UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2023

or

☐ **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)	(I.R.S. Employer Identification No.)

91 43rd Street, Suite 110 Pittsburgh, Pennsylvania 15201
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (412) 432-1500

(Former name, former address and former fiscal year, if changed since last report)

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

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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

Indicate by check mark 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of common stock held by non-affiliates was $18,983,374, based upon 3,906,044 shares at $4.86 per share as reported on the NASDAQ Capital Market.

As of March 18, 2024, the registrant had 4,062,853 shares of common stock, par value $.01 per share outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

PREDICTIVE ONCOLOGY INC.

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PART I

ITEM 1. BUSINESS.

General

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

Cautionary Statement Concerning Forward-Looking Statements

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

Overview

We are a knowledge and science-driven company that applies artificial intelligence ("AI") to support the discovery and development of optimal cancer therapies, which can ultimately lead to more effective treatments and improved patient outcomes. We use AI and a proprietary biobank of 150,000+ tumor samples, categorized by tumor type, to provide actionable insights about drug compounds to improve the drug discovery process and increase the probability of drug compound success. We offer a suite of solutions for oncology drug development from early discovery to clinical trials.

Our mission is to change the landscape of oncology drug discovery and enable the development of more effective therapies for the treatment of cancer. By harnessing the power of machine learning and scientific rigor, we believe that we can improve the probability of success of advancing pharmaceutical and biological drug candidates with a higher degree of confidence.

We operate in three business areas. In our first area, we provide optimized, high-confidence drug-response predictions through the application of AI using our proprietary biobank of tumor samples to enable a more informed selection of drug/tumor combinations and increase the probability of success during development. We also create and develop tumor-specific 3D cell culture models mimicking the physiological environment of human tissue enabling better-informed decision-making during development. In our second business area, we provide services and research using a proprietary self-contained and 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 of biologics. Our third business area produces the United States Food and Drug Administration ("FDA")-cleared STREAMWAY® System and associated products for automated medical fluid waste management and patient-to-drain medical fluid disposal. As of January 1, 2023, we changed our reportable segments to align with these business areas.

We have three reportable segments, which have been delineated by location and business area:

- *Pittsburgh segment:* provides services that include the application of AI using its proprietary biobank of 150,000+ tumor samples. Pittsburgh also creates proprietary 3D culture models used in drug development.
- *Birmingham segment*: provides contract services and research focused on solubility improvements, stability studies, and protein production.
- *Eagan segment*: produces the FDA-cleared STREAMWAY System and associated products for automated medical fluid waste management and patient-to-drain medical fluid disposal.

PITTSBURGH

Drug Discovery Solutions – PEDAL

Patient-centric Drug Discovery using Active Learning ("PEDAL"™), our proprietary AI-driven platform, offered by our Pittsburgh segment, is designed to provide high-confidence drug-response predictions. This platform combines our biobank of samples with a one-of-a-kind database of historical tumor data, and the power of AI to efficiently build predictive models of tumor drug response. Our PEDAL asset is a unique technology that combines one of the largest privately held commercial biobanks of tumor samples, AI active machine learning, and multi-omic historical tumor data – complete with on-site Clinical Laboratory Improvement Amendments ("CLIA") certified lab testing capabilities to inform drug/tumor model predictions. PEDAL offers researchers the opportunity to incorporate patient diversity early, efficiently, and cost-effectively into the drug discovery process by using data from hundreds of patient samples. PEDAL works by iterative cycles of active learning to guide the testing of patient samples against specific compounds. This results in PEDAL efficiently building comprehensive predictive models of patient drug response in a matter of weeks. This predictive model can rank compounds against tumor samples of certain profiles that respond to specific drugs and can also predict the set of compounds that provide the best coverage across patient tumor samples.

We believe leveraging our unique, historical database of tumor drug responses, genomics, biomarkers, digitized pathology slides, and histopathology data with over 150,000 patient tumor samples to efficiently build AI driven predictive models of tumor drug response will provide actionable insights critical to new drug development. Through the course of over 15 years of clinical testing of patient tumor responses to drugs, our Pittsburgh lab has amassed a huge proprietary knowledgebase of data. To provide for our patient-centric approach, this dataset has been rigorously de-identified and aggregated to inform our proprietary process to create models of tumor drug response.

PEDAL can significantly increase the probability of clinical success by introducing patient diversity early in the development process, while also decreasing the time and cost of oncology drug 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, utilizing this highly efficient screening of drug responses against thousands of diverse, well-characterized patient primary tumor samples. With each iteration of a PEDAL campaign, 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. This novel disruptive approach is ideally suited to the early part of drug discovery while also being highly customizable to meet the needs of our collaborators. Our patient-centric drug discovery approach provides for the prioritization of drug compound candidates while accounting for patient tumor diversity. This should dramatically improve the chances of successfully translating discoveries into successful therapies, while simultaneously lowering costs through shortened development timelines, and most importantly, enhanced "speed-to-patient" for new therapies.

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 into 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, provides optimized, efficient, high-confidence drug-response predictions. Our platform is designed to move molecules forward with a higher probability of clinical 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.

3D Modeling

Our Pittsburgh segment also develops tumor-specific in vitro models for oncology drug discovery and research. Our 3D tumor-specific models accelerate the drug development process for our clients and partners by providing drug response predictions with high correlation to clinical response, enabling our biopharma clients to manage pipeline prioritization more efficiently.

The 3D 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 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 3D 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 models support proliferation of malignant and non-malignant cellular components of tissues.

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.

Clinical Testing

Through our wholly owned subsidiary, Helomics Corporation ("Helomics"), reported under our Pittsburgh segment, 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.

Clinical diagnostic testing is comprised of our Tumor Drug Response Testing (ChemoFx™), Genomic Profiling Testing (BioSpeciFx), and other biomarker 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 and biomarker profiling evaluates the expression and/or status of a particular gene or protein related to a patient's tumor specimen.

Testing involves obtaining tumor tissue during biopsy or surgery, which is then sent to our 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 genomic mutation tests associated with drug response and disease prognosis. Physicians can select biomarkers for testing from carefully chosen panels of relevant tests, 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.

BIRMINGHAM

Drug Development Solutions – Formulations for Biologics

Our Birmingham segment focuses on contract services and research for biopharmaceutical company clients and academic collaborators, focused on solubility improvements, stability studies, and protein production. Specifically, Birmingham provides optimized FDA-approved formulations for vaccines, antibodies, and other protein therapeutics in a faster and lower cost basis to its customers, as described below. In addition, our Birmingham segment enables protein degradation studies, which based on current projections, could be a substantial line of business for the Company.

The primary asset of our Birmingham segment is our proprietary automated High Throughput Self-Interaction Chromatography ("HSC"™) platform. Our HSC platform 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 rapidly measures the solubility of protein in different excipients and excipient combinations that promote improved 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 and biology studies necessary to advance fundamental research in areas of unmet medical need.

In addition, our Birmingham segment provides comprehensive protein stability analyses via time-dependent shelf-life studies and forced degradation studies designed to quickly determine which of the additives previously approved by the FDA 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, viscosity, oxidizing agents, and mechanical stress to determine the most promising additives, formulation of *B22* values and validation of 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.

The Birmingham segment 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). Birmingham 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, our Birmingham segment 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. Our Birmingham segment 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, Birmingham provides sample treatment kits to minimize detection interference while using standard detection assays. At our Birmingham facility, we can manufacture high-quality endotoxin detection and removal products to help our customers efficiently meet safety standards. We follow Good Manufacturing Practices (“GMP”), International Council for Harmonization (“ICH”) and Good Laboratory Practice (“GLP”) standards throughout to ensure consistent and standardized products and services.

EAGAN

STREAMWAY® System

Through our wholly owned subsidiary, Skyline Medical Inc. (“Skyline Medical”), reported under our Eagan segment, we sell the STREAMWAY System, as well as proprietary cleaning solution and filters for use with the STREAMWAY System. The STREAMWAY System is an FDA-cleared, automated, patient-to-drain waste fluid disposal system designed for medical environments involving potentially infectious medical waste fluids. 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 of properly. Our products minimize the exposure potential to the healthcare workers who handle such fluids.

Our STREAMWAY System is a wall-mounted system that disposes of an unlimited amount of bodily and irrigation fluids 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 disposables used for operation of the STREAMWAY System are a critical component of our business model, and we expect will provide significant recurring revenues. We have exclusive distribution rights to the disposable cleaning solution.

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. The STREAMWAY System 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.

Industry and Market Background and Analysis

Drug Discovery and Development Solutions

The growing demand for the improvement in the discovery and development process of novel drug therapies is driving the demand for AI-empowered solutions. Growing partnerships and cooperation are expected to fuel global market for AI in drug development. The adoption of AI solutions in the drug development process increases efficiency, reduces cycle time, and increases the productivity and accuracy of the risky and long process. Due to these advantages, the importance of AI in drug discovery and development is expected to drive the global market. AI-powered drug discovery 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 clinical 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.

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 patient-centric 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 prioritize their oncology portfolio. The PEDAL platform supports a biopharma client's decision on the drug molecules with a higher likelihood of clinical success. With PEDAL, we look to improve/enhance the way that the biopharma industry carries out the development of oncology drugs. We believe our platform provides unique financial- and time-saving advantages for pharmaceutical companies.

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 allows for alternatives to animal-testing requirements for the development of drugs and allows drug manufacturers to opt out of animal testing while utilizing other 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 a shift towards more efficient, accurate and predictive models.

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 particularly 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 to 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 of 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 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 medical fluid management and new medical technology.

Competition and Competitive Advantages

Drug Discovery Solutions – PEDAL and 3D Modeling

On average, new oncology drug compounds take 10-12 years to become approved for use, from discovery to commercial launch. Identifying those compounds 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 in clinical trials to meet the therapeutic end points in a large population.

AI companies addressing the needs in the drug discovery market are looking at the drug discovery and development challenges from different angles. However, we believe no other company has access to a comparable privately held biobank with tumor drug responses, genomics, biomarkers, digitized pathology slides, and histopathology data. The ability to pair AI with our biobank provides us with a competitive advantage and creates a barrier to entry for competitors in the drug response prediction space.

We believe this patient-derived, highly curated, multi-omic tumor model offers a better chance of generating 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 new drug development, individualizing patient treatment, drug repurposing, and biomarker development. Identifying cohorts of patient tumors most responsive to candidate drugs informs the early drug candidate selection process in a patient-centric manner that we do not believe is offered elsewhere. The tumor cohorts identified by our models can also be analyzed and stratified to optimize patient selection criteria for improved clinical trials. A deeper analysis of these same tumor cohorts found to be highly responsive to a particular drug candidate can be further utilized for targeted biomarker development and/or targeted assay development.

We also fulfill unmet needs in the drug discovery market with the next-generation technology of our 3D models, based on extensive knowledge 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 provide 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/or disease of interest instead of pursuing a one-size-fits-all approach taken by other companies. Recreating specific tumor microenvironments enables more reliable prediction of tissue response to drugs with varying mechanisms of action. This same technology can also be used to demonstrate potential toxic drug effect on normal tissues by maintaining an accurate reconstruction of cellular and extracellular compartments of human tissues.

Drug Development Solutions – Formulations for Biologics

Our HSC platform is a self-contained, automated system that conducts high-throughput, self-interaction chromatography screens on FDA approved excipients for protein formulations. The HSC system provides clear competitive advantages. First, HSC measures the solubility in all FDA-approved excipients and excipient combinations rather than a limited subset of excipients. The HSC also requires smaller sample sizes and decreased time and manpower to optimize formulations. Using data generated from HSC screens, our proprietary predictive algorithm identifies the optimal combination(s) of buffers, pH, and excipients based on more than 4,000 possible combinations, resulting in increased solubility and physical stability of proteins. The top predictive solubilities are then validated using experimental methods in combination with the HSC to produce multiple formulations to meet customer requirements.

The HSC instrument and its technology has been validated over the past twelve years via industry and academic collaborations. 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.

Infectious and Biohazardous Waste Management

We believe that the STREAMWAY System is unique to the infectious and biohazardous waste management 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 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.

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.

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 $188,305 and $320,320 in 2023 and 2022, 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.

CORE™

We have been granted an exclusive world-wide license to CORE, our computational drug discovery platform that can predict the main effects of drugs on disease-associated targets. The licensed technology is protected by PCT/US2012/025029, U.S. Patent Application Number 16/296,088, China Patent Number 201280013276.2, Japan Patent Number 6133789, and Hong Kong Patent Number 1193197.

3D Modeling

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 and US11,124,756.

STREAMWAY® System

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 on our earlier STREAMWAY System models: US7,469,727 and US8,123,731 (collectively, the "First Generation Patents"). The First Generation Patents will begin to expire on April 17, 2024.

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. We filed both U.S. and European national stage applications from this PCT application. We have two issued U.S. patents claiming priority from the PCT application: US10,253,792 and US10,954,975 (collectively, the "Second Generation Patents"). The Second Generation Patents will begin to expire on January 25, 2034.

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. European Patent #EP2948200 in the following countries: Belgium, Germany, Spain, France, United Kingdom, Ireland, Italy, Netherlands, Norway, Poland, and Sweden. Further, we filed a European divisional application, which was granted as European Patent #EP3437666 on March 26, 2020. European Patent #EP3437666 was validated in the following countries: Belgium, Switzerland, Cyprus, Germany, Spain, France, United Kingdom, Hungary, Ireland, Italy, Liechtenstein, North Macedonia, Malta, Netherlands, Norway, Poland, Sweden, and Turkey. 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. Our 510(k) number is K090759.

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. Our Health Canada Medical Device Establishment License number is 7202.

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 34 full-time employees and 1 part-time employee as of December 31, 2023. 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 91 43rd Street, Suite 110 Pittsburgh, Pennsylvania and our telephone number is (412) 432-1500.

Corporate History

We were originally incorporated in Minnesota 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 https://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 https://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 (https://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 Related to Our Business

There is substantial doubt about our ability to continue as a going concern. We will require significant additional financing to fund operating expenses and implement our business plan. Such financing, if available, may be dilutive.

We have incurred significant and recurring losses from operations for the past several years and had an accumulated deficit of $167,761,883 as of December 31, 2023. We had cash and cash equivalents of $8,728,660 as of December 31, 2023 and need to raise significant additional capital to meet our operating needs. Our short-term obligations as of December 31, 2023 were $3,951,031, consisting primarily of aggregate accounts payable and accrued expenses of $2,973,729 and operating lease obligations of $517,427. As of December 31, 2023, we also had a short-term note payable of $150,408 that bears interest at an annual percentage rate of 9.25% and long-term operating lease obligations of $2,188,979 with a weighted average remaining lease term of 3.99 years. We do not expect to generate sufficient operating revenue to sustain our operations in the near term. During the year ended December 31, 2023, we incurred negative cash flows from operations of $13,189,390. Although we have attempted to improve our operating margin by bolstering revenues and curtailing expenses and continue to seek ways to generate revenue through business development activities, there is no guarantee that we will be able to improve our operating margin sufficiently or achieve profitability in the near term. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date our consolidated financial statements included in this annual report on Form 10-K are issued. We are evaluating alternatives to obtain the required additional funding to maintain future operations. These alternatives may include, but are not limited to, equity financing, issuing debt, entering into other financing arrangements, or monetizing operating businesses or assets. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing stockholders or that result in our existing stockholders losing part or all of their investment. Despite these potential sources of funding, we may be unable to access financing or obtain additional liquidity under acceptable terms, if at all. If such financing or adequate funds from operations are not available, we would be forced to limit our business activities and we could default on existing payment obligations, which would have a material adverse effect on our financial condition and results of operations, and may ultimately be required to cease our operations and liquidate our business.

The use of AI in our business is subject to risks associated with new and rapidly evolving technologies and industries, may result in reputational harm or liability, and may not result in the development of commercially viable therapies, drugs or treatments.

Our business model relies on the use of AI to support the development of optimal cancer therapies. Using AI and our proprietary biobank of 150,000+ tumor samples, categorized by patient type, we make optimized, high-confidence drug-response predictions regarding drug compounds to enable a more informed selection of drug/tumor combinations. While we believe that AI may potentially enable more efficient drug research and clinical development than the conventional model, our approach is novel and has not yet been widely studied. Our use of AI is subject to risks and challenges associated with new, disruptive, and rapidly evolving technologies and industries, which may affect its adoption and the success of our business. The algorithms we use may be flawed, our datasets may be insufficient or contain biased information, and inappropriate or controversial data practices by us or others could impair the acceptance of AI solutions. These deficiencies could undermine the predictions or analysis that AI applications produce, subjecting us to competitive harm, legal liability, and brand or reputational harm. Additionally, changes in laws and regulations could impact the usefulness of our solution and could necessitate modifications in our business to accommodate such changes. The regulatory landscape for AI is continually evolving, and both the FDA and the European Medicines Agency are in the process of issuing comprehensive guidance on AI software which may change how our product is regulated.

Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new drugs as quickly or cost-effectively as expected and, therefore, we may not be able to commercialize our approach as expected at this time.

We have entered into, and may enter into additional, collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements to develop products and to pursue new markets. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products. Our ability to generate revenues from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any future collaborators, they may act in their self-interest, which may be adverse to our best interests, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various due diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

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 we may not 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 significant capital to investments in early-stage companies, all of which may be lost, and our ability to continue to commit capital in other early-stage companies will require us to raise significant additional capital. Our entering into new lines of business could 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. Any investments using cash will deplete our capital resources, meaning we will be required to raise significant amounts of new capital. We may not be successful in raising sufficient capital, and the terms of any such financing may 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 business, 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 in our business. 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 used in our business, if the materials do not meet required quality specifications, or if we cannot obtain acceptable substitute materials, an interruption in our products and services provided to customers 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 products could lead to product liability claims. These claims could allege that the products failed to perform as they were 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 take 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 to our STREAMWAY System 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 may 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, then we or our manufacturing partners may not be able to produce the product in sufficiently higher quantity to satisfy demand.

Likewise, as demand for our molecular diagnostic tests grows, 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. We may not be able to perform our testing on a timely basis at a level consistent with demand, and our efforts to scale our operations may 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 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, financial condition, and results of operations.

Our success depends on the skills, experience, and performance of key members of our management team. Were we to lose one or more members of our management team for any reason, we would be required to expend significant time and money to find 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 may not be able to find satisfactory replacements for members of our management team at all, or on terms that are not unduly expensive or burdensome to us. Such loss of a key member or members of our management team without adequate replacements would have a negative impact on our business, financial condition, and results of operations.

Risk Factors 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 any measure we implement may not 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.

If we breach our license agreements it could have a material adverse effect on our commercialization efforts for our product candidates.

A portion of our patent portfolio is in-licensed. As such, we are a party to license agreements and certain aspects of our business depend on patents and/or patent applications owned by other companies or institutions. The license agreements impose specified diligence, milestone payment, royalty, and other obligations on us and requires that we meet development timelines, or to exercise diligent or commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the license. Our rights with respect to in-licensed patents and patent applications may be lost if the applicable license agreement expires or is terminated or if we fail to satisfy the obligations under the License Agreement. We are likely to enter into additional license agreements to in-license patents and patent applications as part of the development of our business in the future, under which we may not retain control of the preparation, filing, prosecution, maintenance, enforcement, and defense of such patents. If we are unable to maintain these patent rights for any reason, our ability to develop and commercialize our product candidates could be materially harmed.

Our licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability.

