP") Loan pursuant to the CARES Act which has helped fund some payroll costs, we may not be able to access necessary additional capital given the current condition of the financial markets. During the fourth quarter of 2020, we received forgiveness of the amounts outstanding from the PPP. If COVID-19 continues to spread or the response to contain the virus is unsuccessful, we may continue to experience a material adverse effect on our business, financial condition, results of operations, cash flows and stock price.

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 12 – 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.

Reclassifications

Certain reclassifications have been made to the prior years’ financial statements to conform to the current year presentation. The reclassifications had no effect on previously reported results of operations, cash flows or stockholders’ equity.

Cash

The Company has no cash equivalents during the years ended December 31, 2020 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.

Amounts recorded in accounts receivable on the consolidated balance sheet include amounts billed and currently due from customers. The amounts due are stated at their net estimated realizable value. An allowance for doubtful accounts is maintained to provide for the estimated amount of receivables that will not be collected. The Company reviews customers’ credit history before extending unsecured credit and establishes an allowance for uncollectible accounts based upon factors surrounding the credit risk of specific customers, historical trends and other information. Invoices are generally due 30 days after presentation. Accounts receivable over 30 days is generally considered past due. The Company does not accrue interest on past due accounts receivables. Receivables are written off once all collection attempts have failed and are based on individual credit evaluation and specific circumstances of the customer. The allowance for doubtful accounts balance was \$0 as of both December 31, 2020 and 2019.

Fair Value Measurements

As outlined in Accounting Standards Codification (“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, was determined based on Level 1 inputs. The fair value of the Company’s derivative liabilities and debt were determined based on Level 3 inputs. The Company generally uses Black Scholes method for determining the fair value of warrants classified as liabilities on a recurring basis. In addition, the Company uses the Monte Carlo method and other acceptable valuation methodologies when valuing the conversion feature and other embedded features classified as derivatives on a recurring basis. See *Note 8 – Derivative*.

Inventories

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

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. Estimated useful asset life by classification is as follows:

	Years		
Computers, software and office equipment	3	-	10
Leasehold improvements (1)	2	-	5
Manufacturing tooling	3	-	7
Laboratory equipment	4	-	6
Demo equipment		3	

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

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

Long-lived 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. 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. Our impairment testing as of December 31, 2019 resulted in \$770,250 of impairment charges to our intangible assets.

Given the decrease in the Company's market capitalization from June 30, 2020, the Company determined that potential impairment indicators were present and that an impairment assessment was warranted for long-lived assets as of September. In evaluating tradename, estimated fair values were determined using discounted cash flows and implied royalty rates. Based on the results of the tradename assessments, the Company concluded that the fair values of the tradename exceeded the carrying values. The Company concluded there was no impairment of its intangible assets as of December 31, 2020. As a part of the Company's review of the tradename intangible asset associated with its Helomics reportable segment, the Company has determined the asset is a finite lived asset beginning September 30, 2020. The tradename has a remaining useful life of approximately eighteen years.

Because evaluation of other long-lived assets is necessary based on a triggering event, the Company prepared the undiscounted cash flows per ASC 360. The Company concluded that the undiscounted cash flows of the long-lived assets exceeded the carrying values. The Company concluded there was no impairment of its finite lived assets as of December 31, 2020.

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 not amortized but are tested on an annual basis for impairment during the fourth quarter, or whenever events or changes in circumstances indicate that the carrying amount may not be fully recoverable.

To determine whether goodwill is impaired, annually or more frequently if needed, the Company performs a multi-step impairment test. The Company first has the option to 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. The Company may also elect to skip the qualitative testing and proceed directly to the quantitative testing. When performing quantitative testing, the Company first estimates the fair values of its reporting units using discounted cash flows. To determine fair values, the Company is required to 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 including the rate of future revenue growth, capital requirements, and income taxes), long-term growth rates for determining terminal value and discount rates. Comparative market multiples are used to corroborate the results of the discounted cash flow test. These assumptions require significant judgement. 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 also completed a reconciliation between the implied equity valuation prepared and the Company's market capitalization. The majority of the inputs used in the discounted cash flow model are unobservable and thus are considered to be Level 3 inputs. The inputs for the market capitalization calculation are considered Level 1 inputs.

The Company recognized loss on impairment goodwill during the year ended December 31, 2020 of \$12,876,498. See *Note 11 – Goodwill and Intangibles*.

Based upon the Company's annual goodwill impairment test in 2019, the Company concluded that goodwill was impaired as of the testing date of December 31, 2019. The Company's annual impairment test as of December 31, 2019 resulted in \$8,100,000 of impairment expense related to goodwill.

The Company will continue to monitor its reporting units to determine whether events and circumstances warrant further interim impairment testing. Impairment of goodwill is not expected to be deductible for tax purposes. The Company can make no assurances that its goodwill will not be impaired in the future.

Leases – At inception of a contract a determination is made whether an arrangement meets the definition of a lease. A contract contains a lease if there is an identified asset and the Company has the right to control the asset. Operating leases are recorded as right-of-use ("ROU") assets with corresponding current and noncurrent operating lease liabilities on our consolidated balance sheets. Financing leases are included within machinery and equipment with corresponding current and noncurrent financing lease liabilities on our consolidated balance sheets.

ROU assets represent our right to use an underlying asset for the duration of the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Recognition on the commencement date is based on the present value of lease payments over the lease term using an incremental borrowing rate. Leases with a term of 12 months or less at the commencement date are not recognized on the balance sheet and are expensed as incurred.

The Company has lease agreements with lease and non-lease components, which are accounted for as a single lease component for all asset classes. Leases are accounted for at a portfolio level when similar in nature with identical or nearly identical provisions and similar effective dates and lease terms.

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.

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 Skyline reportable segment.

Revenue from Clinical Testing

The Precision Oncology Insights are clinic diagnostic testing comprised of the Company's Tumor Drug Response Testing (formerly ChemoFx) and Genomic Profiling (formerly BioSpeciFx) tests. The Tumor Drug Response test determines how a patient's tumor specimen reacts to a panel of various chemotherapy drugs, while the Genomic Profiling 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, 2020 and 2019, accounts receivable totaled \$256,878 and \$297,055, respectively.

The Company's deferred revenues related primarily to maintenance plans of \$53,028 and \$40,384 as of December 31, 2020 and 2019, 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.

Valuation and accounting for stock options and warrants

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

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

	For the Year Ended December 31,					
	2020		2019			
	Stock Options					
Expected dividend yield	0.0%		0.0%			
Expected stock price volatility	82.6%	-	87%	78.6%	-	82.4%
Risk-free interest rate	0.13%	-	1.78%	1.50%	-	2.76%
Expected life (in years)	10		10			
	Warrants					
Expected dividend yield	0.0%		0.0%			
Expected stock price volatility	82.6%	-	87%	78.6%	-	82.4%
Risk-free interest rate	0.135%	-	0.79%	1.39%	-	2.58%
Expected life (in years)	5/		5.5		5	

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs were \$372,710 and \$422,964 for the years ended 2020 and 2019, respectively.

