

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, 2024

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

(State or other jurisdiction of
incorporation or organization)

33-1007393

(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 ☐

Non-accelerated filer ☒

Accelerated filer ☐

Smaller reporting company ☒

Emerging growth company ☐

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

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

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 28, 2024, 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 \$5,819,537 based upon 5,595,709 shares at \$1.04 per share as reported on the NASDAQ Capital Market.

As of March 26, 2025, the registrant had 8,931,621 shares of common stock, par value \$.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

PREDICTIVE ONCOLOGY INC.

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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS AND SUMMARY OF RISK FACTORS

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. The following summarizes the principal risks of our business:

- There is substantial doubt about our ability to continue as a going concern without additional financing;
- Risks relating to our plans regarding a merger with Renovaro, Inc. pursuant to which we would be acquired by Renovaro, including that the transaction may not occur on a timely basis, if at all, the diversion of management's attention, and possible negative impacts on the trading price of our common stock;
- 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 divestitures, including that we may not realize the anticipated benefits from the divestiture;
- Risks related to our use of artificial intelligence (AI), including any deficiencies that may undermine predictions or analyses that AI applications produce, as well as changes in laws and regulations regarding AI that could affect our use of AI or our commercialization activities;
- 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;
- Risks that our research and development and commercialization efforts for our PEDAL platform may take longer than expected;
- Risk that we will be unable to protect our intellectual property or claims that we are infringing on others' intellectual property;
- 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 impacts of government regulation and scrutiny, changes in laws and regulations and any failure on our part to comply with laws, rules and regulations, which can be expensive and time consuming;
- Risks related to cybersecurity threats, security breaches and/or information technology and communications system failures;
- Adverse results of any legal proceedings, including product liability claims;
- The volatility of our operating results and financial condition; and
- 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.

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.

Significant Transactions and Recent Events

In July 2024, our Board of Directors approved a plan to implement a strategic cost savings initiative, primarily related to our Birmingham laboratory. The Birmingham laboratory was the business that comprised our Birmingham reportable segment, providing contract services and research focused solubility improvements, stability studies and protein production. In September 2024, the laboratory equipment and inventories from the Birmingham laboratory were sold, the related product and service lines were discontinued, and we vacated and ceased use of the Birmingham laboratory and office space. As a result, during the third quarter of 2024, the former Birmingham operating segment met the criteria under US GAAP to be reported as discontinued operations.

On January 1, 2025, we entered into a binding letter of intent with Renovaro, Inc. (“Renovaro”) pursuant to which Renovaro will acquire all of our issued and outstanding common stock in exchange for a newly created series of Renovaro preferred stock (the “Renovaro LOI”). The Renovaro LOI provides that the Renovaro preferred stock will be issued to our shareholders in a 1:1 exchange for shares of our common stock. The preferred stock will be automatically redeemable for \$3.00 per share after 18 months and may also be converted after the closing of the transaction into freely tradeable, registered Renovaro common stock at a 1:1 conversion ratio by either the holders thereof or Renovaro at any time after Renovaro’s common stock has traded at or above \$4.50 per share for 30 consecutive trading days. The Renovaro LOI also provides that Renovaro will have the right to redeem the preferred stock for cash at a redemption price of \$3.00 per share (i) if the trading price of its common stock is \$3.00 or less or (ii) such preferred stock has not been converted within 30 days after the first date on which the holder could request such conversion as described above.

The Renovaro LOI was amended by an extension agreement entered into on February 28, 2025, which extended the parties’ obligation to enter into definitive documentation for the transaction from no later than February 28, 2025, to no later than March 31, 2025. The transaction is subject to a minimum fundraising of \$15 million by Renovaro, as well as formal approval by our shareholders. If our shareholders do not approve the transaction, assuming prior funding by Renovaro, we will be obligated to provide Renovaro a two-year exclusive royalty-free license to our biobank of tumor samples and tumor-specific 3D cell culture models.

On March 14, 2025, we entered into an asset purchase agreement and closed on a transaction to sell and assign to DeRoyal Industries, Inc. the assets and liabilities exclusively related to our business of providing products for automated, direct-to-drain medical fluid disposal, including our STREAMWAY® product line. These assets were operated by our wholly owned subsidiary, Skyline Medical Inc., and were reported in our Eagan reportable operating segment. The Eagan operating segment did not meet the criteria under US GAAP to be reported as discontinued operations as of and for the year ended December 31, 2024, and is reported within continuing operations in the consolidated financial statements included in this Annual Report on Form 10-K.

Our Business

As of December 31, 2024, we operated in two 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 produced 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 a result of the decision to discontinue our former Birmingham operating segment, we had two reportable segments as of December 31, 2024, which were 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.
- *Eagan segment:* produced 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.

EAGAN

STREAMWAY® System

Through our wholly owned subsidiary, Skyline Medical Inc. (“Skyline Medical”), reported under our Eagan segment, we sold the STREAMWAY System, as well as proprietary cleaning solution and filters for use with the STREAMWAY System. As disclosed above under “*Recent Transactions and Significant Events*,” we divested all of the assets and liabilities related to the business operations of our Eagan segment as of March 14, 2025 (the “Eagan Sale”). 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 distributed our products to medical facilities where bodily and irrigation fluids produced during medical procedures must be contained, measured, documented, and disposed of properly. These products minimize the exposure potential to the healthcare workers who handle such fluids.

The 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 manufactured and sold 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. Our exclusive distribution rights to the disposable cleaning solution were included in the assets transferred in connection with the Eagan Sale.

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 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.

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.

Infectious and Biohazardous Waste Management

The STREAMWAY System, which we sold effective March 14, 2025, allows continuous suction but also provides for unlimited capacity, eliminating the need to interrupt a procedure to change canisters, which we believe is unique to the infectious and biohazardous waste management industry. 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.

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 have existing and good relationships with our service vendors.

Research and Development (“R&D”)

We spent \$25,987 and \$122,307 in 2024 and 2023, 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 were 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. In connection with the Eagan Sale, we assigned all of the rights to patents, patent applications and other intellectual property and related proprietary rights owned by us and used exclusively in the Eagan business, effective March 14, 2025.

Government Regulation

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

<i>CLIA and State Clinical Laboratory Licensing</i>	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.
<i>Medicare and Medicaid; Fraud and Abuse</i>	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.
<i>FDA</i>	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.

<i>Environmental, Health and Safety</i>	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)
<i>Privacy and Security of Health and Personal Information</i>	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.

Employees and Human Capital Resources

We had 23 full-time employees and 1 part-time employee as of December 31, 2024. 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 new 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 the Proposed Acquisition of the Company by Renovaro, Inc.

While we have entered into a binding letter of intent and are involved in exclusive negotiations with Renovaro relating to Renovaro's acquisition of us, we cannot assure you that the proposed transaction will be consummated and the failure to complete the proposed transaction could adversely affect our business, results of operations, financial condition and stock price.

On January 1, 2025, we executed a binding letter of intent (the "LOI") with, and are engaged in exclusive negotiations relating to the proposed acquisition of us by, Renovaro. We cannot assure you that we and Renovaro will agree to terms and enter into a definitive agreement for the proposed transaction on a timely basis or at all, which remains subject to satisfactory due diligence and further negotiation, and Renovaro receiving certain financing. Accordingly, the terms of the transaction, if any, may be materially different from the terms outlined in the LOI and this Annual Report on Form 10-K. If we are able to negotiate a definitive agreement, the consummation of the transaction pursuant such agreement will be subject to the approval of our stockholders, among other conditions, certain of which will be out of our control. Accordingly, we cannot provide any assurance that we will consummate the proposed transaction in the manner currently anticipated, or at all.

The proposed transaction gives rise to inherent risks that include:

- if the transaction is not completed, the share price of our common stock will change to the extent that the current market price of our stock reflects an assumption that the transaction will be completed;
- legal or regulatory proceedings, including regulatory approvals from various governmental entities (including any conditions, limitations or restrictions placed on these approvals) and the risk that one or more governmental entities may delay or deny approval, or other matters that affect the timing or ability to complete the transaction;
- potential stockholder litigation relating to the transaction could prevent or delay the transaction or otherwise negatively impact our business and operations;
- the risk that if the proposed transaction is not completed, the market price of our common stock could decline, investor confidence could decline, stockholder litigation could be brought against us, relationships with customers, suppliers and other business partners may be adversely impacted, we may be unable to retain key personnel, and profitability may be adversely impacted due to costs incurred in connection with the proposed transaction.

The announcement of the proposed transaction and the LOI, and pendency of the transaction, may result in disruptions to our business, and the proposed transaction could divert management's attention, disrupt our relationships with third parties and employees, and result in negative publicity or legal proceedings, any of which could negatively impact our operating results and ongoing business.

In connection with the proposed transaction, our current and prospective employees may experience uncertainty about their future roles with us following the transaction, which may materially adversely affect our ability to attract and retain key personnel and other employees while the transaction is pending. Key employees may depart because of issues relating to the uncertainty and difficulty of integration or a desire not to remain with us following the transaction, and may depart prior to the consummation of the transaction. Accordingly, no assurance can be given that we will be able to attract and retain key employees to the same extent that we have been able to in the past.

The proposed transaction could cause disruptions to our business or business relationships with our existing and potential customers, suppliers, partners, vendors, and other business partners, and this could have an adverse impact on our results of operations. Parties with which we have business relationships may experience uncertainty as to the future of such relationships and may delay or defer certain business decisions, seek alternative relationships with third parties, or seek to negotiate changes or alter their present business relationships with us. Parties with whom we otherwise may have sought to establish business relationships may seek alternative relationships with third parties.

The pursuit of the transaction may place a significant burden on management and internal resources, which may have a negative impact on our ongoing business. It may also divert management's time and attention from the day-to-day operation of our business and the execution of our other strategic initiatives. This could adversely affect our financial results. In addition, we have incurred and will continue to incur other significant costs, expenses and fees for professional services and other transaction costs in connection with the proposed transaction, and many of these fees and costs are payable regardless of whether or not the transaction is consummated. We also could be subject to litigation related to the proposed transaction, which could prevent or delay the consummation of the transaction and result in significant costs and expenses.

Any of the foregoing, individually or in combination, could materially and adversely affect our business, financial condition and results of operations and prospects.

While the LOI is in effect we are, and once a definitive agreement is in effect we will be, subject to certain restrictions as to the operation of our business.

The LOI generally requires us to operate our business in the ordinary course, subject to certain exceptions, pending execution of a definitive agreement. It is expected that any definitive agreement we enter into will subject us to customary interim operating covenants that restrict us, without Renovaro's approval, from taking certain specified actions until the transaction is completed or the definitive agreement is terminated in accordance with its terms. These restrictions could prevent us from pursuing certain business opportunities that may arise prior to the execution of a definitive agreement or the consummation of the transaction and may adversely affect our ability to execute our business strategies and attain financial and other goals and may adversely impact our financial condition, results of operations and cash flows.

Risk Factors Related to Our Business

There is substantial doubt about our ability to continue as a going concern. We require significant additional funding to maintain operations and implement our business plan. The financing we have obtained to date has been dilutive, and any additional financing, if available, may also be dilutive.

We have incurred significant and recurring losses from operations for the past several years and, as of December 31, 2024, had an accumulated deficit of \$180,426,271. We had cash and cash equivalents of \$734,673 as of December 31, 2024, and need to raise significant additional capital to meet our operating needs. We had short-term obligations of \$3,593,401 and long-term operating lease obligations of \$1,558,239 as of December 31, 2024. We do not expect to generate sufficient operating revenue to sustain our operations in the near term. During the year ended December 31, 2024, we incurred negative cash flows from continuing operating activities of \$10,974,568. 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 continue to evaluate alternatives to obtain the required additional funding to maintain future operations, but there can be no assurances that such funding will be available under acceptable terms, if at all.

Alternatives to obtain additional funding 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. For example, in May 2024 we raised \$3.58 million in net proceeds through an at-the-market offering of shares of our common stock. In July 2024, we raised \$1.0 million in net proceeds through cash exercises of certain outstanding warrants pursuant to agreements with certain warrant holders to reduce the exercise price of those warrants and issue new warrants as consideration for the cash exercises. In February 2025, we issued shares of our common stock in a registered direct offering for gross proceeds of \$545 thousand. In March 2025, pursuant to an extension agreement in connection with the LOI with Renovaro, Renovaro purchased shares of our common stock for an aggregate of \$500 thousand. In March 2025, we entered into an asset purchase agreement pursuant to which we sold and assigned assets and liabilities exclusively related to the business of providing products for automated, direct-to-drain medical fluid disposal, including our STREAMWAY product line, for \$625 thousand, plus assumed liabilities. Despite these sources of funding, we may be unable to access additional 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 divestiture of our STREAMWAY product line presents risks that could negatively impact our business, financial condition, and results of operations. There is no assurance that we will realize the anticipated benefits of the divestiture consistent with our expectations.