Risks with respect to parties from whom we have obtained intellectual property rights may also arise out of circumstances beyond our control. In spite of our best efforts, our licensors might conclude that we have materially breached our intellectual property agreements and might therefore terminate the intellectual property agreements, thereby removing our ability to market products covered by these intellectual property agreements. If our intellectual property agreements are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our intellectual property agreements are terminated, our former licensors and/or assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on our competitive business position and our financial condition, results of operations and our business prospects.

Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration, and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

Further, recent judicial decisions in the U.S. raised questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will be viewed in the future and whether patent expiration dates may be impacted.

Changes in patent law, including recent patent reform legislation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In September 2011, the America Invents Act (AIA) was enacted in the United States, resulting in significant changes to the U.S. patent system. An important change introduced by the AIA was a transition to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention, which went into effect on March 16, 2013. Therefore, a third party that now files a patent application in the USPTO before we do could be awarded a patent covering an invention of ours even if we created the invention before it was created by the third party. While we are cognizant of the time from invention to filing of a patent application, circumstances could prevent us from promptly filing patent applications for our inventions.

Among some of the other changes introduced by the AIA were changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower burden of proof in USPTO proceedings compared to the burden of proof in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its continued implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, and the patent applications of our existing and future collaborators or licensors and the enforcement or defense of our issued patents.

Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, there is complexity and uncertainty related to European patent laws. For example, the European Patent Convention was amended in April 2010 to limit the time permitted for filing divisional applications. In addition, the EPO patent system is relatively stringent in the type of amendments that are allowed during prosecution. These limitations and requirements could adversely affect our ability to obtain new patents in the future that may be important for our business.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Even if we are successful in defending against these types of claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. Some of our competitors may be able to sustain the costs of this type of litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

Beginning June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court (UPC). Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

Risk Factors Related 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. Any such change could also result in a failure to obtain necessary approvals for our current or future products, which would negatively impact our financial condition and results of operations.

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. The FDA has historically taken the position that it has the authority to regulate Laboratory Developed Tests ("LDTs") as medical devices under the Federal Food, Drug, and Cosmetic Act, but it has a long-standing policy of not exercising general enforcement discretion with regard to LDTs. Accordingly, LDTs have effectively not been 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). However, in September 2023, the FDA published a proposed rule on LDTs that would end the FDA's prior policy of enforcement discretion with respect to LDTs. The proposed rule would phase out the FDA's enforcement discretion policy in five stages over a four-year period from the effective date of the rule. In Phase 1 (effective one year after the rule is finalized), enforcement discretion would end with respect to medical device reporting and correction and removal reporting requirements. In Phase 2 (effective two years post-finalization), enforcement discretion would end with regard to other device requirements, including registration and listing, labeling, and investigational devices, except for quality systems and premarket review. In Phase 3 (effective three years post-finalization), enforcement discretion would end with regard to quality systems requirements. In Phase 4 (effective three and a half years post-finalization, but not before October 1, 2027), enforcement discretion would end with regard to compliance with premarket review requirements for high-risk tests (i.e., tests subject to premarket approval). Finally, in Phase 5 (effective four years post-finalization, but not before April 1, 2028), enforcement discretion would end with regard to premarket review requirements for moderate-risk and low-risk tests. Unlike previous proposals, the proposed rule does not "grandfather in" any existing tests. At this time, the proposed rule has not been finalized, and its ultimate content (including whether the rule will go into effect at all) remains unknown.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced in previous Congresses, including the "Verifying Accurate Leading-edge IVCT Development Act," or VALID Act, 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 being reimbursed at a higher amount from Medicare, Medicaid, and other Federal programs, than what we charge 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. Possible violations of Federal or State regulations may spur investigations or enforcement actions by the FDA, Department of Justice, State agencies, or other legal authorities, and confirmed violations may result in substantial civil, criminal, or other fees, penalties or 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 we received, 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.

Risk Factors 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, financial condition, and results of operations. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team.

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 of Nasdaq informing us that because the closing bid price for our common stock listed on Nasdaq was below $1.00 for 30 consecutive trading days, we did 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. This deadline was subsequently extended by Nasdaq to May 8, 2023.

On April 23, 2023, we effected a 20-for-1 reverse stock split to cure this deficiency. As a result, our stock price increased significantly, and we regained compliance with the Minimum Bid Price Requirement. However, since the reverse stock split, our stock price has declined and, as of March 18, 2024, our closing stock price was $2.70 per share. If we subsequently fail to meet the Minimum Bid Price Requirement or another requirement for continued listing on Nasdaq, we could be delisted.

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 through one or more over-the-counter markets. 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.

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 that 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.

You may experience dilution as a result of future equity offerings.

We may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. Although no assurances can be given that we will consummate a future financing, in the event we do, or in the event we sell shares of common stock or other securities convertible into shares of our common stock in the future, additional and potentially substantial dilution could occur.

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, 2023, we had 1,806,589 warrants outstanding at a weighted average exercise price of $21.52 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 Stock Incentive Plan. Under the 2012 Stock Incentive Plan, 47,664 shares were issuable under outstanding incentive awards at December 31, 2023, and 94,878 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.

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 considering 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 is limited by the Delaware General Corporation Law, which provides that dividends may only be lawfully paid out of a corporation's "surplus," which is generally defined as the amount by which total assets exceed total liabilities. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, and the availability of a liquid trading market in our shares as the only way to realize certain returns on their investment.

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.

Our stock price may be volatile, and you could lose all or part of your investment.

The trading price of our common stock may fluctuate substantially and will depend on several factors, including those described in this "Risk Factors" section, many of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose all or part of your investment in our securities.

In addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political and market conditions such as recessions or interest rate changes, may seriously affect the market price of our common stock, regardless of our actual operating performance.

Further, in the past, following periods of volatility in the overall market and the market prices of particular companies' securities, securities class action litigations have often been instituted against these companies. Litigation of this type, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

General Risk Factors

Business disruptions could harm our operations, lead to a decline in revenue and increase our costs.

Our operations could be disrupted by political and/or civil unrest, acts of war or other military actions, such as recent and ongoing conflicts in Israel/Gaza and Ukraine, epidemics or pandemics, such as a potential resurgence of the COVID-19 pandemic, and other natural or man-made disasters and catastrophic events. Geopolitical and domestic political developments and other events beyond our control, can increase economic volatility globally and disrupt supply chains we rely on. Our operations could be harmed and our costs could increase if manufacturing, logistics or other operations are disrupted for any reason, including economic, business, labor, environmental, public health, or political issues. We monitor and act as necessary to mitigate potential risks of shortages and delays that may impact our ability to obtain new contracts, fulfill product demands and meet our contract obligations. The extent to which business disruptions may impact our financial condition and results of operations remains uncertain and is dependent on numerous evolving 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. The Company performed a Section 382 analysis as of December 31, 2023 which resulted in the limitation and expiration of a substantial portion of the Company's loss carryforwards. In addition, the current net operating loss ("NOL") carryforwards might be further limited by future issuances of our common stock.

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 may be unable to provide stock-based incentives to our employees without an increase in shares available for issuance.

Due to the low number of shares remaining available for issuance, we may be unable to provide stock-based incentives to our employees. Any increase in shares issuable will be subject to stockholder approval, which may not be obtained. Not obtaining stockholder approval could materially impact our ability to provide stock-based incentives to our employees, which could mean that we have to pay more cash, which is currently limited.

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 stockholders' 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 could 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. Also, the indemnification granted by sellers of acquired companies may not 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 do not believe 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 general 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, 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 operations, 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 1C. CYBERSECURITY.

Our Board of Directors (the "Board") recognizes the critical importance of maintaining the trust and confidence of our customers, clients, business partners and employees. The Board exercises oversight of our risk management program, and cybersecurity represents an important component of our overall approach to enterprise risk management ("ERM"). Our cybersecurity policies, standards, processes, and practices are integrated into our ERM program and are based on frameworks established by the National Institute of Standards and Technology ("NIST") and other applicable industry standards. In general, we seek to address cybersecurity risks through a cross-functional approach that is focused on preserving the confidentiality, security, and availability of the information that we collect and store by identifying, preventing, and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Risk Management and Strategy

As one of the critical elements of our overall ERM approach, our cybersecurity program is focused on the following key areas:

- **Governance.** As discussed in more detail under the heading "Governance," the Board maintains an active role concerning cybersecurity risk management including oversight of the Company's employee personnel with extensive experience in the field.

- **Technical Safeguards and Risk Management Processes.** We have implemented a risk management framework to identify, evaluate, and address cybersecurity risks. This framework includes the deployment of tools to detect potential threats, the maintenance of detailed incident logs, and the development of risk mitigation strategies. Our cybersecurity measures and policies are subject to regular testing and continuous improvement to adapt to new threats as they arise.

- **Education and Incident Reporting.** We have instituted a company-wide security awareness training program to educate employees about cybersecurity risks and their role in maintaining our security posture. Continuous education and testing support our workforce in remaining knowledgeable and vigilant to cybersecurity threats. Employees are instructed to report all cybersecurity concerns directly to our internal information technology ("IT") team for immediate assessment and response.

- **Cybersecurity Incident Response Plan.** We maintain a comprehensive incident response plan designed to mitigate the impact of a cybersecurity incident. This plan includes protocols for internal response, external communication, and remediation efforts to minimize the impact on our operations and stakeholders.

- **Third-Party Risk Management.** We maintain a risk-based approach to identifying and overseeing cybersecurity risks presented by third parties, including vendors, service providers and other external users of our systems, as well as the systems of third parties that could adversely impact our business in the event of a cybersecurity incident affecting those third-party systems.

We engage in the periodic assessment and testing of our policies, standards, processes, and practices that are designed to address cybersecurity threats and incidents. These efforts include a range of activities, including audits, assessments, vulnerability testing, and other exercises focused on evaluating the effectiveness of our cybersecurity measures and planning. We engage third parties to perform assessments on our cybersecurity measures, including information security maturity assessments, audits, and independent reviews of our information security control environment and operating effectiveness. The results of such assessments, audits, and reviews are reported to the Board, and we adjust our cybersecurity policies, standards, processes, and practices as necessary based on the information provided by these assessments, audits, and reviews.

Governance

The Board oversees the Company's ERM process, including the management of risks arising from cybersecurity threats. The Board receives reports on cybersecurity risks, which address a wide range of topics including recent developments, evolving standards, vulnerability assessments, third-party and independent reviews, the threat environment, technological trends, and information security considerations arising with respect to the Company's peers and third parties. The Board also receives prompt and timely information regarding any cybersecurity incident that meets established reporting thresholds, as well as ongoing updates regarding any such incident until it has been addressed.

The Senior Director of IT and Cybersecurity, in coordination with our executive officers, work collaboratively across the Company to implement a program designed to protect the Company's information systems from cybersecurity threats and to promptly respond to any cybersecurity incidents in accordance with the Company's incident response plan. To facilitate the Company's cybersecurity risk management program, the Company's internal IT team is deployed to work with business functions across the Company to address cybersecurity threats and to respond to cybersecurity incidents. The Senior Director of IT and Cybersecurity, as leader of the internal IT team, monitors the prevention, detection, mitigation, and remediation of cybersecurity threats and incidents in real time, and reports such threats and incidents to the executive officers and Board when appropriate.

The Senior Director of IT and Cybersecurity has served in various roles in information technology and information security for more than two decades with a track record of managing systems compliant with relevant security standards. The Senior Director of IT and Cybersecurity has industry experience and education aligned with the Company's work and the data we maintain. The Senior Director of IT and Cybersecurity's expertise is complemented by that of the Company's CEO and Interim CFO, each with degrees in their respective fields and extensive leadership experience including experience managing risks at similar companies.

We face a number of cybersecurity risks in connection with our business. Such risks have not materially affected us, including our business strategy, results of operations or financial condition, to date. For more information about the cybersecurity risks we face, see the risk factor entitled "*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.*" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

Our corporate offices are in Pittsburgh, Pennsylvania. We have leases for office and laboratory space that are effective through February 29, 2028.

We lease office and laboratory space in Birmingham, Alabama. This lease is effective through August 31, 2025.

We lease office and manufacturing space in Eagan, Minnesota. This lease is effective through May 31, 2025.

We expect that the current space will be adequate for our current office and laboratory needs.

ITEM 3. LEGAL PROCEEDINGS.

None.

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 18, 2024, there were approximately 155 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, nor do we 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.

ITEM 6. [RESERVED]

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 but not limited to those set forth below and elsewhere in this report. Important factors that may cause actual results to differ from projections include:

- Our ability to continue operating beyond twelve months without additional financing;
- Continued negative operating cash flows;
- Our capital needs to accomplish our goals, including any further financing, which may be highly dilutive and may include onerous terms;
- Risks related to recent and future acquisitions, including 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;
- Risks related to the initiation, formation, or success of our collaboration arrangements, commercialization activities and product sales levels by our collaboration partners and future payments that may come due to us under these arrangements,
- 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 could be materially and adversely affected by disruptions caused by economic and geopolitical uncertainties as well as epidemics or pandemics; 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.

Overview

We are a knowledge and science-driven company that applies artificial intelligence ("AI") to support the discovery and development of optimal cancer therapies, which can ultimately lead to more effective treatments and improved patient outcomes. We use AI and a proprietary biobank of 150,000+ tumor samples, categorized by tumor type, to provide actionable insights about drug compounds to improve the drug discovery process and increase the probability of drug compound success. We offer a suite of solutions for oncology drug development from early discovery to clinical trials.

Our mission is to change the landscape of oncology drug discovery and enable the development of more effective therapies for the treatment of cancer. By harnessing the power of machine learning and scientific rigor, we believe that we can improve the probability of success of advancing pharmaceutical and biological drug candidates with a higher degree of confidence.

We operate in three business areas. In our first area, we provide optimized, high-confidence drug-response predictions through the application of AI using our proprietary biobank of tumor samples to enable a more informed selection of drug/tumor combinations and increase the probability of success during development. We also create and develop tumor-specific 3D cell culture models mimicking the physiological environment of human tissue enabling better-informed decision-making during development. In our second business area, we provide services and research using a proprietary self-contained and 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 of biologics. Our third business area produces the United States Food and Drug Administration ("FDA")-cleared STREAMWAY® System and associated products for automated medical fluid waste management and patient-to-drain medical fluid disposal. As of January 1, 2023, we changed our reportable segments to align with these business areas.

We have three reportable segments, which have been delineated by location and business area:

- *Pittsburgh segment:* provides services that include the application of AI using its proprietary biobank of 150,000+ tumor samples. Pittsburgh also creates proprietary 3D culture models used in drug development.

- *Birmingham segment*: provides contract services and research focused on solubility improvements, stability studies, and protein production.

- *Eagan segment:* produces the FDA-cleared STREAMWAY System and associated products for automated medical fluid waste management and patient-to-drain medical fluid disposal.

Capital Requirements

Since inception, we have been unprofitable. We incurred net losses of $13,983,967 and $25,737,634 for the years ended December 31, 2023, and December 31, 2022, respectively. As of December 31, 2023, and December 31, 2022, we had an accumulated deficit of $167,761,883 and $153,777,916, respectively.

We have never generated sufficient revenues to fund our capital requirements. We have funded our operations through a variety of debt and equity instruments. 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 Corporation in April 2019, two transactions to acquire the assets of three businesses in 2020, and the acquisition of zPREDICTA Inc. ("zPREDICTA") in November 2021, each of which have accelerated our capital needs. See "Liquidity and Capital Resources – Liquidity and Plan of Financing; Going Concern" 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 oncology businesses located in Pittsburgh and Birmingham; our ability to continue to sell our Skyline Medical products and services and to reach profitability in all our businesses; and the availability of future financing to fulfill our business plans. See "Liquidity and Capital Resources – Liquidity and Plan of Financing; Going Concern" below.

Our limited history of operations, especially in our drug discovery business, and our change in the emphasis of our business, starting in 2017, makes prediction of future operating results difficult. We believe that period-to-period comparisons of our operating results should not be relied on as predictive of our future results.

Results of Operations

Comparison of Year Ended December 31, 2023, with Year Ended December 31, 2022

	2023	2022	Difference
Revenue	$ 1,780,093	$ 1,505,459	$ 274,634
Cost of sales	634,796	505,107	(129,689)
General and administrative expense	9,428,496	11,110,735	1,682,239
Operations expense	4,127,268	3,798,425	(328,843)
Sales and marketing expense	1,510,861	1,358,907	(151,954)

Revenue. We recorded revenue of $1,780,093 in 2023, compared to $1,505,459 in 2022. Revenues for the years ended December 31, 2023, and December 31, 2022, were primarily derived from our Eagan operating segment. The Eagan operating segment contributed $1,135,101 and $1,063,493 for the years ended December 31, 2023, and December 31, 2022, respectively, while the Pittsburgh operating segment contributed $492,596 and $358,776, respectively.

Cost of sales. Cost of sales was $634,796 and $505,107 for the years ended December 31, 2023, and December 31, 2022, respectively. Cost of sales increased primarily due to costs associated with Pittsburgh contracted services. The gross profit margin declined to 64% in 2023 from 66% in 2022. The decline in gross profit margin was primarily due to costs related to contracted services provided by our Pittsburgh operating segment.

General and administrative expense. General and administrative ("G&A") expenses primarily consist of management salaries, professional fees, consulting fees, depreciation and amortization, office rents, and general office expenses. G&A expenses decreased by $1,682,239 to $9,428,496 in 2023 from $11,110,735 in 2022. The decrease was primarily due to decreases in staff-related expenses of approximately $1,980,000. Additional decreases included lower amortization expense related to acquired intangible assets impaired in the prior year. These decreases were offset by higher professional fees including consultants supporting our management team and investor relations as well as other G&A expenses.

Operations expense. Operations expenses primarily consist of expenses related to product development, prototyping and testing. Operations expenses increased by $328,843 to $4,127,268 in 2023 compared to $3,798,425 in 2022. The increase in operations expenses in 2023 was primarily due to higher cloud computing expenses and other expenses related to our AI business provided by our Pittsburgh operating segment, offset by lower research and development expenses related to office closures.

Sales and marketing expense. Sales and marketing expenses consist of expenses required to market and sell our products including staff-related expenses for individuals performing this work. Sales and marketing expenses increased by $151,954 to $1,510,861 in 2023 compared to $1,358,907 in 2022. The increase in 2023 was primarily due to approximately $209,000 higher staff-related expenses resulting from the addition of headcount supporting our sales and marketing efforts, offset by lower spend on other marketing activities.

Loss on goodwill impairment. Upon closing our acquisition of zPREDICTA on November 24, 2021, we recorded related goodwill of $7,231,093. During the year ended December 31, 2022, we determined that the goodwill was impaired primarily due to declines in our market capitalization and recorded an impairment loss of $7,231,093. Accordingly, goodwill related to zPREDICTA was $0 at both December 31, 2023, and December 31, 2022. zPREDICTA was merged with Predictive Oncology at the end of 2022 and is now reported as part of the Pittsburgh operating segment. See *Note 5 – Intangible Assets* to our audited consolidated financial statements included in this annual report on Form 10-K.

Loss on finite-lived intangible asset impairment. During the year ended December 31, 2023, we incurred no losses on impairment of finite-lived intangible assets. During the year ended December 31, 2022, we incurred a loss on impairment of finite-lived intangible assets of $3,349,375. The impairment recorded related to the finite-lived intangible assets obtained with our acquisition of zPREDICTA in 2021 and was primarily due to declines in projected future cash flows. The value of the intangible assets of zPREDICTA following the impairment was $0 at December 31, 2022. zPREDICTA was merged with Predictive Oncology at the end of 2022 and is now reported as part of the Pittsburgh operating segment. See *Note 5 – Intangible Assets* to our audited consolidated financial statements included in this annual report on Form 10-K.