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.

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.

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. In addition, the current NOL carryforwards might be further limited by future issuances of our common stock.

Tax years subsequent to 2017 remain open to examination by federal and state tax authorities.

Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash. The Company places its cash with high credit quality financial institutions and, by policy, generally limits the amount of credit exposure to any one financial institution. The Company has a credit risk of \$238,504 for cash amounts held in a single institution that are in excess of amounts insured by the Federal Deposit Insurance Corporation.

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.

The Company has evaluated all of its activities and concluded that no other subsequent events have occurred that would require recognition in the consolidated financial statements or disclosure in the notes to the consolidated financial statements, except as described above and in *Note 17 – Subsequent Events*.

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 TruTumor™ diagnostic platform, which combines a database of genomic and drug response profiles from over 150,000 tumors with an AI based searchable bioinformatics platform. Once a patient's tumor is excised and analyzed, the TruTumor 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 fair values of the assets were determined by the relief-from-royalty method under the income approach. As a part of the Company's review of the tradename intangible asset associated with its Helomics operating segment during the third quarter of 2020, the Company determined the asset is a finite lived asset. The useful life of the tradename has a remaining useful life of eighteen years as of December 31, 2020.

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 TruTumor 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 was recognized in the Helomics acquisition and 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 was deductible for income tax purposes. See *Note 11 – Goodwill and Intangibles*.

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, 2019, with adjustments to give effect to pro forma events that are directly attributable to the acquisition.

	<u>2019</u>
	Unaudited
Revenue	\$ 1,457,625
Net loss attributable to common shareholders	\$ (20,947,033)

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 in 2019 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 for the period January 1, 2019 to April 4, 2019 are presented below:

	Period January 1, 2019 to April 4, 2019
Revenue	\$ 45,835
Gross margin	7,348
Net loss on Operations	(1,555,542)
Net Loss	(1,166,656) ¹

¹The loss to investee was calculated 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 4 – 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:

	December 31, 2020	December 31, 2019
Finished goods	\$ 95,898	\$ 91,410
Raw materials	151,366	69,821
Work-In-Process	42,271	28,925
Total	<u>\$ 289,535</u>	<u>\$ 190,156</u>

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.

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 D Preferred Stock

In April 2019, the Company issued 3,500,000 shares of Series D preferred stock to Helomics as part of its acquisition of Helomics. Each share of Series D preferred stock is subject to automatic conversion, whereby each such share converts automatically on a 10:1 basis into a share of the Company's common stock upon the earlier of (1) the consummation of any fundamental transaction (e.g., a consolidation or merger, the sale or lease of all or substantially all of the assets of Predictive or the purchase, tender or exchange offer of more than 50% of the outstanding shares of voting stock of Predictive,) or (2) the one-year anniversary of the issuance date. On April 4, 2020, 3,500,000 shares of Series D convertible preferred stock were converted into 350,004 shares of common stock.

Series E Convertible Preferred Stock

In June through September 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 shareholder had 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 included a contingent beneficial conversion amount of \$289,935, 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 was accreted through the earliest redemption date of December 13, 2019.

During the first quarter of 2020, 50 shares of Series E convertible preferred stock were converted into 141,191 shares of common stock. In May 2020, we notified the holders of our Series E Convertible Preferred Stock of our election to convert the outstanding shares of Series E Stock into common stock effective on June 13, 2020 pursuant to the terms of the Series E Stock. Prior to the conversion, there were 207.7 shares of Series E Stock outstanding. Each share of Series E Stock converted into 0.056857% of the issued and outstanding shares of common stock immediately prior to conversion; therefore, the 207.7 outstanding shares of Series E Stock on June 13, 2020 converted into 1,257,416 shares of common stock equal to 11.8% of the outstanding shares of common stock as of June 12, 2020.

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. During the year ended December 31, 2020, the Company issued 4,231,073 shares of common stock valued at \$4,891,348 pursuant to the equity line. As of December 31, 2020, there was \$9,789,419 remaining available balance under the equity line, subject to market conditions including trading volume and stock price, and subject to other limitations.

March 2020 Private Placement

On March 18, 2020, we sold and issued to private investors (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) Series A 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) Series B 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. See below for amendment dated September 23, 2020.

In addition, and in lieu of common shares, the investors also 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. As a result of the prefunded warrants exercise price being of a nominal amount, these warrants were included as outstanding shares within our earnings per share calculation during the period from purchase through to exercise during the second quarter 2020.

The sale of the offering shares, prefunded warrants and A and B warrants resulted in gross proceeds of \$3,498,612 and net proceeds of \$3,127,818 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.

Effective September 23, 2020, the Company amended the terms of A and B warrants. Earlier in September, the Company notified the holders of the warrants that the Company would accept an exercise price therefor of \$0.8457, amended from the original exercise price of \$1.88 per share. The amendment also modified the settlement provisions of the warrants under certain circumstances; this change resulted in a classification change from derivative liability to equity classification. See *Note 8 — Derivatives* for discussion of A, B and agent warrants accounted for as derivative liabilities prior to September 23, 2020.

Dr. Schwartz Note Exchange

Effective as of April 21, 2020, the Company and Carl Schwartz, entered into an exchange agreement relating to a promissory note of the Company dated January 31, 2020 issued by the Company in the principal amount of \$2,115,000. Pursuant to the exchange agreement, Dr. Schwartz was issued 1,583,481 shares of newly issued common stock at an exchange rate of \$1.43 per share. See Note 6 – Notes Payable.

May 2020 Registered Direct Offering and Concurrent Private Placement of Warrants

During May 2020, the Company entered into a securities purchase agreement with certain accredited investors for a registered direct offering of 1,396,826 shares of common stock, par value \$0.01 per share. In a concurrent private placement, the Company also issued such investors warrants to purchase up to an aggregate of 1,396,826 shares of common stock. The shares and the warrants were sold at a combined offering price of \$1.575 per share and associated warrant. Each warrant is exercisable immediately upon issuance at an exercise price of \$1.45 per share and will expire five and one-half years from the issue date. The sale of the offering shares and associated warrants resulted in gross proceeds of \$2,200,001 and net proceeds of \$1,930,100 after deducting the placement agent fees and offering expenses payable by the Company. The Company used the net proceeds from the offering to repay certain indebtedness and agreed to use the remaining net proceeds from the offering for general corporate purposes. The offering closed on May 8, 2020.