In March 2025, we divested the assets and liabilities related to our STREAMWAY product line pursuant to an asset purchase agreement (the “APA”) to enable us to focus our business strategy on our core business and also to be able to raise cash and reduce our liabilities. The divestiture of the STREAMWAY business presents risks that could negatively impact our business, financial condition, and the results of operations. For example, following the closing, we are subject to five-year non-competition and non-solicitation covenants that restricts us from directly or indirectly engaging in any other business engaged directly or indirectly in the waste fluid management business. We may also encounter challenges relating to the separation of operations, products, services or personnel, and as a result of any future liabilities for which we have agreed to indemnify the purchaser in the APA. Further, we do not have any assurance that we will realize the financial benefits we anticipated from the divestiture. Although we received \$625 thousand in cash proceeds and will realize reductions in obligations because of the liabilities assumed by the purchase under the APA, we will also realize a significant decrease in revenue as a result of the divestiture, as our Eagan operating segment, which included the STREAMWAY product line, contributed 95% and 70% of our revenues from continuing operations for the years ended December 31, 2024 and 2023, respectively. The occurrence of any of the foregoing could result in significant harm to our business and financial conditions, and our results of operations could be materially adversely affected as a result.

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.

If demand for our 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.

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 (the “Staff”) 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 under Nasdaq Listing 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.

After a subsequent decline in our stock price, on September 19, 2024, we received another letter from the Staff informing us that did not meet the Minimum Bid Price Requirement. The letter stated that we had 180 days, or until March 18, 2025, to regain compliance by maintaining a closing bid price of at least \$1.00 for a minimum of 10 consecutive trading days. We have regained compliance with the Minimum Bid Price Requirement, as since January 3, 2025, our stock price has traded above the minimum requirement.

On November 20, 2024, we received a letter from the Staff notifying us that we were not in compliance with the minimum stockholders’ equity requirement for continued listing as set forth in Nasdaq Listing Rule 5550(b)(1) (the “Stockholders’ Equity Requirement”), because our stockholders’ equity of \$1,966,969, as reported in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2024, was below the required minimum of \$2.5 million, and because, as of the date of the notice, we did not meet either of the alternative compliance standards, relating to market value of listed securities of at least \$35 million or net income from continuing operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years. Under Nasdaq rules and as specified in the notice, we had until Monday, January 6, 2025 to submit to Nasdaq a plan to regain compliance with the Stockholders’ Equity Requirement. If our plan to regain compliance is accepted, Nasdaq may grant an extension of up to 180 calendar days from the date of the Notice for the Company to evidence compliance. We submitted our plan on January 6, 2025, citing the Company’s proposed merger with Renovaro, and requested a 180-day extension to regain compliance with the Stockholders’ Equity Requirement. In response, the Nasdaq requested upon execution, or by no later than March 1, 2025, a copy of the definitive merger documentation and a detailed timeline to complete the merger. On February 28, 2025, the Company notified the Staff that the Company continues to progress in discussions with Renovaro to finalize the merger. The Company also notified the Staff of the Extension Agreement entered into with Renovaro on February 28, 2025, which extended the outside termination date from February 28, 2025, to March 31, 2025.

If we subsequently fail to meet any of the requirements 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. See the Risk Factor titled *“There is substantial doubt about our ability to continue as a going concern. We require significant additional funding to maintain operations and implement our business plan. the financing we have obtained to date has been dilutive, and any additional financing, if available, may also be dilutive.”* and the Management’s Discussion and Analysis of Financial Condition and Results of Operations section of this Annual Report on Form 10-K for information regarding recent equity offerings.

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, 2024, we had 2,750,429 warrants outstanding at a weighted average exercise price of \$8.92 per share. We are able to grant stock options, restricted stock, restricted stock units, stock appreciation rights, bonus stock, and performance awards under our 2024 Equity Incentive Plan (the “2024 Plan”), which was approved by our stockholders on December 30, 2024 (“Effective Date”) as a successor to our Amended and Restated 2012 Stock Incentive Plan (the “2012 Plan”). The 2024 Plan authorizes 1,000,000 shares for issuance, plus the number of shares subject to outstanding awards under the 2012 Plan as of the Effective Date that are forfeited, expire or otherwise terminate without the issuance of shares after the Effective Date. At December 31, 2024, 43,595 shares were issuable under outstanding incentive awards under the 2012 Plan. 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.

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 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 previously 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.

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 are susceptible to attacks by hackers or viruses, or otherwise may be breached due to employee error, malfeasance, or other activities. We have experienced cybersecurity attacks and incidents in the past, though we do not believe that any of them have been material to our business. If a cybersecurity attack or breach were to occur, it could 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, damaging our reputation, and subjecting us to litigation or fines and penalties, 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 leased office and manufacturing space in Eagan, Minnesota that was used for the operations of the Eagan segment. The lease was assigned in connection with the Eagan Sale on March 14, 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 20, 2025, there were approximately 154 stockholders of record of our common stock.

Dividend Policy

We follow a policy of retaining earnings, if any, to finance the expansion of our business. We have not paid, nor do we expect to declare or pay, cash dividends on common stock in the foreseeable future.

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.

During the year ended December 31, 2024, our former Birmingham operating segment met the criteria under US GAAP to be reported as discontinued operations. As a result, as of December 31, 2024, we operated in two 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 produced 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 a result of the decision to discontinue our former Birmingham operating segment, as of December 31, 2024, we had two 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.
- *Eagan segment*: produces the FDA-cleared STREAMWAY System and associated products for automated medical fluid waste management and patient-to-drain medical fluid disposal.

Recent Developments

Renovaro Letter of Intent

On January 1, 2025, we entered into a binding letter of intent (the “LOI”) with Renovaro, Inc. (NASDAQ: RENB) (“Renovaro”) for Predictive Oncology to be acquired by Renovaro in exchange for preferred stock of Renovaro (the “Renovaro Merger”). Under the terms of the LOI, Predictive Oncology will be merged into Renovaro in exchange for a newly created series of preferred stock of Renovaro. The preferred stock will be issued to shareholders of Predictive Oncology in a 1:1 exchange for their existing Predictive Oncology common stock.

On February 28, 2025, we entered into the Extension Agreement with Renovaro, pursuant to which the parties amended the LOI to (i) eliminate Renovaro’s obligation to acquire certain shares of our common stock and (ii) extend the outside termination date of the LOI from February 28, 2025, to March 31, 2025. Additionally, pursuant to the Extension Agreement, Renovaro acquired 467,290 shares of our common stock in March 2025 for an aggregate purchase price of \$500,000 and agreed to purchase an additional 901,298 shares of our common stock for an aggregate of \$964,389 upon, and subject to, the execution of a definitive agreement in respect of the Renovaro Merger.

February 2025 Registered Direct Offering

On February 18, 2025, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with several institutional and accredited investors for the sale by us of 363,336 shares (the “Registered Direct Shares”) of our common stock at a purchase price of \$1.50 per share, in a registered direct offering. The offering closed on February 19, 2025. The gross proceeds to us from the offering were approximately \$545,004, before deducting the placement agent’s fees and other offering expenses. The Registered Direct Shares were offered and sold by us pursuant to an effective shelf registration statement on Form S-3.

We agreed to pay H.C. Wainwright & Co., LLC, the placement agent (“Wainwright”) an aggregate fee equal to 7.0% of the gross proceeds received by us from the sale of the securities in the offering as well as a management fee equal to 1.0% of such gross proceeds, and \$15,000 for fees and expenses of legal counsel. We also issued to Wainwright or its designees warrants to purchase up to 7.0% of the aggregate number of shares of common stock sold in the transactions, or warrants to purchase up to an aggregate of 25,434 shares of common stock (the “Registered Direct Offering Placement Agent Warrants”). The Registered Direct Offering Placement Agent Warrants are exercisable for five years from the commencement of sales in the offering and have an exercise price equal to 125% of the purchase price of share of common stock in the offering, or \$1.875 per share. The Registered Direct Offering Placement Agent Warrants and the shares issuable upon exercise of the Registered Direct Offering Placement Agent Warrants were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and in reliance on similar exemptions under applicable state laws.

Sale of Eagan Operating Segment Business

On March 14, 2025, we entered into an asset purchase agreement and closed the transactions contemplated therein with DeRoyal Industries, Inc., a Tennessee corporation (“DeRoyal”), to sell and assign to DeRoyal assets and liabilities exclusively related to the business of providing products for automated, direct-to-drain medical fluid disposal, including our STREAMWAY® product line. The assets sold pursuant to the asset purchase agreement were operated by and reported in our Eagan reportable operating segment. As previously disclosed, the Eagan segment operated outside the core focus of Predictive Oncology, which is the use of artificial intelligence and machine learning to expedite early drug discovery and enable drug development for the benefit of cancer patients. This transaction was consummated in anticipation of our merger with Renovaro. The Eagan operating segment did not meet the criteria under US GAAP to be reported as discontinued operations as of and for the year ended December 31, 2024. Therefore, discussion of the Eagan segment’s business is included throughout this Annual Report on Form 10-K and reported within continuing operations in the consolidated financial statements. Going forward, our business will be limited to the Pittsburgh segment.

As a result of the sale, we expect that our revenues in future periods will materially decline, as the Eagan reportable segment contributed 95% and 70% of our revenues from continuing operations for the years ended December 31, 2024, and 2023, respectively.

March 2025 Warrant Exercises

On March 25, 2025, certain of our warrant holders exercised 627,315 Series A Common Stock Purchase Warrants (the “Series A Warrants”) and 627,315 Series B Common Stock Purchase Warrants (the “Series B Warrants”) in exchange for a total of 1,254,630 shares of the Company’s common stock. Both the Series A Warrants and Series B Warrants were exercised at a price of \$1.07, resulting in approximately \$1.3 million of proceeds to the Company. The Series A Warrants and Series B Warrants were initially issued in a private placement to certain institutional and accredited investors in July 2024 and were registered in August 2024 on a shelf registration statement on Form S-3.

Capital Requirements

Since inception, we have been unprofitable. We incurred net losses of \$12,664,388 and \$13,983,967 for the years ended December 31, 2024, and December 31, 2023, respectively. As of December 31, 2024, and December 31, 2023, we had an accumulated deficit of \$180,426,271 and \$167,761,883, 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 and reach profitability in our oncology business located in Pittsburgh, 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, 2024, with Year Ended December 31, 2023

	2024	2023	Difference
Revenue	\$ 1,623,817	\$ 1,627,697	\$ (3,880)
Cost of sales	826,137	609,212	(216,925)
General and administrative expense	7,419,892	8,380,917	961,025
Operations expense	2,851,045	3,268,165	417,120
Sales and marketing expense	1,466,213	1,487,139	20,926

Revenue. We recorded revenue of \$1,623,817 in 2024, compared to \$1,627,697 in 2023. Revenues for the years ended December 31, 2024, and 2023, were primarily derived from our Eagan operating segment. The Eagan operating segment contributed \$1,539,005 and \$1,135,101 for the years ended December 31, 2024, and 2023, respectively, while the Pittsburgh operating segment contributed \$84,812 and \$492,596, respectively. Revenues from the Eagan operating segment increased in 2024 primarily due to an increased number of STREAMWAY systems sold, while revenues from the Pittsburgh operating segment decreased in 2024 primarily due to decreased sales of 3D tumor-specific models.

Cost of sales. Cost of sales was \$826,137 and \$609,212 for the years ended December 31, 2024, and 2023, respectively. Cost of sales increased primarily due to costs associated with Eagan operating segment, including increased volume of STREAMWAY systems sold and increased direct labor costs. The gross profit margin declined to 49% in 2024 from 64% in 2023, primarily due to the change in sales mix year over year with lower revenue in 2024 derived from higher margin 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 \$961,025 to \$7,419,892 in 2024 from \$8,380,917 in 2023. The decrease was primarily due to decreases in employee-related expenses, including approximately \$527,000 less in severance expense and lower costs associated with lower headcount. Additional decreases included lower legal fees and investor relations. These decreases were offset by higher professional fees, including consultants supporting our management team, and audit fees.

Operations expense. Operations expenses primarily consist of expenses related to product development, prototyping and testing. Operations expenses decreased by \$417,120 to \$2,851,045 in 2024 compared to \$3,268,165 in 2023. The decrease in operations expenses in 2024 was primarily due to lower employee-related expenses associated with lower headcount, decreased cloud computing expenses, and lower research and development expenses.

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 decreased by \$20,926 to \$1,466,213 in 2024 compared to \$1,487,139 in 2023. The decrease in 2024 was primarily due to decreased staff-related expenses resulting from headcount reductions and revisions to employee sales commission structure, offset by increased severance incurred related to separation of a former executive.

Other income. We earned other income of \$89,367 in 2024 compared to \$152,685 in 2023. Other income primarily consists of interest income. The decrease in other income was primarily due to lower cash balances earning interest, partially offset by improved rates of return on those cash balances due to strategic deployment of cash reserves into money market funds.

Other expense. We incurred other expenses of \$11,478 in 2024 compared to \$64,967 in 2023. Other expenses primarily consist of interest expense and, in the year ended December 31, 2023, losses on a note receivable deemed uncollectible. The decrease in other expenses was primarily due to the writing off a note receivable deemed uncollectible in 2023.

Income Taxes. We incurred zero income tax expense from continuing operations in 2024 and 2023 due to losses in both years.

Liquidity and Capital Resources

Cash Flows

On December 31, 2024, we had \$734,673 in cash and cash equivalents. Cash and cash equivalents decreased by \$7,994,732 from the prior year due to the following factors.