Loss on impairment of tangible long-lived assets. We recorded a loss on impairment of property and equipment of $162,905 during the year ended December 31, 2023. We prepared an undiscounted cash flow for our Birmingham asset group as of June 30, 2023, to evaluate long-lived assets, then completed a fair value assessment which resulted in the impairment. We then allocated the impairment to the assets of the affected asset group. We recorded a loss on impairment of property and equipment of $185,469 during the year ended December 31, 2022. The impairment was primarily due to a decline in projected future cash flows. We completed a fair value assessment which resulted in an impairment. We then allocated the impairment to the assets of each of the affected asset groups. See *Note 4 – Property and Equipment* to our audited consolidated financial statements included in this annual report on Form 10-K.

Other income. We earned other income of $152,776 in 2023 compared to $185,646 in 2022. Other income primarily consists of 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 decrease in other income was primarily due to lower interest income.

Other expense. We incurred other expenses of $64,967 in 2023 compared to $5,275 in 2022. Other expenses primarily consist of interest expense and, in the year ended December 31, 2023, losses on a note receivable deemed uncollectible. The increase in other expenses was primarily due to writing off a note receivable deemed uncollectible.

Gain on derivative instruments. We recorded a gain of $12,457 in 2023 compared to a gain of $115,647 in 2022, primarily related to the changes in fair market value on derivatives.

Income Taxes. We incurred zero income tax expense in 2023 and 2022 due to losses in both years.

Liquidity and Capital Resources

Cash Flows

On December 31, 2023, we had $8,728,660 in cash and cash equivalents. Cash and cash equivalents decreased by $13,342,863 from the prior year due to the following factors.

Net cash used in operating activities was $13,189,390 in 2023, compared to net cash used of $12,370,800 in 2022. Cash used in operating activities increased in 2023 primarily due to cash operating losses as well as changes in working capital including decreases in accrued expenses and contract liabilities, offset by an increase in accounts payable.

Net cash used in investing activities was $302,371 in 2023, compared to $475,697 in 2022. Cash used in investing activities decreased in 2023 primarily due to a decrease in the acquisition of property and equipment.

Net cash provided by financing activities was $148,898 in 2023 compared to $6,715,405 in 2022. Cash provided by financing activities in 2023 was primarily related to proceeds from financing insurance premiums over the insured period with a short-term note payable while the cash provided in 2022 was primarily proceeds from the issuance of common stock and warrants.

Liquidity and Plan of Financing; Going Concern

We have incurred significant and recurring losses from operations for the past several years and, as of December 31, 2023, had an accumulated deficit of $167,761,883. We had cash and cash equivalents of $8,728,660 as of December 31, 2023, and need to raise significant additional capital to meet our operating needs. Our short-term obligations as of December 31, 2023, were $3,951,031, consisting primarily of aggregate accounts payable and accrued expenses of $2,973,729 and operating lease obligations of $517,427. As of December 31, 2023, we also had a short-term note payable of $150,408 that bears interest at an annual percentage rate of 9.25% and long-term operating lease obligations of $2,188,979 with a weighted average remaining lease term of 3.99 years. We do not expect to generate sufficient operating revenue to sustain our operations in the near term. During the year ended December 31, 2023, we incurred negative cash flows from operations of $13,189,390. Although we have attempted to improve our operating margin by bolstering revenues and curtailing expenses and continue to seek ways to generate revenue through business development activities, there is no guarantee that we will be able to improve our operating margin sufficiently or achieve profitability in the near term. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date our consolidated financial statements included in this annual report on Form 10-K are issued. We are evaluating alternatives to obtain the required additional funding to maintain future operations. These alternatives may include, but are not limited to, equity financing, issuing debt, entering into other financing arrangements, or monetizing operating businesses or assets. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing stockholders or that result in our existing stockholders losing part or all of their investment. Despite these potential sources of funding, we may be unable to access financing or obtain additional liquidity when needed or under acceptable terms, if at all. If such financing or adequate funds from operations are not available, we would be forced to limit our business activities and we could default on existing payment obligations, which would have a material adverse effect on our financial condition and results of operations, and may ultimately be required to cease our operations and liquidate our business. The consolidated financial statements for the year ended December 31, 2023, included in this annual report on Form 10-K have been prepared assuming we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

Financing Transactions

We have funded our operations through a combination of debt and equity instruments including short-term borrowings, and a variety of debt and equity offerings. We have no off-balance sheet transactions. There were no financing transactions during the year ended December 31, 2023.

May 2022 Offerings

On May 16, 2022, the Company issued and sold an aggregate of 191,864 shares of its common stock, at a purchase price of $12.00 per share to several institutional and accredited investors in a registered direct offering (the "First Offering"). Pursuant to the securities purchase agreement, the Company also agreed to issue to these purchasers unregistered warrants to purchase up to an aggregate of 191,864 shares of common stock (the "Warrants") in a concurrent private placement. The Warrants have an exercise price equal to $14.00 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 408,136 shares of its common stock, at a purchase price of $12.00 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 816,272 shares of common stock that were previously issued in 2020 and 2021 to those purchasers, with exercise prices ranging from $20.00 to $40.00 per share (the "Existing Warrants"), were amended to: (i) lower the exercise price of the Existing Warrants to $14.00 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 $15.00 per share, with a term of five years (the "Agent Warrants"). The Agent Warrants become exercisable six months after issuance.

Equity Line

On October 24, 2019, the Company entered into an equity purchase agreement with an investor, providing for an equity financing facility. According to the terms and subject to the conditions in the purchase agreement, the investor was 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 5,233 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 were satisfied, the Company could 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 15,750 shares of its common stock valued at $236,009 pursuant to the equity line. 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.

Critical Accounting 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. We evaluate our estimates and assumptions on an on-going basis.

We base our estimates and assumptions on our historical experience and on various other information available to us at the time that these estimates and assumptions are made. We believe that these estimates and assumptions are reasonable under the circumstances and form the basis for our making judgments about the carrying values of our assets and liabilities that are not readily apparent from other sources. Actual results and outcomes could differ from our estimates.

Our significant accounting policies are described in *Note 1 – Summary of Significant Accounting Policies* in Notes to Consolidated Financial Statements of this Annual Report on Form 10-K. We believe that the following discussion addresses our critical accounting estimates 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 generate revenues from Contract Research Organization ("CRO") services related to the development of 3D tumor-specific in vitro models for oncology drug discovery and research. We also generate revenues from CRO services related to development of protein formulations and performance of protein stability analyses. The specific pattern of revenue recognition for CRO services is determined on a case-by-case basis according to the facts and circumstances applicable to a given contract. We evaluate each product or service promised in a contract to determine whether it represents a distinct performance obligation. Determining whether services are considered distinct performance obligations that should be accounted for separately versus together may require significant judgment. Contracts for CRO services generally contain one performance obligation to perform research and deliver appropriate data or reporting. Revenues from CRO services are generally recognized at the point in time when data and reports are provided to customers. See *Note 1 – Summary of Significant Accounting Policies* in Notes to Consolidated Financial Statements of this Annual Report on Form 10-K for further details of our revenue recognition policies.

We also have a collaboration arrangement, under which we have utilized our active learning technology, proprietary biobank, and know-how to provide predictive models of tumor responses to various drug compounds. This collaboration arrangement includes sales-based royalties, under which our collaboration partner is obligated to pay us revenue sharing fees that are based on the net revenue from the collaboration partner's commercialized drugs. The percentage of net revenue varies depending on the stage of development. The revenue sharing fees represent variable consideration, which requires us to estimate the expected value of revenue sharing fees and extent to which those estimates are constrained. These estimates are reassessed at each reporting period. To date, we have not recognized revenues related to revenue sharing fees pursuant to our collaboration arrangement. See *Note 11 – Collaborative Agreement* in Notes to Consolidated Financial Statements of this Annual Report on Form 10-K for further details of our collaboration arrangement.

Stock-Based Compensation.

We account for stock-based compensation under the fair value recognition and measurement provisions for share-based payments of U.S. GAAP. We recognize compensation expense for these service-based equity-classified awards over their requisite service period and adjust for forfeitures as they occur. We estimate the fair value of stock-based payment awards on the date of grant using 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, 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, and the risk-free interest rate. In the case of options to employees, we estimated the life to be the legal term.

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 traded on the NASDAQ Capital Market exchange since 2015 and have experienced significant volatility in our stock price. 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 stock-based compensation expense could be materially different in the future. See *Note 9 – Stockholders' Equity, Stock Options, and Warrants* in Notes to Consolidated Financial Statements of this Annual Report on Form 10-K for further details of our stock-based compensation.

Goodwill Impairment

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 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, we perform a multi-step impairment test. We first have 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. We may also elect to skip the qualitative testing and proceed directly to the quantitative testing. When performing quantitative testing, we first estimate the fair values of our reporting units using discounted cash flows. To determine fair values, we are 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. We also complete a reconciliation between the implied equity valuation prepared and our 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.

Long-lived Asset Impairment

We review long-lived assets, including finite-lived intangible assets and long-lived tangible assets, for impairment whenever events or changes in circumstances indicate the carrying amount may not be recoverable. Identifying and evaluating such events or changes in circumstances involves judgment. Events or changes in circumstances that indicate the carrying amount may not be recoverable include, but are not limited to, a significant change in the medical device marketplace and a significant adverse change in the business climate in which we operate.

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 exceeds its estimated undiscounted future cash flows, we record 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 utilizing discounted cash flow techniques. See *Note 4 – Property and Equipment* and *Note 5 – Intangible Assets* to our audited consolidated financial statements included in this annual report on Form 10-K.

Income Taxes

Deferred income taxes are provided on a liability method, whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences, which are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred income taxes are subject to certain limitations under Section 382. 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 "Recent Accounting Pronouncements" and "Recently Adopted Accounting Standards" under *Note 1 - Summary of Significant Accounting Policies* in Notes to Consolidated Financial Statements of this Annual Report on Form 10-K.

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 Interim 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, 2023. Based on that evaluation, our Chief Executive Officer and Interim 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 effective as of December 31, 2023.

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 Interim 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, 2023 based on the criteria in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in 2013. Based upon this evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2023.

The rules of the SEC do not require, and this Annual Report on Form 10-K does not include, an attestation report of an independent registered public accounting firm regarding internal control over financial reporting.

Material Weakness Remediation Activities

In connection with management's assessment of controls over financial reporting during the year ended December 31, 2022, we determined that we had not maintained adequate accounting resources with a sufficient understanding of U.S. GAAP to allow us to properly identify and account for new complex transactions. To remediate this material weakness, we reevaluated our overall staffing levels within the accounting department and, as a result, during the second quarter of 2023 we hired an additional resource with qualifications that include a high level of experience with complex technical accounting transactions and application of U.S. GAAP. We have improved our procedures for evaluating complex accounting transactions as well as our reporting procedures through the involvement of this additional resource.

During the quarter ended September 30, 2023, we determined that we had a material weakness as we had not maintained effective information technology general controls in the areas of user access management, administrative user access, and segregation of duties within our financial information systems and other financial reporting controls that are relevant to our preparation of financial statements. As a result of those segregation of duties deficiencies, the related manual business process controls were determined to be ineffective. To remediate this material weakness, we evaluated logical access, including administrative user access, eliminated certain segregation of duties conflicts, and implemented additional compensating controls. During the fourth quarter of 2023, we designed, implemented, and tested logical access controls to monitor user access and manage changes to user access. We also designed, implemented, and tested information technology application controls to enforce proper segregation of duties.

Remediation of Material Weaknesses

During the fourth quarter of 2023, with the assistance of an external consulting company, we tested and adopted changes to our internal control over financial reporting related to our remediation efforts described above that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on the actions taken, as well as the evaluation of the design, implementation, and operating effectiveness of the new controls, we determined that the material weaknesses have been remediated as of December 31, 2023.

Changes in Internal Control Over Financial Reporting

Except for the changes described above, 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, 2023, that 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 91 43rd Street, Suite 110, Pittsburgh, PA 15201.

Executive Officers and Directors of the Registrant

The following table identifies the individuals who serve as our executive officers and directors as of March 18, 2024:

Name	Age	Position Held
Raymond F. Vennare	71	Chief Executive Officer and Chairman of the Board of Directors
Josh Blacher	51	Interim Chief Financial Officer
Chuck Nuzum	75	Director Member of the Audit, Compensation, Nominating and Governance, and Merger & Acquisition Committees
Daniel E. Handley, Ph.D.	64	Director Member of the Nominating and Governance Committee
Gregory S. St. Clair, Sr.	58	Director Member of the Audit and Compensation Committees
Nancy Chung-Welch, Ph.D.	63	Director Member of the Audit, Compensation, and Merger & Acquisition Committees
Matthew J. Hawryluk, Ph.D.	46	Director Member of the Compensation and Merger & Acquisition Committees
Veena Rao, Ph.D.	56	Director Member of the Audit, Nominating and Governance, and Merger & Acquisition Committees

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

Our Certificate of Incorporation and Bylaws provide for the division of the members of our Board of 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 2026, and the term of our Class III directors expires in 2024. 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 2026)	CLASS III (term expiring in 2024)
Chuck Nuzum	Matthew J. Hawryluk	Raymond F. Vennare
Daniel E. Handley	Nancy Chung-Welch	Veena Rao
	Gregory S. St. Clair, Sr.	

The Board of Directors met eight times in fiscal year 2023.

Business Experience

Raymond F. Vennare. Mr. Vennare was appointed as our Chief Executive Officer and as Chairman of 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 of Cvergenx, 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. Mr. Vennare was CEO of Cvergenx, Inc., from 2015 until 2022 when he resigned as CEO of Cvergenx upon accepting his position as CEO and Chairman of the Board for Predictive Oncology Inc. 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.

Josh Blacher. Mr. Blacher was appointed as our Interim Chief Financial Officer effective September 30, 2023. Mr. Blacher has served as a consultant with Danforth Advisors, LLC since September 2022 and as Managing Partner of Columbus Circle Capital LLC ("Columbus Circle Capital") since August 2019. During his tenure at Columbus Circle Capital, Mr. Blacher has served as CFO at several public and private companies. Prior to his tenure at Columbus Circle Capital, Mr. Blacher served as Chief Business Officer at Inmed Pharmaceuticals (Nasdaq: INM) from April 2018 to August 2019, as Chief Financial Officer of Therapix Biosciences (Nasdaq: TRPX) from April 2017 to April 2018, and as Chief Financial Officer at Galmed Pharmaceuticals (Nasdaq: GLMD) from October 2014 to March 2017. Mr. Blacher holds a Bachelor of Arts from Yeshiva University and a Master of Business Administration from Columbia Business School.

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

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

Gregory S. St. Clair. Mr. St. Clair was appointed to the Board on July 9, 2020. Mr. St. Clair is the Founder and Managing Member of SunStone Consulting, LLC, a healthcare consulting firm that has served 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.

Matthew J. Hawryluk, Ph.D. Dr. Hawryluk was appointed to the Board on November 29, 2022, to fill the vacancy created by a 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.

Veena Rao, Ph.D. Dr. Rao was appointed to the Board on May 2, 2023. Dr. Rao is an experienced commercial and technical leader with over 25 years of experience in the areas of drug development, med tech, medical devices, and digital health, having held a number of roles in both large and small company environments. She has a background in technology innovation, licensing, and corporate business development in addition to having led launch and go-to-market teams for novel drug and medical device products. Dr. Rao currently serves as President and Chief Business Officer of Portal Instruments, a needle-free drug delivery company, a position she has held since December 2022. Previously, Dr. Rao served as Chief Commercial Officer at Beta Bionics from February 2021 until August 2022, and as Head of Corporate Development & Strategy at Beta Bionics from October 2020 until February 2021. Prior to Beta Bionics, Dr. Rao spent over a decade at Eli Lilly and Company with a number of commercial and technical roles including as Vice President of External Innovation for the Lilly Device team. Dr. Rao has also served on the Board of Directors of Thermalin, Inc, and advisor to the PharmStars program, and an advisor to Digbi Health. Dr. Rao has a B.S. in Chemical Engineering from the University of Minnesota, a PhD in Chemical Engineering from Stanford University and an MBA from the University of Virginia Darden School of Business.

Board Committees

The Board of Directors has a standing Audit Committee, Compensation Committee, Nominating and Governance Committee, and Merger & Acquisition Committee.

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

Audit Committee; Audit Committee Financial Expert

The Audit Committee oversees the Company's corporate accounting and financial reporting processes and audits of its financial statements.

The functions of the Audit Committee, as governed by its charter, include, among other things:

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

Both our independent registered public accounting firm and management periodically meet privately with the Audit Committee. Our Audit Committee currently consists of Mr. Nuzum, as the chairperson, Dr. Chung-Welch, Mr. St. Clair, and Dr. Veena Rao. Each Audit Committee member is a non-employee director of the Board. The Board of Directors reviews the NASDAQ listing standards definition of independence for Audit Committee members on an annual basis and has determined that all current members of our Audit Committee are independent (as independence is currently defined in Rule 5605(a)(2) of the NASDAQ listing standards). The 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. The Audit Committee met seven times in fiscal year 2023.

Compensation Committee

The Compensation Committee of the Board of Directors currently consists of four directors: Mr. Nuzum, as the chairperson, Dr. Chung-Welch, Mr. St. Clair and Dr. Hawryluk. All members of the Compensation Committee are "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. The Compensation Committee met six times in fiscal year 2023.

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 Company's 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

No member of the Compensation Committee who served as such during the year ended December 31, 2023, has been an executive officer or employee of ours while serving on the Committee 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, Mr. Nuzum and Dr. Rao. 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. There were no meetings of the Nominating and Governance Committee during fiscal year 2023.

In furtherance of its purpose, the Nominating and Governance 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. Nuzum, Dr. Chung-Welch, Dr. Rao, and Dr. Hawryluk. 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 and Governance Committee 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). Pursuant to Rules 5605(f) and 5606 of the NASDAQ listing standards, we have made our board diversity matrix available on our website at https://predictive-oncology.com/ under the "For Investors" and "Corporate Governance" tabs.

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, 2023 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 there were no instances where the list of our officers, directors and greater than ten percent beneficial owners failed to file on a timely basis all Section 16(a) filing requirements during the fiscal year ended December 31, 2023.

Code of Ethics

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

Recoupment of Incentive Compensation Policy

We have adopted a Recoupment of Incentive Compensation Policy that applies to certain executive compensation in the event of an accounting restatement to correct a material error. Our policy satisfies the requirements as defined in Rule 5608(d) of the Nasdaq Marketplace Rules 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 2023, (ii) our two most highly compensated other executive officers who were serving as executive officers at the end of 2023 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 2023. We refer to these individuals as our "Named Executive Officers." Our named executive officers are:

- Raymond F. Vennare, Chief Executive Officer;
- Bob Myers, former Chief Financial Officer; and
- Pamela Bush, former Chief Business Officer.

We did not have any other executive officers, as determined in accordance with SEC rules, during 2023.

Summary Compensation Table for Fiscal 2023 and 2022

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, 2023 and December 31, 2022:

Name and Principal Position	Year	Salary	Bonus	(1) Stock Awards	(1) Option Awards	All Other Compensation	Total Compensation
Raymond F. Vennare, CEO	2023	$ 525,000	$ -	$ -	$ -	$ -	$ 525,000
	2022	$ 87,500(2)	$ 34,125(3)	$ -	$ -	$ -	$ 121,625
Bob Myers (4)	2023	$ 316,360	$ -	$ -	$ -	$ 131,316(5)	$ 447,676
	2022	$ 374,900	$ 110,430(6)	$ -	$ -	$ 26,538(7)	$ 511,868
Pamela Bush (8)	2023	$ 402,917	$ -	$ -	$ -	$ -	$ 402,917
	2022	$ -	$ -	$ -	$ -	$ -	$ -

(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 9 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 discretionary bonus for performance in 2022 that was paid to Mr. Vennare on March 15, 2023.