Acquisition from Soluble Therapeutics and BioDtech

On May 27, 2020, the Company entered into an Asset Purchase Agreement with InventaBioTech, Inc. (“InventaBioTech”) and two of its subsidiaries, Soluble Therapeutics, Inc. (“Soluble”), and BioDtech, Inc. (“BioDtech”), and simultaneously completed the acquisition of substantially all of Soluble’s and BioDtech’s assets. In exchange, the Company issued 125,000 shares of common stock and waived all existing claims that the Company has or may have against InventaBioTech (f/k/a CytoBioscience, Inc.), including the nonpayment of \$1,290,000 owing by InventaBioTech to the Company. All of the shares issued in the acquisition were deposited into escrow, with 25,000 to be released upon the six-month anniversary of the closing, 25,000 to be released upon the nine-month anniversary of the closing, and the remaining shares to be released on the one-year anniversary of the closing. Notwithstanding the foregoing, all or some of the escrow shares may be released and returned to the Company for reimbursement in the event that the Company suffers a loss against which InventaBioTech, Soluble, and BioDtech have indemnified the Company pursuant to the Agreement. The Company is also entitled to reclaim 10,000 of the shares if, within six months of the closing, the Company is unable to successfully obtain ownership of all of Soluble’s interest under its license agreement with the UAB Research Foundation. As a result of the acquisition, which was treated as an asset acquisition, the Company recognized fixed assets of \$1,492,500.

June 2020 Warrant exercise and issuance

During June 2020, the Company entered into an agreement with certain accredited institutional investors to immediately exercise for cash an aggregate of 1,396,826 of the warrants issued in connection with the May 2020 Registered Direct Offering, exercisable immediately at the exercise price of \$1.45 per share of common stock plus an additional \$0.125 for each new warrant to purchase up to a number of shares of common stock equal to 100% of the number of shares issued pursuant to the exercise of the existing warrants. The new warrants are exercisable immediately and have a term of five and one-half years and an exercise price per share equal to \$1.80. The Company received \$2,130,701 in gross proceeds and net proceeds of \$1,865,800 after deducting the placement agent fees and offering expenses payable by the Company.

Effective on September 23, 2020, the Company amended the terms of warrants to purchase up to 1,396,826 shares of the Company’s common stock, par value \$0.01 per share. The amendment modified the settlement provisions of the warrants under certain circumstances; this change resulted in a classification change from derivative liability to equity classification.

Acquisition of Quantitative Medicine

On July 1, 2020, the Company entered into an Asset Purchase Agreement with Quantitative Medicine LLC (“QM”), a Delaware limited liability company and its owners and simultaneously completed the acquisition of substantially all of QM’s assets owned by Seller. QM is a biomedical analytics and computational biology company that 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. In exchange for QM’s assets, including CoRE, the Company provided consideration in the form of 954,719 shares of common stock, which, when issued, had a fair value of \$1,470,267. One half of the shares issued or 477,359 shares were deposited and held in escrow upon issuance, while 207,144 of the remaining shares were issued to Carnegie Mellon University (“CMU”) in satisfaction of all pre-closing amounts owed to CMU under a technology licensing agreement that was assumed by the Company on the closing date. Half of the shares held in escrow will be released on the six-month anniversary of the closing date, and the other half will be released on the one-year anniversary of the closing date; provided, however, that all or some of the escrow shares may be released and returned to the Company for reimbursement in the event that the Company suffers a loss against which the Selling Parties have indemnified the Company pursuant to the Agreement.

Warrants Issued in Connection with Helomics’ Acquisition

Effective on September 14, 2020, the Company amended the terms of warrants to purchase up to 1,424,506 shares of the Company’s common stock, par value \$0.01 per share, which were issued to certain holders in connection with the Company’s merger transaction with Helomics on April 4, 2019. In September 2020, the Company notified the holders of the warrants that the Company will accept an exercise price of \$0.845, equal to the last reported per share price of Common Stock on the NASDAQ Capital Market on September 11, 2020, amended from the original exercise price of \$10.00 per share (as adjusted for a one-for-ten (1:10) reverse stock split that was effective on October 29, 2019). The value of the amendment was determined based on the increase in the fair value on the date of modification using the Black Scholes method and equaled \$554,287. The amendment was accounted for as a deemed dividend and increased the loss attributable to the common shareholders when calculating earnings per share. The Warrants were issued on April 4, 2019 to holders of warrants in Helomics; the Warrants expire on April 4, 2024. *See Note 9 – Loss per Share.*

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.

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 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. *See Note 1 – Summary of Significant Accounting Policies – Accounting Policies and Estimates.*

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, 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
Issued	319,851	1.03	8,097,468	1.547
Forfeited	(72,728)	10.58	(127,710)	95.11
Exercised	-	-	(2,786,992)	0.79
Outstanding at December 31, 2020	1,013,547	\$ 5.41	7,353,376	\$ 3.76

At December 31, 2020, 977,420 stock options are fully vested and currently exercisable with a weighted average exercise price of \$5.29 and a weighted average remaining term of 8.76 years. There are 7,353,376 warrants that are fully vested and exercisable. 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 were 2,171,610 warrants that are fully vested and exercisable as of December 31, 2019. Stock-based compensation recognized in 2020 and 2019 was \$780,269 and \$2,250,422, respectively. The Company has \$6,390 of unrecognized compensation expense related to non-vested stock options that are expected to be recognized over the next 18 months.

The following summarizes the status of options and warrants outstanding at December 31, 2020:

Range of Exercise Prices	Shares	Weighted Average Remaining Life
Options:		
\$0.732 – 1.47	258,256	9.82
\$1.54 – 1.64	350,574	7.83
\$2.610 – 8.41	233,919	9.86
\$10.10 – 5,962.50	170,798	7.27
Total	1,013,547	
Warrants:		
\$0.84	3,300,332	2.96
\$1.80 – 2.99	2,019,284	4.77
\$5.00 – 10.00	1,809,679	3.22
\$10.71 – 22.50	224,081	2.17
Total	7,353,376	

Stock options and warrants expire on various dates from August 2022 to December 2030.

Stock Options and Warrants Granted by the Company

The following table is the listing of outstanding stock options and warrants as of December 31, 2020 by year of grant:

Stock Options:

Year	Shares	Price		
2012	143	1.54	–	1,500.00
2013	148	1.54	–	5,962.50
2014	84	1.54	–	4,312.50
2015	397	1.54	–	862.50
2016	9,395	1.54	–	51.25
2017	222,079	1.54	–	21.00
2018	85,955	1.54	–	13.50
2019	383,311	1.54	–	7.90
2020	312,035	0.732	–	3.48
Total	1,013,547	\$ 0.732	–	5,962.50

Warrants:

Year	Shares	Price		
2016	25,373	10.00		
2017	108,295	10.71	–	22.50
2018	196,946	10.00	–	13.125
2019	1,712,286	2.50	–	11.88
2020	5,310,476	0.846	–	2.992
Total	7,353,376	\$ 0.846	–	22.50

NOTE 6– NOTES RECEIVABLE

The Company had a secured promissory note receivable from CytoBioscience for \$1,112,524 (“2017 Promissory Note”), 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 had not received any payments from CytoBioscience since the first quarter of 2019. The Company had evaluated the feasibility of repayment and concluded that it was probable that the Company would be unable to collect all amounts due according to the contractual terms of the receivable. During 2019, the Company recorded a valuation allowance of \$1,037,524 related to the notes receivable balance. During 2019, the Company also recorded a loss on this note for the uncollected balance.