Net cash used in operating activities of continuing operations was \$10,974,568 in 2024, compared to \$11,784,070 in 2023. Cash used in operating activities of continuing operations decreased in 2024 primarily due to lower cash operating losses, partially offset by increases in cash used in working capital. Changes in cash used in working capital included increases in accounts receivable and decreases in accounts payable, offset by a decrease in prepaid expenses and other assets. The increase in accounts receivable was primarily due to timing of sales of STREAMWAY systems near year end where payment was collected after year end.

Net cash used in investing activities of continuing operations was \$9,510 in 2024, compared to \$47,550 in 2023. Cash used in investing activities of continuing operations decreased in 2024 primarily due to a decrease in the acquisition of property and equipment.

Net cash provided by financing activities of continuing operations was \$3,939,194 in 2024 compared to \$148,899 in 2023. Cash provided by financing activities of continuing operations in 2024 was primarily related to proceeds from the issuance of common stock pursuant to the ATM offering completed in May 2024 and proceeds from the exercise of warrants into common stock pursuant to the Warrant Inducement Transaction in July 2024 (as described below), while the cash provided in 2023 was primarily proceeds from financing insurance premiums over the insured period with a short-term note payable.

Net cash used in discontinued operations was \$949,103 in 2024, compared to \$1,660,142 in 2023. Net cash used in operating activities of discontinued operations was \$981,103 and \$1,405,321 for the years ended December 31, 2024, and 2023, respectively. This change primarily relates to cash operating losses and the timing of the discontinuation of the Birmingham segment in the third quarter of 2024. Net cash provided by investing activities of discontinued operations was \$32,000 for 2024, while net cash used in investing activities of discontinued operations was \$254,821 for 2023.

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, 2024, had an accumulated deficit of \$180,426,271. We had cash and cash equivalents of \$734,673 as of December 31, 2024, and need to raise significant additional capital to meet our operating needs. We had short-term obligations of \$3,593,401 and long-term operating lease obligations of \$1,558,239 as of December 31, 2024. We do not expect to generate sufficient operating revenue to sustain our operations in the near term. During the year ended December 31, 2024, we incurred negative cash flows from continuing operating activities of \$10,974,568. Although we have attempted to improve our cash flows from continuing operating activities 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 cash flows from continuing operating activities sufficiently or achieve profitability in the near term. As a result of these conditions, substantial doubt exists 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 continue to evaluate alternatives to obtain the required additional funding to maintain future operations, but there can be no assurances that such funding will be available under acceptable terms, if at all. Alternatives to obtain additional funding 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. For example, in May 2024 we raised \$3.58 million in net proceeds through an at-the-market offering of shares of our common stock and in July 2024, we raised \$1.0 million in net proceeds through cash exercises of certain outstanding warrants pursuant to agreements with certain warrant holders to reduce the exercise price of those warrants and issue new warrants as consideration for the cash exercises, each described further below under “*Financing Transactions*.” In February 2025, we issued shares of our common stock in a registered direct offering for gross proceeds of \$545 thousand. Also, in March 2025, pursuant to an extension agreement in connection with the LOI with Renovaro, Renovaro purchased shares of our common stock for an aggregate of \$500 thousand. In March 2025, we entered into an asset purchase agreement pursuant to which we sold and assigned assets and liabilities exclusively related to the business of providing products for automated, direct-to-drain medical fluid disposal, including our STREAMWAY product line, for \$625 thousand, plus assumed liabilities. Despite these sources of funding, we may be unable to access additional 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 as of and for the year ended December 31, 2024 included in this Annual Report on Form 10-K do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if we were unable to continue as a going concern.

As described above under “*Recent Developments*,” on January 1, 2025, we entered into the LOI with Renovaro for Predictive Oncology to be acquired by Renovaro in exchange for preferred stock of Renovaro. Under the terms of the LOI, Predictive Oncology will be merged into Renovaro in exchange for a newly created series of preferred stock of Renovaro. The preferred stock will be issued to shareholders of Predictive Oncology in a 1:1 exchange for their existing Predictive Oncology common stock. The merger is subject to a minimum fundraising of \$15 million by Renovaro, as well as formal approval by the shareholders of Predictive Oncology.

On February 28, 2025, we entered into the Extension Agreement with Renovaro, pursuant to which the parties amended the LOI to (i) eliminate Renovaro’s obligation to acquire certain shares of our common stock and (ii) extend the outside termination date of the LOI from February 28, 2025, to March 31, 2025. Additionally, pursuant to the Extension Agreement, Renovaro acquired 467,290 shares of our common stock in March 2025 for an aggregate purchase price of \$500,000 and agreed to purchase an additional 901,298 shares of our common stock for an aggregate of \$964,389 upon, and subject to, the execution of a definitive agreement in respect of the Renovaro Merger.

Financing Transactions

We have primarily 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.

May 2024 At The Market Offering

On May 3, 2024, the Company entered into an ATM Sales Agreement (the “Sales Agreement”) with Wainwright, to sell shares of the Company’s common stock having an aggregate sales price of up to \$3,696,000, from time to time, through an “at the market offering” program pursuant to which Wainwright acted as sales agent. Subject to the terms and conditions of the Sales Agreement, Wainwright was permitted to sell the shares by methods deemed to be an “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. Under the Sales Agreement, Wainwright was entitled to compensation for its services of 3.0% of the gross sales price of all shares sold through Wainwright under the Sales Agreement. As of June 30, 2024, the Company sold 1,607,100 shares of common stock at an average price of approximately \$2.30 per share, resulting in aggregate gross proceeds of approximately \$3,696,000. No further shares are available to be sold under the Sales Agreement.

July 2024 Warrant Inducement Transaction

On July 25, 2024, the Company entered into definitive agreements with certain of its existing warrant holders for the exercise of warrants to purchase an aggregate of 958,117 shares of its common stock having a current exercise price of \$14.00 originally issued in February 2021, June 2021 and May 2022, at a reduced exercise price of \$1.32 per share. The gross proceeds to the Company from the exercise of the existing warrants were approximately \$1,265,000, prior to deducting placement agent fees and transaction expenses payable by the Company.

In consideration for the immediate cash exercise of the warrants, the Company concurrently issued to the warrant holders new unregistered Series A warrants to purchase up to 958,117 shares of common stock (the “Series A Warrants”) and new Series B warrants to purchase up to 958,117 shares of common stock (the “Series B Warrants”). The Series A Warrants and the Series B Warrants have an exercise price of \$1.07 per share and are exercisable immediately upon issuance. The Series A Warrants have a term equal to five years from the date of issuance, and the Series B Warrants have a term equal to 18 months from the date of issuance.

The transactions described above closed on July 26, 2024. Wainwright acted as the exclusive placement agent for the above-mentioned transactions. The Company paid Wainwright as consideration (i) an aggregate cash fee equal to 7.0% of the gross proceeds from the exercise of the existing warrants, (ii) a management fee equal to 1.0% of the aggregate gross proceeds from the exercise of the existing warrants, (iii) \$35,000 for expenses, and (iv) \$15,950 for clearing fees. Additionally, the Company issued to Wainwright (or its designees) as compensation, warrants to purchase up to 67,068 shares of common stock of the Company (equal to 7.0% of the aggregate number of existing warrants exercised in the offering) (the “Placement Agent Warrants”). The Placement Agent Warrants have a term of five years from the closing of the offering and an exercise price of \$1.65 per share.

There were no material financing transactions during the year ended December 31, 2023.

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. 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 3 – Collaborative Arrangements and Contracts with Customers* 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 11 – 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.

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 6 – Property and Equipment* and *Note 7 – Intangible Assets* in Notes to Consolidated Financial Statements of this Annual Report on Form 10-K for further details.

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. See *Note 12 – Income Taxes* in Notes to Consolidated Financial Statements of this Annual Report on Form 10-K for further details.

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, 2024. 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, 2024.

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, 2024 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, 2024.

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.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the three months ended December 31, 2024, 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.

Executive Officers and Directors of the Registrant

The following table identifies the individuals who serve as our executive officers and directors as of March 20, 2025:

Name	Age	Position Held
<i>Executive Officers</i>		
Raymond F. Vennare	72	Chief Executive Officer and Chairman of the Board of Directors
Josh Blacher	52	Interim Chief Financial Officer
<i>Directors</i>		
Chuck Nuzum	76	Director Member of the Audit, Compensation, Nominating and Governance, and Merger & Acquisition Committees
Daniel E. Handley, Ph.D.	65	Director Member of the Nominating and Governance Committee
Gregory S. St. Clair, Sr.	59	Director Member of the Audit and Compensation Committees
Nancy Chung-Welch, Ph.D.	64	Director Member of the Audit, Compensation, and Merger & Acquisition Committees
Matthew J. Hawryluk, Ph.D.	47	Director Member of the Compensation and Merger & Acquisition Committees
Veena Rao, Ph.D.	57	Director Member of the Audit, Nominating and Governance, and Merger & Acquisition Committees

Business Experience

Raymond F. Vennare. Mr. Vennare was appointed to the Board on September 13, 2021, and in November 2022, was appointed as our Chief Executive Officer and as Chairman of the Board. 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. Since April 15, 2019, he serves as a Professor and Program Director of Human Genetics and Genomics Graduate Education at Southern California University of Health Sciences, a 501(c)3 educational non-profit institution. Previously, he was the Chief Scientific Officer of the Clinical and Translational Genome Research Institute, a Florida 501(c)3 non-profit corporation. During that time, he also held a courtesy faculty appointment in the Department of Biological Sciences at Florida Gulf Coast University. He previously served as the Chief Scientific Officer for Advanced Healthcare Technology Solutions, Inc., Life-Seq, LLC, as a senior researcher at the Procter & Gamble Co., a senior administrator, researcher, and laboratory manager at the David Geffen UCLA School of Medicine, and as a founding biotechnology inventor for the National Genetics Institute. He holds a B.A. in Biophysics from Johns Hopkins University, an M.S. in Logic and Computation from Carnegie Mellon University, a Ph.D. in Human Genetics from the University of Pittsburgh. He completed his post-doctoral training at Magee-Women's Research Institute researching advanced genomic technologies applied to fetal and maternal health. He is a veteran of the U.S. Navy, having served as a nuclear propulsion instructor and a submarine nuclear reactor operator.

Chuck Nuzum. Mr. Nuzum was appointed to the Board on July 9, 2020. He 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, a financial services company and a company employing advanced technology to construct affordable homes and mentors start-up 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, Sr. Mr. St. Clair was appointed to the Board on July 9, 2020. He 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. He is a nationally recognized expert by government regulators and health law attorneys regarding reimbursement and compliance matters. 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 Accounting and Finance from Juniata College in Huntingdon, 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. Dr. Hawryluk was appointed to the Board as a Class II director. Dr. Hawryluk has served as Chief Business Officer of AIRNA Corporation since January 2025. Prior to AIRNA, Dr. Hawryluk served as Executive Vice President and Chief Business Officer of Gritstone bio, Inc. from November 2015 to December 2024. 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 commercialization launches and go-to-market teams for novel drug and medical device products. Dr. Rao currently serves as Chief Operating Officer at Abvance Therapeutics, a seed-stage biotech developing novel diabetes treatments. Previously, Dr. Rao served as President and Chief Business Officer at Portal Instruments and Chief Commercial Officer at Beta Bionics. Prior to Beta Bionics, Dr. Rao spent over a decade at Eli Lilly and Company holding several commercial and technical roles including as Vice President of External Innovation for the Lilly Device, Delivery, and Digital Health teams. Dr. Rao has also served on the Board of Directors of Thermalin, Inc, advisor to the PharmStars digital health accelerator, and as an advisor to Digbi Health. Dr. Rao holds 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.

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.

Board of Directors

Our Board presently consists of seven directors. The size of the Board may be increased or decreased from time to time by resolution of the stockholders or the Board. 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.

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 2027. 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 2027)
Chuck Nuzum Daniel E. Handley	Matthew J. Hawryluk Nancy Chung-Welch Gregory S. St. Clair, Sr.	Raymond F. Vennare Veena Rao

The Board of Directors met nine times in fiscal year 2024. All of our directors attended at least 75% of the meetings of the Board and committees on which they served. The Company does not have a policy with respect to the attendance of directors at the Company's annual meeting of stockholders.

Director Nomination Process

The Nominating and Governance Committee of the Board is responsible for reviewing 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. The processes followed by the Nominating and Governance Committee are contained in the Committee charter, which is posted on our website. The Committee will consider candidates for the Board recommended by a stockholder, and its process and criteria for analyzing such a candidate do not differ from that applied when a candidate is recommended by another source. To submit a candidate for consideration for nomination, stockholders must submit such recommendation in writing to our Secretary at 91 43rd Street, Suite 110, Pittsburgh, PA 15201.

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 definition of independence for Audit Committee members under the applicable rules of the Nasdaq Stock Market (the “Nasdaq Rules”) on an annual basis and has determined that all current members of our Audit Committee meet the heightened independence requirements under applicable Nasdaq Rules and Rule 10A-3(b)(1) under the Exchange Act. 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, and that all members of the Audit Committee have the financial literacy required by the Nasdaq Rules. The Audit Committee met four times in fiscal year 2024.

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 directors,” as such term is defined by the Nasdaq Rules.

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, 2024, 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 Rules, 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.

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 Dr. Rao, as the chairperson, Mr. Nuzum, Dr. Chung-Welch, 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.

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, 2024 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 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, 2024.

