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, 2022.**

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

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

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

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant 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: $32,051,418 as of June 30, 2022, based upon 78,155,127 shares at $0.41 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 14, 2023, the registrant had 79,403,893 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

Predictive Oncology Inc. ("Predictive Oncology") is a knowledge-driven company focused on applying artificial intelligence ("AI") to support the development of optimal cancer therapies, which can ultimately lead to more effective treatments and improved patient outcomes. Through AI, Predictive Oncology uses a biobank of 150,000+ cancer tumor samples, categorized by patient type, against drug compounds to help the drug discovery process and increase the probability of success. The company offers a suite of solutions for oncology drug development from early discovery to clinical trials.

We operate in four primary business areas: first, the application of AI for optimized, high-confidence drug-response predictions within a large experimental space that enables a more informed selection of drug/tumor combinations to increase the probability of success during development; second, creation and development of tumor-specific 3D cell culture models driving accurate prediction of drug response with high correlation to clinical response; third, contract services and research focused on solubility improvements, stability studies, and protein production, and; fourth, 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 four reportable segments: Helomics®, zPREDICTA®, SolubleTM and Skyline®. The Helomics segment provides services that include the application of AI, collaboration projects and clinical testing. Our zPREDICTA, Inc. ("zPREDICTA") segment specializes in organ-specific disease models that provide 3D reconstruction of human tissues more accurately representing each disease state and mimicking drug response enabling accurate testing of anticancer agents. 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. Going forward, we have determined that we will focus our resources on applying AI to support the development of optimal cancer therapies, partnering with biopharma clients to help prioritize drugs for development and identify biomarker-informed indications. Our platform provides a more informed decision tool to select optimal drug/tumor combinations to increase the probability of success during drug development. As a result of this focused approach, we have consolidated our brand under the Predictive Oncology name. Going forward, we will operate under the Predictive Oncology tradename with laboratory operations in Pittsburgh, Pennsylvania and Birmingham, Alabama.

HELOMICS

Our proprietary AI-driven platform, conducted in our Helomics division, is committed to optimizing, high-confidence drug-response predictions within a large experimental space. Using our proprietary, multi-omic tumor profiling platform, a one-of-a-kind database of historical tumor data, and the power of AI to build predictive models of tumor drug response. Our Patient-centric Drug Discovery using Active Learning asset ("PEDAL"™) is a unique technology that combines the largest privately held commercial biobank of oncology tumor samples, AI technology and historical drug response data—complete with an on-site wet lab for streamlined drug/tumor prediction evaluation. 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 to guide the testing of patient-specific compound responses 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 tumor samples of certain profiles that respond as well as the set of compounds that provide the best coverage across patients.

We believe leveraging our unique, historical database of the drug responses of over 150,000 patient tumor samples to build AI and data-driven multi-omic predictive models of tumor drug response and outcome will provide actionable insights critical to new drug development. 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 dataset has been rigorously de-identified and aggregated to build a unique, proprietary model of tumor drug response. Thus, PEDAL can significantly increase the probability of clinical success, leading to a dramatic improvement in both the therapeutic success, time, and cost of your oncology discovery programs.

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 samples. This novel disruptive patient-centric approach is ideally suited to the early part of drug discovery, resulting in better prioritization of compounds and better coverage of tumor 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.

Business Strategy for Drug Discovery Solutions

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. A key part of our commercialization strategy 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 effective cancer treatments through biomarker discovery, drug screening, drug repurposing, and ultimately clinical trials with higher probability of success.

PEDAL, which incorporates CORE™, our active machine learning program, with tumor profile data and human tumor samples, allows for optimized, high-confidence drug-response predictions within a large experimental space. With each iteration of PEDAL, the program learns, predicts, and then directs the most informative wet lab experimentation, while building the predictive model. This allows for a unique and streamlined approach in which AI-driven predictions are tested against samples from this expansive and diverse biobank to more efficiently and effectively narrow down viable drug-tumor pairings. Our AI-driven platform is powered by a biobank of tumor samples to move molecules forward with a higher probability of success. The focus of our business strategy is to leverage and expand our portfolio of proprietary solutions to advance drug discovery and enable oncology drug development for our biopharma partners.

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 available chemotherapy treatments and which therapies might be indicated by relevant tumor biomarkers.

*C*linic diagnostic testing is comprised of our Tumor Drug Response Testing (ChemoFx™) and Genomic Profiling (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 and/or status of a particular gene related to a patient's tumor specimen.

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.

zPREDICTA

zPREDICTA develops tumor-specific in vitro models for oncology drug discovery and research by biopharmaceutical companies and other clients and partners. zPREDICTA's 3D product models accelerate the drug development process for its clients and partners by leveraging the expertise in carcinogenesis, metastasis and the tumor microenvironment. It develops complex in vitro models that recapitulate the physiological environment of human tissue.

zPREDICTA models provides drug response prediction with high correlation to clinical response, enabling our biopharma clients to manage pipeline prioritization more efficiently by identifying drugs that are effective in patients, from the hundreds, and often thousands, of compounds in development. The tumor-specific models are used by a number of biopharmaceutical companies to evaluate the efficacy and toxicity of their therapeutic pipelines. Our models replicate the extracellular matrix of individual organs and disease-specific soluble microenvironment mimicking the biology of human disease and matching thein vivo milieu of the organ of interest, and as such, demonstrate high correlation with clinical response.

The zPREDICTA 3D tumor-specific models incorporate tissue-specific extracellular matrices and tumor-specific medium supplements allowing for a true reconstruction of tumor microenvironment. Our approach is compatible with multiple classes of immuno-oncology agents from naked antibody and antibody-drug conjugates, to bi- and tri-specific compounds, and CAR-T cells. The organ-specific disease models provide 3D reconstruction of human tissues accurately representing each disease state and mimicking drug response.

Our platform maintains tumor-tumor and tumor-stroma interactions and incorporates both cellular and extracellular elements of tissue microenvironment including soluble factors in an organ- and disease-specific manner. It is compatible with multiple cell types, drug classes, and downstream analysis methods.

Our platform is designed to evaluate drug candidates and drug combinations within the native microenvironment of human tissues. Our technology is a patient-derived 3D culture platform that recreates the complex human organ microenvironment thereby preserving the critical interactions between a tumor and its surroundings. Our platform supports long-term survival and proliferation of malignant and non-malignant cellular components of tissues. This includes tumor cells, stroma, and immune components. Anticancer compounds tested in our models exhibit high correlation with clinical response when comparing treatment outcomes in the clinic with cellular behavior in response to the therapeutic regimen. Our organ-specific technology is compatible with multiple drug classes, including small molecules, antibodies, antibody-drug conjugates, immunomodulatory agents, CAR-T cells, etc. Our platform is fully customizable to the tumor and tissue of interest. It is compatible with multiple cell types, drug classes, and downstream analysis methods.

Applications include providing efficacy screening of anticancer compounds, evaluation of mechanisms of drug resistance, identification of new drug combinations, rescue of failed drug candidates, assessment of off-target toxicity, target discovery and biomarker discovery. Product offerings include preclinical testing services based on our proprietary models directly to clients in the biopharmaceutical industry. As of December 31, 2022, we have merged our zPREDICTA entity with Predictive Oncology and moved all related laboratory operations to our CLIA laboratory in Pittsburgh, Pennsylvania.

SOLUBLE BIOTECH

Our Soluble Biotech business ("Soluble") focuses on contract services and research for biopharmaceutical company clients and academic collaborators, focused on solubility improvements, stability studies, and protein production. 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 based on current projections, could be a 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 excipients previously approved by the FDA 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 AI 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 previously FDA approved additives will improve the solubility and stability of proteins in solutions. Services include pre-formulation development, 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, Soluble supplies proprietary technologies for bacterial endotoxin detection and removal. Endotoxin is an inherent byproduct of bacterial expression of therapeutic proteins. However, therapeutic proteins are required to have extremely low endotoxin levels. Soluble provides a product to remove endotoxin that works through multiple molecular interactions for efficient removal over a wide range of buffer conditions with minimal product loss. The detection of endotoxin can also be adversely affected by the protein therapeutic itself. To address this, Soluble provides sample treatment kits to minimize detection interference while using standard detection assays. At the Soluble GMP facility, we are able to manufacture high-quality endotoxin detection and removal products to help our customers efficiently meet safety standards. We follow GMP, ICH and GLP standards throughout to ensure consistent and standardized products and services. As of December 31, 2022, we have merged Soluble Biotech Inc. with Predictive Oncology.

SKYLINE MEDICAL – The STREAMWAY System

Sold through our subsidiary, Skyline Medical Inc. ("Skyline Medical"), the STREAMWAY System virtually eliminates 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. We continue to operate the Skyline Medical business by continually improving our strategic opportunities, while focusing our resources on our drug discovery, drug development and clinical research.

Industry and Market Background and Analysis

Drug Discovery Solutions

The growing demand for the discovery and development of novel drug therapies are driving the demand for AI empowered solutions in the drug discovery processes. Growing partnerships and cooperation are expected to fuel global market for AI in drug discovery. The adoption of AI solutions in the drug development process eliminates possible obstacles, reduces cycle time, and increases the productivity and accuracy of the clinical trial process. Due to these advantages, the importance of AI in drug discovery and development are expected to drive the global market. AI powered drug discovery market is an emerging approach that considers individual variability in multi-omics, including genes, disease and environment to develop effective therapies. This approach predicts more accurately which treatment, dose, and therapeutic regimen could provide the best possible outcome. Biopharmaceutical companies, contract research organizations, academia, and other stakeholders began integrating AI-based solutions in their drug development processes to enhance outcomes and curb costs. Through the implementation of AI solutions, the screening processes can be accelerated, and the turnaround time can be reduced.

We believe we are uniquely positioned with our PEDAL platform to provide early insights that clients can use to prioritize drugs for development and identify biomarker-informed indications. In addition, the PEDAL platform can be used to re-purpose previously failed drug compounds. We aim to leverage the PEDAL platform for our biopharma clients and help them use it to decide early on which drugs to prioritize for development and which to discontinue. This will allow a biopharma client to be able to predict what are the drugs that they should be moving into development. With our technology, we want to change the way that biopharma companies plan clinical trials and develop oncology drugs. We believe our platform provides money- and time-saving advantages for pharmaceutical companies that are unique in the marketplace.

We believe the passage of the FDA Modernization Act 2.0 will increase the use of non-animal methods to study the mechanisms of diseases and to test the effectiveness of new drugs. The FDA Modernization Act 2.0 eliminates animal-testing requirements for the development of drugs and allows drug manufacturers to opt out of animal testing while utilizing modern testing methods to develop drugs, such as cell-based assays, organ-on-a-chip technology, computer models, and other human biology-based test methods. We expect the market to continue to grow due to the benefits from the elimination of possible obstacles, reduction of clinical trial cycle time, and increased productivity and accuracy of the clinical trial process probability of clinical success.

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.

Competition and Competitive Advantages

Drug Discovery Solutions. New drug compounds take 10-12 years to become medicines, from discovery to commercial launch. Identifying those medicines is a difficult process with a significant majority of compounds failing. This failure is costly in time and resources, particularly when the compounds fail during the clinical trial stages. It is estimated that 90-95% of compounds fail between first human dose and launch. One of the reasons for this high failure rate is the inability of oncology drug compounds to be tested in a large, diverse group of tumor samples.

AI companies addressing the needs in the drug discovery market are looking at the challenges from different angles. However, no other company has access to a privately held biobank with drug response data. The ability to pair AI with Predictive Oncology's biobank provides us with a competitive advantage and barrier to entry from competitors in the drug response prediction space informed by tumor samples that can be tested in a laboratory.

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 and drug repurposing.

3D Modeling. Our next-generation technology based on extensive research of the human tumor microenvironment creating accurate reconstruction of the organ-specific 3D tissue microenvironment enabling evaluation of therapeutic agents under conditions mimicking human physiology. The main competitive advantage of our technology is the tumor-specific nature of its systems. 3D models replicate tissue heterogeneity and provides long-term maintenance of primary human cells, organoids, and cell lines under the native conditions of human disease. The 3D models are formulated to mimic the tissue and disease of interest instead of pursuing a one-size-fits-all approach taken by other companies. Services provide reliable prediction of clinical outcomes based on accurate reconstruction of cellular and extracellular compartments of human tissues.

Formulations and Biologic Development. HSC Technology is a self-contained, automated system that conducts high-throughput, self-interaction chromatography screens on FDA approved excipients for protein formulations. This provides an efficient way of exploring over 4,000 formulation combinations to quickly move the molecule along the development continuum. 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. Our technologies and services help expedite and streamline biologics development —improving yield with expression and purification services; helping prepare for clinical trials with ICH stability profiles; meeting safety standards with endotoxin detection and removal; and manufacturing at our GMP facility.

Skyline Medical. We believe that the STREAMWAY System is unique to the industry because it 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 fully closed 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 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 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 that 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 also have single suppliers for the manufacturing of certain of our Skyline Medical products. Alternative suppliers are available in the market; however, we could experience delays and interruptions that might adversely affect the financial performance of our business including time for machine tooling specific to our products.

We have existing and good relationships with our service vendors.

Research and Development ("R&D")

We spent $320,320 and $315,850 in 2022 and 2021, 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.

3D. Our technology is a patient-derived 3D culture platform that recreates the complex human organ microenvironment thereby preserving the critical interactions between a tumor and its surroundings. Our models replicate the extracellular matrix of individual organs and disease-specific soluble microenvironment mimicking the biology of human disease, and as such, demonstrate high correlation with clinical response. Patents include US10,501,717, US11,124,756 and pending application US16/321,277.

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 potential 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. The FDA may assert regulatory oversight over these areas, and legislative proposals addressing FDA oversight of laboratory developed tests have been introduced in the past and may be enacted in the future. See “Item 1A. Risk Factors” for a discussion of the possible impact of such regulatory or legislative developments.
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 of STREAMWAY System 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 these 510(k) clearances 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 for STREAMWAY System

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 and Human Capital Resources

We had 31 full-time employees and 3 part-time/intern employees as of December 31, 2022. None of our employees are subject to a collective bargaining agreement and we believe our relations with our employees are satisfactory. Our human capital resources objectives include identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees, and we recruit people for positions regardless of gender, ethnicity or other protected traits.

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. 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.

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 drug discovery solutions makes evaluation of our business difficult.

Our drug discovery, drug development and clinical research 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 drug discovery, drug development and clinical research services 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 drug discovery solutions, 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 drug discovery solutions 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 PEDAL platform takes longer than expected, the commercial revenues that use this platform could also be delayed.

Our drug discovery solutions business offers various services to pharma, diagnostics, and biotech companies. These services use our PEDAL platform. This platform is the subject of active R&D to further improve 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 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 biobank;
- 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 drug discovery solutions business, particularly in connection with services using our PEDAL platform, as these are new to the market, which makes it difficult to forecast our future revenues. Although we are committed to the buildout of this business for the long term, we cannot predict at this time, with any certainty, the future viability of this 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 have contracted with a manufacturing company that follows ISO compliance regulations of the FDA and that can manufacture products at high 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 will 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 fund 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 2023. 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 may attempt to raise these funds through equity or debt financing that may include public offerings, private placements, alternative offerings, or other means. Such additional financing would be dilutive to existing stockholders, and there is no assurance that such financing would be available upon terms acceptable to us or at all. 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 may continue to be materially and adversely affected by the COVID-19 pandemic.

The COVID-19 worldwide pandemic has presented substantial public health challenges. 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. The Company continues to experience some disruption due to the global supply chain caused by COVID-19. As a result of COVID-19, the Company has also experienced disruption due staffing shortages within the service and healthcare industries and negative impacts on the demand for our products and services. For example, some customers are managing inventory and capital more conservatively and our suppliers continue to ask for pre-delivery deposits. The Company is monitoring and taking actions to mitigate potential risks of these shortages and delays which may impact the Company's ability to obtain new contracts, the fulfillment of product demand and to meet its contract obligations. The extent to which COVID-19 may impact the Company's financial condition and results of operations remains uncertain and is dependent on numerous evolving factors, including the measures being taken by authorities to mitigate against the spread of COVID-19, the emergence of new variants and the effectiveness of vaccines and therapeutics. The continuation or re-implementation of these measures remains uncertain. 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: Raymond F. Vennare, our Chief Executive Officer ("CEO"), Bob Myers, our Chief Financial Officer ("CFO"), and Pamela Bush, or Chief Business Officer ("CBO"). We have entered into employment agreements with the CEO, CFO and CBO, and we may expand our 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.

We may fail to realize the anticipated benefits of the zPREDICTA acquisition.