(4)Effective September 30, 2023, Mr. Myers resigned as the Company's Chief Financial Officer.

(5)Includes severance payments of $89,583 and an accrued vacation payment of $36,798 paid to Mr. Myers in 2023 pursuant in accordance with his Employment Agreement and a Separation Agreement and Mutual Release dated September 30, 2023, between Mr. Myers and the Company.

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

(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)Effective February 1, 2023, Dr. Bush was named Chief Business Officer and received an annual salary of $410,000. The amount in the table represents Dr. Bush's salary for the entire year, including prior to becoming an executive officer. Dr. Bush left the Company effective February 15, 2024.

Outstanding Equity Awards at Fiscal Year-end for Fiscal 2023

The following table sets forth certain information regarding outstanding equity awards held by the named executive officers as of December 31, 2023:

		Options			
Name	**Grant Date**	**Number of Securities Underlying Options Exercisable**	**Number of Securities Underlying Options Unexercisable**	**Option Exercise Price**	**Option Expiration Date**
Raymond F. Vennare	-	-	-	-	-
Bob Myers	6/22/2017	1,521	-	$ 30.80	6/22/2027
	4/4/2019	830	-	$ 30.80	4/4/2029
Pamela Bush	12/21/2021	500	-	$ 20.60	12/1/2031

Executive Compensation Components for Fiscal 2023

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 may be paid at the discretion of the Compensation Committee and as approved by the Board of Directors based on the Compensation Committee's determination of the performance of the executive officer.

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 may 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, directors, and other employees 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 or appointed during the period required for the option shares to vest. This provides an incentive for an option holder to remain employed or appointed by us. In addition, stock options link employees' compensation to stockholders' interests by providing an incentive to increase stockholder value. Under our Amended and Restated 2012 Stock Incentive Plan (the "2012 Plan"), we may also make grants of common stock, restricted stock awards, restricted stock units, performance stock awards, and stock appreciation rights to executive officers, directors, and other employees. 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. We adopted the 2012 Plan to give us flexibility in the types of awards that we could grant to our executive officers, directors, and other employees. In 2020, 2021, and 2022, our stockholders approved amendments to the 2012 Plan to increase the share reserve under the 2012 Plan by 37,500 shares, 75,000 shares, and 125,000 shares, respectively. As of December 31, 2023, there were stock options to purchase 47,664 shares of common stock outstanding under the 2012 Plan and 94,878 shares remain available for future equity awards.

Limited Perquisites; Other Benefits. We provide our employees, including our executive officers, 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 three-year performance period consisting of fiscal years 2021, 2022 and 2023. Under the LTIP, in May 2021, the Company granted restricted stock units ("RSUs") to the Company's then-current CFO, Bob Myers, under the 2012 Plan.

The LTIP awards consisted of 7,500 RSUs (target). These RSUs required continued employment of the executive through January 1, 2024, and therefore were terminated before vesting as a result of Mr. Myers' departure from the Company in 2023.

Employment Contracts

Employment Agreement with Current Chief Executive Officer

On October 13, 2022, the Company and Raymond 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 former Chief Financial Officer.

Effective September 30, 2023, Mr. Bob Myers resigned as the Chief Financial Officer. Mr. Myers served as Chief Financial Officer since July 1, 2012, under an employment agreement entered on August 13, 2012, which was amended on August 20, 2018. Under the agreement the employment of Mr. Myers was at will.

Mr. Myers' annual base salary was $345,000 until March 1, 2022, at which time Mr. Myers received an increase in his base salary resulting in an annualized base salary of $380,880. On September 23, 2020, Mr. Myers was awarded a one-time, special interim grant of retention equity awards for 2020 of 5,000 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, 2023, resulting in an annualized base salary of $430,000. Base salary for Mr. Myers could have been adjusted by us but could not have been reduced except in connection with a reduction imposed on substantially all employees as part of a general reduction. He would have also been eligible to receive an annual incentive bonus for each calendar year at the end of which he remained employed by us, subject to the attainment of certain objectives.

On May 17, 2021, Mr. Myers received 7,500 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 would receive annual grants of restricted stock units on January 1 of each calendar year starting in 2021. Each grant would consist of 2,500 restricted stock units with vesting of each grant over three years based on performance and continued employment.

Mr. Myers was 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 determined and provided that no vacation time would unreasonably interfere with the duties required to be rendered by employee.

Under the agreement, if his employment was terminated without "cause" or if he terminated his employment for "good reason," in each case as defined in his employment agreement, he would 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 would 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 were conditioned upon the executive's execution of a full and final release of liability. Mr. Myers left the Company in September 2023, and the Company and Mr. Myers entered into a Separation Agreement and Mutual Release on September 30, 2023, that restated the severance payments he was entitled to pursuant to his agreement, provided for the release of liability described above, and in which the Company limited the non-compete provision of the employment agreement to provide that it would only apply to activities related to the discovery, characterization, or evaluation of chemical or biological compositions for the diagnosis or treatment of disease.

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 provided that upon the termination of his employment without cause or for good reason, his options would 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 was less than five years after such termination). In addition, in the event of such employee's retirement, death or disability, such employee's options would 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 payable 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, if 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, if they are serving as a director at the annual appointment date.

Director Compensation Table for Fiscal 2023

The following table summarizes the compensation paid to each individual who served as a director during the fiscal year ended December 31, 2023:

	Fees Paid or Earned in Cash	Stock Awards (1)	Option Awards	Total
Charles Nuzum Sr. (2)	$ 63,893	$ 35,006	$ -	$ 98,899
Daniel Handley (3)	$ 29,444	$ 25,001	$ -	$ 54,445
Greg St. Clair Sr. (4)	$ 32,890	$ 32,670	$ -	$ 65,560
Nancy Chung-Welch (5)	$ 51,668	$ 25,001	$ -	$ 76,669
Matthew J. Hawryluk (6)	$ 40,556	$ 25,001	$ -	$ 65,557
Veena Rao (7)	$ 49,335	$ 24,002	$ -	$ 73,337
David S. Smith (8)	$ 2,333	$ 6,000	$ -	$ 8,333

(1)Represents grant date fair value of stock awards granted during 2023 as determined pursuant to FASB ASC 718, *Stock Compensation*.
(2)Reflects 7,653 shares of common stock received in 2023 for serving on the Board.
(3)Reflects 5,468 shares of common stock received in 2023 for serving on the Board.
(4)Reflects 6,923 shares of common stock received in 2023 for serving on the Board.
(5)Reflects 5,468 shares of common stock received in 2023 for serving on the Board.
(6)Reflects 5,468 shares of common stock received in 2023 for serving on the Board.
(7)Reflects 5,849 shares of common stock received in 2023 for serving on the Board.
(8)Reflects 918 shares of common stock received in 2023 for serving on the Board. Mr. Smith resigned from the Board effective May 2, 2023.

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, 2023:

	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)	47,664	$ 82.23	94,878
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 March 8, 2024, 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 and director nominees;
- 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. We are not aware of any beneficial owners of more than 5% of our issued and outstanding common stock as of March 8, 2024.

Unless otherwise indicated in the footnotes to the table, each stockholder named in the table has sole voting and investment power with respect to the shares of common stock set forth opposite the stockholder's name. We have based our calculation of the percentage of beneficial ownership on 4,062,853 shares of our common stock outstanding on March 8, 2024. Unless otherwise noted below, the address for each person or entity listed in the table is c/o Predictive Oncology Inc., 91 43rd Street, Suite 110 Pittsburgh, Pennsylvania 15201.

Name of Beneficial Owner (1)	**Amount and Nature of Beneficial Ownership**	**Percent of Class**
Raymond F. Vennare	7,122	0.18%
Josh Blacher	-	0.00%
Chuck Nuzum (2)	28,653	0.71%
Gregory St. Clair (3)	19,266	0.47%
Daniel Handley (4)	16,308	0.40%
Nancy Chung-Welch (5)	18,974	0.47%
Matthew J. Hawryluk	7,135	0.18%
Veena Rao	5,849	0.14%
All directors and executive officers as a group (8 persons)	103,307	2.54%

(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 2,014 shares that are exercisable within 60 days of March 8, 2024.

(3) Includes options to purchase 1,332 shares that are exercisable within 60 days of March 8, 2024.

(4) Includes options to purchase 1,643 shares that are exercisable within 60 days of March 8, 2024.

(5) Includes options to purchase 2,014 shares that are exercisable within 60 days of March 8, 2024.

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. Pursuant to the Charter of the Audit Committee, every transaction that must be disclosed pursuant to Item 404(a) of Regulation S-K promulgated under the Exchange Act must be reviewed and approved by the Audit Committee.

During the year ended December 31, 2023, there were no related party transactions.

Information regarding director independence is disclosed under Item 10, above.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

In connection with the audit of the fiscal 2023 and 2022 financial statements, we entered into an engagement agreement with BDO USA, P.C. (2023) and Baker Tilly US, LLP (2022), which set forth the terms by which they performed audit services for us.

The following table represents aggregate fees billed to us by BDO USA, P.C. ("BDO"), the Company's independent public accounting firm for the fiscal year ended December 31, 2023, for services rendered with respect to the fiscal year ended December 31, 2023, and by Baker Tilly US, LLP ("Baker Tilly"), the Company's independent public accounting firm for the fiscal year ended December 31, 2022, for services rendered with respect to the fiscal year ended December 31, 2022. Fees are approved by the Audit Committee on an engagement-by-engagement basis. All fees described below were approved by the Audit Committee.

	2023	2022
Audit Fees (1)	$ 392,006	$ 337,558
Audit-Related Fees	-	-
Tax Fees (2)	-	29,875
All Other Fees (3)	-	102,250
	$ 392,006	$ 469,683

(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 2022 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 with respect to tax compliance during 2022.

(3) Other Fees in 2022 consisted of fees for professional services performed by Baker Tilly with respect to an assessment of the Company's security and compliance activities.

PART IV

ITEM 15. EXHIBIT AND 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 on Form 10-K and can be found beginning at page F-1 of this report:

- Reports of Independent Registered Public Accounting Firms (BDO USA, P.C., Minneapolis, Minnesota, PCAOB Firm ID #243) (Baker Tilly US, LLP, Minneapolis, Minnesota, PCAOB Firm ID #23);
- Consolidated Balance Sheets as of December 31, 2023, and December 31, 2022;
- Consolidated Statements of Net Loss for the Years Ended December 31, 2023, and December 31, 2022;
- Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2023, to December 31, 2022;
- Consolidated Statements of Cash Flows for the Years Ended December 31, 2023, and December 31, 2022; 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 Consolidated Financial Statements.

(3) Exhibits

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, filed 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).
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).
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	Certificate of Designation of Series F Preferred Stock (Filed on March 16, 2023 as an exhibit to the Form 8-A and incorporated herein by reference.)
3.18	Certificate of Amendment to Certificate of Incorporation (Filed on April 20, 2023 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.)
3.19	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/A (File No. 333-198962) and incorporated herein by reference.)
4.2	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.)
4.3	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.)
4.4	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.)
4.5	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.)
4.6	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.)
4.7	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.)
4.8	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.)
4.9	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.)
4.10	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.)
4.11	Form of Helomics Common Stock Purchase Warrant issued April 4, 2019. (Filed on January 24, 2019 as Annex H to Amendment No. 2 to Form S-4 (File No. 333-228031) and incorporated herein by reference.)
4.12	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.)
4.13	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.)
4.14	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.)
4.15	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.)
4.16	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.)

4.17	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.)
4.18	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**	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/A and incorporated herein by reference.)
10.2**	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.)
10.3**	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).
10.4**	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).
10.5**	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).
10.6	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.)
10.7**	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).
10.8**	Employment Agreement dated effective November 1, 2022, by and between the Company and Raymond F. Vennare. (Filed on October 20, 2022 as an exhibit to our Current Report on Form 8-K).
10.9*	Separation Agreement and Mutual Release dated effective September 30, 2023, by and between the Company and Bob Myers.
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: BDO USA, P.C.
23.2*	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
97*	Policy Relating to Recovery of Erroneously Awarded Compensation

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.
***Furnished herewith.

ITEM 16. FORM 10-K SUMMARY.

None.

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 28, 2024

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 28, 2024
/s/ Josh Blacher Josh Blacher	Interim Chief Financial Officer (Principal financial and accounting officer)	March 28, 2024
/s/ Chuck Nuzum Chuck Nuzum	Director	March 28, 2024
/s/ Daniel E. Handley Daniel E. Handley	Director	March 28, 2024
/s/ Gregory St. Clair Sr. Gregory St. Clair Sr.	Director	March 28, 2024
/s/ Nancy Chung-Welch Nancy Chung-Welch	Director	March 28, 2024
/s/ Matthew Hawryluk Matthew Hawryluk	Director	March 28, 2024
/s/ Veena Rao Veena Rao	Director	March 28, 2024

The audited consolidated financial statements for the periods ended December 31, 2023, and December 31, 2022, are included on the following pages:

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
Predictive Oncology Inc.
Pittsburgh, Pennsylvania

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Predictive Oncology Inc. (the "Company") as of December 31, 2023, the related consolidated statements of net loss, stockholders' equity, and cash flows for the year then ended, 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 at December 31, 2023, and the results of its operations and its cash flows for the year then ended**,** in conformity with accounting principles generally accepted in the United States of America.

We also have audited the adjustments to the 2022 consolidated financial statements to retrospectively apply the changes in the share and per share amounts to reflect the reverse stock split and in the change in the reportable segments, as discussed in Notes 1 and 14, respectively. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the 2022 consolidated financial statements of the Company other than with respect to the adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2022 consolidated financial statements taken as a whole.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated 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 consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter 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.

Revenue Recognition – Evaluation of Contract Terms in Certain Contracts with Customers

The Company has revenues of $1,780,093 for the year ended December 31, 2023. As described in Note 1 of the consolidated financial statements, the Company derives its revenues primarily from Contract Research Organization ("CRO") services, sales of medical device products, or maintenance plan services. The Company recognizes revenue in accordance with the five-step process outlined in ASC 606.

We identified the evaluation of contract terms in certain contracts with customers as a critical audit matter, due to the significant judgment by management in identifying and evaluating terms and conditions in contracts that impact revenue recognition. Auditing these elements involved especially subjective and complex auditor judgments due to the nature and extent of audit effort required.

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

- Examination of management's identification and evaluation of the terms and conditions in certain contracts, including management's determination of the impact of those terms and conditions on revenue recognition.

- Testing the completeness and accuracy of management's application of the terms and conditions in certain contracts to how revenue was recognized, by examining revenue arrangements on a test basis.

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2023.

Minneapolis, Minnesota
March 28, 2024

Report Of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet and the related consolidated statements of net loss, stockholders' equity, and cash flows of Predictive Oncology, Inc. (the "Company") for the year ended December 31, 2022, 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 the year ended December 31, 2022, and the results of their operations and their cash flows for the year ended December 31, 2022 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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

/s/ Baker Tilly US, LLP

We served as the Company's auditor from 2020 to 2023.

Minneapolis, Minnesota
March 21, 2023

CONSOLIDATED FINANCIAL STATEMENTS

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash	$ 8,728,660	$ 22,071,523
Accounts receivable	333,697	331,196
Inventories	494,374	430,493
Prepaid expense and other assets	521,700	526,801
Total current assets	10,078,431	23,360,013
Property and equipment, net	1,233,910	1,833,255
Intangibles, net	252,457	253,865
Lease right-of-use assets	2,728,355	211,893
Other long-term assets	124,096	75,618
Total assets	$ 14,417,249	$ 25,734,644
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,342,027	$ 943,452
Note payable	150,408	-
Accrued expenses and other liabilities	1,631,702	2,229,075
Derivative liability	1,376	13,833
Contract liabilities	308,091	602,073
Lease liability	517,427	94,237
Total current liabilities	3,951,031	3,882,670
Other long-term liabilities	5,459	-
Lease liability – net of current portion	2,188,979	86,082
Total liabilities	6,145,469	3,968,752
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 20,000,000 shares authorized inclusive of designated below		
Series B Convertible Preferred Stock, $.01 par value, 2,300,000 shares authorized, 79,246 shares outstanding as of December 31, 2023, and December 31, 2022	792	792
Common stock, $.01 par value, 200,000,000 shares authorized, 4,062,853 and 3,938,160 shares outstanding as of December 31, 2023, and December 31, 2022, respectively	40,629	39,382
Additional paid-in capital	175,992,242	175,503,634
Accumulated deficit	(167,761,883)	(153,777,916)
Total stockholders' equity	8,271,780	21,765,892
Total liabilities and stockholders' equity	$ 14,417,249	$ 25,734,644

See accompanying notes to consolidated financial statements.

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF NET LOSS

	Year Ended December 31, 2023	2022
Revenue	$ 1,780,093	$ 1,505,459
Cost of sales	634,796	505,107
Gross profit	1,145,297	1,000,352
Operating expenses:		
General and administrative expense	9,428,496	11,110,735
Operations expense	4,127,268	3,798,425
Sales and marketing expense	1,510,861	1,358,907
Loss on impairment of goodwill	-	7,231,093
Loss on impairment of finite-lived intangible assets	-	3,349,375
Loss on impairment of property and equipment	162,905	185,469
Total operating expenses	15,229,530	27,034,004
Total operating loss	(14,084,233)	(26,033,652)
Other income	152,776	185,646
Other expense	(64,967)	(5,275)
Gain on derivative instruments	12,457	115,647
Net loss	$ (13,983,967)	$ (25,737,634)
Net loss per common share – basic and diluted	$ (3.48)	$ (6.98)
Weighted average shares used in computation – basic and diluted	4,014,848	3,685,954

See accompanying notes to consolidated financial statements.

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
FOR THE YEAR ENDED
DECEMBER 31, 2023

	Series B Preferred		Series F Preferred		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at 12/31/2022	79,246	$ 792	-	$ -	3,938,160	$ 39,382	$ 175,503,634	$ (153,777,916)	$ 21,765,892
Shares issued to non-employees	-	-	-	-	98,193	982	488,344	-	489,326
Vesting expense, net of forfeitures	-	-	-	-	-	-	2,038	-	2,038
Series F Preferred Stock dividend	-	-	79,404	794	-	-	(794)	-	-
Reverse stock split round up to whole shares	-	-	-	-	25,343	253	(253)	-	-
Series F Preferred redemption	-	-	(79,404)	(794)	-	-	794	-	-
Share issuance to CFO for vesting of RSUs, net of repurchase to cover withholding tax	-	-	-	-	1,157	12	(1,521)	-	(1,509)
Net loss	-	-	-	-	-	-	-	(13,983,967)	(13,983,967)
Balance at 12/31/2023	79,246	$ 792	-	$ -	4,062,853	$ 40,629	$ 175,992,242	$ (167,761,883)	$ 8,271,780

See accompanying notes to consolidated financial statements.

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
FOR THE YEAR ENDED
DECEMBER 31, 2022

	Series B Preferred		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at 12/31/2021	79,246	$ 792	3,280,750	$ 32,808	$ 168,272,366	$ (128,040,282)	$ 40,265,684
Issuance of shares and warrants pursuant to May 2022 private placement, net	-	-	600,000	6,000	6,501,050	-	6,507,050
Shares issued pursuant to Equity Line	-	-	15,750	158	235,851	-	236,009
Share issuance to consultant and other	-	-	29,838	297	355,827	-	356,124
Vesting expense and option repricing	-	-	11,822	119	138,540	-	138,659
Net loss	-	-	-	-	-	(25,737,634)	(25,737,634)
Balance at 12/31/2022	79,246	$ 792	3,938,160	$ 39,382	$ 175,503,634	$ (153,777,916)	$ 21,765,892

See accompanying notes to consolidated financial statements.