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.

Insider Trading Policy

We have adopted a Policy on Avoidance of Insider Trading, applicable to our directors, employees (including officers) and consultants, that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations and applicable listing standards. Our Insider Trading Policy is included as an exhibit to this Annual Report on 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 2024, (ii) our two most highly compensated other executive officers who were serving as executive officers at the end of 2024 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 2024. We refer to these individuals as our “Named Executive Officers.” During 2024, Messrs. Vennare and Blacher and Dr. Bush were our only executive officers. Our Named Executive Officers are:

- Raymond F. Vennare, Chief Executive Officer;
- Josh Blacher, Interim Chief Financial Officer; and
- Pamela Bush, former Chief Business Officer.

Summary Compensation Table for Fiscal 2024 and 2023

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, 2024, and December 31, 2023:

Name and Principal Position	Year	Salary	All Other Compensation	Total Compensation
Raymond F. Vennare	2024	\$ 525,000	\$ -	\$ 525,000
	2023	\$ 525,000	\$ -	\$ 525,000
Josh Blacher (1)	2024	\$ -	\$ 453,940	\$ 453,940
	2023	\$ -	\$ 170,100	\$ 170,100
Pamela Bush (2)	2024	\$ 51,250	\$ 341,342(3)	\$ 392,592
	2023	\$ 402,917	\$ -	\$ 402,917

(1) Effective September 30, 2023, Mr. Blacher was appointed as our Interim Chief Financial Officer, although he remained a consultant employed by Danforth Advisors, LLC (“Danforth”) and was contracted to work for us. The amount shown represents fees and expenses payable to Danforth in connection with the Interim Chief Financial Officer services provided by Mr. Blacher based on a negotiated hourly rate.

(2) Dr. Bush left the Company effective February 15, 2024.

(3) Includes severance payments of \$324,583 and an accrued vacation payment of \$16,759 paid to Dr. Bush in 2024 in accordance with her Employment Agreement and a Separation Agreement and Mutual Release effective February 15, 2024, between Dr. Bush and the Company.

Outstanding Equity Awards at Fiscal Year-end for Fiscal 2024

There were no outstanding equity awards held by the named executive officers as of December 31, 2024.

Executive Compensation Components for Fiscal 2024

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 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 awards 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 2024 Equity Incentive Plan (the "2024 Plan"), which was approved by our stockholders on December 30, 2024 as a successor to our Amended and Restated 2012 Stock Incentive Plan, we may also make grants of common stock, restricted stock, restricted stock units, performance awards, and stock appreciation rights to employees (including officers), directors, consultants, or other independent contractors who provide services to the Company or its subsidiaries. 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 performance metrics, or both. We adopted the 2024 Plan to give us flexibility in the types of awards that we could grant to individuals providing services to the Company. The 2024 Plan authorizes 1,000,000 shares for issuance, plus the number of shares subject to outstanding awards under the 2012 Plan as of December 30, 2024, that are forfeited, expire or otherwise terminate without the issuance of shares after December 30, 2024. As of December 31, 2024, there were stock options to purchase 43,595 shares of common stock outstanding under the 2012 Plan and 1,000,000 shares remain available for future equity awards.

While we have not adopted a formal policy regarding the timing of stock option grants, we do not time the disclosure of material nonpublic information for the purposes of affecting the value of executive compensation and our practice is that the timing of these grants is not scheduled in a manner that intentionally benefits our executive officers or employees.

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.

Employment Contracts

Employment Agreement with Chief Executive Officer

On October 13, 2022, the Company and Raymond F. Vennare, the Company's 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 is also eligible (i) to receive an annual cash bonus equal to up to 50% of his salary, or at the discretion of the Compensation Committee (the "Committee") of the Company's Board of Directors, a higher percentage based on his performance and (ii) to participate in any long-term incentive plan adopted and maintained by the Committee. Mr. Vennare is also eligible to participate in the standard employee benefit plans generally available to executive employees of the Company, and, at the discretion of the Committee, to receive grants of stock options or other equity awards.

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.

Consulting Agreement for Interim Chief Financial Officer Services

In August 2023, we entered into a consulting agreement with Danforth Advisors, LLC pursuant to which Mr. Blacher provides consulting services to us. Mr. Blacher does not receive compensation directly from us.

Employment Agreement with former Chief Business Officer.

Effective February 15, 2024, Dr. Pamela Bush left the Company. Dr. Bush served as Chief Business Officer since February 2023, under an employment agreement entered into on February 23, 2023. Under the agreement, the employment of Dr. Bush was at will. Under the agreement, Dr. Bush's base salary was \$410,000 and she was eligible to receive an annual incentive bonus determined by the Compensation Committee in its discretion, as well as eligible to receive awards of stock options. The agreement provided that in the event of a termination of employment without cause, Dr. Bush would receive all unpaid salary, accrued and unused paid time off, and severance pay in an amount equal to twelve months of her base salary then in effect and a bonus payment on a pro-rata basis through the date of termination. The severance payments were conditioned on the execution of a waiver and release in favor of the Company.

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 under which they were previously issued. 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. During 2024, cash payments were made in lieu of certain quarterly awards of common stock due to limited availability of shares available for issuance under the 2012 Plan. 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 also receives 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 directors under which they were to receive \$7,000 in value of newly issued shares of common stock per year annually for three years, if they were continuing to serve as a director as of June 17 of the given year. Additionally, the directors were to receive a \$3,000 cash payment per year annually for three years, if they were continuing to serve as a director as of June 17 of the given year. Directors who were first elected or appointed after June 17, 2020, receive such an annual award for three years beginning with the first June 17 on which the individual is serving as a director. The awards are payable on or about June 17 each year.

Director Compensation Table for Fiscal 2024

The following table summarizes the compensation earned by or paid to each individual who served as a director during the fiscal year ended December 31, 2024:

	Fees Paid or Earned in Cash	Stock Awards (1)	Option Awards	Total
Charles Nuzum Sr. (2)	\$ 91,899	\$ 8,333	\$ -	\$ 100,232
Daniel Handley (3)	\$ 49,977	\$ 6,000	\$ -	\$ 55,977
Greg St. Clair Sr. (4)	\$ 57,223	\$ 8,333	\$ -	\$ 65,556
Nancy Chung-Welch (5)	\$ 70,668	\$ 6,000	\$ -	\$ 76,668
Matthew J. Hawryluk (6)	\$ 60,346	\$ 6,000	\$ -	\$ 66,346
Veena Rao (7)	\$ 69,925	\$ 8,333	\$ -	\$ 78,258

(1) Represents grant date fair value of stock awards granted during 2024 as determined pursuant to FASB ASC 718, *Stock Compensation*.

(2) Reflects 3,268 shares of common stock received in 2024 for serving on the Board.

(3) Reflects 2,353 shares of common stock received in 2024 for serving on the Board.

(4) Reflects 3,268 shares of common stock received in 2024 for serving on the Board.

(5) Reflects 2,353 shares of common stock received in 2024 for serving on the Board.

(6) Reflects 2,353 shares of common stock received in 2024 for serving on the Board.

(7) Reflects 3,268 shares of common stock received in 2024 for serving on the Board.

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

Equity Compensation Plan Information

The following table presents the equity compensation plan information as of December 31, 2024:

	Number of securities to be issued upon exercise of outstanding restricted stock, warrants and options (a)(1)	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 (2)	43,595	\$ 82.70	1,000,000
Equity compensation plans not approved by security holders	-	\$ -	-

(1) Consists of outstanding options under the 2012 Stock Incentive Plan.

(2) Equity compensation plans approved by security holders include our 2012 Stock Incentive Plan and 2024 Equity Incentive Plan.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth as of March 20, 2025, 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 20, 2025.

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 7,676,991 shares of our common stock outstanding on March 20, 2025. 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%
Josh Blacher	-	*0%
Pamela Bush (2)	-	*
Chuck Nuzum (3)	31,921	*0%
Gregory St. Clair (4)	22,534	*0%
Daniel Handley (5)	18,661	*0%
Nancy Chung-Welch (6)	21,327	*0%
Matthew J. Hawryluk	9,488	*0%
Veena Rao	9,117	*0%
All directors and executive officers as a group (8 persons)	120,170	1.57%

*Less than one percent.

- (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) Dr. Bush left the Company in February 2024. Dr. Bush is not a record holder of the Company's common stock and did not have any equity awards outstanding that vest or are exercisable within 60 days of March 20, 2025. The Company does not have access to information regarding Dr. Bush's current holdings of our common stock, if any.
- (3) Includes options to purchase 2,014 shares that are exercisable within 60 days of March 20, 2025.
- (4) Includes options to purchase 1,332 shares that are exercisable within 60 days of March 20, 2025.
- (5) Includes options to purchase 1,643 shares that are exercisable within 60 days of March 20, 2025.
- (6) Includes options to purchase 2,014 shares that are exercisable within 60 days of March 20, 2025.

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, 2024, 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 2024 and 2023 financial statements, we entered into engagement agreements with KPMG LLP (2024) and BDO USA, P.C. (2023), respectively, which set forth the terms by which they performed audit services for us. Fees are approved by the Audit Committee on an engagement-by-engagement basis. All fees described in the tables below were approved by the Audit Committee.

The following tables represent aggregate fees billed to us by KPMG LLP (“KPMG”), the Company’s independent public accounting firm for the fiscal year ended December 31, 2024, for services rendered with respect to the fiscal year ended December 31, 2024:

	2024
Audit Fees (1)	\$ 593,000
Audit-Related Fees	-
Tax Fees	-
All Other Fees	-
	<u>\$ 593,000</u>

(1) Audit Fees were principally for services rendered for the audit and/or review of our consolidated financial statements. Also includes fees for services rendered in 2024 in connection with the filing of registration statements and other documents with the SEC, the issuance of accountant consents and comfort letters.

The following tables represent 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:

	2023
Audit Fees (2)	\$ 562,250
Audit-Related Fees	-
Tax Fees	-
All Other Fees	-
	<u>\$ 562,250</u>

(2) Audit Fees were principally for services rendered for the audit and/or review of our consolidated financial statements.

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 (KPMG, LLP, Pittsburgh, PA (US Firm), PCAOB Firm ID #185) (BDO USA, P.C., Minneapolis, Minnesota, PCAOB Firm ID #243);
- Consolidated Balance Sheets as of December 31, 2024, and December 31, 2023;
- Consolidated Statements of Net Loss for the Years Ended December 31, 2024, and December 31, 2023;
- Consolidated Statements of Stockholders’ Equity for the Years Ended December 31, 2024, to December 31, 2023;
- Consolidated Statements of Cash Flows for the Years Ended December 31, 2024, and December 31, 2023; 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

<u>Exhibit Number</u>	<u>Description</u>
<u>3.1</u>	<u>Certificate of Incorporation (Filed on December 19, 2013 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference).</u>
<u>3.2</u>	<u>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)</u>
<u>3.3</u>	<u>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).</u>
<u>3.4</u>	<u>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).</u>
<u>3.5</u>	<u>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).</u>
<u>3.6</u>	<u>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).</u>
<u>3.7</u>	<u>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).</u>
<u>3.8</u>	<u>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).</u>

- [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 Unit Purchase Option for the Purchase of Units issued March 29, 2019. \(Filed on April 2, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.\)](#)

- [4.4](#) [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.\)](#)
- [4.5](#) [Form of Common Stock Purchase Warrant Issued on or about October 1, 2019. \(Filed on October 10, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.\)](#)
- [4.6](#) [Common Stock Purchase Warrant issued to Oasis Capital, LLC dated February 5, 2020. \(Filed on February 7, 2020 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.\)](#)
- [4.7*](#) [Description of Registrant's Securities.](#)
- [4.8](#) [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.\)](#)
- [4.9](#) [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.\)](#)
- [4.10](#) [Form of Common Stock Purchase Warrant issued January 12, 2021. \(Filed on January 12, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.\)](#)
- [4.11](#) [Form of Common Stock Purchase Warrant issued January 19, 2021. \(Filed on January 21, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.\)](#)
- [4.12](#) [Form of Placement Agent Warrant to H.C. Wainwright & Co., LLC or its designees in connection with certain financing transactions in 2020 and 2021. \(Filed on January 29, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.\)](#)
- [4.13](#) [Form of Common Stock Purchase Warrant dated February 10, 2021. \(Filed on February 12, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.\)](#)
- [4.14](#) [Form of Common Stock Purchase Warrant dated February 23, 2021. \(Filed on February 22, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.\)](#)
- [4.15](#) [Form of Common Stock Purchase Warrant dated June 16, 2021. \(Filed on June 16, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.\)](#)
- [4.16](#) [Form of Placement Agent Warrant dated June 16, 2021. \(Filed on June 16, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.\)](#)
- [4.17](#) [Form of Series B Warrant dated July 26, 2024. \(Filed on July 29, 2024 as an exhibit to our Current Report on Form 8-K and incorporated by reference.\)](#)
- [4.18](#) [Form of Placement Agent Warrant dated July 26, 2024. \(Filed on July 29, 2024 as an exhibit to our Current Report on Form 8-K and incorporated by reference.\)](#)
- [10.1**](#) [2024 Equity Incentive Plan \(Filed on November 27, 2022 as an appendix to our definitive proxy statement on Schedule 14A and incorporated herein by reference.\)](#)
- [10.2**](#) [Amended and Restated 2012 Stock Incentive Plan. \(Filed on October 18, 2022 as an appendix to our definitive proxy statement on Schedule 14A and incorporated herein by reference.\)](#)