The success of our November 2021 acquisition of zPREDICTA will depend, in part, on our ability to realize growth opportunities and synergies from combining our companies, Predictive Oncology and zPREDICTA. The integration will be a time consuming and expensive process and may disrupt our operations if it is not completed in a timely and efficient manner. In addition, we may not achieve anticipated synergies or other benefits of the acquisition. Following the acquisition, we operate as a combined organization utilizing common information and communication systems, operating procedures, financial controls, and human resources practices. We may encounter the following integration difficulties, resulting in costs and delays:

- failure to successfully manage relationships with customers and other important relationships;
- failure of customers to continue using our services;
- difficulties in successfully integrating our management teams and employees;
- challenges encountered in managing larger operations;
- failure to manage our growth and growth strategies;
- diversion of the attention of management from other ongoing business concerns;
- incompatibility of technologies and systems; and
- incompatibility of business cultures.

If our combined operations do not meet the expectations of our existing or prospective customers, then these customers and prospective customers may cease doing business with us altogether, which would harm our results of operations, financial condition, business prospects reputation. If our management team is not able to develop strategies and implement a business plan that successfully addresses these difficulties, we may not realize the anticipated benefits of the acquisition.

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.

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.

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.

Our common stock could be delisted from The NASDAQ Capital Market, which delisting could hinder your ability to obtain accurate quotations on the price of our common stock or dispose of our common stock in the secondary market.

On May 13, 2022, we received a letter from the Listing Qualifications Department (the "Staff") of The NASDAQ Stock Market LLC ("NASDAQ") informing the Company that because the closing bid price for the Company's common stock listed on NASDAQ was below $1.00 for 30 consecutive trading days, the Company does not comply with the minimum closing bid price requirement for continued listing on The NASDAQ Capital Market under NASDAQ Marketplace Rule 5550(a)(2), requiring a minimum bid price of $1.00 per share (the "Minimum Bid Price Requirement"). The letter stated that we had 180 days, or until November 9, 2022, to regain compliance by maintaining a closing bid price of at least $1.00 for a minimum of 10 consecutive trading days.

On November 10, 2022, Nasdaq notified us that while the Company had not regained compliance with the Minimum Bid Price Requirement, it was eligible for an additional 180-day calendar period, or until May 8, 2023, to regain compliance. Nasdaq's determination was based on our meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on The Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and our written notice to Nasdaq of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If at any time before May 8, 2023 the bid price of the Company's common stock closes at or above $1.00 per share for a minimum of 10 consecutive business days, NASDAQ will provide written notification that the Company has achieved compliance with the Minimum Bid Price Requirement.

If we do not regain compliance with the Minimum Bid Price Requirement by May 8, 2023, the Staff will provide written notification to us that our common stock will be subject to delisting. In the event of such notification, we may appeal the Staff's determination to delist our securities, but there can be no assurance the Staff would grant our request for continued listing.

The Company intends to continue actively monitoring the bid price for its common stock between now and May 8, 2023 and will consider available options to resolve the deficiency and regain compliance with the Minimum Bid Price Requirement, including effectuating a reverse stock split.

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

If, in an attempt to resolve our listing standards deficiency and regain compliance with Nasdaq's Minimum Bid Price Requirement, we elect to pursue and conduct a reverse stock split, the impact of the reverse stock split on the future market price of our common stock and our ability to maintain the listing of our common stock on Nasdaq will be uncertain.

If we elect to pursue and conduct a reverse stock split in an attempt to resolve our listing standards deficiency and regain compliance with Nasdaq's Minimum Bid Price Requirement, we cannot assure stockholders that the proposed reverse stock split will sufficiently increase our stock price or be completed before Nasdaq commences delisting procedures. The effect of a reverse stock split on our stock price cannot be predicted with any certainty, and the history of reverse stock splits for other companies, including those in our industry, is varied, particularly since some investors may view a reverse stock split negatively. It is possible that our stock price after a reverse stock split will not increase in the same proportion as the reduction in the number of shares outstanding, causing a reduction in our overall market capitalization. Further, even if we implement a reverse stock split, our stock price may decline due to various factors, including our future performance and general industry, market and economic conditions. This percentage decline, as an absolute number and as a percentage of our overall market capitalization, may be greater than would occur in the absence of a reverse stock split. If we continue to fail to meet Nasdaq's listing requirements, Nasdaq may suspend trading and commence delisting proceedings.

In addition, a reverse stock split may decrease the liquidity of our common stock and result in higher transaction costs. The liquidity of our common stock may be negatively impacted by the reduced number of shares outstanding after a reverse stock split, which would be exacerbated if the stock price does not increase following the reverse stock split. In addition, a reverse stock split would increase the number of stockholders owning "odd lots" of fewer than 100 shares, trading in which generally results in higher transaction costs. Accordingly, a reverse stock split may not achieve the desired results of increasing marketability and liquidity.

The implementation of a reverse stock split would not have an effect on the actual or intrinsic value of our business or a stockholder's proportional ownership interest (subject to the treatment of fractional shares). However, should the overall value of our common stock decline after a reverse stock split, then the actual or intrinsic value of shares held by stockholders will also proportionately decrease as a result of the overall decline in value.

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 cash 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, 2,300,000 shares have been designated as series B convertible preferred stock, of which 79,246 shares are outstanding. 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. Based on prior equity transactions, the Company believes it has experienced multiple ownership changes including in 2021 as defined by Section 382 of the Code. We have not assessed the potential impact of Sections 382 and 383 for 2021 or other years.

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.

The exercise of outstanding warrants, and issuance of equity awards may have a dilutive effect on our stock, and negatively impact the price of our common stock.

As of December 31, 2022, we had 36,328,731 warrants outstanding at a weighted average exercise price of $7.31 per share. We are able to grant stock options, restricted stock, restricted stock units, stock appreciation rights, bonus stock, and performance awards under our 2012 Equity Incentive Plan. Under the 2012 Stock Incentive Plan, 1,064.393 shares were issuable under outstanding incentive awards at December 31, 2022, and 2,894,413 shares remained available for issuance pursuant to future incentive grants. The exercise of outstanding warrants, and issuance of equity awards may have a dilutive effect on our stock, and negatively impact the price of our common stock

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. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. 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. Additionally, in connection with the COVID-19 pandemic, many of our employees have the ability to work remotely, which may increase the risk of security breaches, loss of data, and other disruptions as a consequence of more employees accessing sensitive and critical information from remote locations.

If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures in connection with security incidents, we may suffer loss of reputation, financial loss, and civil or criminal fines or other penalties. In addition, these breaches and other forms of inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

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 that ended January 31, 2022, and as of December 10, 2021 has a second amended six-month term until July 31, 2022. Management and the landlord have verbally agreed to further extensions as needed.

The offices of our Helomics subsidiary are located in Pittsburgh, Pennsylvania. We lease 20,835 square feet at this location, of which approximately 4,418 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. We entered into two new leases with the primary lease effective March 1, 2023, both of which have an approximate five-year term ending February 28, 2028.

Soluble Biotech’s offices are located in Birmingham, Alabama. We lease approximately 5,274 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 14, 2023, there were approximately 154 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 this Item 5 regarding securities authorized for issuance under equity compensation plans 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:

- Our history of operating losses;
- Current negative operating cash flows;
- Our capital needs to accomplish our goals, and the adequacy of available funds, including our ability to access the capital markets, our ability to obtain additional equity funding from current or new stockholders to fund our business operations and/or future growth plans, and the dilutive effect that raising equity capital would have on the relative equity ownership of our existing investor
- Risks related to prior and future acquisitions, including the possibility of impairment of goodwill acquired 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;
- Risk that our business and operations will continue to be materially and adversely affected by the COVID-19 pandemic, which 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; and
- Other specific risks that may be alluded to in this report.

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

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

Overview

Predictive Oncology is a knowledge-driven company focused on applying AI to support the development of optimal cancer therapies, which can ultimately lead to more effective treatments and improved patient outcomes. Through AI, Predictive Oncology uses a biobank of 150,000+ cancer tumor samples, categorized by patient type, against drug compounds to help the drug discovery process and increase the probability of success. The company offers a suite of solutions for oncology drug development from early discovery to clinical trials.

We operate in four primary business areas: first, the application of AI for optimized, high-confidence drug-response predictions within a large experimental space that enables a more informed selection of drug/tumor combinations to increase the probability of success during development; second, creation and development of tumor-specific 3D cell culture models driving accurate prediction of drug response with high correlation to clinical response; third, contract services and research focused on solubility improvements, stability studies, and protein production, and; fourth, production of the FDA-cleared STREAMWAY System for automated, direct-to-drain medical fluid disposal and associated products.

We have four reportable segments: Helomics, zPREDICTA, Soluble and Skyline. The Helomics segment provides services that include the application of AI, collaboration projects and clinical testing. Our zPREDICTA segment specializes in organ-specific disease models that provide 3D reconstruction of human tissues more accurately representing each disease state and mimicking drug response enabling accurate testing of anticancer agents. 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. Going forward, we have determined that we will focus our resources on applying AI to support the development of optimal cancer therapies, partnering with biopharma clients to help prioritize drugs for development and identify biomarker-informed indications. Our platform provides a more informed decision tool to select optimal drug/tumor combinations to increase the probability of success during drug development. As a result of this focused approach, we have consolidated our brand under Predictive Oncology name. Going forward, we will operate under the Predictive Oncology tradename with laboratory operations in Pittsburgh, Pennsylvania and Birmingham, Alabama.

Capital Requirements

Since inception, we have been unprofitable. We incurred net losses of $25,737,634 and $19,657,174 for the years ended December 31, 2022, and December 31, 2021, respectively. As of December 31, 2022, and December 31, 2021, we had an accumulated deficit of $153,777,916 and $128,040,282, 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, the purchase of the assets of two businesses in 2020 and the acquisition of zPREDICTA in November 2021, each of which have accelerated our capital needs. 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 and zPREDICTA segments; 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 suite of solutions for oncology drug development, 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, 2022 with Year Ended December 31, 2021

	2022	2021	Difference
Revenue	$ 1,505,459	$ 1,420,680	$ 84,779
Cost of sales	505,107	487,024	(18,083)
General and administrative expense	11,110,735	10,932,125	(178,610)
Operations expense	3,798,425	2,698,565	(1,099,860)
Sales and marketing expense	1,358,907	774,530	(584,377)

Revenue. We recorded revenue of $1,505,459 in 2022, compared to $1,420,680 in 2021. Our Skyline division was responsible for the majority of the revenue, with zPREDICTA generating $352,379 and Soluble generating $82,301 in revenue in the year ended December 31, 2022. During the year ended December 31, 2021, revenue of $1,420,680 was primarily generated at Skyline Medical with Soluble generating $233,293. We sold 7 STREAMWAY System units in 2022 and 15 STREAMWAY System units in 2021.

Cost of sales. Cost of sales was $505,107 and $487,024 in 2022 and 2021, respectively. The increase in cost of sales is primarily due to increased cost of disposables and costs associated with our repair and maintenance contracts. The gross profit margin was 66% in each of the years ended December 31, 2022 and 2021, respectively.

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 $178,610 to $11,110,735 in 2022 from $10,932,125 in 2021. The increase was primarily due to increases in staff related expenses of approximately $354,000. Additional increases included higher costs for expenses for office space of approximately $162,000, expenses related to the assessment and risk mitigation efforts related to our cyber security and other minor operating expenses. These increases were offset by approximately $627,000 lower costs for professional fees including consultants supporting our quality assurance efforts, investor relations and lower legal expenses.

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 increased by $1,099,860 to $3,798,425 in 2022 compared to $2,698,565 in 2021. The increase in operations expense in 2022 was primarily due to approximately $760,000 higher payroll costs and higher costs associated with a full year of the expenses associated with the zPREDICTA subsidiary as well as approximately $142,000 higher costs related to laboratory expenses and approximately $184,000 increased headcount at our Helomics division.

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 increased by $584,377 to $1,358,907 in 2022 compared to $774,530 in 2021. The increase in 2022 was primarily due to $578,000 in expenses related to the addition of headcount supporting our sales and marketing efforts as well as consulting expenses related to the overall marketing approach for the company.

Loss on goodwill impairment. During the year ended December 31, 2022, we incurred a loss on impairment of goodwill of $7,231,093 relating to the goodwill acquired in our 2021 zPREDICTA acquisition primarily related to the declines in our market capitalization. Our goodwill, for our zPREDICTA operating segment, following the impairment in 2022 was $0 with the cumulative losses on goodwill are $7,231,093. During the year ended December 31, 2021, we incurred a loss on impairment of $2,813,792 relating to the goodwill acquired in our 2019 Helomics acquisition due to changes in our future projected cash flows and declines in our market capitalization. Our goodwill, for the Helomics operating segment, following the impairment in 2021 was $0 with the cumulative losses on goodwill are $23,790,290. See Note 8 to our audited consolidated financial statements included in this annual report.

Loss on intangible asset impairment. We incurred a loss on impairment of intangibles of $3,349,375 during the year ended December 31, 2022. The impairment recorded relates to the intangible assets of our zPREDICTA operating segment and is primarily due to the declines in projected future cash flows for the operating segment. The value of the intangible assets of the zPREDICTA operating segment following the impairment was $0 at December 31, 2022. We incurred a loss on impairment of intangibles of $2,893,548 during the year ended December 31, 2021 primarily related to the declines in projected future cash flows. The impairment recorded relates to the intangible assets of our Helomics operating segment and none of the Company's other operating segments. The value of the intangible assets of the Helomics operating segment following the impairment was $0 at December 31, 2021. See Note 8 to our audited consolidated financial statements included in this annual report.

Loss on impairment of tangible long-lived assets. We incurred a loss on impairment on certain tangible long-lived assets of $185,469 during the year ended December 31, 2022. The impairment was recorded as a result of our annual assessment and primarily due to the decline in projected future cash flows. We completed a fair value assessment which resulted in the impairment and allocated the impairment to the assets of each of the affected asset groups. During the year ended December 31, 2021, we incurred a loss on impairment on acquired software of $1,249,727 due to the decline in future projected cash flows. The impairment recorded relates to the acquired software asset of our Helomics operating segment and none of the Company's other operating segments. The value of the acquired software asset of the Helomics operating segment following the impairment was $0 at December 31, 2021. Please see Note 8 to our audited consolidated financial statements included in this annual report for further information.

Other income. We earned other income of $185,646 in 2022 compared to $184,528 in 2021. Other income included interest income and in the year ended December 31, 2022 gains associated with equipment abandoned in connection with a sublease and losses on asset disposals. The year ended December 31, 2021 included gains on settlement of outstanding payables during 2021.

Other expense. We incurred other expenses of $5,275 in 2022 compared to $239,631 in 2021. Other expenses consisted primarily of interest expense and in addition in the year ended December 31, 2021 we also incurred expenses related to payment penalties and the amortization of original issue discounts.

Gain on derivative instruments. We incurred a gain of $115,647 in 2022 compared to a gain of $164,902 in 2021, primarily related to the changes in fair market value on derivatives.

Income Taxes. We incurred zero income tax expense in 2022 due to current year losses, compared to a $661,658 income tax benefit in our consolidated statement of net loss in the year ended December 31, 2021 related to the release of the valuation allowance following the zPREDICTA acquisition and zero 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 $12,370,800 in 2022, compared with net cash used of $12,208,929 in 2021. Cash used in operating activities increased in 2022 primarily due to cash operating losses as well as outflows related to payments on accounts payables and payments for inventories and other liabilities.

Cash flows used in investing activities were $475,697 in 2022, and $10,607,536 in 2021. Cash flows used in investing activities in 2022 were primarily for purchases of fixed assets and maintaining intangibles. Cash flows used in investing activities in 2021 were primarily related to the acquisition of our zPREDICTA subsidiary in the amount of $9,590,214 and $910,429 of cash outflows related to purchases of fixed assets.

Net cash provided by financing activities was $6,715,405 in 2022 compared to net cash provided of $50,340,748 in 2021. Cash flows provided by financing activities in 2022 were primarily due from proceeds from the issuance of common stock and warrants in May 2022. Cash flows provided by financing activities in 2021 were primarily due from proceeds from the issuance of common stock and warrants of $50,523,527 in several equity offerings and proceeds from the exercise of warrants into common stock of $4,513,871, offset by repayment of debt and payment penalties of $5,236,214.

Liquidity and Plan of Financing

Since our inception, we have incurred significant losses, and our accumulated deficit was $153,777,916 as of December 31, 2022. We have committed significant capital and management resources to develop our AI business and other new business areas and intend to continue to devote significant resources to the Helomics and zPREDICTA business and other new business in this market. Our business 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 2023. We had revenues of $1,505,459 and $1,420,680 in 2022 and 2021, respectively, but we had negative operating cash flows of $12,370,800 and $12,208,929 in 2022 and 2021, respectively. Our cash balance was $22,071,523 as of December 31, 2022, and our accounts payable and accrued expenses were an aggregate $3,172,527. See "Financing Transactions" below.