On May 27, 2020, the Company entered into an Asset Purchase Agreement with InventaBioTech, Inc. (“InventaBioTech”) and two of its subsidiaries, Soluble Therapeutics, Inc. (“Soluble”), and BioDtech, Inc. (“BioDtech”), and simultaneously completed the acquisition of substantially all of Soluble’s and BioDtech’s assets. In exchange, the Company issued 125,000 shares of common stock and waived all existing claims that the Company has or may have against InventaBioTech (f/k/a CytoBioscience, Inc.). Prior to the completion of the transaction, InventaBioTech owed the Company approximately \$1,290,000 under the 2017 Promissory Note, which was secured by certain intellectual property and equipment useful in CRO. In connection with the asset purchase agreement, the Company recognized a gain on the note previously determined to be uncollectable of \$1,290,000 and recognized fixed assets of \$1,492,500.

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. 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, 2020	December 31, 2019
2018 Investor loan	March 31, 2021	\$ 1,721,776	\$ 1,989,104
Promissory note 2019	March 27, 2021	1,490,833	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
Dr. Schwartz notes	September 30, 2020	-	2,115,000
Promissory note 2020	March 31, 2021	1,464,146	-
Total Notes Payable, gross		4,676,755	5,146,226
Less: Unamortized discount		244,830	350,426
Total Notes Payable, net		\$ 4,431,925	\$ 4,795,800

Secured Notes and Repayment in Full

In September 2018, the Company issued convertible secured promissory notes to two private investors in the original principal amount of an aggregate \$2,297,727 (together, the “2018 Investor Note”) in exchange for cash proceeds of \$2,000,000. As additional consideration for the 2018 Investor Note, 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 2018 Investor Note accrued interest at a rate of 8% per annum. In February 2019, the Company entered into a forbearance agreement with the 2018 Investor Note investors pursuant to which, among other things, the investors agreed to forbear on their rights to accelerate the 2018 Investor Note 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. In September 2019, the 2018 Investor Note of one investor was paid in full. On March 19, 2020, the Company and the L2 Capital, LLC (“L2”) agreed to extend the note maturity to June 28, 2020. The Company and L2 further agreed to extend the due date to July 15, 2020 and then in July 2020 agreed to extend to September 30, 2020. Effective September 30, 2020, L2 and the Company agreed to extend to March 31, 2021.

No payment penalties were paid in relation to payments on the 2018 Investor Note during the year ended December 31, 2020 and \$525,926 in payment penalties were accrued but not paid as of December 31, 2020. The outstanding principal balance of the 2018 Investor Note as of December 31, 2020 was \$1,721,776, with an unamortized discount of \$0.

Each investor received the right to convert all or any part of its portion of the 2018 Investor Note into shares of the Company’s common stock at a discounted price, subject to certain limitations. During the year ended December 31, 2020 and 2019, L2 converted \$267,328 and \$140,000 of the principal balance, respectively and received 170,000 and 47,556 shares of the Company’s common stock, respectively.

During September 2019, the Company issued a secured promissory note with a principal amount of \$847,500 (the “2019 Investor Note”) to Oasis Capital, LLC (“Oasis”), an affiliate of L2, in exchange for cash proceeds of \$700,000. As additional consideration for the loan, the Company issued an aggregate 8,857 shares of its common stock to Oasis 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 2019 Investor Note accrued interest at a rate of 8% per annum. On March 19, 2020, the Company entered into an agreement to extend the due date the 2019 Investor Note from March 2020 to June 27, 2020. The Company increased the principal amount due on the 2019 Investor Note by \$300,000 and issued 30,000 shares of its common stock as consideration for the extension. The change in value resulting from the extension exceeded 10% and as a result the extension was accounted for as an extinguishment under ASC 470, *Debt*. During the first quarter of 2020, the Company incurred a \$300,000 loss on debt extinguishment related to the extension of the note. The Company and Oasis further agreed to extend the due date of the note to July 15, 2020 and then agreed to extend to September 30, 2020. The change in value resulting from the extension to September 30, 2020 exceeded 10% and as a result the extension was accounted for as an extinguishment under ASC 470, *Debt*. During the third quarter of 2020, the Company incurred a \$345,000 loss on debt extinguishment related to the extension of the 2019 Investor Note to September 30, 2020. Effective September 30, 2020, Oasis and the Company agreed to further extend the maturity date of the 2019 Investor Note to March 31, 2021. The change in value resulting from the extension to March 31, 2021 exceeded 10% and as a result the extension was accounted for as an extinguishment under ASC 470, *Debt*. During the third quarter of 2020, the Company incurred a \$690,000 loss on debt extinguishment related to the extension of the note to March 31, 2021. Further, the parties agreed that the note shall be convertible into shares of the Company’s common stock, at a conversion price equal to the lesser of (i) \$1.00 and (ii) 70% of the lowest VWAP (as defined in the note) of the Company’s common stock during the twenty (20) Trading Day (as defined) period ending on either (i) the last complete Trading Day prior to the conversion date or (ii) the conversion date, as determined by the holder in its sole discretion upon such conversion (subject to adjustment). During the fourth quarter of 2020, Oasis converted \$525,000 in outstanding principal of the 2019 Investor Note in exchange for 1,136,448 shares of the Company’s common stock. No payment penalties were paid in relation to payments on this promissory note during the year ended December 31, 2020 and \$320,542 in payment penalties were accrued but not paid as of December 31, 2020. As of December 31, 2020, the remaining balance on the promissory note was \$1,490,833 with \$244,830 unamortized discount.

On February 5, 2020, the Company issued a secured promissory note with a principal amount of \$1,450,000 (the “2020 Investor Note”) to Oasis. Net proceeds of \$400,000 were received for each of the first, second, and third tranches on February 5, 2020, March 5, 2020, and April 5, 2020, respectively. The Company granted to Oasis a security interest in its assets to secure repayment of the note. The 2020 Investor Note accrued interest at a rate of 8% per annum. Subject to certain limitations, the outstanding principal amount of the note and interest thereon were convertible at the election of the investor into shares of the Company’s common stock at a conversion price equal to \$2.589. The conversion price was amended effective September 30, 2020 to a variable price equal to 70% of the lowest VWAP (as defined in the note) of Company’s common stock during the twenty (20) Trading Day (as defined in the note) period ending on either (i) the last complete Trading Day prior to the conversion date or (ii) the conversion date, as determined by the holder in its sole discretion upon such conversion (subject to adjustment). The note contains a conversion feature and a put which were determined to be derivatives and are discussed further below. Effective July 15, 2020, the Company and Oasis agreed to amend the maturity date of the note to September 30, 2020. The change in value resulting from the amendment to maturity to September 30, 2020 exceeded 10% and as a result the amendment was accounted for as an extinguishment under ASC 470, *Debt*. During the third quarter of 2020, the Company incurred a \$172,500 loss on debt extinguishment related to the amendment of the note to September 30, 2020. Effective September 30, 2020, the investor and the Company agreed to further extend the maturity date of the 2020 Investor Note to March 31, 2021. The change in value resulting from the extension to March 31, 2021 exceeded 10% and as a result the extension was accounted for as an extinguishment under ASC 470, *Debt*. During the third quarter of 2020, the Company incurred a \$345,000 loss on debt extinguishment related to the extension of the note to March 31, 2021. As additional consideration, the Company issued to Oasis warrants to purchase 94,631, 92,700 and 92,700 shares of the Company’s common stock at the closing of the first, second and third tranches, respectively. 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 Oasis at the closing of the first tranche. During the fourth quarter of 2020, Oasis converted \$503,354 in outstanding principal in exchange for 1,075,911 shares of the Company’s common stock. No payment penalties were paid in relation to payments on this promissory note during the year ended December 31, 2020 and \$314,011 in payment penalties were accrued but not paid as of December 31, 2020. As of December 31, 2020, the outstanding balance on the promissory note was \$1,464,146 with no remaining unamortized discount.