<u>10.3**</u>	<u>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).</u>
<u>10.4**</u>	<u>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).</u>
<u>10.5**</u>	<u>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).</u>
<u>10.6</u>	<u>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.)</u>
<u>10.7**</u>	<u>Employment Offer Letter dated September 30, 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).</u>
<u>10.8**</u>	<u>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).</u>
<u>14.1</u>	<u>Code of Ethics. (Filed on April 16, 2012 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference.)</u>
<u>19*</u>	<u>Insider Trading Policy</u>
<u>21.1*</u>	<u>Subsidiaries of the Registrant</u>
<u>23.1*</u>	<u>Consent of Independent Registered Public Accounting Firm: KPMG, LLP</u>
<u>23.2*</u>	<u>Consent of Independent Registered Public Accounting Firm: BDO USA, P.C.</u>
<u>31.1*</u>	<u>Certification of Principal Executive Officer required by Rule 13a-14(a)</u>
<u>31.2*</u>	<u>Certification of Principal Financial Officer required by Rule 13a-14(a)</u>
<u>32.1***</u>	<u>Section 1350 Certifications</u>
<u>97</u>	<u>Policy Relating to Recovery of Erroneously Awarded Compensation (Filed on March 28, 2024 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference.)</u>
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

***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 31, 2025

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	
<u>/s/ Raymond F. Vennare</u> Raymond F. Vennare	Chief Executive Officer (Principal executive officer)	March 31, 2025
<u>/s/ Josh Blacher</u> Josh Blacher	Interim Chief Financial Officer (Principal financial and accounting officer)	March 31, 2025
<u>/s/ Chuck Nuzum</u> Chuck Nuzum	Director	March 31, 2025
<u>/s/ Daniel E. Handley</u> Daniel E. Handley	Director	March 31, 2025
<u>/s/ Gregory St. Clair Sr.</u> Gregory St. Clair Sr.	Director	March 31, 2025
<u>/s/ Nancy Chung-Welch</u> Nancy Chung-Welch	Director	March 31, 2025
<u>/s/ Matthew Hawryluk</u> Matthew Hawryluk	Director	March 31, 2025
<u>/s/ Veena Rao</u> Veena Rao	Director	March 31, 2025

The audited consolidated financial statements for the periods ended December 31, 2024, and December 31, 2023, are included on the following pages:

INDEX TO FINANCIAL STATEMENTS

	Page
Financial Statements:	
Reports of Independent Registered Public Accounting Firms (KPMG, LLP, Pittsburgh, PA (US Firm), PCAOB Firm ID #185) (BDO USA, P.C., Minneapolis, Minnesota, PCAOB Firm ID #243)	F-1
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Predictive Oncology Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Predictive Oncology Inc. and subsidiaries (the Company) as of December 31, 2024, the related consolidated statements of net loss, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

Going Concern

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 incurred 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 these 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 a 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 a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for the warrant inducement transaction

As discussed in Note 11 to the consolidated financial statements, in July 2024, the Company entered into definitive agreements with certain of its existing warrant holders for the exercise of warrants to purchase shares of its common stock at a reduced exercise price (warrant inducement transaction). In consideration for the immediate cash exercise of the warrants, the Company concurrently issued to the warrant holders new unregistered Series A and Series B warrants to purchase shares of common stock. The Series A and the Series B warrants have an exercise price of \$1.07 per share and are exercisable immediately upon issuance. At December 31, 2024, the value of the warrants was recorded in additional paid in capital.

We identified the evaluation of the accounting for the Company's July 2024 issuance of Series A and Series B warrants as equity classified as a critical audit matter. Specifically, challenging and complex auditor judgment and specialized skills and knowledge were required in evaluating the application of the relevant accounting guidance and interpretation of complex terms of the agreement for equity classified warrants.

The following are the primary procedures we performed to address this critical audit matter. We inspected the Company's accounting analysis for the transaction. We involved professionals with specialized skills and knowledge, who assisted in:

- inspecting the underlying agreements to understand the terms and conditions of the transaction that were relevant to the classification determination.
- evaluating the Company's interpretation and application of the relevant accounting literature in the classification of the warrants.

/s/ KPMG LLP

We have served as the Company's auditor since 2024.

Pittsburgh, Pennsylvania
March 31, 2025

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.

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.

/s/ BDO USA, P.C.

We served as the Company’s auditor from 2023 to 2024.

Minneapolis, Minnesota

March 28, 2024, except for the effects of discontinued operations discussed in Note 2, and Note 15, as to which the date is March 31, 2025.

CONSOLIDATED FINANCIAL STATEMENTS

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 734,673	\$ 8,728,660
Accounts receivable, net	745,566	277,641
Inventories	385,728	480,803
Prepaid expense and other assets	306,301	512,078
Current assets of discontinued operations	53,649	79,249
Total current assets	2,225,918	10,078,431
Property and equipment, net	369,470	491,214
Intangibles, net	210,113	241,339
Lease right-of-use assets	2,064,507	2,598,091
Other long-term assets	102,509	105,509
Non-current assets of discontinued operations	-	902,665
Total assets	\$ 4,972,517	\$ 14,417,249
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	\$ 1,142,919	\$ 1,334,064
Note payable	-	150,408
Accrued expenses and other liabilities	1,407,987	1,542,948
Derivative liability	-	1,376
Contract liabilities	304,985	302,499
Lease liability	572,739	444,897
Current liabilities of discontinued operations	164,771	174,839
Total current liabilities	3,593,401	3,951,031
Other long-term liabilities	23,487	5,459
Lease liability – net of current portion	1,558,239	2,130,977
Non-current liabilities of discontinued operations	-	58,002
Total liabilities	5,175,127	6,145,469
Stockholders' (deficit) 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, 2024, and December 31, 2023	792	792
Common stock, \$.01 par value, 200,000,000 shares authorized, 6,666,993 and 4,062,853 shares outstanding as of December 31, 2024, and December 31, 2023, respectively	66,670	40,629
Additional paid-in capital	180,156,199	175,992,242
Accumulated deficit	(180,426,271)	(167,761,883)
Total stockholders' (deficit) equity	(202,610)	8,271,780
Total liabilities and stockholders' (deficit) equity	\$ 4,972,517	\$ 14,417,249

See accompanying notes to consolidated financial statements.

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF NET LOSS

	Year Ended December 31,	
	2024	2023
Revenue	\$ 1,623,817	\$ 1,627,697
Cost of sales	826,137	609,212
Gross profit	797,680	1,018,485
Operating expenses:		
General and administrative expense	7,419,892	8,380,917
Operations expense	2,851,045	3,268,165
Sales and marketing expense	1,466,213	1,487,139
Total operating expenses	11,737,150	13,136,221
Total operating (loss)	(10,939,470)	(12,117,736)
Other income	89,367	152,685
Other expense	(11,478)	(64,967)
Gain on derivative instruments	1,376	12,457
Loss from continuing operations	(10,860,205)	(12,017,561)
Loss from discontinued operations	(1,804,183)	(1,966,406)
Net (loss)	\$ (12,664,388)	\$ (13,983,967)
Loss per common share, basic and diluted:		
Loss from continuing operations	(1.99)	(2.99)
Loss from discontinued operations	(0.33)	(0.49)
Net (loss) per common share, basic and diluted	\$ (2.32)	\$ (3.48)
Weighted average shares used in computation – basic and diluted	5,453,632	4,014,848

See accompanying notes to consolidated financial statements.

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
FOR THE YEAR ENDED
DECEMBER 31, 2024

	Series B Preferred		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at 12/31/2023	79,246	\$ 792	4,062,853	\$ 40,629	\$ 175,992,242	\$ (167,761,883)	\$ 8,271,780
Issuance of shares to non-employees	-	-	38,923	389	98,864	-	99,253
Vesting expense, net of forfeitures	-	-	-	-	1,143	-	1,143
Issuance of shares pursuant to At-The-Market financing, net of issuance costs	-	-	1,607,100	16,071	3,105,931	-	3,122,002
Issuance of shares pursuant to Warrant Inducement Transaction, net of issuance costs	-	-	958,117	9,581	958,019	-	967,600
Net loss	-	-	-	-	-	(12,664,388)	(12,664,388)
Balance at 12/31/2024	79,246	\$ 792	6,666,993	\$ 66,670	\$ 180,156,199	\$ (180,426,271)	\$ (202,610)

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	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	
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	<u>79,246</u>	<u>\$ 792</u>	<u>-</u>	<u>\$ -</u>	<u>4,062,853</u>	<u>\$ 40,629</u>	<u>\$ 175,992,242</u>	<u>\$ (167,761,883)</u>	<u>\$ 8,271,780</u>

See accompanying notes to consolidated financial statements.

PREDICTIVE ONCOLOGY INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2024	2023
Cash flow from continuing operating activities:		
Net loss	\$ (12,664,388)	\$ (13,983,967)
Less: (loss) from discontinued operations	(1,804,183)	(1,966,406)
Net loss from continuing operations	(10,860,205)	(12,017,561)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	162,079	244,788
Amortization of operating lease right-of-use assets	533,584	480,020
Vesting expense	1,118	1,167
Common stock issued for consulting and other	99,253	299,430
(Gain) on derivative instruments	(1,376)	(12,457)
Loss on disposal of property and equipment	803	903
Loss on disposal of intangible assets	4,738	-
Changes in assets and liabilities:		
Accounts receivable	(467,925)	19,003
Inventories	95,075	(65,448)
Prepaid expense and other assets	208,776	(41,146)
Accounts payable	(191,145)	399,207
Accrued expenses and other	(134,961)	(384,149)
Contract liabilities	2,486	(266,803)
Operating lease liability	(444,896)	(446,483)
Other long-term liabilities	18,028	5,459
Net cash (used in) continuing operating activities:	(10,974,568)	(11,784,070)
Cash flow from continuing investing activities:		
Purchase of property and equipment	(9,510)	(21,533)
Acquisition of intangibles	-	(26,017)
Net cash (used in) continuing investing activities:	(9,510)	(47,550)
Cash flow from continuing financing activities:		
Proceeds from issuance of common stock and warrants	4,960,562	-
Costs to issue common stock and warrants	(870,960)	-
Repurchase of common stock upon vesting of restricted stock units	-	(1,509)
Proceeds from issuance of financing note payable	275,098	364,721
Repayment of note payable	(425,506)	(214,313)
Net cash provided by continuing financing activities	3,939,194	148,899
Discontinued operations:		
Net cash (used in) operating activities	(981,103)	(1,405,321)
Net cash provided by (used in) investing activities	32,000	(254,821)
Net cash provided by (used in) financing activities	-	-
Net cash (used in) discontinued operations	(949,103)	(1,660,142)
Net (decrease) in cash	(7,993,987)	(13,342,863)
Cash and cash equivalents at beginning of period	8,728,660	22,071,523
Cash and cash equivalents at end of period	\$ 734,673	\$ 8,728,660
Supplemental disclosure for cash flow information:		
Cash payments for interest	\$ 11,466	\$ 13,904
Non-cash transactions:		
Equipment transferred from discontinued operations	\$ 5,140	\$ -
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 boards' compensation	-	189,896
Common stock issued to management upon vesting of restricted stock units	-	4,934
Redemption of Series F Preferred Stock	-	(794)
Common stock issued in connection with reverse stock split	-	253

See accompanying notes to consolidated financial statements.

PREDICTIVE ONCOLOGY INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations

Predictive Oncology Inc. (“Predictive Oncology” or the “Company”) is a knowledge-driven company focused on applying artificial intelligence (“AI”) to support the development of optimal cancer therapies, which can ultimately lead to more effective treatments and improved patient outcomes. Through AI, Predictive Oncology uses its proprietary biobank of 150,000+ cancer tumor samples, categorized by patient type, against drug compounds to help the drug discovery process and increase the probability of successful drug development. 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.

During the year ended December 31, 2024, the Company’s former Birmingham operating segment, which provided contract services and research focused on solubility improvements, stability studies and protein production, met the criteria to be reported as discontinued operations. As a result, the Company operated in two remaining business areas as of December 31, 2024. 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 produced 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 a result of the decision to discontinue its former Birmingham operating segment, the Company had two reportable segments as of December 31, 2024, which were delineated by location and business area, as further described in *Note 15 – 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.
- *Eagan segment*: produced the FDA-cleared STREAMWAY System and associated products for automated medical fluid waste management and patient-to-drain medical fluid disposal.

On January 1, 2025, the Company entered into a binding letter of intent (the “LOI”) with Renovaro, Inc. (NASDAQ: RENB) (“Renovaro”) for Predictive Oncology to be acquired by Renovaro in exchange for preferred stock of Renovaro (the “Renovaro Merger”). Under the terms of the LOI, Predictive Oncology will be merged into Renovaro in exchange for a newly created series of preferred stock of Renovaro. The preferred stock will be issued to shareholders of Predictive Oncology in a 1:1 exchange for their existing Predictive Oncology common stock, as further discussed in *Note 16 – Subsequent Events*.