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (13,983,967)	$ (25,737,634)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	739,316	1,313,075
Vesting expense	2,038	166,312
Common stock issued to non-employees	299,430	356,125
Gain on valuation of equity-linked instruments and derivative liability	(12,457)	(115,647)
Loss on impairment of goodwill	-	7,231,093
Loss on impairment of finite-lived intangible assets	-	3,349,375
Loss on impairment of property and equipment	162,905	185,469
Loss on property and equipment disposal	903	14,346
Changes in assets and liabilities:		
Accounts receivable	(2,501)	23,000
Inventories	(63,881)	(42,808)
Prepaid expense and other assets	(43,377)	78,425
Accounts payable	398,575	(78,322)
Accrued expenses and other liabilities	(397,851)	869,987
Contract liabilities	(293,982)	41,819
Other long-term liabilities	5,459	(25,415)
Net cash used in operating activities:	(13,189,390)	(12,370,800)
Cash flows from investing activities:		
Purchase of property and equipment	(276,352)	(419,869)
Acquisition of intangibles	(26,019)	(55,828)
Net cash used in investing activities:	(302,371)	(475,697)
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net	-	6,507,050
Proceeds from issuance of common stock pursuant to equity line	-	236,009
Repurchase of common stock upon vesting of restricted stock units	(1,510)	(27,654)
Proceeds from note payable	364,721	-
Repayment of note payable	(214,313)	-
Net cash provided by financing activities	148,898	6,715,405
Net decrease in cash	(13,342,863)	(6,131,092)
Cash at beginning of period	22,071,523	28,202,615
Cash at end of period	$ 8,728,660	$ 22,071,523
Supplemental disclosure for cash flow information:		
Cash payments for interest	$ 13,904	$ 3,821
Non-cash transactions:		
Adjustment to goodwill for acquisition of zPREDICTA contract liabilities	$ -	$ 373,303
Right-of-use assets obtained in exchange for lease liabilities	2,997,181	-
Series F Preferred Stock dividend	794	-
Common stock issued to settle accrued board of directors' and advisory board compensation	189,896	-
Redemption of Series F Preferred Stock	(794)	-
Common stock issued in connection with reverse stock split	253	-
Common stock issued to management upon vesting of restricted stock units	4,934	-

See accompanying notes to unaudited consolidated financial statements.

NOTE 1 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations

Predictive Oncology Inc. ("Predictive Oncology") is a knowledge and science-driven company that applies artificial intelligence ("AI") to support the discovery and development of optimal cancer therapies, which can ultimately lead to more effective treatments and improved patient outcomes. The Company uses AI and a proprietary biobank of 150,000+ tumor samples, categorized by patient type, to provide actionable insights about drug compounds to improve the drug discovery process and increase the probability of drug compound success. The Company offers a suite of solutions for oncology drug development from early discovery to clinical trials.

Predictive Oncology's mission is to change the landscape of oncology drug discovery and enable the development of more effective therapies for the treatment of cancer. By harnessing the power of machine learning and scientific rigor, the Company believes that it can improve the probability of success of advancing pharmaceutical and biological drug candidates with a higher degree of confidence.

The Company operates in three business areas. In its first area, the Company provides optimized, high-confidence drug-response predictions through the application of AI using its proprietary biobank of tumor samples to enable a more informed selection of drug/tumor combinations and increase the probability of success during drug development. The Company also creates and develops tumor-specific 3D cell culture models mimicking the physiological environment of human tissue enabling better-informed decision-making during development. In its second business area, the Company provides services and research using a proprietary self-contained and 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 of biologics. The Company's third business area produces the United States Food and Drug Administration ("FDA")-cleared STREAMWAY® System and associated products for automated medical fluid waste management and patient-to-drain medical fluid disposal. As of January 1, 2023, the Company changed its reportable segments to align with these business areas.

The Company has three reportable segments, which have been delineated by location and business area, as further described in *Note 14 – Segments*:

- *Pittsburgh segment:* provides services that include the application of AI using its proprietary biobank of 150,000+ tumor samples. Pittsburgh also creates proprietary 3D culture models used in drug development.
- *Birmingham segment*: provides contract services and research focused on solubility improvements, stability studies, and protein production.
- *Eagan segment*: produces the FDA-cleared STREAMWAY System and associated products for automated medical fluid waste management and patient-to-drain medical fluid disposal.

Going Concern

The Company has incurred significant and recurring losses from operations for the past several years and, as of December 31, 2023, had an accumulated deficit of $167,761,883. The Company had cash and cash equivalents of $8,728,660 as of December 31, 2023 and needs to raise significant additional capital to meet its operating needs. The Company's short-term obligations as of December 31, 2023 were $3,951,031, consisting primarily of aggregate accounts payable and accrued expenses of $2,973,729 and operating lease obligations of $517,427. As of December 31, 2023, the Company also had a short-term note payable of $150,408 that bears interest at an annual percentage rate of 9.25% and long-term operating lease obligations of $2,188,979 with a weighted average remaining lease term of 3.99 years. The Company does not expect to generate sufficient operating revenue to sustain its operations in the near term. During the year ended December 31, 2023, the Company incurred negative cash flows from operations of $13,189,390. Although the Company has attempted to improve its operating margin by bolstering revenues and curtailing expenses and continues to seek ways to generate revenue through business development activities, there is no guarantee that the Company will be able to improve its operating margin sufficiently or achieve profitability in the near term. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. The Company is evaluating alternatives to obtain the required additional funding to maintain future operations. These alternatives may include, but are not limited to, equity financing, issuing debt, entering into other financing arrangements, or monetizing operating businesses or assets. These possibilities, to the extent available, may be on terms that result in significant dilution to the Company's existing stockholders or that result in the Company's existing stockholders losing part or all of their investment. Despite these potential sources of funding, the Company may be unable to access financing or obtain additional liquidity when needed or under acceptable terms, if at all. If such financing or adequate funds from operations are not available, the Company would be forced to limit our business activities and the Company could default on existing payment obligations, which would have a material adverse effect on its financial condition and results of operations, and may ultimately be required to cease its operations and liquidate its business. The Company's consolidated financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustment relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

Reverse Stock Split

On April 19, 2023, the Company completed a one-for-twenty reverse stock split that was effective for trading purposes on April 24, 2023. All numbers of shares and per-share amounts in this report have been adjusted to reflect the reverse stock split ("Reverse Split").

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.

Principles of Consolidation

The Company has two wholly owned subsidiaries, Helomics Corporation and Skyline Medical, Inc., as of and for the year ended December 31, 2023. The Company had multiple wholly owned subsidiaries for the year ended December 31, 2022. The consolidated financial statements include the accounts of the Company and these wholly owned subsidiaries after elimination of intercompany transactions and balances as of and for the years ended December 31, 2023, and 2022.

Reclassifications

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

Recent Accounting Pronouncements

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 consolidated financial statements of the Company.

In November 2023, the FASB issued ASU 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures." This ASU updates reportable segment disclosures by expanding the frequency and extent of segment disclosures. This ASU will become effective for the Company's fiscal year beginning January 1, 2024, and for the Company's interim periods beginning in the Company's fiscal year 2025. Early adoption is permitted and requires the retrospective adoption method. Management is currently evaluating this ASU to determine its impact on the Company's disclosures.

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." This ASU requires more detailed income tax disclosures. The guidance requires entities to disclose disaggregated information about their effective tax rate reconciliation as well as expanded information on income taxes paid by jurisdiction. The disclosure requirements will be applied on a prospective basis, with the option to apply them retrospectively. The standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. Management is currently evaluating this ASU to determine its impact on the Company's disclosures.

Recently Adopted Accounting Standards

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. The Company adopted the provisions of ASU 2016-13 on January 1, 2023, using the modified-retrospective approach, and its adoption did not have a material impact on the Company's consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, "Debt – Debt with Conversion and Other Options and Derivatives and Hedging – Contracts in Entity's Own Equity" ("ASU 2020-06"). ASU 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. The new guidance also modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. As a smaller reporting company pursuant to Rule *12b-2* of the Securities Exchange Act of *1934,* as amended, ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, including interim periods within those annual periods. Early adoption is permitted, including interim periods within those fiscal years. Entities should adopt the guidance as of the beginning of its annual fiscal year and are allowed to adopt the guidance through either a modified retrospective method of transition or a fully retrospective method of transition. The Company early adopted ASU 2020-06 on January 1, 2023, and its adoption did not have a material impact on the Company's financial statements.

In September 2022, the FASB issued ASU 2022-04, "Liabilities – Supplier Finance Programs" ("ASU 2022-04"). ASU 2022-04 was issued to enhance the transparency of supplier finance programs used by an entity in connection with the purchase of goods and services. The standard requires entities that use supplier finance programs to disclose the key terms, including a description of payment terms, the confirmed amount outstanding under the program at the end of each reporting period, a description of where those obligations are presented on the balance sheet, and an annual rollforward, including the amount of obligations confirmed and the amount paid during the period. The guidance does not affect the recognition, measurement, or financial statement presentation of obligations covered by supplier finance programs. ASU 2022-04 is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, except for the required rollforward information, which is effective for fiscal years beginning after December 15, 2023. The Company adopted ASU 2022-04 on January 1, 2023, using the retrospective approach, and its adoption did not have a material impact on the Company's financial statements.

Cash

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 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 is maintained to provide for the estimated amount of receivables that will not be collected. The Company determines the allowance based on historical experience as well as external business factors expected to impact collectability such as economic factors. The Company reviews customers' credit history before extending unsecured credit and establishes an allowance 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 accounts receivable balance was $0 as of both December 31, 2023, and 2022.

Fair Value Measurements

As outlined in ASC 820, *Fair Value Measurement*, fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The accounting standards ASC 820 establishes a three-level fair value hierarchy that prioritizes information used in developing assumptions when pricing an asset or liability as follows:

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

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

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

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

The fair values of the Company's derivative liabilities were determined based on Level 3 inputs. The Company generally uses the 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 2 – Fair Value Measurements* and *Note 8 – Derivatives*.

When comparing the carrying amount of an asset group to its fair value as part of a long-lived asset impairment analysis, the Company estimates the fair value of the asset group by making assumptions about the long-lived assets comprising the asset group. The majority of the inputs used by the Company to estimate the fair value of the long-lived assets are unobservable and thus are considered to be Level 3 inputs. See *Note 4 – Property and Equipment* and *Note 5 – Intangible Assets*.

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 5 – Intangible Assets*.

Inventories

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

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the respective assets. Estimated useful asset life by classification is as follows:

	Years		
Computers, software, and office equipment	3	-	10
Leasehold improvements (1)	1	-	2
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 property and equipment, the cost and related accumulated depreciation are removed from the consolidated balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations expense as incurred.

Finite-lived Intangible Assets

Finite-lived intangible assets consist of patents and trademarks, licensing fees, developed technology, acquired software, customer relationships, and tradenames, and are amortized over their estimated useful life. Accumulated amortization is included in Intangibles, net in the accompanying consolidated balance sheets.

Long-lived Assets

The Company reviews long-lived 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 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 exceeds its estimated undiscounted future cash flows, the Company records 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 utilizing discounted cash flow techniques.

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, the Company performs a multi-step impairment test, either on an annual basis, or more frequently if needed. 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 ASC 350, 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 fair value, 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 5 – Intangible Assets*.

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.

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 consolidated 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. Variable lease payments generally represent the Company's share of the landlord's expenses and are recorded when incurred. 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.

Collaboration Arrangements

The Company enters into collaboration arrangements with oncology drug development partners, under which the Company utilizes its active learning technology, proprietary biobank, and know-how to provide predictive models of tumor responses to various drug compounds and treatments of partners. Consideration under these contracts may include an upfront payment, development and regulatory milestones and other contingent payments, expense reimbursements, royalties based on net sales of approved drugs, and commercial sales milestone payments.

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements*, which includes determining whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. To the extent that the arrangement falls within the scope of ASC 808, the Company assesses whether the payments between the Company and its collaboration partner fall within the scope of other accounting literature. If the Company concludes that payments from the collaboration partner to the Company would represent consideration from a customer, the Company accounts for those payments within the scope of Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers*. However, if the Company concludes that its collaboration partner is not a customer for certain activities and associated payments, the Company presents such payments as a reduction of research and development expense or general and administrative expense, based on where the Company presents the underlying expense.

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. The Company recognizes revenue in accordance with the five-step process outlined in ASC 606: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. Sales taxes are imposed on the Company's sales to nonexempt customers. The Company collects the taxes from the customers and remits the entire amount to the governmental authorities. Sales taxes are excluded from revenue and expenses. Advertising costs incurred in the Company's efforts to obtain new customers are expensed as incurred.

Revenues from Services

The Company generates revenues from Contract Research Organization ("CRO") services related to the development of 3D tumor-specific in vitro models for oncology drug discovery and research. The organ-specific disease models provide 3D reconstruction of human tissues accurately representing each disease state and mimicking drug response. Revenue from development of 3D models is reported under the Pittsburgh reportable segment.

The Company also generates revenues from CRO services related to development of protein formulations and performance of protein stability analyses. Using the Company's proprietary High Throughput Self-Interaction Chromatography ("HSC") platform, the Company conducts screens on excipients previously approved by the FDA to develop protein formulations with increased solubility and physical stability. The Company also provides comprehensive protein stability analyses via time-dependent shelf-life studies and forced degradation studies designed to quickly determine which of the additives previously approved by the FDA will improve the solubility and stability of proteins in solutions. Revenues from development of protein formulations and performance of protein stability analyses are reported under the Birmingham reportable segment.

The specific pattern of revenue recognition for CRO services is determined on a case-by-case basis according to the facts and circumstances applicable to a given contract. The Company may execute a master service agreement with a customer that provides terms and conditions for the relationship between the Company and the customer. Detailed Statements of Work (SOWs) are then prepared to outline the specific services to be provided. The SOW and master service agreement, if applicable, form the contract with the customer under ASC 606. The Company evaluates each product or service promised in a contract to determine whether it represents a distinct performance obligation. Determining whether services are considered distinct performance obligations that should be accounted for separately versus together may require significant judgment. Contracts for CRO services generally contain one performance obligation to perform research and deliver appropriate data or reporting. The Company typically requires partial payment for CRO services prior to performance of the research service with the remainder of the transaction price due 30 days after delivery of data or reporting. Revenues from CRO services are generally recognized at the point in time when data and reports are provided to customers.

The Company also generates revenues from services provided under maintenance plans related to the Company's STREAMWAY System. Customers may purchase maintenance plans, which require the Company to service the customer's STREAMWAY System for a period of one year. Payment due under the maintenance plan is typically due at the start of the service period. The maintenance plan is considered a separate performance obligation from the sale of the STREAMWAY System, 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 toward complete satisfaction of the performance obligation 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. Revenues from maintenance plans related to the Company's STREAMWAY System are reported under the Eagan reportable segment.

Revenues from Product Sales

The Company generates revenues from the sale of medical device products consisting primarily of sales of the STREAMWAY System (i.e., hardware), as well as sales of the proprietary cleaning fluid and filters for use with the STREAMWAY System (i.e., disposables). Currently, the Company sells its medical device products directly to hospitals and other medical facilities using employed sales representatives. 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 sales agreement is a dually executed agreement providing explicit terms and conditions supporting the sale of the STREAMWAY System and related products and services. The Company considers the combination of a purchase order and sales agreement providing its terms and conditions to form the contract with the customer in all cases.

Product sales for medical devices consist of a single performance obligation that the Company satisfies at a point in time following the transfer of control of such products to the customer. Transfer of control may occur when products are shipped from the Company's facilities ("FOB origin", which is the Company's standard shipping terms) or upon delivery at the customer's facilities ("FOB Destination"), dependent on the shipping terms specified in the contract with the customer. Transfer of control may also occur prior to shipment under bill and hold arrangements. In such arrangements, the Company recognizes revenue when the bill-and-hold arrangement has a substantive reason, the product is identified separately as belonging to the customer, the product is ready for physical transfer to the customer, and the Company does not have the ability to use the product or direct it to another customer. The Company's standard payment terms for its customers purchasing medical devices 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. 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. Revenues from the sale of medical device products are reported under the Eagan reportable segment.

Royalty Revenue and Variable Consideration

The Company has a collaboration arrangement that includes sales-based royalties, under which our collaboration partner is obligated to pay revenue sharing fees that are based on the net sales of the collaboration partner's commercialized drugs. The Company would recognize royalty revenue when the underlying sales occur based on its best estimate of sales of the drugs. To date, the Company has not recognized revenues related to revenue sharing fees pursuant to its collaboration arrangement. See *Note 11 – Collaboration Agreement*.

Warranty

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

Contract Balances

The Company records a receivable when it has an unconditional right to receive consideration after the performance obligations are satisfied. As of December 31, 2023, and 2022, accounts receivable totaled $333,697 and $331,196, respectively. As of December 31, 2021, accounts receivable totaled $354,196.

Advance payments received in excess of revenues recognized are classified as contract liabilities until such time as the revenue recognition criteria have been met. The Company's contract liabilities related primarily to 3D services and maintenance plans were $313,550 and $602,073 as of December 31, 2023, and 2022, respectively. The Company's long-term contract liabilities are reported in Other long-term liabilities in the consolidated balance sheets. The Company's contract liabilities as of December 31, 2023 primarily represent its remaining performance obligations. The Company recognized revenue of $277,767 primarily related to 3D services earned during the year ended December 31, 2023, that was included in contract liabilities as of December 31, 2022. As of December 31, 2021, contract liabilities totaled $186,951.

Practical Expedients

The Company has elected not to determine whether contracts with customers contain significant financing components as contracts are generally for less than one year. The Company immediately expenses contract costs that would otherwise be capitalized and amortized over a period of less than one year. The Company recognizes shipping and handling costs at point of sale.

Stock-Based Compensation

The Company accounts for stock-based compensation expense in accordance with ASC 718, *Compensation—Stock Compensation*, which requires the Company to measure and recognize compensation expense in the financial statements based on the fair value at the date of grant for stock-based awards. The Company recognizes compensation expense for service-based equity-classified awards over their requisite service period and adjusts for forfeitures as they occur.

ASC 718 requires companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. The Company uses 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 the Company's common stock price over the expected term, and the risk-free interest rate.

When an option or warrant is granted in place of cash compensation for services, the Company deems the value of the service rendered to be the value of the option or warrant. In most cases, however, an option or warrant is granted in addition to other forms of compensation and its separate value is difficult to determine without utilizing an option pricing model. For that reason the Company also uses the Black-Scholes option-pricing model to value options and warrants granted to non-employees, which requires the input of significant assumptions including an estimate of the average period that investors or consultants will retain vested stock options and warrants before exercising them, the estimated volatility of the Company's common stock price over the expected term, and the risk-free interest rate. In the case of options granted to employees, the Company estimates the life to be the legal term.

The Company also has 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 financial or operating metrics, and/or market performance of the Company's common stock. 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, the Company determines 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.

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's common stock has been traded on the NASDAQ Capital Market exchange since 2015 and the Company has experienced significant volatility in its stock price. 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 the Company uses different assumptions, its stock-based compensation expense could be materially different in the future.