We believe that our existing capital resources will be sufficient to support our operating plan for the next twelve months and beyond from the date of this Annual Report on Form 10-K. 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

On December 31, 2022, we had $22,071,523 in cash and cash equivalents. Cash and cash equivalents decreased by $6,131,092 from the prior year due to the factors described in the "Cash Flow Summary" above. Our primary source of liquidity, other than our holdings of cash and cash equivalents, has been cash flows from issuances of debt and equity securities. Our operations from inception have been funded with private placements of convertible debt securities and equity securities, public offerings, and loan agreements. Since late 2020, these financing transactions have consisted of a number of public offerings, registered direct offerings and private placements, including an equity line arrangement.

May 2022 Offerings

On May 16, 2022, the Company, issued and sold to several institutional and accredited investors pursuant in a registered direct offering (the "First Offering") an aggregate of 3,837,280 shares of its common stock, at a purchase price of $0.60 per share. Pursuant to the securities purchase agreement, in a concurrent private placement, the Company also issued to these purchasers unregistered warrants to purchase up to an aggregate of 3,837,280 shares of common stock (the "Warrants"). The Warrants have an exercise price equal to $0.70 per share, became exercisable six months from the date of issuance, and will expire five and one-half years from the date of issuance.

In addition, in a concurrent registered direct offering (the "Second Offering"), on May 16, 2022, the Company entered into a securities purchase agreement with several institutional and accredited investors pursuant to which the Company issued and sold to several institutional and accredited investors pursuant an aggregate of 8,162,720 shares of its common stock, at a purchase price of $0.60 per share. The Company also entered into a warrant amendment agreement (the "Warrant Amendment") with each of the purchasers in the Second Offering. Under the Warrant Amendment, certain existing warrants to purchase up to 16,325,435 shares of common stock that were previously issued in 2020 and 2021 to those purchasers, with exercise prices ranging from $1.00 to $2.00 per share (the "Existing Warrants"), were amended to: (i) lower the exercise price of the Existing Warrants to $0.70 per share, (ii) provide that the Existing Warrants, as amended, would not be exercisable until six months following the closing date of the Second Offering, and (iii) extend the original expiration date of the Existing Warrants until five and one-half years following the close of the Second Offering.

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 provided the placement agent expense allowance of $65,000 for non-accountable and other 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, or $0.75 per share, with a term of five years (the "Agent Warrants"). The Agent Warrants became exercisable six months after issuance.

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 June 2021, the Company completed a registered direct offering of common stock and warrants. The warrants became exercisable on the effective date of an increase in the number of shares of the Company's authorized common stock, which occurred on August 17, 2021, and expire three years after the initial exercise date. 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 (three years for the June 2021 offering) or five and one-half years for the private placement.

These 2021 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)	3,650,840	$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
June 16, 2021 (registered direct)	15,520,911	$1.375	15,520,911	$1.25	1,164,068	$1.71875	$21,341,252	$19,446,296
Total	38,057,775		26,786,843		2,853,958		$55,737,571	$50,523,528

***** Sale price includes one share and a warrant to purchase one-half share (or one whole share in the case of the June 16, 2021 offering).

Secured Notes and Repayment in Full

On March 1, 2021, the Company used $5,906,802 of the proceeds of the private placement on February 23, 2021, described above under "2021 Offerings", to repay in full the outstanding principal and interest and applicable premium amounts under the convertible secured promissory notes to two private investors in the original principal amount of an aggregate $2,297,727 issued in September 2018, the secured promissory note with a principal amount of $847,500 issued during September 2019 and the secured promissory note with a principal amount of $1,450,000 issued on February 5, 2020.

2021 Warrant Exercises

During the year ended December 31, 2021, the holders of outstanding investor warrants have exercised such warrants for the total purchase of 5,269,059 shares at a weighted average exercise price of $0.86 per share, for total proceeds of $4,513,871.

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 the year ended December 31, 2021, the Company issued 647,504, shares of its common stock valued at $675,590 pursuant to the equity line. During the year ended December 31, 2022, the Company issued 315,000, shares of its common stock valued at $236,009 pursuant to the equity line. As of December 31, 2021, there was $9,113,829 of remaining available balance under the equity line, subject to shareholder approval required for additional purchases, as well as requirements for market conditions including trading volume and stock price, and subject to other limitations. In connection with the May 2022 offerings, the Company agreed not to access the remaining balance for a period of one year after the May 18, 2023 closing date. The equity line expired on October 23, 2022.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our audited consolidated 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 and income taxes.

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 audited consolidated 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 audited consolidated 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. Clinic diagnostic testing is comprised of our Tumor Drug Response Testing (ChemoFx) and Genomic Profiling (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 and/or status 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. Payment 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 Accounting Standards Codification ("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. Revenues are 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 contract liabilities until such time as the revenue recognition criteria have been met. Payment terms are generally 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 service-based equity-classified awards over their requisite service period and adjust for forfeitures as they occur. We also have certain awards which vest upon a combination of the satisfaction of service-based and performance-based conditions. The performance-based conditions generally are satisfied upon achieving specified performance targets, such as our financial or operating metrics, and/or market performance of our common stock.

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. In the case of options to employees, we estimated the life to be the legal term.

For performance-based awards, we generally recognize expense over the requisite service period unless there was a compelling reason to make it shorter and when performance-based conditions are considered probable to be satisfied. For market-based awards, we determine the grant-date fair value utilizing a Monte Carlo valuation model, which incorporates various assumptions including expected stock price volatility, expected term and risk-free interest rates.

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 have 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.

Business Combination. We accounted for the zPREDICTA 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 acquisition date. 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 intangible asset and is not amortized.

Goodwill is not amortized but is tested on an annual basis for impairment at the reporting unit level as of December 31, 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 completes 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. See *Note 8 – Intangible Assets and Goodwill* in our audited consolidated financial statements included in this annual report.

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. The cumulative losses on goodwill are $23,790,290 as of December 31, 2021. See *Note 8 – Intangible Assets and Goodwill* in our audited consolidated financial statements included in this annual report.

On November 24, 2021, the Company recorded goodwill of $7,231,093 in connection with the acquisition of zPREDICTA. During the year ended December 31, 2022, the Company determined the value of the goodwill associated with the zPREDICTA reporting unit was fully impaired and recorded a loss on impairment. The cumulative losses on goodwill are $7,231,093 as of December 31, 2022. See *Note 8 – Intangible Assets and Goodwill* to our audited consolidated financial statements included in this annual report.

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.

The Company evaluated its long-lived assets based on a triggering event per ASC 360 as of December 31, 2022. The Company concluded that the carrying values of certain of its the long-lived assets within the zPREDICTA, Soluble and enterprise asset groups as of December 31, 2022 could not be supported. The Company determined the value of the intangible assets were impaired as of December 31, 2022 and recognized an impairment loss on its long-lived intangible assets of $3,349,375 and $185,469 impairment loss related to its long-lived tangible assets. See Note 8 – Intangible Assets and Goodwill.

The Company prepared an undiscounted cash flow as of December 31, 2021 to evaluate long-lived assets based on a triggering event per ASC 360. The Company concluded that the undiscounted cash flows did not support the carrying values of its the long-lived assets within the Helomics asset group as of December 31, 2021. The Company determined the value of the intangibles and the software license acquired were fully impaired as of December 31, 2021 and recognized an impairment loss on its long-lived intangible assets of $2,893,548 and $1,249,727 impairment loss related to the acquired software. See *Note 8 – Intangible Assets and Goodwill* in our audited consolidated financial statements included in this annual report.

I**ncome 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 Consolidated 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, 2022. 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, 2022 due to the material weakness in internal control over financial reporting 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, 2022 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, 2022.

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 complex technical accounting transactions. Management has determined that this represents a material weakness in our internal control over financial reporting. Notwithstanding the material weakness in our internal control over financial reporting, we have concluded that the consolidated financial statements and other financial information included in our annual and quarterly filings fairly present in all material respects our financial condition, results of operations and cash flows as of, and for, the periods presented.

Material Weakness Remediation Activities. To remediate the material weakness in our internal control over financial reporting described above, we have reevaluated our overall staffing levels within the accounting department and have determined we need to hire additional resources with qualifications that include a high level of experience with complex technical accounting transactions and application of U.S. GAAP. Once these processes have been in operation for a sufficient period of time for our management to conclude that the material weakness has been fully remediated and our internal controls over financial reporting are effective, we will consider this material weakness fully addressed.

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, 2022 that has materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

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 a plurality 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 for a term that coincides with the term of the class to which such director shall have been elected. See "Classified Board of Directors" below.

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 the individuals who serve as our executive officers and directors as of March 14, 2023:

Name		Age	Position Held
Raymond F. Vennare	(1) (6)	70	Chief Executive Officer and Chairman of the Board of Directors
Bob Myers		68	Chief Financial Officer
Pamela Bush	(2)	49	Chief Business Officer
Chuck Nuzum	(3) (4) (5) (6) (7)	74	Director
Daniel E. Handley, Ph.D.	(5)	63	Director
Gregory S. St. Clair	(3) (4)	57	Director
Nancy Chung-Welch, Ph.D.	(3) (4) (6) (7)	62	Director
David S. Smith	(5) (6) (8)	67	Director
Matthew J. Hawryluk	(9)	45	Director

(1) Raymond F. Vennare was appointed Chief Executive Officer on November 1, 2022. Mr. Vennare resigned from the Nominating and Governance Committee concurrently with his appointment as CEO.
(2) Pamela Bush was appointed Chief Business Office on January 30, 2023.
(3) Member of the Audit Committee
(4) Member of the Compensation Committee
(5) Member of the Nominating and Governance Committee
(6) Member of the Merger & Acquisition Committee
(7) Member of the Finance Committee
(8) Mr. Smith was appointed effective October 19, 2022
(9) Dr. Hawryluk was appointed effective November 29, 2022

Our directors 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 directors into three classes, with the term of each class expiring in different years. The term of our Class I directors expires in 2025, the term of our Class II directors expires in 2023, and the term of our Class III directors expires in 2024. 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 2025)	CLASS II (term expiring in 2023)	CLASS III (term expiring in 2024)
Chuck Nuzum	Matthew J. Hawryluk	David S. Smith
Daniel E. Handley	Nancy Chung-Welch	Raymond F. Vennare
	Gregory S. St. Clair	

Business Experience

Raymond F. Vennare. was appointed to the Board effective November 1, 2022. Mr. Vennare brings more than thirty years of experience to his work as an accomplished senior executive, board director and biotechnology entrepreneur. As a professional who has built and managed companies on behalf of institutional investors, private foundations and research institutions, he is recognized as an expert in the practice of company creation, technology commercialization, business development and corporate governance. Mr. Vennare is currently (and has been since 2015), Chairman of the Board and CEO of Cvergenx, Inc., (Mr. Vennare resigned as CEO of Cvergenx upon beginning his position as CEO and Chairman of the Board for Predictive Oncology Inc.) a genomic informatics company developing decision-support tools for radiation oncology, and since 2019 has been on the Board of Directors of Cvergenx Technologies India Private, Ltd. He also serves as a trusted and confidential advisor to clients as diverse as nationally ranked universities and philanthropic foundations to multi-national publicly traded companies and early-stage start-ups. Previously Mr. Vennare was Co-founder, President and CEO of ThermalTherapeutic Systems, Inc. (Medical Device); President and Chief Executive Officer of ImmunoSite, Inc. (Diagnostics); Senior Vice President and Chief Information Officer, TissueInformatics, Inc. (Bioinformatics); Founder, President and Partner in VSInteractive (Information Technology) and, Founder and President of the Fine Art Inventory Network (On-line Commerce). From June 2018 to December 2020, he was Vice Chairman of Guangzhou INDA Biotechnology Company, Ltd. Mr. Vennare has a Master's Degree in Business and Ethics from Duquesne University, a Master's Degree in Art History and Museum Studies from Case Western Reserve University and a Bachelor's Degree from the University of Pittsburgh.

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.

Pamela Bush, Chief Business Officer. Dr. Bush was appointed as our Chief Business Officer on January 30, 2023. Dr. Bush has served as the Company's Senior Vice President of Strategic Sales and Business Development since December 2021. Before joining the Company, Dr. Bush worked at Eli Lilly & Company from September 2009 until June 2016, and again from January 2019 until November 2021. While at Eli Lilly & Company, Dr. Bush served in various roles including Corporate Business Development, Finance and Patient Services. She served as the Director of Immunology at Lilly Patient Services, Eli Lilly & Company, primarily focusing on managing vendor performance and relationships, as well as negotiating contracts and finding workflow efficiencies. Before that, Dr. Bush served as Director of Corporate Business Development at Eli Lilly & Company. Between June 2016 and January 2019, Dr. Bush founded BluGene Consulting, a consultancy supporting emerging life science companies that focused on new client acquisition and private investor fundraising, where she served as managing partner. Pamela Bush earned her Ph.D. in Molecular Biology from Carnegie Mellon University (CMU) and MBA from CMU's Tepper School of Business.

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 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 Huntington, Pennsylvania.

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.

David S. Smith, JD. Mr. Smith was appointed to the Board on October 19, 2022 and was appointed to the Board as a Class III director. Mr. Smith was appointed to fill the vacancy created by the resignation of Christina Jenkins, M.D. in August 2022. Mr. Smith is a life sciences and corporate attorney, veteran biotech industry executive and leading authority on the legal issues surrounding the therapeutic use of human tissue and cells. Mr. Smith has extensive transactional experience, including venture financings and regulatory matters for life sciences companies and investors. Mr. Smith frequently speaks on matters related to the commercial development of tissue, cell and stem cell technologies, and has authored extensively on topics such as human tissue therapies and tissue engineering research. Mr. Smith currently serves on the Board of Directors of Foundation for Cell and Gene Medicine and is a Fellow and past member of the executive committee of Tissue Engineering and Regenerative Medicine International Society. Mr. Smith was previously a member of the Board of Directors of the Pennsylvania Biotechnology Association and past officer of the Pittsburgh Tissue Engineering Initiative.

Matthew J. Hawryluk, Ph.D. Dr. Hawryluk was appointed to the Board on November 29, 2022 to fill the vacancy created by J. Melville Engle's retirement in October 2022. Dr. Hawryluk was appointed to the Board as a Class II director. Dr. Hawryluk has served as Executive Vice President and Chief Business Officer of Gritstone bio, Inc. since November 2015. Since March 2020, Dr. Hawryluk has served as an Advisory Board Member of PathAI, Inc. Prior to Gritstone, from April 2011 to October 2015, Dr. Hawryluk held positions of increasing responsibility at Foundation Medicine, Inc., then a public molecular diagnostics company (subsequently acquired by Roche), most recently serving as Vice President, Corporate and Business Development. Previously, he held roles in business development, marketing, and product management across multiple divisions of Thermo Fisher Scientific, Inc. Dr. Hawryluk received a B.S. from the University of Notre Dame, a Ph.D. in cell biology and protein biochemistry from the University of Pittsburgh School of Medicine and an M.B.A. at Carnegie Mellon University's Tepper School of Business as a Swartz Entrepreneurial Fellow.

Board Committee Structures

The Board of Directors has determined that each current member of the Audit Committee, the Compensation Committee and the Nominating and Governance Committee meets the applicable SEC and NASDAQ rules and regulations regarding "independence" and that each member is free of any relationship that would impair their individual exercise of independent judgment with regard to us.

Below is a description of each committee of the Board of Directors as such committees are presently constituted.

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.

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 Dr. Chung-Welch. 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 within the meaning of NASDAQ's listing standards. The Audit Committee met eight times in fiscal 2022.

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 Dr. Chung-Welch 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. Nuzum, as the chairperson, Dr. Chung-Welch and Mr. St. Clair. The 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 2022, 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

During the year ended December 31, 2022, Mr. Nuzum, as the chairperson, Dr. Chung-Welch and Mr. St. Clair served as members of the Compensation Committee. No member of the Compensation Committee who served during the year ended December 31, 2022 has ever been an executive officer or employee of ours or had a relationship requiring disclosure under Item 404 of Regulation S-K promulgated under the Securities Exchange Act of 1934, as amended. 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.

Nominating and Governance Committee

The Nominating and Governance Committee of the Board of Directors currently consists of Dr. Handley, as the chairperson, and Messrs. Nuzum and Smith. Mr. Smith joined the Committee subsequent to his Board appointment. All members of the Nominating and Governance Committee 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. In fiscal 2022, the Nominating and Governance Committee met four times.

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 its charter, our Certification of Incorporation, Bylaws and governing law as the Committee or the Board deems appropriate.

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. Smith, as the chairperson, Mr. Nuzum and Dr. Chung-Welch. The Merger & Acquisition Committee advises the Company with respect to any considered mergers, acquisitions, joint ventures and/or consolidations of any type.