On February 28, 2025, Predictive Oncology entered into an extension agreement with Renovaro (the “Extension Agreement”), pursuant to which the parties amended certain terms of the LOI, including to extend the outside termination date of the LOI from February 28, 2025, to March 31, 2025, as further discussed in *Note 16 – Subsequent Events*.

On March 14, 2025, the Company entered into an asset purchase agreement and closed the transactions contemplated therein with DeRoyal Industries, Inc., a Tennessee corporation (“DeRoyal”), to sell and assign to DeRoyal assets and liabilities exclusively related to the business of providing products for automated, direct-to-drain medical fluid disposal, including the Company’s STREAMWAY® product line. Refer to *Note 16 – Subsequent Events* for further discussion of the asset purchase agreement with DeRoyal. The assets subject to the asset purchase agreement were operated by and reported in the Company’s Eagan reportable operating segment. The Eagan operating segment did not meet the criteria under US GAAP to be reported as discontinued operations as of and for the year ended December 31, 2024. Therefore, the Eagan operating segment is reported within continuing operations in these consolidated financial statements.

Going Concern

These consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

The Company has incurred significant and recurring losses from operations for the past several years and, as of December 31, 2024, had an accumulated deficit of \$180,426,271. The Company had cash and cash equivalents of \$734,673 as of December 31, 2024, and needs to raise significant additional capital to meet its operating needs. The Company had short-term obligations of \$3,593,401 and long-term operating lease obligations of \$1,558,239 as of December 31, 2024. The Company does not expect to generate sufficient operating revenue to sustain its operations in the near term. During the year ended December 31, 2024, the Company incurred negative cash flows from continuing operating activities of \$10,974,568. Although the Company has attempted to improve its cash flows from continuing operating activities by bolstering revenues 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 cash flows from continuing operating activities sufficiently or achieve profitability in the near term. As a result of these conditions, substantial doubt exists about the Company’s ability to continue as a going concern within one year after the date these consolidated financial statements are issued.

The Company continues to evaluate alternatives to obtain the required additional funding to maintain future operations, including the Renovaro Merger and the Sale of Eagan Assets to DeRoyal (further detailed in *Note 16 – Subsequent Events*). 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 its 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 the Company may ultimately be required to cease its operations and liquidate its business. The consolidated financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern.

NASDAQ Notice of Non-Compliance

On September 19, 2024, the Company received a letter from the Listing Qualifications Department (the “Staff”) of The Nasdaq Stock Market LLC (“Nasdaq”) indicating that the bid price for the Company’s common stock had closed below \$1.00 per share for 30 consecutive business days, and that the Company was therefore not in compliance with the minimum bid price requirement for continued listing on The Nasdaq Capital Market under Nasdaq Marketplace Rule 5550(a)(2) (the “Minimum Bid Price Requirement”). The notification had no immediate effect on the listing of the Company’s common stock and the Company had a period of 180 calendar days, or until March 18, 2025, to regain compliance with the Minimum Bid Price Requirement. On January 22, 2025, the Company received a letter from the Staff of the Nasdaq indicating that the closing bid price of the Company’s common stock had been at \$1.00 per share or greater for the last 11 consecutive business days, from January 3, through 21, 2025. Accordingly, the Company has regained compliance with the Minimum Bid Price Requirement.

On November 20, 2024, the Company received a letter (the “Notice”) from the Staff of the Nasdaq notifying the Company that it was not in compliance with the minimum stockholders’ equity requirement for continued listing on The Nasdaq Capital Market as set forth in Nasdaq Listing Rule 5550(b)(1) (the “Stockholders’ Equity Requirement”), because the Company’s stockholders’ equity of \$1,966,969, as reported in the Company’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2024, was below the required minimum of \$2.5 million, and because, as of the date of the Notice, the Company did not meet either of the alternative compliance standards, relating to market value of listed securities of at least \$35 million or net income from continuing operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years.

The Notice had no immediate effect on the listing of the Company's common stock on The Nasdaq Capital Market, and, therefore, the Company's listing remains fully effective, subject to the Company's compliance with the other continued listing requirements, and the Company's regaining compliance with the Stockholders' Equity Requirement. Under Nasdaq rules and as specified in the Notice, the Company had 45 calendar days from November 20, 2024, or until Monday, January 6, 2025, to submit to Nasdaq a plan to regain compliance with the Stockholders' Equity Requirement. If the Company's plan to regain compliance was accepted, Nasdaq may grant an extension of up to 180 calendar days from the date of the Notice for the Company to evidence compliance.

On January 6, 2025, the Company submitted to Nasdaq a plan to regain compliance with the Stockholders' Equity Requirement, citing the Company's proposed merger with Renovaro, and requested a 180-day extension to regain compliance with the Stockholders' Equity Requirement. In response, the Nasdaq requested upon execution, or by no later than March 1, 2025, a copy of the definitive merger documentation and a detailed timeline to complete the merger. On February 28, 2025, the Company notified the Staff that the Company continues to progress in discussions with Renovaro to finalize the merger. The Company also notified the Staff of the Extension Agreement entered into with Renovaro on February 28, 2025, which extended the outside termination date from February 28, 2025, to March 31, 2025.

Principles of Consolidation

The Company has prepared the consolidated financial statements in accordance with GAAP and the rules and regulations of the Securities and Exchange Commission ("SEC") for consolidated financial statements.

The Company had two wholly owned subsidiaries, Helomics Corporation and Skyline Medical Inc. ("Skyline Medical"), as of and for the years ended December 31, 2024, and 2023. 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, 2024, and 2023.

Discontinued Operations

During the year ended December 31, 2024, the Company disposed of its former Birmingham operating segment. Disposal groups that meet the discontinued operations criteria provided in the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") 205-20-45 are classified as discontinued operations. Assets and liabilities of discontinued operations are presented separately in the Company's consolidated balance sheets and results of discontinued operations are reported as a separate component of net loss in the Company's consolidated statements of net loss for all periods presented, resulting in changes to the presentation of certain prior period amounts. Results of discontinued operations are excluded from segment results for all periods presented. Cash flows from discontinued operations are also reported separately in the Company's consolidated statements of cash flows.

Refer to *Note 2 – Discontinued Operations* for additional discussion of discontinued operations. All other notes to these consolidated financial statements present the results of continuing operations and exclude amounts related to discontinued operations for all periods presented.

Use of Estimates

The preparation of consolidated financial statements in conformity with 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 consolidated financial statements and during the reporting period. Actual results could materially differ from those estimates. Estimates are used in the following areas, among others: variable consideration associated with revenue recognition, stock-based compensation expense, fair value of long-lived assets for impairment analyses, the valuation allowance included in the deferred income tax calculation, accrued expenses, and fair value of derivative liabilities.

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.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk primarily consist of cash and cash equivalents and accounts receivable. The Company maintains its cash and cash equivalent balances with high quality financial institutions and, consequently, the Company believes that such funds are subject to minimal credit risk. The Company is exposed to credit risk in the event of default by the financial institutions to the extent amounts recorded on the consolidated balance sheets are in excess of insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds.

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 4 – Fair Value Measurements* and *Note 10 – 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 6 – Property and Equipment* and *Note 7 – 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.

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 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. Advance payments received in excess of revenues recognized are classified as contract liabilities until such time as the revenue recognition criteria have been met.

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.

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.

The Company has 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 \$25,987 and \$122,307 for the years ended December 31, 2024, and 2023, 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 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. See *Note 12 – Income Taxes*.

Tax years after 2004 remain open to examination by federal and state tax authorities due to unexpired net operating loss carryforwards.

Risks and Uncertainties

The Company is subject to risks common to companies in the biopharmaceutical industry, including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with regulations of the 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 16 – Subsequent Events*.

Recent Accounting Pronouncements

The Company considers the applicability and impact of all Accounting Standards Updates (“ASUs”) issued by 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 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. This ASU 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.

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. This ASU requires more detailed disclosures related to certain costs and expenses. The guidance requires entities to disclose amounts of certain expense categories included in expense captions presented on the face of the income statement, including purchases of inventory, employee compensation, depreciation, and intangible asset amortization. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The disclosure requirements may be applied either prospectively or retrospectively. Management is currently evaluating this ASU to determine its impact on the Company’s disclosures.

Recently Adopted Accounting Standards

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 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The ASU requires the retrospective adoption method. The Company adopted ASU 2023-07 for annual periods beginning in the fiscal year ending December 31, 2024. The company plans to adopt ASU 2023-07 for interim periods beginning in the fiscal year ending December 31, 2025. See Note 15 to these consolidated financial statements for additional discussion.

NOTE 2 – DISCONTINUED OPERATIONS

On July 25, 2024, the Company’s Board of Directors approved a plan to implement a strategic cost savings initiative, primarily related to the Company’s Birmingham laboratory. In August 2024, the Company explored options for the leased Birmingham laboratory and office space, including potential sublease arrangements.

In September 2024, the Company transferred certain pieces of computer hardware with alternative use to the Pittsburgh laboratory, while the rest of the laboratory equipment and inventories from the Birmingham laboratory were marketed for sale and the related product and service lines were discontinued. The Company executed a sales agreement for all remaining laboratory equipment and inventories from the Birmingham laboratory and all items were removed from the laboratory premises as of September 30, 2024. As of September 30, 2024, the Company vacated and ceased use of the Birmingham laboratory and office space. The Company’s lease continues through August 2025.

The Company concluded that, in aggregate, the disposal of these assets comprising the former Birmingham operating segment met the criteria for discontinued operations presentation in the third quarter of 2024. As a result, the former Birmingham operating segment has been reclassified to discontinued operations in these consolidated financial statements for all periods presented.

The following table presents a reconciliation of the carrying amounts of the major classes of assets and liabilities to the current assets and liabilities of discontinued operations as presented in the Company's consolidated balance sheets:

	December 31, 2024	December 31, 2023
Assets:		
Accounts receivable, net	34,853	56,056
Inventories	-	13,571
Prepaid expense and other assets	18,796	9,622
Total current assets of discontinued operations	53,649	79,249
Property and equipment, net	-	742,696
Intangibles, net	-	11,118
Lease right-of-use assets	-	130,264
Other long-term assets	-	18,587
Total assets of discontinued operations	\$ 53,649	\$ 981,914
Liabilities:		
Accounts payable	\$ -	\$ 7,964
Accrued expenses and other liabilities	75,731	94,345
Lease liability	89,040	72,530
Total current liabilities of discontinued operations	164,771	174,839
Lease liability – net of current portion	-	58,002
Total liabilities	\$ 164,771	\$ 232,841

The following table provides details about the major classes of line items constituting the loss from discontinued operations presented in the Company's consolidated statements of net loss:

	Year Ended December 31,	
	2024	2023
Revenue	\$ 32,790	\$ 152,396
Cost of sales	3,295	25,328
Gross profit (loss) from discontinued operations	29,495	127,068
Operating expenses:		
General and administrative expense	855,855	1,047,578
Operations expense	506,011	859,360
Sales and marketing expense	4,385	23,722
Loss on impairment of property and equipment	-	162,905
Total operating expenses	1,366,251	2,093,565
Total operating (loss) from discontinued operations	(1,336,756)	(1,966,497)
Loss on disposal of discontinued operations	(463,127)	-
Other income (expense)	(4,300)	91
Net (loss) from discontinued operations	\$ (1,804,183)	\$ (1,966,406)

The loss on disposal of discontinued operations represents the loss on impairment of assets sold, including laboratory equipment and inventories, and impairment of other non-current assets.

NOTE 3 – COLLABORATIVE ARRANGEMENTS AND CONTRACTS WITH CUSTOMERS

Collaboration 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 used its PEDAL technology to evaluate CRH pre-clinical drug inhibitors of Glutaminase to determine which cancer types and patient populations were most likely to respond to treatment with those compounds (the "Project"). Under the CRH Agreement, both parties retained rights to their respective background intellectual property. Rights to reports, findings, supporting data, and materials ("Project Intellectual Property") that were generated by the Company pursuant to its performance under the CRH Agreement vested exclusively in CRH. Each party funded its own participation in the Project. Costs incurred to participate in the CRH Agreement were recorded in Cost of sales in the Company's Consolidated Statement of Net Loss for the year ended December 31, 2023.

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 (each as defined in the CRH Agreement). 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, *Revenue from Contracts with Customers* based on the actual net revenues earned by CRH under Relevant Transfer Agreements (as defined in the CRH Agreement) 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 years ended December 31, 2024, and 2023, the Company recognized no revenue under the CRH Agreement.

Contracts with Customers and 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, 2024, and 2023, accounts receivable totaled \$745,566 and \$277,641, respectively. The allowance for accounts receivable balance was \$3,850 as of both December 31, 2024, and 2023.

As of December 31, 2024, accounts receivable from three customers represented 19%, 12%, and 11% of the Company's total accounts receivable, respectively. As of December 31, 2023, accounts receivable from two customers represented 19% and 11% of the Company's total accounts receivable, respectively.

During the year ended December 31, 2024, revenues from a single customer were 28% of the Company's total revenue. During the year ended December 31, 2023, revenues from a single customer were 30% of the Company's total revenue.

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 development of 3D models and STREAMWAY maintenance plans, were \$328,472 and \$307,958 as of December 31, 2024, and 2023, respectively. During the year ended December 31, 2024, the Company recognized revenue of \$74,766 from contract liabilities recorded as of December 31, 2023, primarily related to deposits for development of 3D models and STREAMWAY maintenance plans. The Company's contract liabilities as of December 31, 2024, represent its remaining performance obligations. The Company's long-term contract liabilities are reported in Other long-term liabilities in the consolidated balance sheets.