On January 1, 2023, the Company adopted a sequencing policy under ASC 815-40-35 ("ASC 815") that will apply if reclassification of contracts from equity to liabilities is necessary. If the Company is unable to demonstrate it has sufficient authorized shares, shares will be allocated based on the earliest issuance date of potentially dilutive financial instruments, with the earliest financial instruments receiving the first allocation of shares. Pursuant to ASC 815, stock-based awards issued to the Company's employees are not subject to the sequencing policy.

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 $188,305 and $320,320 for the years ended December 31, 2023, and 2022, respectively.

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 that 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 Company performed a Section 382 analysis at December 31, 2023, which resulted in the limitation and expiration of a substantial portion of the Company's loss carryforwards. In addition, the current net operating loss ("NOL") carryforwards might be further limited by future issuances of our common stock. See *Note 10 – Income Taxes*.

Tax years after 2003 remain open to examination by federal and state tax authorities due to unexpired net operating loss carryforwards.

Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash. The Company places its cash with financial institutions and, by policy, generally limits the amount of credit exposure to any one financial institution. As of December 31, 2023, the Company had $142,118 of credit risk for cash amounts held in a single institution that are in excess of amounts insured by the Federal Deposit Insurance Corporation.

Risks and Uncertainties

The Company is subject to risks common to companies in the medical device and biopharmaceutical industries, including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with regulations of the Food and Drug Administration, Clinical Laboratory Improvement Amendments, and other governmental agencies.

The Company is also subject to general economic and geopolitical uncertainties caused by inflation, rising interest rates, supply chain disruptions, tight labor markets, wage inflation, pricing volatility for certain goods and services, banking and financial sector disruptions, instability and volatility in the global markets, disruptions from a global pandemic, and geopolitical conflict. The impacts of economic and other global events could have a material adverse effect on our business, results of operations, liquidity or financial condition and heighten or exacerbate risks related to the Company.

The Company has evaluated all 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 15 – Subsequent Events*.

NOTE 2 – FAIR VALUE MEASUREMENTS

The following table summarizes the Company's fair value hierarchy for its liabilities measured at fair value on a recurring basis:

December 31, 2023	Fair Value	Level 1	Level 2	Level 3
Liabilities:				
Derivatives	$ 1,376	$ -	$ -	$ 1,376

December 31, 2022	Fair Value	Level 1	Level 2	Level 3
Liabilities:				
Derivatives	$ 13,833	$ -	$ -	$ 13,833

NOTE 3 – INVENTORIES

Inventory balances consist of the following:

	As of December 31, 2023	As of December 31, 2022
Raw materials	$ 239,998	$ 133,183
Work-in-process	-	6,694
Finished goods	254,376	290,616
Total	$ 494,374	$ 430,493

NOTE 4 – PROPERTY AND EQUIPMENT

The Company's property and equipment consist of the following:

	As of December 31, 2023	As of December 31, 2022
Computers, software, and office equipment	$ 480,882	$ 463,292
Leasehold improvements	506,162	535,527
Laboratory equipment	3,670,097	3,559,362
Manufacturing tooling	133,285	121,120
Demo equipment	31,554	31,554
Total	4,821,980	4,710,855
Less: Accumulated depreciation	(3,588,070)	(2,877,600)
Total Property and Equipment, Net	$ 1,233,910	$ 1,833,255

In the second quarter of 2023, the Company identified a change in future projected cash flows related to its Birmingham asset group. The Company prepared an undiscounted cash flow for its Birmingham asset group as of June 30, 2023, as required under ASC 360 and determined the carrying amount of the asset group exceeded its estimated undiscounted future cash flows. The Company determined the fair value of the Birmingham asset group using replacement cost and market approaches based on the in-exchange value. The Company recognized an impairment loss of $162,905 of its property and equipment in the Birmingham operating segment during the second quarter of 2023.

In the fourth quarter of 2022, the Company identified a change in its future projected cash flows related to certain of its asset groups. The Company prepared an undiscounted cash flow for the asset groups as of December 31, 2022, as required under ASC 360 and determined the carrying amounts exceeded the estimated undiscounted future cash flows for those asset groups. The Company determined the fair value of the asset groups and recognized an impairment loss of $185,469 of its property and equipment in the Birmingham and Corporate asset groups during the fourth quarter of 2022. The Company also concluded that the finite-lived intangible assets of its former zPREDICTA asset group, which is now reported within the Pittsburgh operating segment, were fully impaired as of December 31, 2022, and recognized an impairment loss on those finite-lived intangible assets during the fourth quarter of 2022. See *Note 5 –Intangible Assets.*

Depreciation expense was $711,890 and $898,369 in 2023 and 2022, respectively.

NOTE 5 – INTANGIBLE ASSETS

Finite-lived Intangible Assets

Finite-lived intangible assets consist of patents and trademarks, developed technology, customer relationships, and tradenames, and are amortized over their estimated useful life. Amortization expense was $27,426 and $414,706 in 2023 and 2022, respectively. Accumulated amortization is included in intangibles, net in the accompanying consolidated balance sheets. The Company reviews finite-lived intangible assets for impairment in accordance with ASC 360, 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, 2023, there were $252,457 in net intangibles as compared to $253,865 in net intangibles as of December 31, 2022.

The components of intangible assets were as follows:

	As of December 31, 2023			As of December 31, 2022			
	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount	Gross Carrying Costs	Accumulated Amortization	Impairment	Net Carrying Amount
Patents & Trademarks	$ 535,096	$ (286,639)	$ 252,457	$ 509,141	$ (255,276)	$ -	$ 253,865
Developed Technology	-	-	-	3,500,000	(386,459)	(3,113,541)	-
Customer Relationships	-	-	-	200,000	(22,083)	(177,917)	-
Tradename	-	-	-	80,000	(22,083)	(57,917)	-
Total	$ 535,096	$ (286,639)	$ 252,457	$ 4,289,141	$ (685,901)	$ (3,349,375)	$ 253,865

The following table outlines the estimated future amortization expense related to intangible assets held as of December 31, 2023:

Year ending December 31,	Expense
2024	$ 27,451
2025	27,451
2026	27,451
2027	27,451
2028	27,451
Thereafter	115,202
Total	$ 252,457

No impairment charges related to finite-lived intangible assets were incurred during the year ended December 31, 2023.

In the fourth quarter of 2022, the Company identified a change in its future projected cash flows related to certain of its asset groups. The Company prepared an undiscounted cash flow for these asset groups as of December 31, 2022 as required under ASC 360 and determined the carrying amounts exceeded the estimated undiscounted future cash flows for those asset groups. The Company determined the fair value of the asset groups and concluded that the finite-lived intangible assets of its former zPREDICTA asset group, which is now reported within the Pittsburgh operating segment, were fully impaired as of December 31, 2022, and recognized an impairment loss of $3,349,375 on those finite-lived intangible assets during the fourth quarter of 2022. The Company also recognized an impairment loss on its property and equipment in the Soluble and Corporate asset groups during the fourth quarter of 2022. See *Note 4 – Property and Equipment*.

Goodwill

Goodwill of $7,231,093 was recognized in the zPREDICTA acquisition in 2021 and represented the excess of the consideration transferred over the fair values of assets acquired and liabilities assumed. 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 former 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 former 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 majority of the inputs used in the discounted cash flow model were unobservable and thus are considered to be Level 3 inputs. The inputs for the market capitalization calculation were considered Level 1 inputs. zPREDICTA Inc. was merged with Predictive Oncology Inc. at the end of 2022 and is now reported as part of the Pittsburgh operating segment.

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

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	$	-

NOTE 6 – LEASES

The Company's corporate offices and other offices are in Pittsburgh, Pennsylvania. Upon expiration of previous leases for office space and laboratory operations, the Company entered two new leases for office space and laboratory operations on January 4, 2023. The leases each have an approximate five-year term ending February 29, 2028, and the Company recorded corresponding right of use ("ROU") assets and liabilities of $2,922,365.

The Company has an additional office in Birmingham, Alabama, which is used for office space and laboratory operations. The lease is effective through August 31, 2025.

The Company has an office in Eagan, Minnesota, which is used for office space and manufacturing. Since July 31, 2022, the lease was month-to-month tenancy. On June 1, 2023, the lease was amended for two additional years until May 31, 2025 and the Company recorded a corresponding ROU asset and liability of $74,816.

Lease expense under operating lease arrangements was $892,993 and $746,590 for 2023 and 2022, respectively.

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

	December 31, 2023	**December 31, 2022**
Weighted average remaining lease term – operating leases in years	3.99	1.72
Weighted average discount rate – operating leases	12%	8%

The Company's operating lease obligation as of December 31, 2023, which includes expected lease extensions that are reasonably certain of renewal, are as follows:

2024	$	818,463
2025		857,622
2026		803,724
2027		827,909
2028		139,022
Total lease payments		3,446,740
Less interest		(740,334)
Present value of lease liabilities	$	2,706,406

NOTE 7 – NOTE PAYABLE

In June 2023, the Company purchased Directors and Officers insurance policies with a policy period ending June 2024. In July 2023, the Company financed $364,721 of its total premium by entering into a note payable with a finance provider that requires ten monthly installment payments through April 2024. The note is secured by a first priority lien on the financed policies. The short-term note bears interest at an annual percentage rate of 9.25% over the life of the note. As of December 31, 2023, the outstanding balance of the note was $150,408 including interest.

NOTE 8 – DERIVATIVES

Certain warrants issued to placement agents were determined to be 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.

The fair value of the placement agent warrants issued in connection with the March 2020 private placement was determined to be $135 and $3,355 as of December 31, 2023, and December 31, 2022, respectively. The Company recorded gains on the change in fair value of the placement agent warrants of $3,220 and $37,981 during the year ended December 31, 2023, and December 31, 2022, respectively. The placement agent warrants expire in March 2025.

The fair value of the placement agent warrants issued in connection with the May 2020 offering of securities was determined to be $333 and $4,479 as of December 31, 2023, and December 31, 2022, respectively. The Company recorded gains on the change in fair value of the placement agent warrants of $4,146 and $38,167 during the year ended December 31, 2023, and December 31, 2022, respectively. The placement agent warrants expire in May 2025.

The placement agent warrants issued in connection with the June 2020 warrant exercise and issuance had a fair value of $908 and $5,999 as of December 31, 2023, and December 31, 2022, respectively. The Company recorded gains on the change in fair value of the placement agent warrants of $5,091 and $39,499 during the year ended December 31, 2023, and December 31, 2022, respectively. The placement agent warrants expire in June 2025.

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

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
Gain recognized to revalue derivative instrument at fair value		(12,457)
Derivative liability balance at December 31, 2023	**$**	1,376

NOTE 9 – STOCKHOLDERS' EQUITY, STOCK OPTIONS AND WARRANTS

Series F Preferred Stock Dividend and Reverse Stock Split

On March 16, 2023, the Board of Directors of the Company authorized the issuance of 80,000 shares of Series F Preferred Stock, par value $0.01 per share.

On March 16, 2023, the Board of Directors of the Company declared a dividend of one one-thousandth of a share of Series F Preferred Stock, par value $0.01 per share, for each outstanding share of the Company's common stock held on record as of March 27, 2023. 79,404 shares of Series F Preferred Stock were issued pursuant to the stock dividend. Each share of Series F Preferred Stock entitled the holder thereof to 1,000,000 votes per share to vote together with the outstanding shares of common stock of the Company as a single class to adopt an amendment to the Company's Certificate of Incorporation to affect a reverse stock split.

On April 19, 2023, the Company completed a one-for-twenty reverse stock split that was effective for trading purposes on April 24, 2023. No fractional shares were issued as a result of the reverse stock split. Any fractional shares that would otherwise have resulted from the reverse stock split were rounded up to the next whole number. The number of authorized shares of common stock under the Company's certificate of incorporation, as amended, remained unchanged at 200,000,000 shares. All numbers of shares and per-share amounts in this report have been adjusted to reflect the reverse split. Proportionate reductions were made to the number of shares of common stock reserved for future issuance under our 2012 Equity Incentive Plan and the number of shares of common stock that may be issued upon exercise or vesting of outstanding equity incentive awards and warrants, and proportionate increases were made to the exercise price or share-based performance criteria, if any, applicable to such awards and warrants.

Redemption of Series F Preferred Stock

On April 17, 2023, the Company convened a special meeting of stockholders, which was adjourned due to the lack of a quorum and reconvened on April 19, 2023 (the "Special Meeting"), at which the Company's stockholders approved a proposal to amend the Company's certificate of incorporation to effect a reverse stock split of the Company's common stock at a ratio in the range of 1-for-2 to 1-for-25, with such ratio to be determined by the Company's Board of Directors (the "Reverse Split Proposal"). All shares of Series F Preferred Stock that were not present in person or by proxy at the Special Meeting as of immediately prior to the opening of the polls (the "Initial Redemption Time") were automatically redeemed (the "Initial Redemption"). All outstanding shares of Series F Preferred Stock that were not redeemed pursuant to the Initial Redemption were redeemed automatically upon the approval by the Company's stockholders of the Reverse Split Proposal (the "Subsequent Redemption" and, together with the Initial Redemption, the "Redemption"). Both the Initial Redemption and the Subsequent Redemption occurred on April 19, 2023. As a result, no shares of Series F Preferred Stock remain outstanding.

May 2022 Offerings

On May 16, 2022, the Company issued and sold an aggregate of 191,864 shares of its common stock, at a purchase price of $12.00 per share to several institutional and accredited investors in a registered direct offering (the "First Offering"). Pursuant to the securities purchase agreement, the Company also agreed to issue to these purchasers unregistered warrants to purchase up to an aggregate of 191,864 shares of common stock (the "Warrants") in a concurrent private placement. The Warrants have an exercise price equal to $14.00 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 408,136 shares of its common stock, at a purchase price of $12.00 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 816,272 shares of common stock that were previously issued in 2020 and 2021 to those purchasers, with exercise prices ranging from $20.00 to $40.00 per share (the "Existing Warrants"), were amended to: (i) lower the exercise price of the Existing Warrants to $14.00 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 $15.00 per share, with a term of five years (the "Agent Warrants"). The Agent Warrants become exercisable six months after issuance.

Equity Line

On October 24, 2019, the Company entered into an equity purchase agreement with an investor, providing for an equity financing facility. According to the terms and subject to the conditions in the purchase agreement, the investor was 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 5,233 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 were satisfied, the Company could 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 15,750 shares of its common stock valued at $236,009 pursuant to the equity line. 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.

Series B Convertible Preferred Stock

As of December 31, 2023, and December 31, 2022, there were 79,246 shares of Series B Convertible Preferred Stock outstanding. The conversion rate of Series B Convertible Preferred Stock to Common Stock is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations, or similar events. The 79,246 shares of Series B Convertible Preferred Stock outstanding at December 31, 2023 were convertible to 16 shares of common stock. In addition, the Series B Convertible Preferred Stock will automatically convert into shares of common stock upon the occurrence of a fundamental transaction, as described in the certificate of designations for the Series B Convertible Preferred Stock including mergers, sales of the company's assets, changes in control and similar transactions. The Series B Convertible Preferred Stock is not convertible by the holder of such preferred stock to the extent (and only to the extent) that the holder or any of its affiliates would beneficially own in excess of 4.99% of the common stock of the Company. The Series B Convertible Preferred Stock has no voting rights, except for the right to approve certain amendments to the certificate of designations or similar actions. With respect to payment of dividends and distribution of assets upon liquidation or dissolution or winding up of the Company, the Series B Convertible Preferred Stock shall rank equal to the common stock of the Company. No sinking fund has been established for the retirement or redemption of the Series B Convertible Preferred Stock.

Equity Incentive Plan

The Company's Amended and Restated 2012 Stock Incentive Plan (the "2012 Plan") allows for the issuance of incentive and non-qualified stock options, stock appreciation rights, stock awards, restricted stock, restricted stock units ("RSUs") 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.

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 162,500 to 287,500 reserve shares.

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.

During the year ended December 31, 2021, the Company issued 22,500 RSUs under the plan which had market, performance, and service vesting conditions through January 1, 2024. 16,667 RSUs became vested during the year ended December 31, 2022. At December 31, 2022, there were 4,167 RSUs outstanding under the plan. At December 31, 2023, there were no RSUs outstanding under the plan.

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

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:

	Year Ended December 31,	
	2023	**2022**
	Stock Options	
Expected dividend yield	0.0%	0.0%
Expected stock price volatility	90.8% –98.2%	86.5% –92.2%
Risk-free interest rate	3.38% –3.95%	1.83% –4.26%
Expected life (years)	10	10
	Warrants	
Expected dividend yield	0.0%	0.0%
Expected stock price volatility	0%	92.2%
Risk-free interest rate	0%	2.96% –2.97%
Expected life (years)	0	5 – 5.5

Stock Options and Warrants Granted by the Company

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, 2021	53,144	$ 96.60	1,584,995	$ 33.20
Issued	1,599	8.40	1,053,136	14.00
Forfeited	(2,013)	17.60	-	-
Expired	(3,677)	208.40	(5,422)	329.60
Cancelled	-	-	(816,272)	30.20
Outstanding at December 31, 2022	49,053	$ 91.60	1,816,437	$ 22.60
Issued	1,075	5.45	-	-
Forfeited	(49)	6.18	-	-
Expired	(2,415)	139.30	(9,848)	219.60
Outstanding at December 31, 2023	47,664	$ 82.23	1,806,589	$ 21.52

At December 31, 2023, 46,814 stock options were fully vested and currently exercisable with a weighted average exercise price of $83.61 and a weighted average remaining term of 5.56 years. At December 31, 2023, there were 1,806,589 warrants that were fully vested and currently exercisable.

At December 31, 2022, 47,682 stock options were fully vested and exercisable with a weighted average exercise price of $93.80 and a weighted average remaining term of 6.54 years. At December 31, 2022, there were 1,816,437 warrants that were fully vested and currently exercisable.

Stock-based compensation recognized in 2023 and 2022 was $2,038 and $108,596, respectively. The Company has $1,644 of unrecognized compensation expense related to non-vested stock options that are expected to be recognized over the next 16 months.

The following summarizes the status of options and warrants outstanding at December 31, 2023:

Range of Exercise Prices	Shares	Weighted Average Remaining Life
Options		
$ 3.44 –14.65	12,029	6.67
$ 16.28 –29.40	4,935	7.57
$ 30.80 –52.20	16,049	4.13
$ 101.00 –69,375.00	14,651	3.52
Total	47,664	
Warrants:		
$ 14.00 –20.00	1,168,465	3.62
$ 21.05 –30.00	368,246	2.06
$ 34.38 –40.00	180,314	5.87
$ 43.75 –200.00	89,564	1.83
Total	1,806,589	

Stock options and warrants expire on various dates from February 2024 to July 2033.

The following table is the listing of outstanding stock options and warrants as of December 31, 2023 by year of grant:

Stock Options:

Year	Shares	Range of Exercise Prices		
2014	3	$ 32,500.00	–	69,375.00
2015	12	30.80	–	17,250.00
2016	296	30.80	–	850.00
2017	10,478	30.80	–	420.00
2018	2,893	30.80	–	226.00
2019	14,970	30.80	–	158.00
2020	14,883	14.65	–	32.80
2021	2,248	14.40	–	29.40
2022	846	7.70	–	14.65
2023	1,035	3.44	–	7.68
Total	47,664	$ 3.44	–	$ 69,375.00

Warrants:

Year	Shares	Range of Exercise Prices		
2019	84,514	$ 16.90	–	200.00
2020	65,586	36.00	–	59.84
2021	603,353	16.00	–	48.75
2022	1,053,136	14.00	–	15.00
Total	1,806,589	$ 14.00	–	$ 200.00

NOTE 10 – INCOME TAXES

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

The Company incurred zero income tax expense during the years ended December 31, 2023, and December 31, 2022, due to losses in both years.