Diversity

The Nominating Committee and Governance of the Board of Directors considers and makes recommendations to the Board on all matters pertaining to the effectiveness of the Board, such as the size and composition of the Board; including the recognition of Equal Opportunity (which is the policy of treating Directors and others without discrimination, especially on the basis of their sex, ethnicity, religion, disability, national origin, sexual orientation or identification, veteran status, race or age).

Delinquent Section 16(a) Reports

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. Based solely on review of the copies of Forms 3 and 4 and amendments thereto filed with the SEC during the fiscal year ended December 31, 2022 and Forms 5 and amendments thereto filed with the SEC 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, 2022: Mr. Vennare late reporting covering 1 transaction, Dr. Chung-Welch late reporting covering 1 transaction and Dr. Jenkins late reporting covering 1 transaction.

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 (i) each individual who served as our principal executive officer during 2022, (ii) our two most highly compensated other executive officers who were serving as executive officers at the end of 2022 and who received more than $100,000 in the form of salary and bonus during such year, and (iii) up to two additional individuals for whom disclosure would have been provided pursuant to (ii) above but for the fact that the individual was not serving as an executive officer at the end of 2022. We refer to these individuals as our "Named Executive Officers." Our named executive officers are:

- Raymond F. Vennare, Chief Executive Officer;
- Bob Myers, Chief Financial Officer; and
- J. Melville Engle, former Chief Executive Officer

We did not have any other executive officers, as determined in accordance with SEC rules, during 2022.

Summary Compensation Table for Fiscal 2022 and 2021

The following table provides information regarding the compensation awarded to or earned by each of the Named Executive Officers during the fiscal years ended December 31, 2022 and December 31, 2021:

Name and Principal Position	Year	Salary	Bonus	(1) Stock Awards	(1) Option Awards	All Other Compensation	Total Compensation
Raymond F. Vennare	2022	$ 87,500(2)	$ 34,125(3)	$ -	$ -	$ -	$ 121,625
Bob Myers, CFO (3)	2022	$ 374,900	$ 110,430(4)	$ -	$ -	$ 26,538	$ 511,868
	2021	$ 371,965	$ 106,950(6)	$ 28,190(7)	$ -	$ -	$ 507,105
J. Melville Engle (8)	2022	$ 406,917	$ 139,000	$ -	$ -	$ 630,780(8)	$ 1,176,697(10)
	2021	$ 391,342	$ 191,760(11)	$ 57,838(9)	$ -	$ -	$ 640,940

(1) These amounts have been calculated in accordance with FASB ASC Topic 718. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. For a discussion of the assumptions relating to our valuations of these stock awards and stock options, please see Notes 1 and 4 to the financial statements included in this Annual Report on Form 10-K. These amounts reflect our accounting expense for these stock awards and stock options and do not correspond to the actual value that may be recognized by the Named Executive Officer.

(2) Effective November 1, 2022 Mr. Vennare was named Chief Executive Officer. Mr. Vennare received an annual salary of $525,000.

(3) Reflects a bonus for performance in 2022 that was paid to Mr. Vennare on March 15, 2023.

(4) Reflects a bonus for performance in 2022 that was paid to Mr. Myers in 2023.

(6) Reflects a bonus for performance in 2021 that was paid to Mr. Myers in 2022.

(7) Reflects the grant date fair value of restricted stock units (RSUs) granted on May 17, 2021.The RSUs comprise a Long-Term Incentive Program ("LTIP") structured to reward performance. See "Long Term Incentive Plan for Executive Officers" below.

(8) On March 19, 2021 Mr. Engle was named Chief Executive Officer. Mr. Engle received an annual salary of $475,000. Mr. Engle retired for the Company effective October 31, 2022. Mr. Engle received a retirement package for $524,400 in base salary, unused accrued vacation for $67,567 and the vesting of all RSU's equaling 300,000 shares of POAI common stock, par value $0.01.

(9) Reflects the grant date fair value of restricted stock units (RSUs) granted on May 17, 2021.The RSUs comprise a Long-Term Incentive Program ("LTIP") structured to reward performance. See "Long Term Incentive Plan for Executive Officers" below.

(10) Includes severance payments of $109,250 paid to Mr. Engle in 2022 pursuant to a Transition and Separation Agreement dated September 15, 2022 between Mr. Engle and the Company, and the incremental fair value resulting from the acceleration of 300,000 restricted stock units pursuant to the Transition and Separation Agreement, computed as of the modification date in accordance with FASB ASC Topic 718.

(11) Reflects a bonus for performance in 2021 that was paid to Mr. Engle in 2022.

Outstanding Equity Awards at Fiscal Year-end for Fiscal 2022

The following table sets forth certain information regarding outstanding equity awards held by the named executive officers as of December 31, 2022:

	Options					Restricted Stock Units	
	Grant Date	Number of Securities Underlying Options Exercisable	Number of Securities Underlying Options Unexercisable	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
J. Melville Engle	12/31/2016	179		$ 28.00	12/31/2026	—	—
	3/31/2017	238		$ 21.00	3/31/2027	—	—
	6/22/2017	12,500		$ 14.70	6/22/2027	—	—
	6/30/2017	340		$ 14.70	6/30/2027	—	—
	9/30/2017	344		$ 14.54	9/30/2027	—	—
	12/31/2017	2,475		$ 10.10	12/31/2027	—	—
	3/31/2018	455		$ 11.00	3/31/2028	—	—
	6/30/2018	443		$ 11.30	6/30/2028	—	—
	9/30/2018	472		$ 10.60	9/30/2028	—	—
	12/31/2018	4,038		$ 6.19	12/31/2028	—	—
	3/31/2019	667		$ 7.50	3/31/2029	—	—
	4/4/2019	12,500		$ 7.48	4/4/2029	—	—
	6/30/2019	669		$ 7.48	6/30/2029	—	—
	9/30/2019	990		$ 5.05	9/30/2029	—	—
	12/31/2019	13,410		$ 2.61	12/31/2029	—	—
	3/31/2020	3,174		$ 1.58	3/31/2030	—	—
	4/3/2020	15,267		$ 1.31	4/3/2030	—	—
	6/30/2020	3,049		$ 1.64	6/30/2030	—	—
	9/30/2020	6,142		$ 0.81	9/30/2030	—	—
	12/31/2020	47,788		$ 0.73	12/31/2030	—	—
Bob Myers	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	—		—	—	33,334	$ 10,220
	5/17/2021	—		—	—	50,000	$ 15,330

Executive Compensation Components for Fiscal 2022

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 bonus and equity incentive programs.

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. Bonuses 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 incentive compensation in the form of stock options or other equity based incentive award 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. On August 17, 2021, our stockholders approved amendments to the 2012 Plan to increase the share reserve under the 2012 Plan by an aggregate 1,500,000 shares from the most recent reserve of 1,750,000 shares to an aggregate 3,250,000 shares. On December 2, 2022, our stockholders approved amendments to the 2012 Plan to increase the share reserve under the 2012 Plan by an aggregate 2,500,000 shares from the most recent reserve of 1,500,000 shares to an aggregate 5,750,000 shares. As of December 31, 2022, options to purchase 981,060 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 incentive compensation in the form of restricted stock units to our executive officers.

Restricted stock units represent the right to receive shares of our common stock (or, in some cases, the value thereof in cash) upon vesting, with vesting generally being time-based, based on achievement of certain perform metrics, or both.

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.

Long Term Incentive Plan for Executive Officers

On May 17, 2021, the Committee adopted and approved a 2021 Long Term Incentive Plan (the "LTIP") to provide incentives to the Company's executive officers over the critical three-year performance period consisting of fiscal years 2021, 2022 and 2023. Under the LTIP, the Company granted restricted stock units ("RSUs") to the Company's then-current CEO, J. Melville Engle, and its CFO, Bob Myers, pursuant to the 2012 Plan.

The LTIP awards consist of 300,000 RSUs (target) for the CEO and 150,000 RSUs (target) for the CFO granted as of May 17, 2021. Each RSU award consists of three equal tranches, corresponding to the three years in the performance period. These RSUs will vest on January 1, 2024, with the level of vesting of each tranche based on (1) the level of achievement of performance goals for the corresponding fiscal year (see below) and (2) continued employment of the executive through January 1, 2024. For each tranche, the RSUs will vest at the 100% level for performance at the target level; 50% for performance at the threshold level (with no vesting below the threshold level); and 150% for maximum performance (in other words, for maximum performance on both performance components in a fiscal year, the payout for that year would be 150% of the number of RSUs in the corresponding tranche). The level of vesting for each component is prorated between the threshold level and the target level, and between the target level and the maximum level. To the extent vested, the awards will vest on or before March 15, 2024, following the determination of the Company's earnings per share in 2023.

Performance-based vesting of the RSUs in the tranche for each fiscal year (100,000 RSUs (target) per year for the CEO and 50,000 RSUs (target) per year for the CFO) will be based equally on two components of performance:

(1) *Stock Price*. A stock price component is based on the average closing share price of the Company's common stock over the last 20 trading days of the fiscal year, as set forth in the LTIP.

(2) *Earnings (Loss) Per Share*. An earnings component is based on the Company's earnings (loss) per common share for that fiscal year, as set forth in the LTIP.

If the Committee determines that circumstances have changed and modification is required to reflect the original intent of the performance goals, the Committee may in its discretion increase (but not decrease) the number of RSUs that vest for any of the covered years.

To the extent vested, all RSUs awarded under the LTIP will be paid in shares of common stock.

Employment Contracts

Employment Agreement with Former Chief Executive Officer

On April 5, 2021, the Company and J. Melville Engle, former Chief Executive Officer of the Company, entered into an Employment Agreement (the "Agreement") effective as of March 19, 2021, the first date of Mr. Engle's employment. Pursuant to the Agreement, Mr. Engle was entitled to an annual base salary of $475,000. He was also eligible (i) to receive an annual cash bonus equal to up to 50% of his salary, or at the discretion of the Compensation Committee (the "Committee") of the Company's Board of Directors, a higher percentage based on his performance and (ii) to participate in a long-term incentive plan to be adopted and maintained by the Committee. The Agreement provided that Mr. Engle would receive 100,000 restricted shares of Company common stock or restricted stock units for each of the first three calendar years of his employment, vesting over three years and subject to continued employment, with the amount that vests to be based on his performance. Mr. Engle was also eligible to participate in the standard employee benefit plans generally available to executive employees of the Company, and, at the discretion of the Committee, to receive grants of stock options or other equity awards. Any grants of equity awards, including those above, were to be made from the Company's 2012 Plan or successor plans.

Under the Agreement, Mr. Engle's employment by the Company was at-will. If his employment was terminated by the Company without "cause" or if he voluntarily resigned with "good reason" (in each case as defined in the Agreement), then Mr. Engle would have been entitled to receive from the Company payment of his base salary then in effect through his last date of employment, plus accrued, unused vacation pay. In addition, Mr. Engle would have been entitled to (a) severance pay in an amount equal to 12 months of his base salary then in effect, less applicable taxes and withholdings; and (b) a bonus payment on a pro-rata basis through the date of his termination.

The Agreement also contained customary provisions with respect to confidentiality and intellectual property, in addition to ones prohibiting Mr. Engle from soliciting the Company's employees and from engaging in certain activities that are competitive with the Company for a period of 12 months after termination of his employment.

Retirement of Former Chief Executive Officer

On September 15, 2022, Mr. Engle announced that he would retire as the Chief Executive Officer and as a member of the Board of Directors, effective October 31, 2022. To ensure an orderly transition of his responsibilities, the Company and Mr. Engle entered into a Transition and Separation Agreement (the "Transition Agreement") pursuant to which Mr. Engle continued to serve as Chief Executive Officer until October 31, 2022 under the terms of the Agreement, while the Company conducted a search for his replacement. The Transition Agreement provided for certain separation benefits to be paid to Mr. Engle following termination of his employment, subject to Mr. Engle executing and delivering a general release of claims in favor of the Company at such time, including $524,400 (gross) in severance pay, which amount is equal to one year of Mr. Engle's base salary, a pro-rata bonus for 2022 in the amount of $139,000 (gross), and accelerated vesting of 300,000 restricted stock units previously granted to Mr. Engle as part of the Company's 2021 Long-Term Incentive Plan.

Employment Agreement with Current Chief Executive Officer

On October 13, 2022, the Company and Robert F. Vennare, the Company's current Chief Executive Officer, entered into an Employment Agreement (the "Agreement"), effective as of November 1, 2022, the first date of Mr. Vennare's employment. Pursuant to the Agreement, Mr. Vennare is entitled to an annual base salary of $525,000. He will also be eligible (i) to receive an annual cash bonus equal to up to 50% of his salary, or at the discretion of the Compensation Committee (the "Committee") of the Company's Board of Directors, a higher percentage based on his performance (prorated for 2022) and (ii) to participate in a long-term incentive plan to be adopted and maintained by the Committee. Mr. Vennare will also be eligible to participate in the standard employee benefit plans generally available to executive employees of the Company, and, at the discretion of the Committee, to receive grants of stock options or other equity awards. Any grants of equity awards, including those above, will be made from the Company's Amended and Restated 2012 Stock Incentive Plan or successor plans.

Under the Agreement, Mr. Vennare's employment by the Company is at-will. If his employment is terminated by the Company without "cause" or if he voluntarily resigns with "good reason" (in each case as defined in the Agreement), then Mr. Vennare will be entitled to receive from the Company payment of his base salary then in effect through his last date of employment, plus accrued, unused vacation pay. In addition, Mr. Vennare will be entitled to (a) severance pay in an amount equal to 12 months of his base salary then in effect, less applicable taxes and withholdings; and (b) a bonus payment on a pro-rata basis through the date of his termination.

The Agreement also contains customary provisions with respect to confidentiality and intellectual property, in addition to ones prohibiting Mr. Vennare from soliciting the Company's employees and from engaging in certain activities that are competitive with the Company for a period of 12 months after termination of his employment.

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, which agreement was amended on August 20, 2018. Under the agreement the employment of Mr. Myers is at will.

Throughout 2021, Mr. Myers' annual base salary was $345,000. On September 23, 2020, 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. Mr. Myers received an increase in his base salary on March 1, 2022 resulting in an annualized base salary of $380,880. Base salary 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.

On May 17, 2021, Mr. Myers received 150,000 restricted stock units (target) pursuant to the 2021 Long Term Incentive Plan (the "LTIP"). See "Long Term Incentive Plan for Executive Officers" above. 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," in each case as defined in his employment agreement, he shall be entitled to receive severance pay in an amount equal to twelve months of base salary, 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.

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 Plan. However, the stock option agreements awarded to Bob Myers provide that upon the termination of his employment without cause or for good reason, his 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 June 17, 2021 the Board adopted a Director Compensation Program under which the members of the Board of Directors receive quarterly awards of common stock and cash as compensation for their services as directors and annual awards of common stock and cash for services as committee members. These awards were implemented to replace a previous program of quarterly stock option grants to directors. The June 2020 annual common stock award remains in place as described below.

The compensation program pays all of the compensation in the form of stock and cash awards (with the cash component payable in additional shares at the election of the director. The cash component is equal to 28% of the total value of the award (or 38.9% of the share component of the award), intended to pay the tax on the full award.

Each director receives a quarterly award of $8,333 on the last day of the quarter, consisting of (i) shares with a value of $6,000 and (ii) $2,333 in cash (or additional shares).

For each board committee, each director receives an additional annual award of $11,112, consisting of (i) shares with a value of $8,000 and (ii) $3,112 in cash (or additional shares), payable on December 31.

Starting in 2022, director compensation became limited to Non-Employee Directors (directors who are not employees of Predictive Oncology or any subsidiary and who do not receive regular long-term cash compensation as consultants).

Effective as of January 25, 2023, under an Amended and Restated Director Compensation Program, the Lead Independent Director, will also receive an annual award of $11,112, consisting of (i) shares with a value of $8,000 and (ii) $3,112 in cash (or additional shares).

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.