On March 1, 2021, the Company used \$5,906,802 of the proceeds of the private placement on February 23, 2021, described below under “2021 Offerings”, to repay in full the outstanding principal and interest and applicable premium amounts under the 2018 Investor Note, the 2019 Investor Note and the 2020 Investor Note. See *Note 17 – Subsequent events*.

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.

During January 2020, the Company entered into an exchange agreement with 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. The Company determined that the exchange agreement had, in substance, occurred at December 31, 2019.

Effective as of April 21, 2020, the Company and Carl Schwartz, entered into an exchange agreement relating to a promissory note of the Company dated January 31, 2020 issued by the Company in the principal amount of \$2,115,000. The note bore twelve percent (12%) interest per annum and had a maturity date of September 30, 2020. The accrued interest on the note through April 21, 2020 was \$77,878, resulting in a total balance of \$2,192,878 in principal and accrued interest on the Note as of such date. Dr. Schwartz and the Company agreed to exchange the note for newly issued shares of common stock of the Company at market value. Pursuant to the exchange agreement, Dr. Schwartz was issued 1,583,481 shares of newly issued common stock at an exchange rate of \$1.43 per share, equal to the closing price of the common stock on April 21, 2020. Dr. Schwartz agreed (1) not to sell or otherwise transfer 766,740 shares for three months after the date of the exchange agreement, and (2) not to sell or otherwise transfer the remaining 766,741 shares for six months after the date of the exchange agreement. In 2021, the Company determined that due to a calculation error, the balance of the 2020 Schwartz Note should have been higher by \$143,574 at the time of the exchange agreement, and on February 24, 2021, the Company issued an additional 100,401 shares to Dr. Schwartz.

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.

Short Term Borrowings

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 year ended December 31, 2020, the Company issued short term notes for a total of \$1,098,684 for cash proceeds of \$1,020,000 and repaid \$1,459,973 of principal using a portion of proceeds from the equity financing facility. Payment penalties of \$247,327 were paid in relation to payments on these short-term borrowings during the year ended December 31, 2020. There were no amounts outstanding under the short-term borrowings as of December 31, 2020.

April 2020 Paycheck Protection Program

On April 20, 2020, the Company entered into a promissory note with Park State Bank, which provides for an unsecured loan of \$541,867 pursuant to the Paycheck Protection Program (the "PPP") under the Coronavirus Aid, Relief, and Economic Security Act and applicable regulations (the "CARES Act"). The promissory note has a term of 2 years with a 1% per annum interest rate. Payments are deferred for 6 months from the date of the promissory note and the Company can apply for forgiveness of all or a portion of the promissory note after 60 days for covered use of funds.

Pursuant to the terms of the PPP, the promissory note, or a portion thereof, may be forgiven if proceeds are used for qualifying expenses as described in the CARES Act, such as payroll costs, costs used to continue group health care benefits, mortgage interest payments, rent and utilities. The Company has used all proceeds for qualifying expenses. The Company received forgiveness for the loan under the Paycheck Protection Program and recognized a gain in other income for the full amount of the loan during the fourth quarter of 2020.

NOTE 8 - DERIVATIVES

The Company concluded the September 2018 Investor Note contains a conversion feature which is an embedded derivative and required bifurcation. The embedded derivative's value was determined using the discounted stock price for the 20-trading days preceding the balance sheet date and the assumption of conversion on that date, as management believed it was probable that the notes would be convertible based on management's expectation that additional financing would be required. During the year ended December 31, 2020, the maximum number of conversions was reached. The Company recognized an unrealized gain or (loss) for the corresponding change in fair value of \$50,989 and \$221,757 for the year ended December 31, 2020 and December 31, 2019, respectively. The fair value of the derivative liability related to the bridge loan was zero as of December 31, 2020 and \$50,989 as of December 31, 2019.

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 and voided all previously issued warrants related to these notes.

The Company concluded the Promissory Note 2020 contains a conversion feature and a put each of which is an embedded derivative and are required to be bifurcated. In accordance with ASC 815, *Derivatives and Hedging*, the Company combined these two embedded derivatives into a single derivative and determined the fair value to record within the derivative liability on the consolidated balance sheet. At inception, the fair value of the derivative liability was \$68,796, \$52,125 and \$20,542 for the first, second and third tranches, respectively. During the year ended December 31, 2020, the Company recognized a gain of \$87,923 on the change in the fair value of the derivative liability. As of December 31, 2020, the fair value of the derivative liability was \$104,529.

The Company concluded the A, B and agent warrants issued in connection with the March 2020 Private Placement discussed above are a derivative liability due to certain features of the warrants which could, in certain circumstances, result in the holder receiving the Black Scholes value of the outstanding warrants in the same type of consideration as the common stockholders. As a result, in those circumstances, the amount of consideration would differ from that provided to holders of common stock, therefore, the warrants were classified as a liability. At inception, the A, B and agent warrants had a fair value of \$2,669,995. During the third quarter of 2020, the A and B warrants were amended as discussed in *Note 7 - Notes Payable* above. As a result of this amendment, the warrants no longer represented a liability to the Company and were reclassified to equity. Prior to reclassification, a gain on the change in fair value of \$700,910 was recorded during the year ended December 31, 2020. As of December 31, 2020, the fair value of the agent warrants was determined to be \$33,654 and the Company recorded a gain on the change in fair value of \$69,479 during the year ended December 31, 2020.