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

	Year Ended December 31,	
	2023	2022
Statutory federal income tax benefit	$ 2,936,633	$ 5,404,903
State tax benefit, net of federal taxes	599,958	856,735
Foreign tax benefit	-	-
Foreign operations tax rate differential	-	-
State rate adjustment	(125,150)	(7,795,184
Nondeductible/nontaxable items	121,708	(7,709)
Goodwill impairment	-	(1,654,212)
NOL and deferred only adjustments	(59,913,532)	(1,149,895)
Other	(5,182)	89,162
Valuation allowance decrease	56,385,565	4,256,200
Total income tax benefit	$ -	$ -

Deferred taxes consist of the following:

	December 31, 2023	December 31, 2022
Deferred tax assets:		
Noncurrent:		
Inventory	$ -	$ -
Compensation accruals	87,131	150,168
Accruals and reserves	204,083	254,213
Deferred revenue	36,169	51,198
Charitable contribution carryover	1,724	1,766
Derivatives	349	3,192
Intangibles	852,414	1,191,874
Capitalized R&D	919,789	635,862
Depreciation	59,511	-
Lease liabilities	703,026	6,925
NQSO compensation	627,997	1,625,108
NOL and credits	21,737,285	77,042,831
Total deferred tax assets	25,229,478	80,963,137
Deferred tax liabilities:		
Noncurrent:		
Depreciation	-	(39,213)
Lease right-of-use assets	(691,119)	-
Total deferred tax liabilities	(691,119)	(39,213)
Net deferred tax assets	24,538,359	80,923,924
Less: valuation allowance	(24,538,359)	(80,923,924)
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 NOL carryforwards and other deferred tax assets. As such, the Company has determined that it is more likely than not that it will not realize its deferred tax assets.

Pursuant to the Internal Revenue Code of 1986, as amended (the "Code") Sections 382 and 383, annual use of a company's NOL and research and development credit carryforwards may be limited if there is a cumulative change in ownership of greater than 50% within a three-year period. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

During the year-ended December 31, 2023, the Company completed an assessment of the available NOL and tax credit carryforwards under Section 382 and 383 and determined that the Company underwent several ownership changes during the period from 2008 to 2022. The Company has adjusted its NOL and tax credit carryforwards to reflect the limitations resulting from the identified ownership changes. The Company reduced its available gross federal and state NOL carryforwards by $237,816,096 and $178,311,455, respectively, and recorded a reduction of $49,941,380 and $7,344,800, respectively, to the federal and state deferred tax asset, each of which related to losses generated for the years ended December 31, 2022, and prior. Accordingly, the NOL and tax credit carryforwards presented above for the year ended December 31, 2023, were reduced by $57,446,259, with a corresponding reduction to the valuation allowance. The Company has recorded the adjustments noted above in 2023 as an out-of-period adjustment and concluded that the adjustments were not material to the 2022 consolidated financial statements and evaluated the recording of this prior year item in the current period and concluded that the net accounting impact is not material to the 2023 consolidated financial statements.

As of December 31, 2023, the Company had $86,840,808 of NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2024, subject to the Section 382 limitation described above. The federal NOLs of $43,354,286 begin to expire in 2024 if unused and $43,486,522 will carry forward indefinitely. The Company also had $59,425,348 of NOLs to reduce future state taxable income as of December 31, 2023. The state NOLs will begin to expire in 2024 if unused. The Company's net deferred tax assets, which include the NOLs, are subject to a full valuation allowance. As of December 31, 2023, the federal and state valuation allowances were $20,558,729 and $3,979,630, respectively.

As of December 31, 2022, prior to the Section 382 analysis, the Company had $316,548,085 of NOLs to reduce future federal taxable income, the majority of which were expected to be available for use in 2023. The federal NOLs of $254,897,407 were to begin to expire in 2023 if unused and $60,829,929 were to carry forward indefinitely. Prior to the Section 382 state analysis, the Company also had $232,097,127 of NOLs to reduce future state taxable income at December 31, 2022. As of December 31, 2022, the federal and state valuation allowances were $66,733,005 and $14,190,055, respectively.

Tax years after 2003 remain open to examination by federal and state tax authorities due to unexpired NOL 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. Due to the existence of the valuation allowance, changes in the Company's unrecognized tax benefits are not expected to impact the Company's effective tax rate.

The Company recognizes interest and penalties on unrecognized tax benefits as well as interest received from favorable tax settlements within income tax expense. As of December 31, 2023, and 2022, the Company recorded no accrued interest or penalties related to uncertain tax positions.

NOTE 11 – COLLABORATIVE AGREEMENT

Collaborative Agreement with Cancer Research Horizons

On March 16, 2023, the Company entered into a Collaboration Agreement (the "CRH Agreement") with Cancer Research Horizons ("CRH"), pursuant to which the Company will use its PEDAL technology to evaluate CRH pre-clinical drug inhibitors of Glutaminase to determine which cancer types and patient populations are most likely to respond to treatment with these compounds (the "Project"). Under the CRH Agreement, both parties will retain rights to their respective background intellectual property. Rights to reports, findings, supporting data, and materials ("Project Intellectual Property") that are generated by the Company pursuant to its performance under the CRH Agreement vest exclusively in CRH. Each party funds its own participation in the Project. Costs incurred to participate in the CRH Agreement are recorded in Cost of Sales in the Company's consolidated Statements of Net Loss.

Pursuant to the CRH Agreement, the Company shall receive a percentage of net revenue, as defined in the agreement, received by CRH for the commercialization of the CRH Candidates and any CRH Derivatives. The percentage of net revenue varies depending on the stage of development. The revenue sharing fees represent variable consideration, which is measured using the expected value method under ASC 606 based on the actual net revenues earned by CRH under Relevant Transfer Agreements relating to the CRH Candidates and CRH Derivatives. Due to the uncertainty associated with the timing and amount of revenue sharing fees, the Company concluded that the revenue sharing fees should be fully constrained until such time that Relevant Transfer Agreements have been entered and net revenues have been earned. These estimates will be reassessed at each reporting period. During the year ended December 31, 2023, the Company recognized no revenue under the CRH Agreement.

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 2023 and 2022, the Company matched 100% of the employee's contribution up to 4.0% of their earnings. Employer contributions were $192,499 and $99,924 in 2023 and 2022, respectively. There were no discretionary contributions to the plan in 2023 and 2022.

NOTE 13 – LOSS PER SHARE

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

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss attributable to common stockholders per common share: basic and diluted calculation	$ (13,983,967)	$ (25,737,634)
Denominator:		
Weighted average common shares outstanding-basic	4,014,848	3,685,954
Effect of diluted stock options, warrants and preferred stock (1)	-	-
Weighted average common shares outstanding-diluted	4,014,848	3,685,954
Loss per common share-basic and diluted	$ (3.48)	$ (6.98)

(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,	
	2023	2022
Options	47,664	49,053
RSUs	-	4,167
Warrants	1,806,589	1,816,437
Preferred stock: Series B	16	16

NOTE 14 – SEGMENTS

The Company has determined its operating segments in accordance with ASC 280 – Segment Reporting. Factors used to determine the Company's reportable segments include the availability of separate financial statements, the existence of locally based leadership across geographic regions, the economic factors affecting each segment, and the evaluation of operating results at the segment level. The Chief Operating Decision Maker ("CODM") allocates the Company's resources for each of the operating segments and evaluates their relative performance. Each operating segment listed below has separate financial statements and locally based leadership that are evaluated based on the results of their respective segments. It should be noted that the operating segments below have different products and services. The financial information is consolidated and evaluated regularly by the CODM in assessing performance and allocating resources. As of January 1, 2023, the Company changed its reportable segments to align with its business areas. The Company has retrospectively revised the reported segment information for all periods presented for consistency.

The Company has three reportable segments, which have been delineated by location and business area:

- *Pittsburgh segment:* provides services that include the application of AI using its proprietary biobank of 150,000+ tumor samples. Pittsburgh also creates proprietary 3D culture models used in drug development.
- *Birmingham segment*: provides contract services and research focused on solubility improvements, stability studies, and protein production.
- *Eagan segment*: produces the FDA-cleared STREAMWAY System and associated products for automated medical fluid waste management and patient-to-drain medical fluid disposal.

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 segment revenues and segment net losses for the year ended December 31, 2023, and 2022 are included in the table below. All revenues are earned from external customers.

The tables below summarize the Company's segment reporting as of and for years ended December 31, 2023, and 2022.

	Year Ended December 31, 2023				
	Pittsburgh	Birmingham	Eagan	Corporate	Total
Revenue	$ 492,596	$ 152,396	$ 1,135,101	$ -	$ 1,780,093
Depreciation and amortization	(207,658)	(494,527)	(29,750)	(7,381)	(739,316)
Impairment expense – long-lived tangible assets	-	(162,905)	-	-	(162,905)
Net loss	$ (4,503,906)	$ (1,966,406)	$ (969,281)	$ (6,544,374)	$ (13,983,967)

	December 31, 2023				
	Pittsburgh	Birmingham	Eagan	Corporate	Total
Assets	$ 3,263,270	$ 981,914	$ 1,390,031	$ 8,782,034	$ 14,417,249
Expenditures for additions to long-lived assets	7,424	254,819	24,691	15,437	302,371

	Year Ended December 31, 2022				
	Pittsburgh	Birmingham	Eagan	Corporate	Total
Revenue	$ 358,776	$ 82,301	$ 1,063,493	$ 889	$ 1,505,459
Depreciation and amortization	(836,671)	(378,708)	(28,481)	(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	$ (15,741,206)	$ (1,817,283)	$ (417,774)	$ (7,761,371)	$ (25,737,634)

	December 31, 2022				
	Pittsburgh	Birmingham	Eagan	Corporate	Total
Assets	$ 1,055,228	$ 1,353,434	$ 946,394	$ 22,379,588	$ 25,734,644
Expenditures for additions to long-lived assets	76,636	157,334	29,362	212,365	475,697

In each of the years ended December 31, 2023, and 2022, substantially all the Company revenues were located or derived from operations in the United States. As of December 31, 2023, all the Company's long-lived assets were located within the United States. During the year ended December 31, 2023, revenues of $489,921 reported in the Company's Pittsburgh segment were attributable to a single customer. As of December 31, 2023, accounts receivable due from this customer was $52,072.

NOTE 15 – SUBSEQUENT EVENTS

Departure of Chief Business Officer

On February 2, 2024, the Company and Pamela Bush, Ph.D., MBA, the Company's Chief Business Officer, agreed that Dr. Bush would leave the Company effective February 15, 2024. In accordance with her Employment Agreement, the Company and Ms. Bush entered into a Separation Agreement and Mutual Release whereby the Company agreed to pay a separation benefit of $410,000 over the subsequent twelve months.

Exhibit 10.9

SEPARATION AGREEMENT AND MUTUAL RELEASE

This Separation Agreement and Mutual Release ***("Agreement")*** is made by and between **Robert Myers** ***("Employee")*** and **Predictive Oncology Inc.** (the ***"Company"),*** each of whom enter into this Agreement intending to be legally bound.

1. **Terms of Employment; Separation Date.**

   a. The terms of Employee's employment with the Company are set forth in that certain Employment Agreement, dated August 11, 2012, and Amendment to Employment Agreement, dated August 20, 2018 (together, the ***"Employment Agreement")***.

   b. Employee's employment will terminate effective as of September 30, 2023 (the ***"Separation Date")***. Regardless of whether Employee signs this Agreement, Employee will receive timely payment of his final paycheck.

2. **Separation Benefits.** In accordance with the Employment Agreement, and in exchange for Employee's waiver and release of claims set forth in Section 3 and other promises set forth in this Agreement, and provided that Employee (i) signs, dates, and returns this Agreement within the time period described in Section 4, (ii) does not rescind this Agreement within the time period described in Section 4; and (iii) successfully completes the transition obligations set forth in Section 7(g) of this Agreement, the Company agrees to pay to Employee the following amounts (collectively, the ***"Separation Benefits")***:

   a. an amount equal to twelve (12) months of Employee's current base salary ($430,000), less applicable taxes and withholdings, payable as salary continuation in accordance with the Company's ordinary payroll procedures;

   b. if any bonus shall be paid to the Company's Chief Executive Officer for 2023, payment of Employee's pro-rata bonus earned for 2023, less applicable taxes and withholdings; and

   c. a lump sum in the amount of $36,797.94 in payment of Employee's unused vacation time for 2023, less applicable taxes and withholdings.

The first installment of the Separation Benefits shall be paid with the Company's first administratively feasible payroll date following the Effective Date (defined below).

3. **Waiver and Release of Claims.**

   a. Employee's General Release and Waiver of Claims.

In exchange for the Separation Benefits set forth in Section 2, Employee agrees to unconditionally waive and release any and all claims, complaints, causes of action, and

demands of whatever kind which Employee has or may have against the Released Parties (as defined below) to the maximum extent permitted by applicable law up to the moment Employee signed this Agreement, including any claims, complaints, causes of action, or demands relating in any way to Employee's employment with the Company and Employee's separation from employment with the Company including, but not limited to, the following:

i. All claims under Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, the Family and Medical Leave Act (regarding existing but not prospective claims), the Fair Labor Standards Act, the Equal Pay Act, the Employee Retirement Income Security Act (regarding unvested benefits), the Civil Rights Act of 1991, Section 1981 of U.S.C. Title 42, the Fair Credit Reporting Act, the Worker Adjustment and Retraining Notification Act, the National Labor Relations Act, the Uniform Services Employment and Reemployment Rights Act, the Genetic Information Nondiscrimination Act, the Immigration Reform and Control Act, the Minnesota Human Rights Act, the Minnesota Whistleblower Act, the Minnesota Equal Pay for Equal Work law, all claims allowed under Minnesota Statute Chapter 181, and retaliation claims under Minn. Stat. §176.82, including without limitation any and all amendments to each of the foregoing and their respective implementing regulations, and any other federal, state, local, or foreign law (statutory, regulatory, common law, or otherwise) that may be legally waived and released; however, the identification of specific statutes is for purposes of example only, and the omission of any specific statute or law shall not limit the scope of this general release in any manner;

ii. All claims arising under tort, contract, and quasi-contract law, including but not limited to claims of breach of an express or implied contract, wrongful or retaliatory discharge, fraud, defamation, negligent or intentional infliction of emotional distress, tortious interference with a contract or prospective business advantage, breach of the implied covenant of good faith and fair dealing, promissory estoppel, detrimental reliance, invasion of privacy, false imprisonment, nonphysical injury, personal injury or sickness, or any other harm;

iii. All claims for any other form of pay, compensation, or employee benefits of any kind that is not provided in this Agreement including, without limitation, bonuses, commissions, deferred compensation, stock-based incentive compensation, stock options, phantom stock, equity of any kind, vacation pay, expense reimbursement, and any other claims under any applicable federal, state, and local law, statute, ordinance, or regulation to the fullest extent permitted by law;

iv. All claims for monetary or equitable relief, including but not limited to attorneys' fees, back pay, front pay, reinstatement, experts' fees, medicalfees or expenses, costs and disbursements, punitive damages, liquidated damages, and penalties.

Employee understands and agrees that the above list contains examples only and does not contain all claims that Employee is releasing. By signing this Agreement, Employee is fully and finally waiving and releasing, to the fullest extent permitted by law, all claims against the Released Parties. Employee agrees that the Company's payment of the Separation Benefits is full and fair payment for the waiver and release of Employee's claims and has a value greater than anything Employee is entitled to if Employee does not sign this Agreement. However, this general release and waiver of claims excludes, and the Employee does not waive, release, or discharge: (A) any claims that by law cannot be released in a private agreement; (B) any claims that arise after the date Employee signed this Agreement; (C) any claims that relate to the obligations of Employee or the Company under this Agreement; (D) any right to file an unfair labor practice charge under the National Labor Relations Act or otherwise access the National Labor Relations Board's processes; and (E) any rights to vested benefits, such as pension or retirement benefits, the rights to which are governed by the terms of the applicable plan documents and award agreements.

For purposes of this Agreement, the term "Released Parties" means the Company and all of the Company's past and present parents, subsidiaries, and affiliated companies, and all and each of the past and present employees, officers, officials, managers, members, directors, agents, insurers, representatives, counsel, shareholders, owners, partners, predecessors, successors, and assigns of any and all of the foregoing entities and persons. In addition, for purposes of Section 3, the term "Employee" means Robert Myers and any person who has or obtains any legal rights or claims against the Company or the Released Parties through Robert Myers, including without limitation any and all heirs, executors, agents and assignees.

b. Company's General Release and Waiver of Claims. Company fully and completely releases Employee and Employee's representatives, attorneys, predecessors, heirs, successors, and permitted assigns ("Employee Parties") from any and all claims or causes of action that Company may have against the Employee Parties, known or unknown, including claims or causes of action that relate in any way to Employee's employment with any Company party or the termination thereof, from the beginning of time through the date Company signs this Agreement.

c. Company's Partial Waiver and Non-Enforcement of Non-Compete. Company agrees to partially waive and to not enforce the non-competition provision in Section 6(a) of the Employment Agreement to the extent Employee is not engaged, directly or indirectly, as an employee, owner, consultant or in any other capacity whatsoever, for Employee's own behalf or on behalf of any other person or entity, anywhere in the United States of America in the discovery, characterization or evaluation of chemical or biological compositions for the diagnosis or treatment of disease. For the avoidance of doubt, all other provisions in Section 6 of the Employment Agreement survive, remain valid and are fully enforceable.

4. **Employee's Legal Rights.**

   a. **Advice to Consult With an Attorney.** This Agreement is a legal document. Employee has been advised in writing to consult with an attorney prior to executing the Agreement.

   b. **Period to Consider this Agreement.** Employee was given this Agreement on September 15, 2023. Employee has twenty-one (21) days following receipt of the Agreement to consider the offer as expressed. Signing this Agreement before the 21-day period expires constitutes a waiver by Employee of any remaining time period for review and consideration to which Employee may be entitled. If Employee does not sign this Agreement within the 21-day consideration period, the offer contained within this Agreement will expire. Employee agrees and understands that if Employee does not sign this Agreement within the 21-day consideration period, this Agreement will be null and void and Employee will not receive the Separation Benefits in Section 2.

   c. **Period to Revoke this Agreement.** Employee understands that Employee has the right to revoke this Agreement within fifteen (15) calendar days after the date on which Employee signs this Agreement. This Agreement shall not become effective or enforceable until the 15-day revocation period has expired without Employee's revoking this Agreement. Provided that Employee does not revoke this Agreement, it shall become effective on the day immediately following the foregoing revocation period (such date, the "Effective Date").

   d. **Revocation Procedure.** To revoke, Employee must put the revocation in writing and deliver it to the Company by overnight delivery or e-mail to Raymond Vennare (Predictive Oncology Inc. c/o Raymond Vennare, 91 43rd Street, Ste. 210, Pittsburgh, PA 15201; rvennare@predictive-oncology.com) within the 15-day period.

   If Employee rescinds this Agreement as described in this Section 4, Employee understands that (i) this Agreement is null and void, (ii) the Company shall have no further obligation under this Agreement, (iii) Employee will not receive the Separation Benefits in Section 2 of this Agreement or any other benefits listed within this document, and (iv) Employee's employment will still end on the Separation Date.