Director Compensation Table for Fiscal 2022

The following table summarizes the compensation paid to each individual who served as a director during the fiscal year ended December 31, 2022:

	Fees Paid or Earned in Cash	Stock Awards (1)	Option Awards	Total
Charles Nuzum Sr.	$ -	$ 140,562(2)	$ -	$ 140,562
Daniel Handley	$ 13,111	$ 60,781(3)	$ -	$ 73,892
Greg St. Clair Sr.	$ 7,778	$ 77,225(4)	$ -	$ 85,003
Nancy Chung-Welch	$ 23,338	$ 95,001(5)	$ -	$ 118,339
David S. Smith	$ 8,557	$ 27,000(6)	$ -	$ 35,557
Matthew J. Hawryluk	$ 2,333	$ 6,000(7)	$ -	$ 8,333
Raymond F. Vennare	$ 22,451	$ 57,002(8)	$ -	$ 79,453
Christina S. Jenkins	$ 13,111	$ 33,002(9)	$ -	$ 46,113
J. Melvin Engle	$ -	$ 19,445(10)	$ -	$ 19,445

(1) Represents the actual compensation cost granted during 2023 as determined pursuant to FASB ASC 718, *Stock Compensation*.
(2) Reflects 120,156 shares of common stock received in 2022 for serving on the Board and 172,150 shares of common stock received on January 3, 2023 and 26,770 common stock received on January 31, 2023 for 2022 service on the Board and the Audit, Compensation, Governance Finance and Merger & Acquisition Committees.
(3) Reflects 75,698 shares of common stock received in 2022 for serving on the Board and 63,422 shares of common stock received on January 3, 2023 for 2022 service on the Board and the Governance Committee.
(4) Reflects 88,702 shares of common stock received in 2022 for serving on the Board and 99,664 shares of common stock received on January 3, 2023 for 2022 service on the Board and the Compensation Committee.
(5) Reflects 107,898 shares of common stock received in 2022 for serving on the Board and 97,848 shares of common stock and $11,669 in cash received on January 3, 2023 for 2022 service on the Board and the Audit, Compensation, Finance and Merger & Acquisition Committees.
(6) Reflects 18,911 shares of common stock received in 2022 for serving on the Board and 90,666 shares of common stock and $8,557 in cash received on January 3, 2023 for 2022 service on the Board and the Compensation and Governance Committees.
(7) Reflects 13,762 shares of common stock received in 2022 for serving on the Board and 19,570 shares of common stock and $2,333 in cash on January 3, 2023 for 2022 service on the Board and the Compensation and Governance Committee.
(8) Reflects 69,218 shares of common stock received in 2022 for serving on the Board and 58,708 shares of common stock and $7,007 in cash on January 3, 2023 for 2022 service on the Board and the Governance Committee.
(9) Dr. Jenkins resigned from the Board effective August 31, 2022. Dr. Jenkins was awarded 52,551 shares of common stock for serving on the Board.
(10) Mr. Engle resigned from the Board effective October 31, 2022. Mr. Engel was awarded 20,428 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, 2022:

	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)	1,064,394	$ 4.58	3,527,530
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.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth as of December 31, 2021 certain information regarding beneficial ownership of our common stock by:

- each person, or group of affiliated persons, who are known by us to beneficially own more than 5% of the outstanding shares of common stock;
- each of our directors
- each of the Named Executive Officers, as identified in this Annual Report on Form 10-K; and
- All of our current 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 79,403,892 shares of our common stock outstanding on March 4, 2023. 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 (1) Owner	**Amount and Nature of Beneficial Ownership**	**Percent of Class**
Officers and Directors		
Raymond Vennare	142,438	0.18%
Bob Myers (2)	118,743	0.15%
Pamela Bush (3)	47,373	0.06%
Chuck Nuzum (4)	619,981	0.78%
Gregory St. Clair (5)	246,834	0.31%
Daniel Handley (6)	216,781	0.27%
Nancy Chung-Welch (7)	270,116	0.34%
David S. Smith	90,666	0.11%
Matthew J. Hawryluk	33,332	0.04%
Other Named Executive Officers		
J. Melville Engle (8)	541,832	0.68%
All directors and executive officers as a group (9 persons)	2,256,109	2.83%

1. Under Rule 13d-3, a beneficial owner of a security includes any person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares: (1) voting power, which includes the power to vote, or to direct the voting of shares; and (2) investment power, which includes the power to dispose or direct the disposition of shares. Certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire the shares (for example, upon exercise of an option) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares outstanding is deemed to include the number of shares beneficially owned by such person (and only such person) by reason of these acquisition rights. As a result, the percentage of outstanding shares of any person as shown in this table does not necessarily reflect the person's actual ownership or voting power with respect to the number of shares of common stock actually outstanding.
2. Includes options to purchase 47,478 shares that are exercisable within 60 days of December 31, 2022.
3. Pamela Bush was appointed Chief Business Officer on January 30, 2023.
4. Includes options to purchase 40,277 shares that are exercisable within 60 days of December 31, 2022.
5 Includes options to purchase 26,623 shares that are exercisable within 60 days of December 31, 2022.
6. Includes options to purchase 32,846 shares that are exercisable within 60 days of December 31, 2022.
7. Includes options to purchase 40,277 shares that are exercisable within 60 days of December 31, 2022.
8. Includes options to purchase 125,139 shares that are exercisable within 60 days of December 31, 2022.

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.

During the year ended December 31, 2022, there were no related party transactions.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

In connection with the audit of the fiscal 2022 and 2021 financial statements, we entered into an engagement agreement with Baker Tilly US, LLP, which sets forth the terms by which they will perform audit services for us.

The following table represents aggregate fees billed to us for the fiscal years ended December 31, 2022 and December 31, 2021, by Baker Tilly US, 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 2022 and 2021 financial statements were attributed to work performed by persons who were not employed full time on a permanent basis by Baker Tilly US, LLP.

	2022	2021
Audit Fees (1)	$ 337,558	$ 396,246
Audit-Related Fees	-	-
Tax Fees (2)	29,875	28,265
All Other Fees (3)	102,250	99,537
	$ 469,683	$ 524,048

(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) 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 2022 and 2021.

(3) Other Fees in 2022 consisted of fees for assessment of the Company's security and compliance activities. Other Fees in 2021 consisted of fees for auditing zPREDICTA for 2020 and 2019, and for reviewing zPREDICTA for the three and nine months ended September 30, 2020 and September 30, 2021 related to the acquisition of zPREDICTA by the Company.

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, PCOAB Firm ID #23 dated March 21, 2023;
- Consolidated Balance Sheets as of December 31, 2022 and December 31, 2021;
- Consolidated Statements of Net Loss for the Years Ended December 31, 2022 and December 31, 2021;
- Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2022 to December 31, 2021;
- Consolidated Statements of Cash Flows for the Years Ended December 31, 2022 and December 31, 2021; 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 21, 2023

Predictive Oncology Inc.

By /s/ Raymond F. Vennare
Raymond F. Vennare
Chief Executive Officer

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

Signatures	Title	
/s/ Raymond F. Vennare Raymond F. Vennare	Chief Executive Officer (Principal executive officer)	March 21, 2023
/s/ Bob Myers Bob Myers	Chief Financial Officer (Principal financial and accounting officer)	March 21, 2023
/s/ Chuck Nuzum Chuck Nuzum	Director	March 21, 2023
/s/ Daniel E. Handley Daniel E. Handley	Director	March 21, 2023
/s/ Gregory St. Clair Sr. Gregory St. Clair Sr.	Director	March 21, 2023
/s/ Nancy Chung-Welch Nancy Chung-Welch	Director	March 21, 2023
/s/ David S. Smith David S. Smith	Director	March 21, 2023
/s/ Matthew Hawryluk Matthew Hawryluk	Director	March 21, 2023

EXHIBIT INDEX
PREDICTIVE ONCOLOGY INC.
FORM 10-K

Exhibit Number	Description
2.1	Agreement and Plan of Merger dated November 24, 2021 by and among the Company, Golden Gate Acquisition, Inc., zPREDICTA, Inc. and Tom Kelly, as Representative (Filed on December 1, 2021 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference).
3.1	Certificate of Incorporation (Filed on December 19, 2013 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference).
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. (Filed on October 24, 2014 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference)
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. (Filed on June 30, 2015 as an appendix to our Information Statement on Schedule 14C, and incorporated herein by reference).
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. (Filed on September 16, 2016 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference).
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. (Filed on October 27, 2016 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference).
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. (Filed on January 27, 2017 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference).

Exhibit Number	Description
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. (Filed on January 2, 2018 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference).
3.8	Certificate of Amendment to Certificate of Incorporation to effect name change, filed with the Delaware Secretary of State on February 1, 2018. (Filed on February 6, 2018 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference).
3.9	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock. (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.
3.10	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock. (Filed on November 29, 2017 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference).
3.11	Certificate of Amendment to Certificate of Incorporation dated March 22, 2019. (Filed on March 22, 2019 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference).
3.12	Certificate of Designation Of Preferences, Rights And Limitations of Series D Convertible Preferred Stock. (Filed on April 1, 2020 as an exhibit to our Annual Report on Form 10-K, and incorporated herein by reference).
3.13	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock Effective June 13, 2019. (Filed on June 19, 2019 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference).
3.14	Certificate of Amendment of Certificate of Incorporation, changing name from Precision Therapeutics Inc. to Predictive Oncology Inc. (Filed on June 13, 2019 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference).
3.15	Certificate of Amendment of Certificate of Incorporation, amending number of shares of common stock and preferred stock, effecting a reverse stock split. (Filed on October 28, 2019 as an exhibit to our Current Report on Form 8-K).

Exhibit Number	Description
3.16	Certificate of Amendment to the Certificate of Incorporation, doubling number of shares of common stock and preferred stock due to stock split. (Filed on August 19, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
3.17	Second Amended and Restated Bylaws of the Company, effective as of September 9, 2022 (Filed on September 30, 2022 as an exhibit to our Registration Statement on Form S-1 (File No. 333-267689).
4.1	Form of specimen certificate evidencing shares of Series B Convertible Preferred Stock. (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.)
4.2	Investor Warrant issued November 28, 2017. (Filed on November 29, 2017 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
4.3	Common Stock Purchase Warrant issued to L2 Capital, LLC dated September 28, 2018. (Filed on October 4, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
4.4	Common Stock Purchase Warrant issued to Peak One Opportunity Fund, LP dated September 28, 2018. (Filed on October 4, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
4.5	Form of Unit Purchase Option issued February 27, 2019. (Filed on March 1, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
4.6	Form of Common Stock Purchase Warrant issued March 29, 2019. (Filed on April 2, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
4.7	Form of Unit Purchase Option for the Purchase of Units issued March 29, 2019. (Filed on April 2, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
4.8	Common Stock Purchase Warrant Issued to Oasis Capital, LLC dated September 27, 2019. (Filed on September 30, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)

Exhibit Number	Description
4.9	Form of Specimen Common Stock Certificate. (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.)
4.10	Form of Common Stock Purchase Warrant Issued on or about October 1, 2019. (Filed on October 10, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
4.11	Common Stock Purchase Warrant issued to Oasis Capital, LLC dated February 5, 2020. (Filed on February 7, 2020 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
4.12	Description of Registrant's Securities. (Filed on March 31, 2022 as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 2021 and incorporated herein by reference.)
4.13	Common Stock Purchase Warrant issued to Oasis Capital, LLC dated March 6, 2020. (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.)
4.14	Form of Helomics Common Stock Purchase Warrant issued April 4, 2019. (Filed on October 10, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.) Exhibit 4.18
4.15	Form of Common Stock Purchase Warrant issued January 12, 2021. (Filed on January 12, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
4.16	Form of Common Stock Purchase Warrant issued January 19, 2021. (Filed on January 21, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
4.17	Form of Placement Agent Warrant to H.C. Wainwright & Co., LLC or its designees in connection with certain financing transactions in 2020 and 2021. (Filed on January 29, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
4.18	Form of Common Stock Purchase Warrant dated February 10, 2021. (Filed on February 12, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
4.19	Form of Common Stock Purchase Warrant dated February 23, 2021. (Filed on February 22, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)

Exhibit Number	Description
4.20	Form of Common Stock Purchase Warrant dated June 16, 2021. (Filed on June 16, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
4.21	Form of Placement Agent Warrant dated June 16, 2021. (Filed on June 16, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
10.1	Office Lease Agreement between the registrant and Roseville Properties Management Company, as agent for Lexington Business Park, LLC. (Filed on November 12, 2008 as an exhibit to our Registration Statement on Form S-1 and incorporated herein by reference.)
10.2**	Employment Agreement with Robert Myers dated August 11, 2012. (Filed on November 5, 2012 as an exhibit to our Registration Statement on Form S-1 and incorporated herein by reference.)
10.3	Amended Lease with Roseville Properties Management Company, Inc. dated January 29, 2013. (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.)
10.4**	Amended and Restated 2012 Stock Incentive Plan. (Filed on October 18, 2022 as an appendix to our definitive proxy statement on Schedule 14A and incorporated herein by reference.)
10.5**	Form of Stock Option Agreement for Employees under Amended and Restated 2012 Stock Incentive Plan (Filed on March 31, 2022 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference).
10.6**	Form of Stock Option Agreement for Executive Officers under Amended and Restated 2012 Stock Incentive Plan (Filed on March 31, 2022 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference).

Exhibit Number	Description
10.7**	Form of Stock Option Agreement for Directors under Amended and Restated 2012 Stock Incentive Plan (Filed on March 31, 2022 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference).
10.8**	Amendment to Employment Agreement by and between the Issuer and Bob Myers dated August 20, 2018 (Filed on April 1, 2019 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference.)
10.9	Equity Purchase Agreement by and between the Issuer and Oasis Capital, LLC dated October 24, 2019. (Filed on October 25, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
10.11	Securities Purchase Agreement by and among the Company and the Investors dated March 15, 2020. (Filed on March 16, 2020 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
10.13	Form of Securities Purchase Agreement dated January 8, 2021, by and between Predictive Oncology Inc. and certain Purchasers. (Filed on January 12, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
10.14	Form of Securities Purchase Agreement dated January 19, 2021, by and between Predictive Oncology Inc. and certain Purchasers. (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.)
10.15	Form of Securities Purchase Agreement dated January 21, 2021, by and between Predictive Oncology Inc. and certain Purchasers. (Filed on January 21, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
10.16	Form of Securities Purchase Agreement dated February 10, 2021, by and between Predictive Oncology Inc. and certain Purchasers. (Filed on February 12, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
10.17	Form of Securities Purchase Agreement dated February 18, 2021, by and between Predictive Oncology Inc. and certain Purchasers. (Filed on February 22, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)

Exhibit Number	Description
10.18	Form of Registration Rights Agreement dated February 18, 2021, by and between Predictive Oncology Inc. and certain Purchasers. (Filed on February 22, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
10.21**	Offer Letter by and between the Company and J. Melville Engle dated March 19, 2021. (Filed on March 23, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
10.22**	Employment Agreement by and between the Company and J. Melville Engle dated effective as of March 19, 2021 (Filed on April 7, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
10.23**	2021 Long Term Incentive Plan (Filed on May 20, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
10.24	Form of Securities Purchase Agreement, dated June 14, 2021, by and between Predictive Oncology Inc. and certain Purchasers. (Filed on June 16, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
10.25	Form of Securities Purchase Agreement, dated May 16, 2022, by and between Predictive Oncology Inc. and certain Purchasers. (Filed on May 16, 2022 as an exhibit to our Current Report on Form 8-K)
10.26	Form of Securities Purchase Agreement, dated May 16, 2022, by and between the Company and certain Purchasers. (Filed on May 16, 2022 as an exhibit to our Current Report on Form 8-K)
10.27**	Transition and Separation Agreement dated September 15, 2022, by and between the Company and J. Melville Engle (Filed on September 15, 2022 as an exhibit to our Current Report on Form 8-K)
10.28**	Employment Offer Letter dated September 30, 2022, by and between the Company and Raymond F. Vennare. (Filed on September 22, 2022 as an exhibit to our Current Report on Form 8-K).
10.29**	Employment Agreement dated effective November 1, 2022, by and between the Company and Raymond F. Vennare. (Filed on September 22, 2022 as an exhibit to our Current Report on Form 8-K).

Exhibit Number	Description
10.30**	Employment Agreement dated February 23, 2023 by and between the Company and Pamela Bush (Filed on January 30, 2022 as an exhibit to our Current Report on Form 8-K).
14.1	Code of Ethics. (Filed on April 16, 2012 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference.)
21.1*	Subsidiaries of the Registrant
23.1*	Consent of Independent Registered Public Accounting Firm: Baker Tilly US, 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*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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

The audited consolidated financial statements for the periods ended December 31, 2022 and December 31, 2021 are included on the following pages:

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the shareholders and the board of directors of Predictive Oncology Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Predictive Oncology Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of net loss, stockholders' equity, and cash flows for the years ended December 31, 2022 and 2021, 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, 2022 and 2021, and the results of their operations and their cash flows for the years ended December 31, 2022 and 2021, in conformity with accounting principles generally accepted in the United States of America.