The Company concluded the warrants and agent warrants issued in connection with the May 2020 Offering discussed above are a derivative liability due to certain features of the warrants which could, in certain circumstances, result in the holder receiving the Black Scholes value of the outstanding warrants in the same type of consideration as the common stockholders. As a result, in those circumstances, the amount of consideration would differ from that provided to holders of common stock, therefore, the warrants were classified as a liability. At inception, the warrants and agent warrants had a fair value of \$1,324,184. The Company recorded a loss on the change in fair value of the warrants of \$460,065 during the year ended December 31, 2020. During June 2020, the investors exercised the warrants and exchanged the warrants for shares of common stock as discussed above. As of December 31, 2020, the fair value of the agent warrants was determined to be \$33,819 and the Company recorded a gain on the change in fair value of the agent warrants of \$48,675 during the year ended December 31, 2020.

In connection with the June 2020 Warrant exercise and issuance, the Company concluded the warrants and agent warrants issued in connection with the June 2020 Warrant exercise and issuance, discussed above, are a derivative liability due to certain features of the warrants which could, in certain circumstances, result in the holder receiving the Black Scholes value of the outstanding warrants in the same type of consideration as the common stockholders. As a result, in those circumstances, the amount of consideration would differ from that provided to holders of common stock, therefore, the warrants were classified as a liability. At inception, the warrants and agent warrants had a fair value of \$1,749,721. During the year ended December 31, 2020, the June warrants were amended. As a result of this amendment, the warrants no longer represented a liability to the Company and were reclassified to equity. Prior to reclassification, the Company recorded a gain on the change in fair value of the warrants of \$834,520 during the year ended December 31, 2020. The Company recorded a gain on the change in fair value of the agent warrants of \$79,045 during the year ended December 31, 2020. As of December 31, 2020, the fair value of the agent warrants was \$32,701.

On September 30, 2020, the Promissory Note 2019 was amended. The Company concluded the Promissory Note 2019 contains a conversion feature which is an embedded derivative and is required to be bifurcated. In accordance with ASC 815, *Derivatives and Hedging*, the Company determined the fair value to record within the derivative liability on the consolidated balance sheet. At inception, the fair value of the derivative liability was \$495,100. The Company recorded a gain on the change in fair value of the agent warrants of \$405,420 during the year ended December 31, 2020. As of December 31, 2020, the fair value of the agent warrants was \$89,680.

The table below discloses changes in value of the Company's embedded derivative liabilities discussed above.

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
Derivative instrument recognized for A, B and Agent Warrants	2,669,995
Derivative instrument related to Promissory Note 2020	120,921
Derivative instrument recognized for May 2020 Warrants	1,324,184
Derivative instrument recognized for June 2020 Warrants	1,749,721
Derivative instrument related to Promissory Note 2020	20,542
Reclassification of Warrant liabilities to Equity on exercise	(1,701,756)
Reclassification of Warrant liabilities to Equity	(2,669,408)
Derivative instrument related to September 30 debt amendments	495,100
Gain recognized to revalue derivative instrument at fair value	(1,765,906)
Derivative liability balance at December 31, 2020	\$ 294,382

NOTE 9 - LOSS PER SHARE

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

	Year Ended December 31,	
	2020	2019
Numerator:		
Net loss attributable to common shareholders per common share: basic and diluted calculation	\$ (26,438,684)	\$ (19,680,701)
Denominator:		
Weighted average common shares outstanding-basic	11,950,154	2,870,132
Effect of diluted stock options, warrants and preferred stock (1)	-	-
Weighted average common shares outstanding-diluted	11,950,154	2,870,132
Loss per common share-basic and diluted	\$ (2.21)	\$ (6.86)

(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:

	Year Ended December 31,	
	2020	2019
Options	1,013,547	766,424
Warrants	7,353,376	2,171,610
Convertible debt	1,107,544	82,751
Preferred stock: Series B	79,246	79,246
Preferred stock: Series D	-	350,000
Preferred stock: Series E	-	594,383

NOTE 10 – INCOME TAXES

The provision for income taxes consists of an amount for taxes currently payable and a provision for tax consequences deferred to future periods. Deferred income taxes are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

There is no 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:

	Year Ended December 31,	
	2020	2019
Statutory federal income tax benefit	\$ 5,434,463	\$ 3,977,561
State tax benefit, net of federal taxes	578,746	368,635
Foreign tax benefit	62,146	104,050
Foreign operations tax rate differential	(44,120)	(73,869)
State rate adjustment	65,112	(17,585)
R&D tax credit	-	51,143
Nondeductible/nontaxable items	(268,968)	1,183,535
Goodwill impairment	(2,762,014)	(1,701,000)
NOL adjustments	(1,141,662)	(1,054,778)
OID and derivatives	-	141,908
Helomics purchase adjustment	-	66,394,188
Other	(461,020)	115,896
Valuation allowance increase	(1,462,683)	(69,489,684)
Total income tax benefit	\$ -	\$ -

Deferred taxes consist of the following:

	December 31, 2020	December 31, 2019
Deferred tax assets:		
Noncurrent:		
Depreciation	\$ -	\$ -
Inventory	7,196	6,891
Compensation accruals	63,846	56,670
Accruals and reserves	162,628	-
Deferred revenue	11,641	7,480
Charitable contribution carryover	4,331	3,740
Derivatives	63,145	10,708
Related party investments	-	657,633
Intangibles	297,639	295,941
Right of use asset	13,861	-
NSQO compensation	1,738,217	1,589,430
NOL and credits	80,038,356	78,417,618
Total deferred tax assets	<u>82,400,860</u>	<u>81,046,111</u>
Deferred tax liabilities:		
Noncurrent:		
Original issue discount	-	(14,021)
Depreciation	(295,775)	(389,689)
Total deferred tax liabilities	<u>(295,775)</u>	<u>(403,710)</u>
Net deferred tax assets	82,105,085	80,642,401
Less: valuation allowance	(82,105,085)	(80,642,401)
Total	<u>\$ -</u>	<u>\$ -</u>

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 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, 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.

At December 31, 2020, the Company had \$297,735,754 of gross NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2021, subject to the Section 382 limitation described above. The federal NOL's of \$261,455,216 expire beginning in 2022 if unused and \$36,280,538 will carryforward indefinitely. The Company also had \$222,290,524 of gross NOLs to reduce future state taxable income at December 31, 2020. The state NOL's will expire beginning in 2021 if unused. The Company dissolved its Belgium subsidiary in 2020 and all carryforward tax losses will be eliminated on the final 2020 Belgium tax return filed. The Company's net deferred tax assets, which include the NOLs, are subject to a full valuation allowance. At December 31, 2020, the federal, state, and foreign valuation allowances were \$59,913,739, \$22,191,346, and \$0, respectively.

Tax years subsequent to 2017 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, 2020 and 2019, the Company recorded no accrued interest or penalties related to uncertain tax positions.

NOTE 11 – Goodwill and Intangibles

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. Amortization expense was \$313,709 and \$290,552 in 2020 and 2019, 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. During 2019, the Company reviewed 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, 2020, there were \$3,398,101 in net intangibles as compared to \$3,649,412 in net intangibles as of December 31, 2019.