NOTE 4 – FAIR VALUE MEASUREMENTS

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

December 31, 2024	Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	\$ 300,000	\$ 300,000	\$ -	\$ -
Liabilities:				
Derivatives	\$ -	\$ -	\$ -	\$ -
December 31, 2023	Fair Value	Level 1	Level 2	Level 3
Liabilities:				
Derivatives	\$ 1,376	\$ -	\$ -	\$ 1,376

NOTE 5 – INVENTORIES

Inventory balances were as follows:

	As of December 31, 2024	As of December 31, 2023
Raw materials	\$ 175,177	\$ 227,110
Work-in-process	18,500	-
Finished goods	192,051	253,693
Total	<u>\$ 385,728</u>	<u>\$ 480,803</u>

NOTE 6 – PROPERTY AND EQUIPMENT, NET

The Company's property and equipment, net consisted of the following:

	As of December 31, 2024	As of December 31, 2023
Computers, software, and office equipment	\$ 237,726	\$ 467,716
Leasehold improvements	306,961	306,961
Laboratory equipment	1,692,230	1,696,430
Warehouse and manufacturing equipment	139,763	133,285
Demo equipment	31,554	31,554
Total	2,408,234	2,635,946
Less: Accumulated depreciation	(2,038,764)	(2,144,732)
Total Property and equipment, net	<u>\$ 369,470</u>	<u>\$ 491,214</u>

Depreciation expense, recorded within general and administrative expenses of continuing operations, was \$135,591 and \$218,325 for the years ended December 31, 2024, and 2023, respectively.

No impairment charges related to property and equipment held and used in continuing operations were incurred during the years ended December 31, 2024, and 2023.

NOTE 7 – INTANGIBLES, NET

The Company's intangibles, net consisted of the following:

	As of December 31, 2024			As of December 31, 2023		
	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount
Patents & Trademarks	\$ 515,948	\$ (305,835)	\$ 210,113	\$ 521,621	\$ (280,282)	\$ 241,339

Finite-lived intangible assets are amortized over their estimated useful lives. Amortization expense, recorded within general and administrative expenses of continuing operations, was \$26,488 and \$26,463 during the years ended December 31, 2024, and 2023, respectively. Accumulated amortization is included in Intangibles, net in the consolidated balance sheets.

The following table outlines the estimated future amortization expense related to intangible assets held as of December 31, 2024:

Year Ending December 31,	Expense
2025	\$ 26,489
2026	26,489
2027	26,489
2028	26,489
2029	26,489
Thereafter	77,669
Total	<u>\$ 210,113</u>

The Company reviews finite-lived intangible assets for impairment in accordance with ASC 360, *Property, Plant, and Equipment* whenever events or changes in circumstances indicate the carrying amount may not be recoverable. Events or changes in circumstances that indicate the carrying amount may not be recoverable include, but are not limited to, a significant change in the medical device marketplace and a significant adverse change in the business climate in which the Company operates. No impairment charges related to finite-lived intangible assets held and used in continuing operations were incurred during the years ended December 31, 2024, and 2023.

NOTE 8 – LEASES

The Company's corporate offices and other offices are located in Pittsburgh, Pennsylvania. The leases are effective through February 29, 2028.

The Company also has an office in Eagan, Minnesota, which is used for office space and manufacturing. This lease is effective through May 31, 2025.

Lease expense under operating lease arrangements, recorded within general and administrative expenses of continuing operations, was \$827,363 and \$811,090 for the years ended December 31, 2024, and 2023, respectively.

The following table summarizes other information related to the Company's operating leases used in continuing operations:

	December 31, 2024	December 31, 2023
Weighted average remaining lease term – operating leases in years	3.14	4.11
Weighted average discount rate – operating leases	13%	13%

The Company's operating lease obligations as of December 31, 2024, which include expected lease extensions that are reasonably certain of renewal, were as follows:

2025	798,262
2026	803,724
2027	827,909
2028	139,022
Total lease payments	<u>2,568,917</u>
Less: interest	<u>(437,939)</u>
Present value of lease liabilities	<u>\$ 2,130,978</u>

NOTE 9 – NOTE PAYABLE

In June 2024, the Company purchased director and officer insurance policies with a policy period ending June 2025 and financed \$275,098 of its total premium by entering into a note payable with a finance provider that required ten monthly installment payments through April 2025. The note was secured by a first priority lien on the financed policies. The short-term note bore interest at an annual percentage rate of 8.00% over the life of the note. As of December 31, 2024, there was no outstanding balance on the note.

In June 2023, the Company purchased director and officer 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 required ten monthly installment payments through April 2024. The note was secured by a first priority lien on the financed policies. The short-term note bore 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. The note was fully paid during the year ended December 31, 2024.

NOTE 10 – DERIVATIVES

Certain warrants issued to placement agents in 2020 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 fair 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 \$0 and \$135 as of December 31, 2024, and 2023, respectively. The Company recorded gains on the change in fair value of the placement agent warrants of \$135 and \$3,220 during the years ended December 31, 2024, and 2023, 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 \$0 and \$333 as of December 31, 2024, and 2023, respectively. The Company recorded gains on the change in fair value of the placement agent warrants of \$333 and \$4,146 during the years ended December 31, 2024, and 2023, 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 \$0 and \$908 as of December 31, 2024, and 2023, respectively. The Company recorded gains on the change in fair value of the placement agent warrants of \$908 and \$5,091 during the years ended December 31, 2024, and 2023, 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, 2022	\$	13,833
Gain recognized to revalue derivative instrument at fair value		(12,457)
Derivative liability balance at December 31, 2023	\$	1,376
Gain recognized to revalue derivative instrument at fair value		(1,376)
Derivative liability balance at December 31, 2024	\$	-

NOTE 11 – STOCKHOLDERS' EQUITY, STOCK OPTIONS AND WARRANTS

At The Market Offering

On May 3, 2024, the Company entered into an ATM Sales Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), to sell shares of the Company's common stock, par value \$0.01 per share (the "Shares"), having an aggregate sales price of up to \$3,696,000, from time to time, through an "at the market offering" program pursuant to which Wainwright acted as sales agent. Subject to the terms and conditions of the Sales Agreement, Wainwright was permitted to sell the Shares by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. Under the Sales Agreement, Wainwright was entitled to compensation for its services of 3.0% of the gross sales price of all shares sold through Wainwright under the Sales Agreement. As of June 30, 2024, the Company sold 1,607,100 shares of common stock at an average price of approximately \$2.30 per share, resulting in aggregate gross proceeds of approximately \$3,696,000. No further shares are available to be sold under the Sales Agreement.

Warrant Inducement Transaction

On July 25, 2024, the Company entered into definitive agreements with certain of its existing warrant holders for the exercise of warrants to purchase an aggregate of 958,117 shares of its common stock having a current exercise price of \$14.00 originally issued in February 2021, June 2021 and May 2022, at a reduced exercise price of \$1.32 per share. The gross proceeds to the Company from the exercise of the existing warrants were approximately \$1,265,000, prior to deducting placement agent fees and transaction expenses payable by the Company. The reduction of the exercise price represented a modification to the existing warrants, which was recognized as an equity issuance cost of \$594,033 charged against the proceeds of the offering.

In consideration for the immediate cash exercise of the warrants, the Company concurrently issued to the warrant holders new unregistered Series A warrants to purchase up to 958,117 shares of common stock (the “Series A Warrants”) and new Series B warrants to purchase up to 958,117 shares of common stock (the “Series B Warrants”). The Series A Warrants and the Series B Warrants have an exercise price of \$1.07 per share and are exercisable immediately upon issuance. The Series A Warrants have a term equal to five years from the date of issuance, and the Series B Warrants have a term equal to 18 months from the date of issuance.

The transactions described above closed on July 26, 2024. Wainwright acted as the exclusive placement agent for the above-mentioned transactions. The Company paid Wainwright as consideration (i) an aggregate cash fee equal to 7.0% of the gross proceeds from the exercise of the existing warrants, (ii) a management fee equal to 1.0% of the aggregate gross proceeds from the exercise of the existing warrants, (iii) \$35,000 for expenses, and (iv) \$15,950 for clearing fees. Additionally, the Company issued to Wainwright (or its designees) as compensation, warrants to purchase up to 67,068 shares of common stock of the Company (equal to 7.0% of the aggregate number of existing warrants exercised in the offering) (the “Warrant Inducement Placement Agent Warrants”). The Warrant Inducement Placement Agent Warrants have a term of five years from the closing of the offering and an exercise price of \$1.65 per share.

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.

Series B Convertible Preferred Stock

As of December 31, 2024, and 2023, 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, 2024 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

On December 30, 2024, the Company's stockholders approved the 2024 Equity Incentive Plan (the "2024 Plan") at the Company's Annual Meeting of Stockholders and the 2024 Plan became effective. The 2024 Plan allows for the issuance of non-statutory stock options and incentive stock options, stock appreciation rights, stock awards, restricted stock, restricted stock units, and performance awards to employees, directors, and consultants of the Company, where permitted under the plan. Due to the approval of the 2024 Plan, no new awards will be granted under the Company's Amended and Restated 2012 Stock Incentive 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.

ASC 718, *Compensation – Stock Compensation* ("ASC 718"), requires that a company that issues equity as compensation record compensation expense 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.

VALUATION AND ACCOUNTING FOR STOCK OPTIONS AND WARRANTS

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

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

	Year Ended December 31,	
	2024	2023
Stock Options		
Expected dividend yield	-	0.0%
Expected stock price volatility	-	90.8% –98.2%
Risk-free interest rate	-	3.38% –3.95%
Expected life	-	10 years
Warrants		
Expected dividend yield	0.0%	-
Expected stock price volatility	97.3%	-
Risk-free interest rate	4.06% –4.58%	-
Expected life	1.5 – 5 years	-

STOCK OPTIONS AND WARRANTS GRANTED BY THE COMPANY

The following summarizes transactions for stock options and warrants for the period indicated:

	Stock Options		Warrants	
	Number of Shares	Average Exercise Price	Number of Shares	Average Exercise Price
Outstanding as of December 31, 2023	47,664	\$ 82.23	1,806,589	\$ 21.52
Issued	-	-	1,983,302	1.09
Forfeited	(309)	5.04	-	-
Expired	(3,760)	83.05	(81,345)	37.90
Exercised	-	-	(958,117)	1.32
Outstanding as of December 31, 2024	43,595	\$ 82.70	2,750,429	\$ 8.92

As of December 31, 2024, 43,576 stock options were fully vested and currently exercisable with a weighted average exercise price of \$82.74 and a weighted average remaining term of 4.47 years. As of December 31, 2024, there were 2,750,429 warrants that were fully vested and currently exercisable.

As of 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. As of December 31, 2023, there were 1,806,589 warrants that were fully vested and currently exercisable.

Stock-based compensation expense, net of forfeitures, recognized for the years ended December 31, 2024, and 2023, was \$1,118 and \$1,168, respectively. Stock-based compensation expense is recorded within each of the captions comprising Operating expenses from continuing operations. The Company has no unrecognized compensation expense related to unvested stock options that is expected to be recognized after December 31, 2024.

The following summarizes the status of options and warrants outstanding as of December 31, 2024:

Range of Exercise Prices	Shares	Weighted Average Remaining Life
Options		
\$6.22 – 8.47	810	7.92
\$14.65 – 25.00	12,158	5.97
\$26.20 – 32.80	14,223	3.90
\$52.20 – 17,250.00	16,404	3.69
Total	43,595	
Warrants:		
\$1.07 – 1.65	1,983,302	2.88
\$14.00 – 25.00	462,336	0.14
\$27.40 – 40.00	226,448	3.26
\$43.75 – 125.00	78,343	1.03
Total	2,750,429	

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, 2024, by year of grant:

Stock Options:

Year	Shares	Range of Exercise Prices
2015	12	\$ 30.80 – \$ 17,250.00
2016	276	30.80 – 850.00
2017	10,353	30.80 – 420.00
2018	2,893	30.80 – 226.00
2019	13,932	30.80 – 158.00
2020	14,710	14.65 – 32.80
2021	540	25.00 – 26.60
2022	729	7.70 – 14.65
2023	150	6.22 – 6.22
Total	43,595	\$ 6.22 – \$ 17,250.00

Warrants:

Year	Shares	Range of Exercise Prices
2019	3,168	\$ 125.00 – \$ 125.00
2020	65,586	36.00 – 59.84
2021	603,353	16.00 – 48.75
2022	95,020	14.00 – 15.00
2023	-	-
2024	1,983,302	1.07 – 1.65
Total	2,750,429	\$ 1.07 – \$ 125.00

NOTE 12 – 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 from continuing operations during the years ended December 31, 2024, and 2023, due to losses in both years.