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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 audits 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 audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates 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 consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Long-Lived Asset Impairment

Critical Audit Matter Description

As described in Notes 1 and 8 to the consolidated financial statements, the Company performs an analysis of the carrying value of long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of the long-lived assets may not be recoverable. The Company's long-lived asset groups are comprised of property and equipment and finite-lived intangibles that exist at each asset group. For asset groups identified with carrying values not recoverable by future undiscounted cash flows, impairment charges are measured based on the excess of carrying value over the location's fair value, subject to certain limitations. To determine the fair value of tangible assets given the nature of the assets, the Company engaged a third-party valuation specialist who utilized an indirect cost approach given the lack of a secondary market for the assets. The resulting impairment is therefore determined at the individual asset level. As of December 31, 2022, the Company had $1.8 million in property and equipment, net. During the year ended December 31, 2022, the Company recognized $3,349,375 and $185,469 of long-lived asset impairments related to intangible assets for zPREDICTA and tangible assets for the Helomics and Soluble asset groups, respectively.

We identified the impairment of the carrying value of long-lived assets as a critical audit matter. For asset groups with indicators of impairment, a high degree of auditor judgment and an increased extent of effort was required when performing audit procedures to evaluate the reasonableness of management's estimates, including projected future cash flows and significant assumptions for estimating fair value of long-lived assets. This required a high degree of auditor judgment, including the involvement of valuation specialists with specialized skills and knowledge.

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 judgements and assumptions used in management's process for determining the fair value of the asset groups, which included the following procedures:

- We performed inquiries of management regarding the process and assumptions used to identify potential indicators of impairment.
- We evaluated management’s ability to forecast sales and operating expenses for certain asset groups by comparing actual results to management’s historical forecasts.
- With the assistance of our internal valuation specialists, we evaluated the appropriateness of the fair value valuation methodologies and assumptions used by management to estimate the fair value of the long-lived assets.
- Tested the completeness and accuracy of underlying data used in the valuation methods.
- Tested a sample of assets and reviewed supporting documentation for the fair value of the asset.

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

/s/ Baker Tilly US, LLP

Minneapolis, Minnesota
March 21, 2023

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 22,071,523	$ 28,202,615
Accounts Receivable	331,196	354,196
Inventories	430,493	387,684
Prepaid Expense and Other Assets	526,801	513,778
Total Current Assets	23,360,013	29,458,273
Fixed Assets, net	1,833,255	2,511,571
Intangibles, net	253,865	3,962,118
Operating Lease Right-of-Use Assets	211,893	814,454
Other Long-Term Assets	75,618	167,065
Goodwill	-	6,857,790
Total Assets	$ 25,734,644	$ 43,771,271
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 943,452	$ 1,021,774
Accrued Expenses and other liabilities	2,229,075	1,262,641
Derivative Liability	13,833	129,480
Contract Liabilities	602,073	186,951
Operating Lease Liability – Net of Long-Term Portion	94,237	639,662
Total Current Liabilities	3,882,670	3,240,508
Other Long-Term Liabilities	-	25,415
Operating Lease Liability, long-term portion	86,082	239,664
Total Liabilities	3,968,752	3,505,587
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 shares outstanding	792	792
Common Stock, $.01 par value, 200,000,000 authorized, 78,762,701 and 65,614,597 outstanding	787,627	656,146
Additional Paid-in Capital	174,755,389	167,649,028
Accumulated Deficit	(153,777,916)	(128,040,282)
Total Stockholders' Equity	21,765,892	40,265,684
Total Liabilities and Stockholders' Equity	$ 25,734,644	$ 43,771,271

See Notes to Consolidated Financial Statements

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF NET LOSS

	Year Ended December 31,	
	2022	**2021**
Revenue	$ 1,505,459	$ 1,420,680
Cost of sales	505,107	487,024
Gross profit	1,000,352	933,656
General and administrative expense	11,110,735	10,932,125
Operations expense	3,798,425	2,698,565
Sales and marketing expense	1,358,907	774,530
Loss on goodwill impairment	7,231,093	2,813,792
Loss on impairment of intangibles	3,349,375	2,893,548
Loss on impairment of tangible fixed assets	185,469	1,249,727
Total operating loss	(26,033,652)	(20,428,631)
Other income	185,646	184,528
Other expense	(5,275)	(239,631)
Gain on derivative instruments	115,647	164,902
Loss before income tax benefit	$ (25,737,634)	(20,318,832)
Income tax benefit	-	(661,658)
Net loss	(25,737,634)	$ (19,657,174)
Loss per common share - basic and diluted	$ (0.35)	$ (0.36)
Weighted average shares used in computation - basic and diluted	72,997,987	54,876,044

See Notes to Consolidated Financial Statements

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Series B Preferred		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at 12/31/2021	79,246	$ 792	65,614,597	$ 656,146	$ 167,649,028	$ (128,040,282)	$ 40,265,684
Issuance of shares and warrants pursuant to May 2022 private placement, net			12,000,000	120,000	6,387,050		6,507,050
Shares issued pursuant to Equity Line			315,000	3,150	232,859		236,009
Share issuance to consultant and other			596,670	5,967	350,158		356,125
Vesting expense and option repricing			236,434	2,364	136,294		138,658
Net loss			-	-	-	(25,737,634)	(25,737,634)
Balance at 12/31/2022	79,246	$ 792	78,762,701	$ 787,627	$ 174,755,389	$ (153,777,916)	$ 21,765,892

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Series B Preferred		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at 12/31/2020	79,246	$ 792	19,804,787	$ 198,048	$ 110,826,949	$ (108,383,108)	$ 2,642,681
Shares issued pursuant to agreement with former CEO related to accrued interest			100,401	1,004	142,569		143,573
Issuance of shares and warrants pursuant to Shelf offerings, net			13,488,098	134,881	14,877,611		15,012,492
Issuance of shares and warrants pursuant to February 2021 private placement, net			9,043,766	90,438	15,974,301		16,064,739
Exercise of warrants			5,269,059	52,702	4,461,169		4,513,871
Shares issued pursuant to convertible debt			1,107,544	11,075	502,936		514,011
Issuance of shares and warrants pursuant to June 2021 direct placement, net			15,520,911	155,209	19,291,087		19,446,296
Shares issued pursuant to transition agreement with former CEO			400,000	4,000	(4,000)		-
Shares issued pursuant to Equity Line			647,504	6,475	669,115		675,590
Share issuance to consultant and other			174,954	1,750	203,443		205,193
Vesting expense and option repricing			57,573	564	703,848		704,412
Net loss			-	-	-	(19,657,174)	(19,657,174)
Balance at 12/31/2021	79,246	$ 792	65,614,597	$ 656,146	$ 167,649,028	$ (128,040,282)	$ 40,265,684

See Notes to Consolidated Financial Statements

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2022	**2021**
Cash flow from operating activities:		
Net loss	$ (25,737,634)	$ (19,657,174)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,313,075	1,340,301
Vesting expense	166,312	715,938
Equity instruments issued for management, consulting, and other	356,125	205,193
Amortization of debt discount	-	244,830
Gain on valuation of equity-linked instruments	(115,647)	(164,902)
Benefit from release of valuation allowance	-	(661,658)
Loss on goodwill impairment	7,231,093	2,813,792
Loss on intangible impairment	3,349,375	2,893,548
Loss on long-lived tangible asset impairment	185,469	1,249,727
Loss on fixed asset disposal	14,346	5,858
Changes in assets and liabilities:		
Accounts receivable	23,000	(20,769)
Inventories	(42,808)	(98,149)
Prepaid expense and other assets	78,425	(194,363)
Accounts payable	(78,322)	(350,296)
Accrued expenses	869,987	(499,563)
Contract liabilities	41,819	54,548
Other liabilities	(25,415)	(85,790)
Net cash used in operating activities:	(12,370,800)	(12,208,929)
Cash flow from investing activities:		
Acquisition of zPREDICTA, net of cash acquired	-	(9,590,214)
Purchase of fixed assets	(419,869)	(910,429)
Acquisition of intangibles	(55,828)	(51,893)
Loan activities	-	(55,000)
Net cash used in investing activities	(475,697)	(10,607,536)
Cash flow from financing activities:		
Proceeds from issuance of common stock, net	6,507,050	50,523,527
Proceeds from exercise of warrants into common stock	-	4,513,871
Repayment of debt	-	(4,162,744)
Payment penalties	-	(1,073,470)
Proceeds from issuance of stock pursuant to equity line	236,009	675,590
Repurchase of common stock upon vesting of restricted stock units	(27,654)	(11,526)
Other liabilities	-	(124,500)
Net cash provided by financing activities	6,715,405	50,340,748
Net increase (decrease) in cash and cash equivalents	(6,131,092)	27,524,283
Cash and cash equivalents at beginning of year	28,202,615	678,332
Cash and cash equivalents end of year	$ 22,071,523	$ 28,202,615

See Notes to Consolidated Financial Statements

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS continued

	Year Ended December 31,	
	2022	**2021**
Non-cash transactions		
Shares issued pursuant to former CEO per agreement related to accrued interest	$ -	$ 143,573
Increase to operating lease right of use asset and lease liability due to new and modified leases	-	77,128
Inducement shares issued pursuant to convertible debt	-	514,011
Adjustment to goodwill for acquisition of zPREDICTA contract liabilities	373,303	-
Cash paid during the period for:		
Interest paid on debt	$ 3,821	$ 690,508

See 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") filed with the Secretary of State of Delaware a Certificate of Amendment to its Certificate of Incorporation to change the corporate name to Predictive Oncology Inc. on June 10, 2019, trading under the new ticker symbol "POAI," effective June 13, 2019.

The Company operate in four primary business areas: first, the application of artificial intelligence ("AI") for optimized, high-confidence drug-response predictions within a large experimental space that enables a more informed selection of drug/tumor combinations to increase the probability of success during development.; second, creation and development of tumor-specific 3D cell culture models driving accurate prediction of clinical outcomes; third, contract services and research focused on solubility improvements, stability studies, and protein production, and; fourth, production of the United States Food and Drug Administration ("FDA")-cleared STREAMWAY® System for automated, direct-to-drain medical fluid disposal and associated products.

The Company has four reportable segments: Helomics®, zPREDICTA®, SolubleTM and Skyline®. The Helomics segment includes contract services that include the application of AI, partnering projects and clinical testing. The zPREDICTA, Inc. ("zPREDICTA") segment specializes in organ-specific disease models that provide 3D reconstruction of human tissues accurately representing each disease state and mimicking drug response enabling accurate testing of anticancer agents. The 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. The Skyline segment consists of the STREAMWAY System product sales. Going forward, the Company has determined that it will focus its resources on applying AI to develop optimal cancer therapies, partnering with biopharma clients to prioritize drugs for development and identify biomarker-informed indications enabling a more informed selection of drug/tumor combinations to increase the probability of success during drug development. As a result of this focused approach, the Company has consolidated its brand under Predictive Oncology name. Going forward, the Company will operate under the Predictive Oncology tradename with laboratory operations in Pittsburgh, Pennsylvania and Birmingham, Alabama.

Impact of the Coronavirus Disease 2019

In response Coronavirus Disease 2019 ("COVID-19"), the Company continues to closely manage manufacturing and supply chain resources. The Company monitors its sites to protect the safety of its staff and employees. The Company continues to experience some disruption due to the global supply chain caused by COVID-19. As a result of COVID-19, the Company is also experiencing disruption due staffing shortages within the service and healthcare industries and negative impacts on the demand for our products and services. For example, some customers are managing inventory and capital more conservatively and our suppliers continue to ask for pre-delivery deposits. The Company is monitoring and taking actions to mitigate potential risks of these shortages and delays which may impact the Company's ability to obtain new contracts, the fulfillment of product demand and to meet its contract obligations. The extent to which COVID-19 may impact the Company's financial condition and results of operations remains uncertain and is dependent on numerous evolving factors, including the measures being taken by authorities to mitigate against the spread of COVID-19, the emergence of new variants and the effectiveness of vaccines and therapeutics. The continuation or re-implementation of these measures remains uncertain. 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.

Recently Adopted Accounting Standards

The Company considers the applicability and impact of all Accounting Standards Updates ("ASUs") issued by the Financial Accounting Standards Board (the "FASB"). Recently issued ASUs not listed below either were assessed and determined to be not applicable or are currently expected to have no impact on the condensed consolidated financial statements of the Company.

In June 2016, the FASB issued ASU 2016-13, "Financial Instruments – Credit Losses." This ASU added a new impairment model (known as the current expected credit loss ("CECL") model) that is based on expected losses rather than incurred losses. Under the new guidance, an entity recognizes as an allowance its estimate of expected credit losses. The CECL model applies to most debt instruments, trade receivables, lease receivables, financial guarantee contracts, and other loan commitments. The CECL model does not have a minimum threshold for recognition of impairment losses and entities will need to measure expected credit losses on assets that have a low risk of loss. As a smaller reporting company pursuant to Rule 12b-2 of the Securities Exchange Act of 1934, as amended, these changes become effective for the Company on January 1, 2023. Management is currently evaluating the potential impact of these changes on the consolidated financial statements of the Company.

Accounting Policies and Estimates

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

Cash and cash equivalents

The Company considers all highly liquid instruments with maturities when purchased of three months or less to be cash equivalents. The Company places its cash with high quality financial institutions and believes its risk of loss is limited to amounts in excess of that which is insured by the Federal Deposit Insurance Corporation.

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 sheets 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, 2022 and 2021.

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 and cash equivalents, 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 7 – Derivatives*. When performing quantitative testing related to goodwill impairment analysis, the Company 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. The majority of the inputs used in the discounted cash flow model are unobservable and thus are considered to be Level 3 inputs. See *Note 8 – Goodwill and Intangibles*.

The acquisition of zPREDICTA 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 acquisition date. The majority of the inputs used in the discounted cash flow model, the relief-from-royalty method under the income approach, the distributor method under the income approach and the multi-period excess earnings method under the income approach, each are unobservable and thus are considered to be Level 3 inputs. See *Note 2 – zPREDICTA Acquisition*.

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	-	10
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, acquired software 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.

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 is tested on an annual basis for impairment at the reporting unit level as of December 31, 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 completes 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. See *Note 8 – Intangible Assets and Goodwill*.

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 fixed assets with corresponding current liability within other current liabilities and noncurrent liability within other long-term liabilities on our consolidated balance sheets as financing leases are not significant.

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

*C*linic diagnostic testing is comprised of our Tumor Drug Response Testing (ChemoFx) and Genomic Profiling (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 and/or status 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 term 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 Soluble, Helomics and zPREDICTA segments.

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. The Company has not experienced any material warranty claims.

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, 2022 and 2021, accounts receivable totaled $331,196 and $354,196, respectively.

The Company's contract liabilities related primarily to our zPREDICTA 3D services revenue and maintenance plans of our Skyline Medical operating segment. As of December 31, 2022 and 2021, contract liabilities were $602,073 and $186,951, 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,					
	2022			2021		
	Stock Options					
Expected dividend yield		0.0%			0.0%	
Expected stock price volatility	86.5%	-	92.2%	84.8%	-	89.6%
Risk-free interest rate	1.83%	-	4.26%	0.93%	-	1.66%
Expected life (years)		10			10	
	Warrants					
Expected dividend yield		0.0%			0.0%	
Expected stock price volatility		92.2%			84.8%	
Risk-free interest rate	2.96%	-	2.97%	0.42%	-	0.69%
Expected life (years)	5/		5.5	5/		5.5

For performance-based awards, we generally recognize expense over the requisite service period unless there was a compelling reason to make it shorter and when performance-based conditions are considered probable to be satisfied. For market-based awards, we determine the grant-date fair value utilizing a Monte Carlo valuation model, which incorporates various assumptions including expected stock price volatility, expected term and risk-free interest rates.

Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognizes that. The Company has been on the NASDAQ Capital Market since 2015 and have had a volatile stock including reverse stock splits. The assumptions used in calculating the fair value of stock-based payment awards represent the Company's best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and different assumptions are used, equity-based consulting and interest expense could be materially different in the future.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs, included within operations expense in the accompanying consolidated statements of net loss were $320,320 and $315,850 for the years ended December 31, 2022 and 2021, 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.

Income Taxes

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

The Company reviews income tax positions expected to be taken in income tax returns to determine if there are any income tax uncertainties. The Company recognizes tax benefits from uncertain tax positions only if it is more likely than not that the tax positions will be sustained on examination by taxing authorities, based on technical merits of the positions. The Company has identified no income tax uncertainties.

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. Consequently, the limitation, if any, could result in the expiration of the Company's loss carryforwards before they can be utilized. Based on prior equity transactions, the Company believes it has experienced multiple ownership changes in prior years including in 2021 as defined by Section 382 of the Code. 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. In addition, the current NOL carryforwards might be further limited by future issuances of our common stock.

Tax years subsequent to 2002 remain open to examination by federal and state tax authorities due to unexpired net operating loss carryforwards.

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. As of December 31, 2022, the Company did not have credit risk for cash amounts held in a single institution that are in excess of amounts issued 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 13 – Subsequent Events*.