The components of intangible assets were as follows:

	December 31, 2020			December 31, 2019		
	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount
Patents & Trademarks	\$ 401,421	\$ (211,110)	\$ 190,311	\$ 339,023	\$ (195,286)	\$ 143,737
Developed Technology	2,882,000	(252,175)	2,629,825	2,882,000	(108,075)	2,773,925
Customer Relationships	445,000	(259,583)	185,417	445,000	(111,250)	333,750
Tradename	398,000	(5,452)	392,548	398,000	-	398,000
Total	\$ 4,126,421	\$ (728,320)	\$ 3,398,101	\$ 4,064,023	\$ (414,611)	\$ 3,649,412

The following table outlines the estimated future amortization expense related to intangible assets held as of December 31, 2020:

Year ending December 31,	Expense
2021	\$ 331,071
2022	219,821
2023	182,738
2024	182,738
2025	182,738
Thereafter	2,298,995
Total	\$ 3,398,101

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.

No impairment charges were incurred during 2020. 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.

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.

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. During the third quarter of 2020, the Company's share price experienced a sustained reduction in trading values. This was also reflective of broader difficulties in the general economic conditions due to the COVID pandemic. Based on our examination of these and other qualitative factors at September 30, 2020, the Company concluded that that potential impairment indicators were present and that an impairment assessment was warranted for goodwill.

In testing goodwill for impairment as of September 30, 2020, 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 quantitative goodwill impairment test, the Company concluded that goodwill was impaired as of the testing date of September 30, 2020. The quantitative review as of September 30, 2020 resulted in \$2,997,000 of impairment expense related to goodwill.

When evaluating the fair value of Helomics reporting unit the Company used a discounted cash flow model and market comparisons. 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 25% 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 10% for risks related to the term of the forecasts.

In testing goodwill for impairment as of December 31, 2020, 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, 2020. 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, 2020 resulted in \$9,879,458 of impairment expense related to goodwill. A decrease in the growth rate of 0.5% or an increase of 0.5% to the discount rate would reduce the fair value of Helomics reporting unit by approximately an additional \$588,000 and \$988,000, respectively. As of December 31, 2020, the cumulative impairment recorded was \$20,976,498.

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 in 2020 included: (a) expected cash flow for the 10-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 5.0% determined based on the growth prospects of the reporting unit; and (c) a discount rate of 14.0% 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 1.0% for risks related to the term of the forecasts. The Company further used a probability weighting of various forecasts to address forecast risk.

The following tables present changes in the carrying value of goodwill our consolidated balance sheet:

Goodwill balance at December 31, 2018	\$ -
Acquired	23,790,290
Impairment	(8,100,000)
Goodwill balance at December 31, 2019	\$ 15,690,290
Impairment	(12,876,498)
Goodwill balance at December 31, 2020	\$ 2,813,792

The majority of the inputs used in the discounted cash flow model are unobservable and thus are considered to be Level 3 inputs. The inputs for the market capitalization calculation are considered Level 1 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.

Correction of Immaterial Misstatement to Prior Period Financial Statements

During fiscal 2020, the Company identified an error that existed in the presentation of the loss on goodwill impairment and the loss on intangibles impairment in the Consolidated Statement of Net Loss for the year ended December 31, 2019. The loss on goodwill impairment of \$8,100,000 and the loss on intangible impairment of \$770,250 were each presented separately and were classified below the operating loss line in the Company’s Consolidated Statement of Net Loss for the year ended December 31, 2019. Per FASB ASC 350-20-45-2, goodwill impairment losses should be presented as a separate line item in the income statement before the subtotal “income from continuing operations” (or similar caption).

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

Accordingly, the Company restated its presentation of loss on goodwill impairment and loss on intangible impairment to reflect the presentation of these losses as distinct line items included within the Company’s loss from operations for the fiscal period ended December 31, 2019.

NOTE 12 – LEASES

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. The lease was amended subsequent to December 31, 2020 for one additional year until January 31, 2022.

The offices of our Helomics subsidiary are located in Pittsburgh, Pennsylvania. The lease, as amended, has a three-year term ending February 28, 2023. 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.

Soluble Biotech’s offices are located in Birmingham, Alabama. We lease approximately 4,314 square feet at this location. The lease is effective through August 25, 2025.

Skyline Medical Europe’s offices were located in Belgium. The Company leased 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 was terminated in the fourth quarter of 2020.

Lease expense under operating lease arrangements was \$565,581 and \$431,170 for 2020 and 2019, respectively.

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

	December 31, 2020	December 31, 2019
Weighted average remaining lease term – operating leases in years	2.33	3.28
Weighted average discount rate – operating leases	8%	8%

The Company's lease obligation as of December 31, 2020 which include lease extensions entered into after December 31, 2020 due to certainty of renewal, are as follows:

2021	689,368
2022	725,759
2023	170,910
2024	71,420
2025	48,552
Total lease payments	1,706,009
Less interest	263,411
Present value of lease liabilities	<u>\$ 1,442,598</u>

NOTE 13 – Property, Plant and Equipment

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, software and office equipment	3	- 10
Leasehold improvements ⁽¹⁾		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, 2020	December 31, 2019
Computers, software and office equipment	\$ 3,638,520	\$ 508,143
Leasehold improvements	315,297	188,014
Manufacturing tooling	1,144,116	1,510,165
Demo equipment	56,614	73,051
Total	5,154,547	2,279,373
Less: Accumulated depreciation	1,331,847	771,574
Total fixed assets, net	<u>\$ 3,822,700</u>	<u>\$ 1,507,799</u>

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 \$711,139 and \$414,331 in 2020 and 2019, respectively.

NOTE 14 – SEGMENTS

The Company has determined its reportable 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 reportable segments and evaluates their relative performance. Each reportable 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 reportable 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 third quarter of 2020, the Company considered, whether under ASC 280-10-50-3, there was a change in its reportable segments. As a result of the formation of the new Soluble subsidiary, the Company believes the Soluble business represents a reportable segment. Soluble signed its first contract during the third quarter of 2020. The Company also believes it is appropriate to combine our Skyline Medical and Skyline Europe entities into a single reportable segment based on the changes to our physical presence and intent to sign future contracts through the US entity. Finally, the Company believes the Helomics business continues to be a reportable segment.

The Company has three reportable segments: Skyline, Helomics and Soluble. See discussion of revenue recognition in Note 1 – Summary of Significant Accounting Policies for a description of the products and services recognized in each segment. The reported financial information below has been reclassified to conform to the current presentation. This information is intended to assist investors in making comparisons of the Company’s historical financial information with future financial information.

The table below summarizes the reclassified presentation of the Company’s segment reporting as of and for years ended December 31, 2020 and 2019.