5. **Filings.** Employee understands that, without being penalized or having an obligation to notify the Company, this Agreement does not prohibit Employee from filing an administrative charge of discrimination or complaint with the Equal Employment Opportunity Commission, National Labor Relations Board, Occupational Safety and Health Administration, the Equal Employment Opportunity Commission, Securities and Exchange Commission, Civil Rights Division, Minnesota Department of Human Rights, or any other federal, state, or local governmental agency or commission or law enforcement agency ("Government Agencies"). Employee understands that this

Agreement does not limit Employee's ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agencies, including providing documents or other information, without notice to the Company. If Employee had filed or files a charge or complaint, Employee agrees that the Company's payment of the Separation Benefits completely satisfies any and all claims for monetary relief in connection with such charge or complaint, and this Agreement does not limit Employee's right to receive an award for information (a) provided pursuant to the Securities and Exchange Commission's whistleblower protections and incentives; or (b) provided to any other Government Agencies. Employee is not entitled to any other monetary relief of any kind with respect to the claims that Employee has released in this Agreement unless Employee's waiver and release of claims is deemed unlawful or otherwise invalid.

6. **Governing Law/Venue.** The laws of the State of Minnesota will govern the validity, construction, and performance of this Agreement, without regard to the conflict of law provisions of any other jurisdictions. Employee irrevocably consents to the exclusive jurisdiction of courts in Minnesota for the purposes of any action arising out of or related to this Agreement or any dispute between the Company and Employee, including any actions for temporary, preliminary, and permanent equitable relief.

7. **Additional Agreements and Understandings.**

   a. **Company Property.** By the Separation Date, Employee must return to the Company all the Company property in Employee's possession or under Employee's control including, but not limited to, all corporate credit cards, identification badges, computer hardware and software, cell phones, tablets, PDAs, books, records, documents, data, access cards, financial data, confidential information, trade secrets, files, notebooks, passwords, plans, sales reports, records, and all other property, equipment, or information owned by the Company or to which Employee was provided access by the Company during Employee's employment (collectively, "Company Property"). Employee further agrees that by no later than the Separation Date, to the fullest extent permitted by law, Employee will conduct a thorough search for and return to the Company and subsequently irrevocably delete any and all intangible Company Property which exists or is stored (i) in any personal e-mail account (ii) in any personal "cloud" account; or (iii) on any personal computer, tablet, cellular phone, smartphone, flash drive, laptop or other electronic storage device, the foregoing of which are accessible, controlled or owned by Employee (and not by the Company). By signing this Agreement, Employee represents that Employee has complied with the terms of this paragraph.

   b. **Post-Employment Obligations.** Employee acknowledges that any and all post-employment obligations to which Employee is or may be subject, whether set forth in the Employment Agreement or otherwise, including without limitation regarding confidentiality, non-disclosure of confidential information, non-competition and non-solicitation, shall remain in full force and effect and are incorporated by reference into this Agreement as if fully restated herein.

The Company advises Employee as follows under the federal Defend Trade Secrets Act: An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order. Nothing in this Agreement is intended to conflict with 18 U.S.C. § 1833(b) or create liability for disclosures of trade secrets that are expressly allowed by 18 U.S.C. § 1833(b).

c. **Consideration.** Employee agrees that (i) the Separation Benefits in Section 2 are above and beyond that to which Employee would be entitled if Employee did not sign this Agreement, (ii) the Separation Benefits in Section 2 constitute independent and sufficient consideration for all aspects of this Agreement, and (iii) Employee is not eligible for any other payments or benefits except for those expressly described in this Agreement, provided that Employee signs and returns this Agreement within the specified time period and does not revoke this Agreement.

d. **References.** Should anyone contact the Company for a reference, the Company will only verify Employee's employment dates, job title, and compensation.

e. **Non-Disparagement.** Employee agrees not to make disparaging or defamatory remarks about the Company or the Company's services, products, or other matters pertaining to its business. This non-disparagement provision does not apply to Employee's legally protected communications and does not prohibit Employee from (i) filing an administrative charge or complaint with, or cooperating, assisting, testifying, or participating in an investigation or legal proceeding conducted or initiated by, any Government Agencies, or (ii) inquiring about, discussing, or disclosing Employee's and other employees' pay, hours, and other terms and conditions of employment. Company's Board of Directors serving as of the Separation Date each agree that they will not knowingly or intentionally make, or cause to be made, any statement (oral or written) that disparages Employee.

f. **Confidentiality.** Employee agrees that Employee is to keep the terms and conditions of this Agreement strictly confidential. Employee agrees that Employee will not disclose, discuss, or reveal the existence or the terms of this Agreement except as follows: (i) as required by court order or as required by law; (ii) to Employee's immediate family; or (iii) to Employee's attorneys, financial planners, and accountants. Employee must ensure that any person or entity described in subsections (ii) and (iii) to whom such disclosures are made will, as a condition of such disclosure, agrees to keep the terms of this Agreement strictly confidential. Employee understands that the foregoing does not prohibit him from filing an administrative charge or complaint with, or cooperating, assisting, testifying, or participating in an investigation or legal proceeding conducted or initiated by, any Government Agencies; or inquiring about, discussing, or disclosing his and other employees' pay, hours, and other terms and conditions of employment.

g. **Transition and Cooperation.** Employee agrees to successfully transition his work responsibilities prior to the Separation Date as and to the extent requested by the Company. Employee represents that he has delivered or will deliver all passwords for any Company devices and/or accounts in use at the time of the Separation Date. Employee will cooperate with the Company and use his best efforts to transition his work during the remaining period of employment and shall agree to be available, on a reasonable basis, to answer questions that may arise after the Separation Date, as necessary to achieve a smooth transition. Employee also agrees to be available to and cooperate with the Company and its counsel in connection with any investigation, administrative proceeding or litigation relating to any matter, occurring during his employment, in which he was involved or of which he has knowledge, and that Employee will be compensated for such cooperation activities at an hourly rate equivalent to his base salary divided by 2,080 hours. Employee understands and agrees that such cooperation includes, but is not limited to, making himself available to the Company and/or its counsel upon reasonable notice for: interviews and factual investigations; preparing for and appearing to give testimony in a deposition or at trial without requiring service of a subpoena or other legal process; volunteering to the Company or its counsel pertinent information; and turning over all relevant documents which are or may come into his possession.

h. **Non-Admission.** It is expressly understood that this Agreement does not constitute, nor shall it be construed as, an admission by the Company of any liability or unlawful conduct whatsoever. The Company specifically denies any liability or unlawful conduct on the Company's pai1.

i. **Successors and Assigns.** This Agreement is personal to Employee and may not be assigned by Employee without the written agreement of the Company. The rights and obligations of this Agreement shall inure to the successors and assigns of the Company.

j. **Severability.** If a court finds any term of this Agreement to be invalid, unenforceable, or void, Employee and the Company agree that the court shall modify such term to make it enforceable to the maximum extent possible. If the term cannot be modified, Employee and the Company agree that the term shall be severed and all other terms of this Agreement shall remain in effect. Employee and the Company agree that Employee's waiver and release of claims should be interpreted as broadly as possible to achieve Employee's intention of releasing all claims against the Released Parties.

k. **Entire Agreement.** This Agreement constitutes the sole understanding of Employee and the Company with respect to the matters provided for herein. Employee and the Company agree that this Agreement supersedes and terminates any and all other written and oral agreements and understandings between Employee and the Company concerning separation benefits Employee may have been eligible for or entitled to from the Company. Notwithstanding anything in this Agreement to the contrary, Employee agrees and acknowledges that the postemployment obligations set forth in the Employment Agreement remain in full force and effect after the Separation Date. This Agreement may not be modified, altered, or changed in any way except by written agreement signed by Employee and the Company's Chief Executive Officer.

l. **No Waiver.** No claim or right arising out of a breach or default under this Agreement may be discharged by a waiver of that claim or right unless the waiver is made in writing and signed by the Company's Chief Executive Officer. A waiver by any party of a breach or default of the other party of any provision contained in this Agreement shall not be deemed a waiver of future compliance of such provisions, and such provisions shall remain in full force and effect.

m. **Remuneration.** Employee acknowledges and agrees that the Company will pay Employee any and all monies, wages, salary, accrued unused paid time off, expenses, bonuses, and commissions (if applicable) due to Employee through the Separation Date on the first regular payday following the Separation Date, or as otherwise required by law. Employee is not entitled to any additional remuneration from the Company other than the consideration outlined within this Agreement. In addition, Employee acknowledges that Employee is not aware of any time worked during Employee's employment for which Employee has not already been fully compensated.

n. **Acknowledgements.** Employee acknowledges and agrees that: (i) Employee has not suffered any work-related injury for which Employee has not already filed a claim; and (ii) Employee has been properly provided any leave of absence including for Employee's own or a family member's health condition.

o. **Taxes.** Employee acknowledges that Employee has not relied on any tax advice provided by the Company and that, if necessary, Employee is solely responsible for properly reporting the payment received pursuant to this Agreement and paying any applicable taxes, penalties, and interest. Employee acknowledges and agrees that Employee has been provided with the opportunity to consult legal and financial counsel with respect to the tax treatment of the payment Employee will receive pursuant to this Agreement and on account of Employee's separation from employment. Employee has been advised by the Company to consult with such counsel.

8. **Execution/Counterparts.** Employee agrees not to sign this Agreement prior to the end of Employee's workday on the Separation Date. To accept this Agreement, Employee must deliver this signed and dated Agreement to Raymond Vennare, by email (rvennare@predictive-oncology.com), hand or by mail (Predictive Oncology Inc. c/o Raymond Vennare, 91 43rd Street, Ste. 210, Pittsburgh, PA 15201) within the time period set forth in Section 4. This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. This Agreement may be executed either by original or facsimile, either of which will be equally binding.

Dated: 9/29/2023

/s/ Robert Myers
Robert Myers

Dated: 9/30/2023

PREDICTIVE ONCOLOGY INC.
By: /s/ Raymond F. Vennare
Its: Chief Executive Officer

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 hereby 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. 333-186464, 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 28, 2024, relating to the consolidated financial statements which appears in this Annual Report on Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, P.C.
Minneapolis, Minnesota

March 28, 2024

Exhibit 23.2

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. 333-186464, 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.

/s/ Baker Tilly US, LLP

Minneapolis, Minnesota
March 28, 2024

Exhibit 31.1

CERTIFICATION
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

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 15d-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 28, 2024

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

Exhibit 31.2

CERTIFICATION
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Josh Blacher, 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 in light of the circumstances under which some 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 15d-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 28, 2024

/s/ Josh Blacher
Josh Blacher
Interim Chief Financial Officer

Exhibit 32.1

CERTIFICATION
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, 2023 as filed with the Securities and Exchange Commission (the "Report"), I, Raymond F. Vennare, Chief Executive Officer (Principal Executive Officer) and, I, Josh Blacher, Interim Chief Financial Officer (Principal Financial Officer) of the Company, hereby certify as of the date hereof, solely for purposes of § 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1350, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and

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

Date: March 28, 2024

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

Date: March 28, 2024

/s/ Josh Blacher
Josh Blacher
Interim Chief Financial Officer
(Principal Financial Officer)

PREDICTIVE ONCOLOGY INC.
POLICY ON RECOUPMENT OF INCENTIVE COMPENSATION

Purpose

The purpose of this policy is to set forth the procedures established by the Predictive Oncology (the "Company") Board of Directors (the "Board") for the recoupment of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with the financial reporting requirements under the U.S. federal securities laws in accordance with the terms and conditions set forth herein.

Definitions

For purposes of this policy, the terms set forth below shall have the following meanings:

Code: the U.S. Internal Revenue Code of 1986, as amended, and the regulations and guidance thereunder.

Committee: the Compensation Committee of the Board.

Covered Compensation: any Incentive-Based Compensation granted, vested, or paid to a person who served as an Executive Officer at any time during the performance period for the Incentive-Based Compensation and that was received (i) on or after October 2, 2023, (ii) after the person became an Executive Officer, and (iii) at a time that the Company had a class of securities listed on a U.S. national securities exchange.

For purposes of this policy, Incentive-Based Compensation is deemed "received" in the Company's fiscal period during which the Financial Reporting Measure specified in or otherwise relating to the Incentive-Based Compensation award is attained, even if the grant, vesting, or payment of the Incentive-Based Compensation occurs after the end of that period.

Erroneously Awarded Compensation: the amount of Covered Compensation granted, vested, or paid to a person during the fiscal period when the applicable Financial Reporting Measure relating to such Covered Compensation was attained that exceeds the amount of Covered Compensation that otherwise would have been granted, vested, or paid to the person had such amount been determined based on the applicable Restatement, computed without regard to any taxes paid (i.e., on a pre-tax basis). For Covered Compensation based on stock price or total stockholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Restatement, the Committee will determine the amount of such Covered Compensation that constitutes Erroneously Awarded Compensation, if any, based on a reasonable estimate of the effect of the Restatement on the stock price or total stockholder return upon which the Covered Compensation was granted, vested, or paid and the Committee shall maintain documentation of such determination and provide such documentation to the NASDAQ.

Exchange Act: the Securities Exchange Act of 1934, as amended, and the rules promulgated thereunder.

Executive Officer: those persons who are designated by the Board as an "officer" of the Corporation as such term is defined in Rule 16a-1(f) under the Exchange Act. Both current and former Executive Officers are subject to this policy in accordance with its terms.

Financial Reporting Measure: (i) any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, (ii) stock price, or (iii) total stockholder return. For the avoidance of doubt, any such measure does not need to be presented within the Company's financial statements or included in a filing with the SEC to constitute a Financial Reporting Measure.

Incentive-Based Compensation: any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure. For purposes of this policy, "Incentive-Based Compensation" shall also be deemed to include any amounts which were determined based on (or were otherwise calculated by reference to) Incentive-Based Compensation (including, without limitation, any amounts under any long-term disability, life insurance, or supplemental retirement or severance plan or agreement or any notional account that is based on Incentive-Based Compensation, as well as any earnings accrued thereon).

Lookback Period: the three completed fiscal years (plus any transition period of less than nine months that is within or immediately following the three completed fiscal years and that results from a change in the Company's fiscal year) immediately preceding the date on which the Company is required to prepare a Restatement for a given reporting period, with such date being the earlier of: (i) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement, or (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare a Restatement. Recovery of any Erroneously Awarded Compensation under this policy is not dependent on if or when the Restatement is actually filed.

NASDAQ: the National Association of Securities Dealers Automated Quotations.

Restatement: a required accounting restatement of any Predictive Oncology financial statement due to the material noncompliance of the Company with any financial reporting requirement under U.S. federal securities laws, including (i) to correct an error in previously issued financial statements that is material to the previously issued financial statements or (ii) to correct an error in previously issued financial statements that is not material to the previously issued financial statements but that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. Recovery of any Erroneously Awarded Compensation under this policy is not dependent on fault, fraud, or misconduct by any person in connection with the Restatement.
For purposes of this policy, a Restatement shall not be deemed to occur in the event of a revision of the Company's financial statements due to an out-of-period adjustment (i.e., when the error is immaterial to the previously issued financial statements and the correction of the error is also immaterial to the current period) or a retrospective (1) application of a change in accounting principles; (2) revision to reportable segment information due to a change in the structure of the Company's internal organization; (3) reclassification due to a discontinued operation; (4) application of a change in reporting entity, such as from a reorganization of entities under common control; or (5) revision for stock splits, reverse stock splits, stock dividends, or other changes in capital structure.

SEC: the U.S. Securities and Exchange Commission.

Recoupment of Erroneously Awarded Compensation

In the event of a Restatement, any Erroneously Awarded Compensation received during the Lookback Period prior to the Restatement (a) that is then-outstanding but has not yet been paid shall be automatically and immediately forfeited and (b) that has been paid to any person shall be subject to reasonably prompt repayment to the Company. The Committee must pursue (and shall not have the discretion to waive) the forfeiture and/or repayment of such Erroneously Awarded Compensation, except as provided below.

Notwithstanding the foregoing, the Committee may determine not to pursue the forfeiture and/or recovery of Erroneously Awarded Compensation from any person if the Committee determines that such forfeiture and/or recovery would be impracticable due to any of the following circumstances: (i) the direct expense paid to a third party to assist in enforcing this policy would exceed the amount to be recovered (following reasonable attempts by the Company to recover such Erroneously Awarded Compensation, the documentation of such attempts, and the provision of such documentation to the NASDAQ); or (ii) recovery would likely cause any otherwise tax-qualified retirement plan, under which benefits are broadly available to employees, to fail to meet the requirements of Sections 401(a)(13) or 411(a) of the Code.

Notwithstanding anything to the contrary herein, the Company has no obligation to seek recoupment of amounts that are granted, vested, or earned based solely upon the occurrence or non-occurrence of non-financial events. Such exempt compensation includes, without limitation, base salary; time-vesting awards; compensation awarded on the basis of the achievement of metrics that are not Financial Reporting Measures; and compensation awarded solely at the discretion of the Committee, the Board, or a group composed entirely of independent members of the Board; provided that such amounts are in no way contingent on, and were not in any way granted on the basis of, the achievement of any Financial Reporting Measure.

Means of Repayment

In the event that the Committee determines that any person shall repay any Erroneously Awarded Compensation, the Committee shall provide written notice to such person by email or certified mail to the physical address on file with the Company for such person, and the person shall satisfy such repayment in a manner and on such terms as required by the Committee, and the Company shall be entitled to set off the repayment amount against any amount owed to the person by the Company, to require the forfeiture of any award granted by the Company to the person, or to take any and all necessary actions to reasonably promptly recoup the repayment amount from the person, in each case, to the fullest extent permitted under applicable law, including, without limitation, Section 409A of the Code. If the Committee does not specify a repayment timing in the written notice described above, the applicable person shall be required to repay the Erroneously Awarded Compensation to the Company by wire, cash, or cashier's check no later than thirty (30) days after receipt of such notice.

No Indemnification

The Company shall not indemnify any person, directly or indirectly, for any losses that such person may incur in connection with the recovery of Erroneously Awarded Compensation pursuant to this policy, including through the payment of insurance premiums or gross-up payments.

Administration

This policy shall be administered and interpreted by the Committee. The Committee shall make all determinations regarding the application and operation of this policy in its sole discretion (including the manner and timing for promptly recouping Erroneously Awarded Compensation), and all such determinations shall be final and binding. In the event that the Committee determines that any person shall repay any Erroneously Awarded Compensation, the person shall satisfy such repayment in a manner and on such terms as required by the Committee to the fullest extent permitted under applicable law including, without limitation, Section 409A of the Code.

Other

This policy is intended to comply with the requirements of Section 10D of the Exchange Act and Section 5608 of the NASDAQ Stock Market LLC Rules. The provisions of this policy shall be interpreted in a manner that satisfies such requirements and this policy shall be operated accordingly. If any provision of this policy would otherwise frustrate or conflict with this intent, the provision shall be interpreted and deemed amended so as to avoid such conflict.

Any applicable award agreement or other document setting forth the terms and conditions of any compensation covered by this policy shall be deemed to include the restrictions imposed herein and incorporate this policy by reference and, in the event of any inconsistency, the terms of this policy will govern.

The provisions in this policy are intended to be applied to the fullest extent of the law. To the extent that any provision of this policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to applicable law. The invalidity or unenforceability of any provision of this policy shall not affect the validity or enforceability of any other provision of this policy.

The rights of the Company under this policy to seek forfeiture or reimbursement are in addition to, and not in lieu of, any rights of recoupment, or remedies or rights other than recoupment, that may be available to the Company pursuant to the terms of any law, government regulation, or stock exchange listing requirement or any other policy, plan, or agreement of the Company; provided, however, that any amounts recouped under any other policy that would be recoupable under this policy shall count toward any required recoupment under this policy and vice versa.