NOTE 2 – zPREDICTA ACQUISITION

On November 24, 2021, the Company entered into an Agreement and Plan of Merger (the "Agreement") among the Company, a wholly-owned subsidiary of the Company (the "Merger Sub"), zPREDICTA, and a representative for certain parties who held interests in zPREDICTA. Also on November 24, 2021, the Company acquired zPREDICTA through the merger of Merger Sub with and into zPREDICTA, with zPREDICTA surviving as a wholly-owned subsidiary of the Company.

As consideration for the acquisition, the stockholders and certain holders of interests in zPREDICTA as of immediately prior to the transaction collectively received consideration of approximately $10.0 million in cash. The Agreement contains customary and negotiated representations, warranties, and indemnity provisions.

The acquisition costs of $895,297 related to the acquisition are presented in legal, accounting and consulting expenses within general and administrative expenses in the accompanying consolidated statements of net loss.

During the three months ended June 30, 2022, the Company identified an out-of-period error related to the application of ASC 606 with respect to the recognition of revenue associated with zPREDICTA customer contracts. As a result, the Company has recorded an adjustment to the purchase price allocation of zPREDICTA and the associated acquisition date fair values of assets acquired, and liabilities assumed. The Company has determined that $373,303 of additional contract liabilities should have been recorded which results in an increase to the fair value of goodwill acquired by the same amount to a value of $7,231,093. The Company corrected the error in the financial statements during the three months ending June 30, 2022 by increasing contract liability and goodwill by $373,303.

The Company evaluated the materiality of these errors both qualitatively and quantitatively in accordance with Staff Accounting Bulletin ("SAB") No. 99, *Materiality* and SAB No. 108, *Considering the Effects of Prior Year Misstatements in Current Year Financial Statements*, and determined the effect of these corrections was not material to the consolidated financial statements as of and for the year ended December 31, 2021 and 2022.

The Company had previously disclosed the acquisition date fair values of assets acquired and liabilities assumed, and the consideration transferred, the following table reflects the adjustment discussed above:

Cash consideration	$	10,015,941
Assets acquired:		
Cash		425,727
Accounts receivable		76,549
Prepaid expenses		25,733
Intangible assets		3,780,000
Liabilities assumed:		
Accrued expenses		(408,825)
Deferred tax liability		(661,658)
Contract liabilities		(452,678)
Goodwill	$	7,231,093

The purchase price allocation has been derived from estimates. The Company's judgements used to determine the estimated fair value assigned to each class of assets acquired and liabilities assumed can materially affect the consolidated operations of the consolidated Company. The total purchase price has been allocation to identifiable assets acquired and liabilities assumed based upon valuation studies and procedures performed to date. The fair value and useful life for the intangible assets are (a) tradename $80,000 b) developed technology $3,500,000 and c) customer relationships $200,000 with useful lives of 4 years, 10 years and 10 years, respectively all using a straight-line method.

The Company acquired zPREDICTA through a non-taxable reverse triangular merger combination. As part of purchase accounting there was $3,780,000 in fair value assigned to purchased intangibles which the Company established a related deferred tax liability as a result of the stock merger combination that offset the acquired deferred assets including NOL's and other temporary timing differences.

Identifiable Intangible Assets

The Company acquired intangible assets related to trademarks for the acquired zPREDICTA trade name with an estimated fair market value of $80,000. The fair values of the asset were determined by the relief-from-royalty method under the income approach. The Company determined the asset is a finite lived asset. The useful life of the tradename has a useful life of 4 years.

The Company acquired intangible assets with a useful life of 10 years and an estimated value of $200,000 related to customer relationships stemming from stable and predictable cash flow streams associated with customers. zPREDICTA's customer base includes contract research partnerships with pharmaceutical, diagnostic, biotechnology, and research companies. The customer relationships were valued using the distributor method under the income approach.

The Company acquired intangible assets with a useful life of 10 years and an estimated value of $3,500,000 related to developed technology stemming from the 3D tumor model technology. Since the model technology was identified as the primary asset, this technology was valued using the multi-period excess earnings method under the income approach.

The Company prepared an undiscounted cash flow as of December 31, 2022 to evaluate long-lived assets based on a triggering event per ASC 360 and recognized and impairment loss of $3,349,375 for its long-lived intangible assets. See *Note 8 – Goodwill and Intangibles*.

Goodwill

Goodwill of $7,231,093, as adjusted, was recognized in the zPREDICTA 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 will be deductible for income tax purposes.

In testing goodwill for impairment as of June 30, 2022, the Company performed a quantitative impairment test and concluded that goodwill was impaired as of the testing date of June 30, 2022. The quantitative review as of June 30, 2022 resulted in $7,231,093 of impairment expense related to goodwill. See *Note 8 – Goodwill and Intangibles*.

Financial Results

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

Pro Forma (unaudited)

The following unaudited pro forma information presents the combined results of operations of the Company and zPREDICTA as if the acquisition of zPREDICTA had been completed on January 1, 2020, with adjustments to give effect to pro forma events that are directly attributable to the acquisition and reflects the correction of application of ASC 606 as discussed above.

	Twelve months ended December 31, 2021	Twelve months ended December 31, 2020
	Unaudited	Unaudited
Revenue	$ 2,056,484	$ 1,815,560
Net loss attributable to common shareholders	$ (19,251,734)	$ (26,946,564)

The primary adjustments include the inclusion of the revalued amortization for zPREDICTA 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 – 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, 2022	December 31, 2021
Finished goods	$ 290,616	$ 193,287
Raw materials	133,183	183,410
Work-In-Process	6,694	10,987
Total	$ 430,493	$ 387,684

NOTE 4 – STOCKHOLDERS' EQUITY, STOCK OPTIONS AND WARRANTS

Authorized Shares

At the special meeting on August 17, 2021, the stockholders approved a proposal to increase the number of authorized shares of common stock to 200,000,000 shares of common stock, $0.01 par value. The amendment to the certificate of incorporation to affect this increase was filed on August 17, 2021.

May 2022 Offerings

On May 16, 2022, the Company, issued and sold to several institutional and accredited investors in a registered direct offering (the "First Offering") an aggregate of 3,837,280 shares of its common stock, at a purchase price of $0.60 per share. Pursuant to the securities purchase agreement, in a concurrent private placement, the Company also agreed to issue to these purchasers unregistered warrants to purchase up to an aggregate of 3,837,280 shares of common stock (the "Warrants"). The Warrants have an exercise price equal to $0.70 per share, will become exercisable six months from the date of issuance, and will expire five and one-half years from the date of issuance.

In addition, in a concurrent registered direct offering (the "Second Offering"), on May 16, 2022, the Company issued and sold to several institutional and accredited investors an aggregate of 8,162,720 shares of its common stock, at a purchase price of $0.60 per share. The Company also entered into a warrant amendment agreement (the "Warrant Amendment") with each of the purchasers in the Second Offering. Under the Warrant Amendment, the Company agreed to amend certain existing warrants to purchase up to 16,325,433 shares of common stock that were previously issued in 2020 and 2021 to those purchasers, with exercise prices ranging from $1.00 to $2.00 per share (the "Existing Warrants"), were amended to: (i) lower the exercise price of the Existing Warrants to $0.70 per share, (ii) provide that the Existing Warrants, as amended, will not be exercisable until six months following the closing date of the Second Offering, and (iii) extend the original expiration date of the Existing Warrants by five and one-half years following the close of the Second Offering.

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 provided the placement agent expense allowance of $65,000 for non-accountable and other 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, or $0.75 per share, with a term of five years (the "Agent Warrants"). The Agent Warrants become exercisable six months after issuance.

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 June 2021, the Company completed a registered direct offering of common stock and warrants. The warrants became exercisable on the effective date of an increase in the number of shares of the Company's authorized common stock, which occurred on August 17, 2021, and expire three years after the initial exercise date. 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 (three years for the June 2021 offering) or five and one-half years for the private placement.

These 2021 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)	3,650,840	$ 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
June 16, 2021 (registered direct)	15,520,911	$ 1.375	15,520,911	$ 1.25	1,164,068	$ 1.71875	$21,341,252	$19,446,296
Total	38,057,775		26,786,843		2,853,958		$55,737,571	$50,523,528

***** Sale price includes one share and a warrant to purchase one-half share (or one whole share in the case of the June 16, 2021 offering).

2021 Warrant Exercises

During the year ended December 31, 2021, the holders of outstanding investor warrants have exercised such warrants for the total purchase of 5,269,059 shares at a weighted average exercise price of $0.86 per share, for total proceeds of $4,513,871.

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 the year ended December 31, 2022, the Company issued 315,000, shares of its common stock valued at $236,009 pursuant to the equity line. As of December 31, 2021, there was $9,113,829 of remaining available balance under the equity line, subject to shareholder approval required for additional purchases, as well as requirements for market conditions including trading volume and stock price, and subject to other limitations. In connection with the May 2022 offerings, the Company agreed not to access the remaining balance for a period of one year after the closing date, or May 18, 2022. The equity line expired on October 23, 2022.

Equity Incentive Plan

The Company has an equity incentive plan, which allows issuance of incentive and non-qualified stock options, stock appreciation rights, stock awards, restricted stock, restricted stock units and performance awards 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.

At the special meeting on August 17, 2021, the stockholders approved a proposal to increase the reserve shares of common stock authorized for issuance under the Amended and Restated 2012 Stock Incentive Plan by 1,500,000 to 3,250,000 reserve shares. On December 1, 2022 during the 2022 annual meeting of stockholders (the "Annual Meeting"), the stockholders approved a proposal to increase the reserve shares of common stock authorized for issuance under the Amended and Restated 2012 Stock Incentive Plan by 3,250,000 to 5,750,000 reserve shares.

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, 2020	1,013,547	$ 5.41	7,353,376	$ 1.99
Issued	147,230	1.06	29,640,801	1.44
Forfeited	(92,593)	8.64	-	-
Expired	-	-	(25,233)	10.00
Exercised	(5,313)	0.74	(5,269,059)	0.86
Outstanding at December 31, 2021	1,062,871	$ 4.83	31,699,885	$ 1.66
Issued	31,970	0.42	21,062,714	0.70
Forfeited	(40,241)	0.88	-	-
Expired	(73,540)	10.42	(108,435)	16.48
Cancelled	-	-	(16,325,433)	1.51
Outstanding at December 31, 2022	981,060	$ 4.58	36,328,731	$ 1.13

At December 31, 2022, 953,635 stock options are fully vested and currently exercisable with a weighted average exercise price of $4.69 and a weighted average remaining term of 6.54 years. There are 36,328,731 warrants at December 31, 2022 that are fully vested and exercisable. At December 31, 2021, 949,615 stock options are fully vested and currently exercisable with a weighted average exercise price of $5.27 and a weighted average remaining term of 8.14 years.

During the year ended December 31, 2021, the Company issued 450,000 RSUs under the plan which have market, performance and service vesting conditions through January 1, 2024. 333,333 RSUs became vested during the year ended December 31, 2022 and 33,333 vested during the year ended December 31, 2021. At December 31, 2022, there were 83,334 RSUs outstanding under the plan.

For performance-based awards, the Company generally recognizes expense over the requisite service period unless there is a compelling reason to make it shorter and when performance-based conditions are considered probable to be satisfied. For market-based awards, we determine the grant-date fair value utilizing a Monte Carlo valuation model, which incorporates various assumptions including stock price volatility, expected term and risk-free interest rates. The stock-based compensation for performance-based awards is insignificant.

There were 31,699,885 warrants that are fully vested and exercisable as of December 31, 2021. Stock-based compensation recognized in 2022 and 2021 was $108,596 and $146,714, respectively.

Stock-based compensation recognized in 2022 and 2021 was $108,596 and $146,714, respectively. The Company has $16,045 of unrecognized compensation expense related to non-vested stock options and RSUs that are expected to be recognized over the next 23 months.

The following summarizes the status of options and warrants outstanding at December 31, 2022:

Range of Exercise Prices	Shares	Weighted Average Remaining Life
Options:		
$ 0.26 –0.81	266,382	8.10
$ 1.02 –1.25	50,795	8.82
$ 1.25 –1.64	318,686	5.99
$ 2.610 –7.90	208,040	6.49
$ 10.10 –5,962.50	137,157	4.55
Total	981,060	
Warrants:		
$ 0.70 –0.80	21,626,850	4.83
$ 0.84 –1.72	10,271,436	1.68
$ 1.80 –2.18	2,758,881	3.37
$ 2.25 –10.00	1,555,778	2.51
$ 10.71 –22.50	115,786	2.25
Total	36,328,731	

Stock options and warrants expire on various dates from March 2023 to December 2032.

Stock Options and Warrants Granted by the Company

The following table is the listing of outstanding stock options and warrants as of December 31, 2022 by year of grant:

Stock Options:

Year	Shares	Price		
2013	123	$ 1.54	–	5,962.50
2014	84	1.54	–	3,468.75
2015	239	1.54	–	862.50
2016	6,641	1.54	–	42.50
2017	214,555	1.54	–	21.00
2018	57,868	1.54	–	13.50
2019	306,663	1.54	–	7.50
2020	297,669	0.73	–	3.48
2021	76,812	0.72	–	1.47
2022	20,406	0.26	–	0.7361
Total	981,060	$ 0.40	–	$ 5,962.50

Warrants:

Year	Shares	Price		
2018	196,946	$ 8.36	–	13.13
2019	1,690,286	0.85	–	11.80
2020	1,311,731	0.85	–	2.99
2021	12,067,054	0.80	–	2.44
2022	21,062,714	0.70	–	0.75
Total	36,328,731	$ 0.70	–	$ 13.13

NOTE 5 - DERIVATIVES

The Company concluded the Promissory Note 2020 contained a conversion feature and a put each of which was 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 sheets. 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. The Company recorded a gain on the fair value of the derivative of $104,529 during the year ended December 31, 2021. As a result of the repayment of the note as of March 1, 2021, the embedded derivative had a fair value of zero prior to the repayment.

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 and as a result of this amendment, the warrants no longer represented a liability to the Company and were reclassified to equity. As of December 31, 2022, the fair value of the agent warrants was determined to be $3,355 and the Company recorded a gain on the change in fair value of $37,981 during the year ended December 31, 2022. As of December 31, 2021, the fair value of the agent warrants was determined to be $41,336 and the Company recorded a loss on the change in fair value of $7,683 during the year ended December 31, 2021.

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. The fair value of the agent warrants was determined to be $4,479 and $31,120 as of December 31, 2022 and as of December 31, 2021, respectively. The Company recorded a gain on the change in fair value of the agent warrants of $38,167 during the year ended December 31, 2022 and a loss on the change in fair value of the agent warrants of $8,827 during the year ended December 31, 2021.

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 $39,499 during the year ended December 31, 2022 and a loss on the change in fair value of the agent warrants of $12,797 during the year ended December 31, 2021. The fair value of the agent warrants was $5,999 and $45,498 as of December 31, 2022 and as of December 31, 2021, respectively.

On September 30, 2020, the Promissory Note 2019 was amended. The Company concluded the Promissory Note 2019 contained 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. The Company recorded a gain on the fair value of the derivative of $89,680 during the year ended December 31, 2021. At inception, the fair value of the derivative liability was $495,100. As a result of the repayment of the note as of March 1, 2021, the embedded derivative had a fair value of zero prior to the repayment.

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

Derivative liability balance at December 31, 2020	**$**	**294,382**
Gain recognized to revalue derivative instrument at fair value		(164,902)
Derivative liability balance at December 31, 2021	**$**	**129,480**
Gain recognized to revalue derivative instrument at fair value		(115,647)
Derivative liability balance at December 31, 2022	**$**	**13,833**

NOTE 6 - LOSS PER SHARE

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

	Year Ended December 31,	
	2022	**2021**
Numerator:		
Net loss attributable to common shareholders per common share: basic and diluted calculation	$ (25,737,634)	$ (19,657,174)
Denominator:		
Weighted average common shares outstanding-basic	72,997,987	54,876,044
Effect of diluted stock options, warrants and preferred stock (1)	-	-
Weighted average common shares outstanding-diluted	72,997,987	54,876,044
Loss per common share-basic and diluted	$ (0.35)	$ (0.36)

(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,	
	2022	**2021**
Options	981,060	1,062,871
RSUs	83,334	366,667
Warrants	36,328,731	31,699,885
Preferred stock: Series B	79,246	79,246

NOTE 7 – INCOME TAXES

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

The Company incurred zero income tax expense at December 31, 2022 due to current year losses, compared to an income tax benefit of $661,658 in our consolidated statement of net loss for the year ended December 31, 2021 related to the release of valuation allowance as a result of the zPREDICTA business combination. However, due to the cumulative operating losses, the Company determined that a 100% valuation allowance for the net deferred tax assets at December 31st is appropriate.