	Year Ended December 31, 2020				
	Skyline	Helomics	Soluble	Corporate	Total
Revenue	\$ 1,185,214	\$ 64,188	\$ 2,870	\$ -	\$ 1,252,272
Depreciation and Amortization	(38,310)	(761,105)	(184,071)	(41,362)	(1,024,848)
Impairment expense	-	(12,876,498)	-	-	(12,876,498)
Loss on equity method investment	-	-	-	-	-
Operating Loss	\$ (1,132,251)	\$ (15,112,131)	\$ (671,367)	\$ (8,968,648)	\$ (25,884,397)

	December 31, 2020				
	Skyline	Helomics	Soluble	Corporate	Total
Assets	\$ 1,191,439	\$ 9,773,902	\$ 1,883,585	\$ 211,510	\$ 13,060,436

	Year Ended December 31, 2019				
	Skyline	Helomics	Soluble	Corporate	Total
Revenue	\$ 1,363,118	\$ 48,447	\$ -	\$ -	\$ 1,411,565
Depreciation and Amortization	(48,420)	(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)
Operating Loss	\$ (3,135,290)	\$ (12,354,108)	\$ -	\$ (3,901,368)	\$ (19,390,766)

	December 31, 2019				
	Skyline	Helomics	Soluble	Corporate	Total
Assets	\$ 969,793	\$ 21,275,306	\$ -	\$ 130,411	\$ 22,375,510

In 2020, substantially all the Company revenues were located or derived from operations in the United States. As of December 31, 2020, all of the Company’s long-lived assets were located within the United States.

NOTE 15 – 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. From January 1, 2019 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 16 – 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 \$119,555 and \$110,714 in 2020 and 2019, respectively. There were no discretionary contributions to the plan in 2020 and 2019.

NOTE 17 – SUBSEQUENT EVENTS

2021 Offerings

In January and February 2021, the Company completed a series of five offerings, all of which were priced at-the-market under applicable NASDAQ rules. The first four offerings were registered direct offerings of common stock under its shelf registration statement, and in each such case, in a concurrent private placement, the Company also issued such investors one warrant to purchase common stock for each two shares purchased in the transaction. Following those four offerings, the Company completed a private placement of common stock, with each investor receiving one warrant to purchase common stock for each two shares purchased in the transaction. In each case, each such investor warrant is exercisable immediately upon issuance and will expire five and one-half years from the issue date. In each case, the Company paid to the placement agent an aggregate fee equal to 7.5% of the aggregate gross proceeds received by the Company in the offering and a management fee equal to 1% of the aggregate gross proceeds received by the Company in the offering and reimbursed the placement agent for certain non-accountable and out-of-pocket expenses. In addition, the Company granted to the placement agent or its assigns warrants to purchase 7.5% of the shares sold to investors in the offering at an exercise price equal to 125% of the price of the shares in the transaction, with a term of five years for the registered direct offerings or five and one-half years for the private placement. These offerings were as follows:

Offering Closing Date	Shares	Sale Price per Share*	Investor Warrants	Exercise Price per Share – Investor Warrants	Placement Agent Warrants	Exercise Price per Share – Placement Agent Warrants	Gross Proceeds of Offering	Net Proceeds of Offering
January 12, 2021 (registered direct)	3,655,840	\$ 0.842	1,825,420	\$ 0.80	273,813	\$ 1.0525	\$ 3,074,007	\$ 2,731,767
January 21, 2021 (registered direct)	2,200,000	\$ 1.00	1,100,000	\$ 1.00	165,000	\$ 1.25	\$ 2,200,000	\$ 1,932,050
January 26, 2021 (registered direct)	3,414,970	\$ 1.20	1,707,485	\$ 1.20	256,123	\$ 1.50	\$ 4,097,964	\$ 3,668,687
February 16, 2021 (registered direct)	4,222,288	\$ 1.75	2,111,144	\$ 2.00	316,672	\$ 2.1875	\$ 7,389,004	\$ 6,679,989
February 23, 2021 (private placement)	9,043,766	\$ 1.95	4,521,883	\$ 2.00	678,282	\$ 2.4375	\$ 17,635,344	\$ 16,064,739
Total	22,536,864		11,265,932		1,689,890		\$ 34,396,319	\$ 31,077,232

* Sale price includes one share and a warrant to purchase one-half share.

2021 Warrant Exercises

During the period January 1, 2021 through February 25, 2021, the holders of outstanding investor warrants have exercised such warrants for the total purchase of 4,964,994 shares at a weighted average exercise price of \$0.63 per share, for total proceeds of \$4,269,617.

On March 1, 2021, the Company used \$5,906,802 of the proceeds of the private placement on February 23, 2021, to repay in full the outstanding principal and interest and applicable premium amounts under the 2018 Investor Note, the 2019 Investor Note and the 2020 Investor Note.

Description of Registrant's Securities

As of March 10, 2021, 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, and 300,000 shares have been designated Series B Convertible Preferred Stock, of which 79,246 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”.

**PREDICTIVE ONCOLOGY INC.
SUBSIDIARIES OF THE REGISTRANT**

Subsidiary**Jurisdiction of Incorporation**

Helomics Holding Corporation
TumorGenesis Inc.
Extraordinary Vaccine Development Corporation
Soluble Biotech Inc.
Skyline Medical, Inc.
Helomics Intermediate Corporation
Helomics Corporation

Delaware
Delaware
Delaware
Delaware
Delaware
Delaware
Delaware

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File No. 333-215005, 333-234366, 333-239207, 333-252584, and 333-252585) Form S-3 (File No. 333-213766, 333-221966, 333-228908, 333-234073, 333-235441, 333-237581, and 333-239851), Form S-4 (File No. 333-228031) and Form S-8 (File No. 333-169556, 333-175565, 333-186464, 333-188510, 333-198378, 333-213742, 333-216711, 333-230704, and 333-250149) of Predictive Oncology Inc. of our report dated March 15, 2021, relating to the consolidated financial statements, which report expresses an unqualified opinion on the consolidated financial statements for the year ended December 31, 2020, appearing herein.

/s/ Baker Tilly US, LLP (formerly known as Baker Tilly Virchow Krause, LLP)
Minneapolis, Minnesota
March 15, 2021

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, 333-230704, and 333-250149 on Form S-8; and in Registration Statement Nos. 333-213766, 333-221966, 333-228908, 333-234073, 333-235441, 333-237581, and 333-239851 on Form S-3; and in Registration Statement Nos. 333-215005, 333-234366, 333-239207, 333-252584, and 333-252585 on Form S-1; and in Registration Statement No. 333-228031 on Form S-4 of our report dated March 31, 2020 (March 15, 2021 as to the effects of the correction to the 2019 financial statements discussed in Note 11), relating to the financial statements of Predictive Oncology Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2020.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, Minnesota
March 15, 2021

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 15, 2021

/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 15, 2021

/s/ Bob Myers

Bob Myers
Chief Financial Officer (Principal Financial
Officer)

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

In connection with the Annual Report on Form 10-K of Predictive Oncology Inc. (the "Company") for the year ended December 31, 2020 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 15, 2021

/s/ Carl Schwartz

Carl Schwartz

Chief Executive Officer

(Principal Executive Officer)

/s/ Bob Myers

Bob Myers

Chief Financial Officer

(Principal Financial Officer)