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

	Year Ended December 31,	
	2024	2023
Statutory federal income tax benefit	\$ 2,280,643	\$ 2,523,688
State tax benefit, net of federal taxes	406,186	515,593
State rate adjustment	(24,434)	(125,150)
Nondeductible/nontaxable items	(10,951)	121,708
NOL and deferred only adjustments	(571,133)	(59,913,532)
Other	(6,641)	(5,182)
Change in valuation allowance	(2,073,670)	56,882,875
Total income tax benefit	\$ -	\$ -

Deferred taxes consist of the following:

	December 31, 2024	December 31, 2023
Deferred tax assets:		
Compensation accruals	\$ 42,893	\$ 87,131
Accruals and reserves	191,804	204,083
Deferred revenue	80,005	36,169
Charitable contribution carryover	1,742	1,724
Derivatives	-	349
Intangibles	696,622	852,414
Capitalized R&D	1,016,330	919,789
Depreciation	-	59,511
Lease liabilities	551,917	703,026
NQSO compensation	542,609	627,997
NOL and credits	24,479,583	21,737,285
Total deferred tax assets	27,603,505	25,229,478
Deferred tax liabilities:		
Depreciation	(31,863)	-
Lease right-of-use assets	(513,256)	(691,119)
Total deferred tax liabilities	(545,119)	(691,119)
Net deferred tax assets	27,058,386	24,538,359
Less: valuation allowance	(27,058,386)	(24,538,359)
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.

As of December 31, 2024, the Company had \$99,731,593 of NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2025, subject to the Section 382 limitation described above. The federal NOLs of \$11,885,918 begin to expire in 2025 if unused and \$87,845,675 will carry forward indefinitely. The Company also had \$55,735,192 of NOLs to reduce future state taxable income as of December 31, 2024. The state NOLs will begin to expire in 2025 if unused. The Company's net deferred tax assets, which include the NOLs, are subject to a full valuation allowance. As of December 31, 2024, the federal and state valuation allowances were \$23,121,946 and \$3,936,440, respectively.

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 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.

As of December 31, 2023, the Company had \$86,840,808 of NOLs to reduce future federal taxable income, the majority of which were expected to be available for use in 2024, subject to the Section 382 limitation described above. The federal NOLs of \$43,354,286 were to 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 began to expire in 2024. The Company's net deferred tax assets, which include 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.

Tax years after 2004 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.

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, 2024, and 2023, the Company recorded no accrued interest or penalties related to uncertain tax positions.

NOTE 13 – RETIREMENT SAVINGS PLAN

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 2024 and 2023, the Company matched 100% of the employee's contribution up to 4.0% of their earnings. Employer contributions were \$125,328 and \$192,499 in 2024 and 2023, respectively. There were no discretionary contributions to the plan in 2024 and 2023.

NOTE 14 – LOSS PER SHARE

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

	Year Ended December 31,	
	2024	2023
Numerator:		
Net (loss) from continuing operations	\$ (10,860,205)	\$ (12,017,561)
Net (loss) from discontinued operations	(1,804,183)	(1,966,406)
Net loss attributable to common stockholders	<u>\$ (12,664,388)</u>	<u>\$ (13,983,967)</u>
Denominator:		
Weighted average common shares outstanding - basic	5,453,632	4,014,848
Dilutive effect of stock options, warrants and preferred stock (1)	-	-
Weighted average common shares outstanding - diluted	<u>5,453,632</u>	<u>4,014,848</u>
Net (loss) from continuing operations attributable to common stockholders per common share – basic and diluted	\$ (1.99)	\$ (2.99)
Net (loss) from discontinued operations attributable to common stockholders per common share – basic and diluted	(0.33)	(0.49)
(Loss) per common share - basic and diluted	<u>(2.32)</u>	<u>(3.48)</u>

- (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,	
	2024	2023
Options	43,595	47,664
Warrants	2,750,429	1,806,589
Preferred stock: Series B	16	16

NOTE 15 – 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 Company’s Chief Operating Decision Maker (“CODM”), its chief executive officer, allocates the Company’s resources for each of the operating segments and evaluates their relative performance based on gross profit, operating loss, and net loss. Operating expenses are disaggregated by department for purposes of evaluating each segment’s 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 Company has two 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.
- *Eagan segment*: produces the FDA-cleared STREAMWAY System and associated products for automated medical fluid waste management and patient-to-drain medical fluid disposal.

As described in Note 2, the Company's former Birmingham operating segment met the criteria to be reported as discontinued operations during the third quarter of 2024. As such, the former Birmingham segment is excluded from the tables below, which only reflect continuing operations for all periods presented.

See discussion of revenue recognition in *Note 1 – Organization and Summary of Significant Accounting Policies* for a description of the products and services recognized in each segment. All revenues are earned from external customers.

The tables below summarize the Company's segment reporting as of and for the years ended December 31, 2024, and 2023.

	Year Ended December 31, 2024			
	Pittsburgh	Eagan	Corporate	Total
Revenue	\$ 84,812	\$ 1,539,005	\$ -	\$ 1,623,817
Cost of sales	78,285	747,852	-	826,137
Gross profit	6,527	791,153	-	797,680
General and administrative expenses	2,022,732	184,095	5,213,065	7,419,892
Operations expenses	2,234,501	609,584	6,960	2,851,045
Sales and marketing expenses	5	633,015	833,193	1,466,213
Total operating (loss)	(4,250,711)	(635,541)	(6,053,218)	(10,939,470)
Other segment items	(606)	(9)	79,880	79,265
Segment (loss)	\$ (4,251,317)	\$ (635,550)	\$ (5,973,338)	\$ (10,860,205)

	December 31, 2024			
	Pittsburgh	Eagan	Corporate	Total
Assets	\$ 2,615,291	\$ 1,410,090	\$ 893,487	\$ 4,918,868
Depreciation and amortization	124,939	29,743	7,397	162,079
Expenditures for additions to long-lived assets	3,032	6,478	-	9,510

	Year Ended December 31, 2023			
	Pittsburgh	Eagan	Corporate	Total
Revenue	\$ 492,596	\$ 1,135,101	\$ -	\$ 1,627,697
Cost of sales	195,105	414,107	-	609,212
Gross profit	297,491	720,993	-	1,018,485
General and administrative expenses	2,364,640	518,017	5,498,260	8,380,917
Operations expenses	2,443,316	806,658	18,192	3,268,165
Sales and marketing expenses	299	364,697	1,122,142	1,487,139
Total operating (loss)	(4,510,763)	(968,379)	(6,638,594)	(12,117,736)
Other segment items	6,857	(902)	94,220	100,175
Segment (loss)	\$ (4,503,906)	\$ (969,281)	\$ (6,544,374)	\$ (12,017,561)

	December 31, 2023			
	Pittsburgh	Eagan	Corporate	Total
Assets	\$ 3,263,270	\$ 1,390,031	\$ 8,782,034	\$ 13,435,335
Depreciation and amortization	207,658	29,750	7,381	244,788
Expenditures for additions to long-lived assets	7,424	24,691	15,437	47,550

Other segment items are comprised of other income, other expenses, and gain on derivative instruments. Other income primarily consists of interest income. Other expenses primarily consist of interest expense and, in the year ended December 31, 2023, losses on a note receivable deemed uncollectible.

In each of the years ended December 31, 2024, and 2023, substantially all the Company revenues were located or derived from operations in the United States. As of December 31, 2024, all the Company's long-lived assets were located within the United States. During the year ended December 31, 2024, revenues of \$459,369 reported in the Company's Eagan operating segment were attributable to a single customer. As of December 31, 2024, accounts receivable due from this customer was \$144,880. 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 16 – SUBSEQUENT EVENTS

Renovaro Letter of Intent and Extension Agreement

On January 1, 2025, the Company entered into a binding letter of intent with Renovaro for Predictive Oncology to be acquired by Renovaro in exchange for preferred stock of Renovaro, as discussed in *Note 1* above. Under the terms of the LOI, Predictive Oncology will be merged into Renovaro in exchange for a newly created series of preferred stock of Renovaro. The preferred stock will be issued to shareholders of Predictive Oncology in a 1:1 exchange for their existing Predictive Oncology common stock. The preferred stock will be automatically redeemable for \$3.00 per share after 18 months and may also be converted to freely tradeable, registered Renovaro common stock at a 1:1 conversion ratio by either the holders thereof or Renovaro at any time after Renovaro's common stock has traded at or above \$4.50 per share for 30 consecutive trading days. Renovaro also will have the right to redeem the preferred stock for cash at a redemption price of \$3.00 per share (i) if the trading price of its common stock is \$3.00 or less or (ii) such preferred stock has not been converted within 30 days after the first date on which the holder could request such conversion as described above. The merger is subject to a minimum fundraising of \$15 million by Renovaro, as well as formal approval by the shareholders of Predictive Oncology. A failure to obtain shareholder approval, assuming prior funding by Renovaro, will entitle Renovaro to a two-year exclusive royalty-free license to Predictive Oncology's biobank of tumor samples and tumor-specific 3D cell culture models.

On February 28, 2025, the Company entered into the Extension Agreement with Renovaro, pursuant to which the parties amended the LOI to (i) eliminate Renovaro's obligation to acquire certain shares of Predictive Oncology's common stock and (ii) extend the outside termination date of the LOI from February 28, 2025, to March 31, 2025. Additionally, pursuant to the Extension Agreement, Renovaro acquired 467,290 shares of Predictive Oncology's common stock for an aggregate purchase price of \$500,000 and agreed to purchase an additional 901,298 shares of Predictive Oncology common stock for an aggregate of \$964,389 upon, and subject to, the execution of a definitive agreement in respect of the Renovaro Merger.

February 2025 Registered Direct Offering

On February 18, 2025, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with several institutional and accredited investors for the sale by the Company of 363,336 shares (the "Shares") of the Company's common stock, par value \$0.01 per share (the "Common Stock"), at a purchase price of \$1.50 per share, in a registered direct offering. The offering closed on February 19, 2025. The gross proceeds to the Company from the offering are approximately \$545,004, before deducting the placement agent's fees and other offering expenses. The Shares were offered and sold by the Company pursuant to an effective shelf registration statement on Form S-3, which was filed with the SEC on May 21, 2024 and subsequently declared effective on May 21, 2024 (File No. 333-279123), and a related prospectus supplement filed on February 19, 2025.

The Company agreed to pay Wainwright an aggregate fee equal to 7.0% of the gross proceeds received by the Company from the sale of the securities in the offering as well as a management fee equal to 1.0% of such gross proceeds, and \$15,000 for fees and expenses of legal counsel. The Company also issued to Wainwright or its designees warrants to purchase up to 7.0% of the aggregate number of shares of Common Stock sold in the transactions, or warrants to purchase up to an aggregate of 25,434 shares of Common Stock (the "Registered Direct Offering Placement Agent Warrants"). The Registered Direct Offering Placement Agent Warrants are exercisable for five years from the commencement of sales in the offering and have an exercise price equal to 125% of the purchase price of share of Common Stock in the offering, or \$1.875 per share. The Registered Direct Offering Placement Agent Warrants and the shares issuable upon exercise of the Registered Direct Offering Placement Agent Warrants were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and in reliance on similar exemptions under applicable state laws.

Sale of Eagan Assets to DeRoyal

On March 14, 2025, the Company entered into an asset purchase agreement (the "APA") and closed the transactions contemplated therein with DeRoyal Industries, Inc., a Tennessee corporation ("DeRoyal"), to sell and assign to DeRoyal assets and liabilities exclusively related to the business of providing products for automated, direct-to-drain medical fluid disposal, including the Company's STREAMWAY® product line (the "Eagan Business"). These assets were operated by the Company's wholly owned subsidiary, Skyline Medical Inc. and have reported in the Company's Eagan reportable operating segment in these consolidated financial statements.

The purchased assets exclusively related to the Eagan Business included (a) inventories, prototypes, packaging, supplies, parts, and equipment of the Business; (b) trademarks, service marks, trade names, copyrights, trade secrets and know-how, patents and patent applications, and other intellectual property and related proprietary rights exclusively related to the Eagan Business; (c) books and records exclusively related to the Eagan Business, including all drawings, documentation, research and development files, device master records, design history files, validation data, test reports, manufacturing instructions and procedures, records and data; (d) permits, licenses, franchises, approvals, certifications, authorizations, and consents required to be obtained from Governmental Authorities; (e) contracts with customers; (f) furniture, fixtures, equipment, supplies and other tangible personal property; (g) real property leased by Seller and exclusively used in connection with the Eagan Business; and (h) cash and accounts receivable due within ninety (90) days after the Closing Date exclusively related to the Eagan Business. The total purchase price for the purchased assets was \$625,000, plus the assumption of certain liabilities related to the Eagan Business including the lease for the office and warehouse space located at 2915 Commers Drive Suite 900 Eagan, MN 55121, accounts payable due within 90 days after the closing date, and contract liabilities associated with the Eagan Business. The APA included certain post-closing covenants customary for a transaction of this nature.

March 2025 Warrant Exercises

On March 25, 2025, certain of the Company's warrant holders exercised 627,315 Series A Common Stock Purchase Warrants (the "Series A Warrants") and 627,315 Series B Common Stock Purchase Warrants (the "Series B Warrants") in exchange for a total of 1,254,630 shares of the Company's common stock. Both the Series A Warrants and Series B Warrants were exercised at a price of \$1.07, resulting in approximately \$1.3 million of proceeds to the Company. The Series A Warrants and Series B Warrants were initially issued in a private placement to certain institutional and accredited investors in July 2024 and were registered on Registration Statement No. 333-281579, which was declared effective on August 23, 2024.