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

	Year Ended December 31, 2022	2021
Statutory federal income tax benefit	$ 5,404,903	$ 4,266,955
State tax benefit, net of federal taxes	856,735	793,282
Foreign tax benefit	-	-
Foreign operations tax rate differential	-	-
State rate adjustment	(7,795,184)	5,153
Nondeductible/nontaxable items	(7,709)	(260,768)
Goodwill impairment	(1,654,212)	(605,420)
NOL adjustments	(1,149,895)	(612,588)
Other	89,162	150,083
Valuation allowance increase	4,256,200	(3,075,039)
Total income tax benefit	$ -	$ (661,658)

Deferred taxes consist of the following:

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Noncurrent:		
Inventory	$ -	$ -
Compensation accruals	150,168	58,829
Accruals and reserves	254,213	50,537
Deferred revenue	51,198	26,198
Charitable contribution carryover	1,766	1,095
Derivatives	3,192	27,859
Intangibles	1,827,736	700,876
Right of use asset	6,925	18,543
NSQO compensation	1,625,108	1,602,429
NOL and credits	77,042,831	82,814,111
Total deferred tax assets	80,963,137	85,300,477
Deferred tax liabilities:		
Noncurrent:		
Depreciation	(39,213)	(120,353)
Total deferred tax liabilities	(39,213)	(120,353)
Net deferred tax assets	80,923,924	85,180,124
Less: valuation allowance	(80,923,924)	(85,180,124)
Total	$ -	$ -

The Company has determined, based upon its history, that it is probable that future taxable income may be insufficient to fully realize the benefits of the net operating loss (“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 Company believes it has experienced multiple ownership changes in prior years including in 2021 as defined by Section 382 of the Code. 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. As a result, the ability to utilize the Company’s NOLs is limited. In addition, the current NOL carryforwards might be further limited by future issuances of our common stock. 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, 2022, the Company had $316,548,085 of gross NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2023, subject to the Section 382 limitation described above. The federal NOL's of $254,897,407 expire beginning in 2023 if unused and $60,829,929 will carryforward indefinitely. The Company also had $232,097,127 of gross NOLs to reduce future state taxable income at December 31, 2022. The state NOL's will expire beginning in 2022 if unused. The Company's net deferred tax assets, which include the NOLs, are subject to a full valuation allowance. At December 31, 2022, the federal, and state valuation allowances were $66,733,005 and $14,190,055, respectively.

At December 31, 2021, the Company had $308,990,822 of gross NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2022, subject to the Section 382 limitation described above. The federal NOL's of $259,490,005 expire beginning in 2023 if unused and $49,500,817 will carryforward indefinitely. The Company also had $227,277,399 of gross NOLs to reduce future state taxable income at December 31, 2021. The state NOL's will expire beginning in 2022 if unused. The Company's net deferred tax assets, which include the NOLs, are subject to a full valuation allowance. At December 31, 2021, the federal and state valuation allowances were $62,034,750 and $23,145,374 respectively.

The decrease in state valuation allowance from prior year is due to revaluation of state NOL's from favorable future state tax rate changes to apply to taxable income in the years in which the NOL's are expected to be utilized.

Tax years subsequent to 2002 remain open to examination by federal and state tax authorities due to unexpired net operating loss carryforwards.

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, 2022 and 2021, the Company recorded no accrued interest or penalties related to uncertain tax positions.

NOTE 8 – Goodwill and Intangibles

Intangible Assets

Finite-lived intangible assets consist of patents and trademarks, licensing fees, developed technology, acquired software and customer relationships, and are amortized over their estimated useful life. Amortization expense was $414,706 and $374,328 in 2022 and 2021, 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.

As of December 31, 2022, there were $253,865 in net intangibles as compared to $3,962,118 in net intangibles as of December 31, 2021.

The components of intangible assets were as follows:

	December 31, 2022				December 31, 2021			
	Gross Carrying Costs	Accumulated Amortization	Impairment	Net Carrying Amount	Gross Carrying Costs	Accumulated Amortization	Impairment	Net Carrying Amount
Patents & Trademarks	$ 509,141	$ (255,276)	$ -	$ 253,865	$ 453,314	$ (230,572)	$ -	$ 222,742
Developed Technology	3,500,000	(386,459)	(3,113,541)	-	6,382,000	(432,733)	(2,485,725)	3,463,542
Customer Relationships	200,000	(22,083)	(177,917)	-	645,000	(410,000)	(37,083)	197,917
Tradename	80,000	(22,083)	(57,917)	-	478,000	(29,344)	(370,740)	77,917
Total	$ 4,289, 141	$ (685,901)	$ (3,349,375)	$ 253,865	$ 7,958,314	$ (1,102,649)	$ (2,893,548)	$ 3,962,118

The following table outlines the estimated future amortization expense related to intangible assets held as of December 31, 2022:

Year ending December 31,	Expense
2023	$ 25,774
2024	25,774
2025	25,774
2026	25,774
2027	25,774
Thereafter	124,995
Total	$ 253,865

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.

The Company prepared an undiscounted cash flow as of December 31, 2022 to evaluate long-lived assets based on a triggering event per ASC 360 primarily due to the declines in projected future cash flows. The Company concluded that the undiscounted cash flows did not support the carrying values of its asset groups as of December 31, 2022. The Company determined the value of the zPREDICTA intangibles were fully impaired as of December 31, 2022 and recognized and impairment loss of $3,349,375 for its long-lived intangible assets. The Company also concluded there was an impairment of its other finite lived tangible assets as of December 31, 2022 based on the fair value of the assets based on the in-exchange premise of value. The Company recorded an impairment loss of $185,469 in the fourth quarter of 2022 related to these assets in its Soluble and Corporate operating segment.

The Company prepared an undiscounted cash flow as of December 31, 2021 to evaluate long-lived assets based on a triggering event per ASC 360. The Company concluded that the undiscounted cash flows did not support the carrying values of its Helomics asset group at December 31, 2021. The Company determined the value of the intangibles and the software license acquired were fully impaired as of December 31, 2021 and recognized and impairment loss of $2,893,548 for its long-lived intangible assets and $1,249,727 for the acquired software. The Company concluded there was no impairment of its other finite lived tangible assets as of December 31, 2021.

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 as of December 31, 2019, 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.

During the third quarter of 2021, the Company concluded that potential impairment indicators were present and that an impairment assessment was warranted for goodwill. In testing goodwill for impairment as of September 30, 2021, 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 fully impaired as of September 30, 2021.

The quantitative review as of September 30, 2021 resulted in $2,813,792 of impairment expense related to goodwill. As of September 30, 2021, the cumulative impairment recorded was $23,790,290.

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 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 4.0% determined based on the growth prospects of the reporting unit; and (c) a discount rate of 15% based on management's best estimate of the after-tax weighted average cost of capital. The Company further used a probability weighting of various forecasts to address forecast risk.

Goodwill of $7,231,093 was recognized in the zPREDICTA 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 will be deductible for income tax purposes. See *Note 2 – zPREDICTA acquisition*.

During the second quarter of 2022, the Company concluded that potential impairment indicators were present and that an impairment assessment was warranted for goodwill. In testing goodwill for impairment as of June 30, 2022, the Company performed a quantitative impairment test, including computing the fair value of the zPREDICTA 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 fully impaired as of June 30, 2022. When evaluating the fair value of the zPREDICTA 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 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) and (b) an estimated terminal value using a terminal year growth rate of 4.0% determined based on the growth prospects of the reporting unit. The Company further used a probability weighting of various forecasts to address forecast risk. The Company used an estimated discount rate of 65% based on management's best estimate and considering the Company's current market capitalization.

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

Goodwill balance at December 31, 2020	$	2,813,792
Impairment		(2,813,792)
Acquisition of zPREDICTA		6,857,790
Goodwill balance at December 31, 2021	$	6,857,790
Adjustment to fair value		373,303
Impairment		(7,231,093)
Goodwill balance at December 31, 2022	$	-

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.

NOTE 9 – LEASES

The Company's corporate offices are located in Eagan, Minnesota. The lease as amended has a three-year term ended January 31, 2021. The Company leases 5,773 square feet at this location, of which 2,945 square feet is used for office space and 2,828 is used for manufacturing. The lease is month-to-month tenancy.

The offices of our Helomics subsidiary are located in Pittsburgh, Pennsylvania. We lease 20,835 square feet at this location, of which approximately 4,418 square feet are used for office space and 16,417 square feet is used for laboratory operations. We have two leases, with the primary lease as amended, having a two-year term ending February 28, 2023 and the second lease term ending December 31, 2022. We entered into two new leases effective March 1, 2023 which each having an approximate five-year term ending February 28, 2028.

zPREDICTA's offices were located in San Jose, California. The Company leased approximately 1,236 square feet at this location. The lease was month-to-month tenancy and the Company ended the lease as of January 31, 2023.

Soluble Biotech's offices are located in Birmingham, Alabama. The Company leases approximately 5,274 square feet at this location. The lease is effective through August 25, 2025.

TumorGenesis's offices were located in Salem, Massachusetts. The Company leased approximately 1,450 square feet at this location. The Company terminated the lease in September 2022.

Lease expense under operating lease arrangements was $746,590 and $595,669 for 2022 and 2021, respectively.

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

	December 31, 2022	December 31, 2021
Weighted average remaining lease term – operating leases in years	1.72	1.69
Weighted average discount rate – operating leases	8%	8%

The Company's operating lease obligation as of December 31, 2022 which includes expected lease extensions that are reasonably certain of renewal, are as follows:

2023	$ 127,986
2024	71,420
2025	48,552
Total lease payments	247,958
Less interest	67,639
Present value of lease liabilities	$ 180,319

NOTE 10 – Property, Plant and Equipment

Fixed Assets

The Company's fixed assets consist of the following:

	December 31, 2022	December 31, 2021
Computers, software and office equipment	$ 463,292	$ 517,488
Laboratory equipment	3,559,362	3,456,091
Leasehold improvements	535,527	428,596
Manufacturing tooling	121,120	121,120
Demo equipment	31,554	56,614
Total	4,710,855	4,579,909
Less: Accumulated depreciation	2,877,600	2,068,338
Total fixed assets, net	$ 1,833,255	$ 2,511,571

Upon retirement or sale or 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.

The Company prepared an undiscounted cash flow as of December 31, 2022 to evaluate long-lived assets based on a triggering event per ASC 360 and recognized an impairment loss of $3,349,375 on those intangibles. The Company also concluded there was an impairment of its other finite lived tangible assets as of December 31, 2022 and recognized an impairment of $185,469 during the fourth quarter of 2022. See *Note 8 – Goodwill and Intangibles.*

The Company prepared an undiscounted cash flow as of December 31, 2021 to evaluate long-lived assets based on a triggering event per ASC 360 and recognized and impairment loss of $2,893,548 for its long-lived intangible assets and $1,249,727 for the acquired software. The Company concluded there was no impairment of its other finite lived tangible assets as of December 31, 2021. See *Note 8 – Goodwill and Intangibles.*

Depreciation expense was $898,369 and $965,973 in 2022 and 2021, respectively.

NOTE 11 – 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.

The Company has four reportable segments: Helomics, zPREDICTA, Soluble and Skyline. 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 Company's segment reporting as of and for years ended December 31, 2022 and 2021.

	Year Ended December 31, 2022					
	Skyline	**Helomics**	**Soluble**	**zPREDICTA**	**Corporate**	**Total**
Revenue	$ 1,063,493	$ 6,397	$ 82,301	$ 352,379	$ 889	$ 1,505,459
Depreciation and Amortization	(28,481)	(445,686)	(378,708)	(390,985)	(69,215)	(1,313,075)
Impairment expense – goodwill	-	-	-	(7,231,093)	-	(7,231,093)
Impairment expense – intangibles	-	-	-	(3,349,375)	-	(3,349,375)
Impairment expense – Long-lived tangible assets	-	-	(115,775)	-	(69,694)	(185,469)
Net loss	$ (417,774)	$ (4,122,444)	$ (1,817,283)	$ (11,618,762)	$ (7,761,371)	$ (25,737,634)

	December 31, 2022					
	Skyline	**Helomics**	**Soluble**	**zPREDICTA**	**Corporate**	**Total**
Assets	$ 946,394	$ 931,721	$ 1,353,434	$ 123,507	$ 22,379,588	$ 25,734,644

	Year Ended December 31, 2021					
	Skyline	**Helomics**	**Soluble**	**zPREDICTA**	**Corporate**	**Total**
Revenue	$ 1,169,811	$ 13,367	$ 233,293	$ 90	$ 4,119	$ 1,420,680
Depreciation and Amortization	(30,002)	(886,642)	(366,713)	(40,625)	(16,319)	(1,340,301)
Impairment expense – goodwill	-	(2,813,792)	-	-	-	(2,813,792)
Impairment expense – intangibles	-	(2,893,548)	-	-	-	(2,893,548)
Impairment expense – acquired software	-	(1,249,727)	-	-	-	(1,249,727)
Net loss	$ (520,822)	$ (11,326,948)	$ (1,251,564)	$ 531,446	$ (7,089,286)	$ (19,657,174)

	December 31, 2021					
	Skyline	**Helomics**	**Soluble**	**zPREDICTA**	**Corporate**	**Total**
Assets	$ 906,977	$ 1,802,792	$ 1,742,445	$ 10,782,568	$ 28,536,489	$ 43,771,271

In each December 31, 2022 and 2021, substantially all the Company revenues were located or derived from operations in the United States. As of December 31, 2022, all of the Company's long-lived assets were located within the United States.

NOTE 12 – RETIREMENT SAVINGS PLANS

The Company has a pre-tax salary reduction/profit-sharing plan under the provisions of Section 401(k) of the Internal Revenue Code, which covers employees meeting certain eligibility requirements. During 2022 and 2021, the Company matched 100% of the employee's contribution up to 4.0% of their earnings. The employer contribution was $99,924 and $127,953 in 2022 and 2021, respectively. There were no discretionary contributions to the plan in 2022 and 2021.

NOTE 13 – SUBSEQUENT EVENTS

The Company's Board of Directors declared a dividend of one one-thousandth of a share of newly designated Series F Preferred Stock, par value $0.01 per share, for each outstanding share of the Company's common stock held of record as of 5:00 p.m. Eastern Time on March 27, 2023 (the "Preferred Stock"). The Preferred Stock will vote together with the outstanding shares of the Company's common stock, as a single class, exclusively with respect to a reverse stock split, as well as any proposal to adjourn any meeting of stockholders called for the purpose of voting on the reverse stock split and will not be entitled to vote on any other matter, except to the extent required under the Delaware General Corporation Law. Subject to certain limitations, each outstanding share of Preferred Stock will have 1,000,000 votes per share (or 1,000 votes per one one-thousandth of a share of Preferred Stock).

All shares of Preferred Stock that are not present in person or by proxy at the meeting of stockholders held to vote on the reverse stock split as of immediately prior to the opening of the polls at such meeting will automatically be redeemed by the Company. Any outstanding shares of Preferred Stock that have not been so redeemed will be redeemed if such redemption is ordered by the Company's Board of Directors or automatically upon the approval by the Company's stockholders of an amendment to the Company's certificate of incorporation effecting the reverse stock split at such meeting.

The Preferred Stock will be uncertificated, and no shares of Preferred Stock will be transferable by any holder thereof except in connection with a transfer by such holder of any shares of the Company's common stock held by such holder. The Certificate of Designation of Preferred Stock dated March 16, 2023 contains the full rights, powers and preferences, and the qualifications, limitations and restrictions of the Preferred Stock.

Exhibit 21.1

PREDICTIVE ONCOLOGY INC.
SUBSIDIARIES OF THE REGISTRANT

Subsidiary	**Jurisdiction of Incorporation**
Helomics Corporation	Delaware
Skyline Medical, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File No. 333-239207, 333-252584, 333-252585, and 333-267689); Form S-3 (File No. 333-221966, 333-228908, 333-235441, 333-237581, 333-239851, 333-254309 and 333-255582); 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, 333-250149, and 333-259264) of Predictive Oncology Inc. (the "Company") of our report dated March 21, 2023, relating to the consolidated financial statements, which report expresses an unqualified opinion on the consolidated financial statements for the year ended December 31, 2022, appearing herein.

/s/ Baker Tilly US, LLP
Minneapolis, Minnesota
March 21, 2023

EXHIBIT 31.1

CERTIFICATION

I, Raymond F. Vennare, 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 21, 2023

/s/ Raymond F. Vennare

Raymond F. Vennare
Chief Executive Officer (Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Bob Myers, certify that:

1. I have reviewed this annual report on Form 10-K of 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 21, 2023

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

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED 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, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Raymond F. Vennare, 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:

(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 21, 2023

/s/ Raymond F. Vennare
Raymond F. Vennare
Chief Executive Officer
(Principal Executive Officer)

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