SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2022

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-36790

Predictive Oncology Inc.
(Exact name of registrant as specified in its charter)

Delaware	33-1007393
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2915 Commers Drive, Suite 900	Eagan, Minnesota 55121
(Address of principal executive offices)	(Zip Code)

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

(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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

☒ Yes ☐ No

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

As of November 4, 2022, the registrant had 78,753,475 shares of common stock, par value $0.01 per share outstanding.

PREDICTIVE ONCOLOGY INC.

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PREDICTIVE ONCOLOGY INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2022	December 31, 2021
	(unaudited)	(audited)
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 25,393,738	$ 28,202,615
Accounts Receivable	324,708	354,196
Inventories	493,722	387,684
Prepaid Expense and Other Assets	645,153	513,778
Total Current Assets	26,857,321	29,458,273
Fixed Assets, net	2,202,102	2,511,571
Intangibles, net	3,701,603	3,962,118
Lease Right-of-Use Assets	329,565	814,454
Other Long-Term Assets	75,618	167,065
Goodwill	-	6,857,790
Total Assets	$ 33,166,209	43,771,271
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 917,271	$ 1,021,774
Accrued Expenses and other liabilities	1,813,580	1,262,641
Derivative Liability	22,099	129,480
Contract Liabilities	495,365	186,951
Lease Liability	219,763	639,662
Total Current Liabilities	3,468,078	3,240,508
Lease Liability – Net of current portion	5,483	239,664
Other long-term liabilities	99,770	25,415
Total Liabilities	3,573,331	3,505,587
Stockholders' Equity:		
Preferred Stock, 20,000,000 authorized inclusive of designated below		
Series B Convertible Preferred Stock, $.01 par value, 2,300,000 shares authorized, 79,246 shares outstanding	792	792
Common Stock, $.01 par value, 200,000,000 shares authorized, 78,407,473 and 65,614,597 outstanding	784,074	656,146
Additional paid-in capital	174,669,817	167,649,028
Accumulated Deficit	(145,861,805)	(128,040,282)
Total Stockholders' Equity	29,592,878	40,265,684
Total Liabilities and Stockholders' Equity	$ 33,166,209	$ 43,771,271

See Notes to Condensed Consolidated Financial Statements

PREDICTIVE ONCOLOGY INC.
CONDENSED CONSOLIDATED STATEMENTS OF NET LOSS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue	$ 455,827	$ 313,663	$ 1,141,986	$ 944,187
Cost of goods sold	108,151	110,165	351,669	350,800
Gross profit	347,676	203,498	790,317	593,387
General and administrative expense	3,287,918	2,061,458	8,063,265	7,410,208
Operations expense	857,130	648,935	2,657,314	1,791,543
Sales and marketing expense	333,377	172,869	908,867	447,298
Loss on goodwill impairment	-	2,813,792	7,231,093	2,813,792
Total operating loss	(4,130,749)	(5,493,556)	(18,070,222)	(11,869,454)
Other income	63,047	58,830	146,524	144,122
Other expense	(2,001)	(7,413)	(5,207)	(244,214)
Gain on derivative instruments	10,219	4,122	107,381	68,884
Net loss	$ (4,059,484)	$ (5,438,017)	$ (17,821,524)	$ (11,900,662)
Net loss attributable to common shareholders per common shares-basic and diluted	$ (4,059,484)	$ (5,438,017)	$ (17,821,524)	$ (11,900,662)
Loss per common share basic and diluted	$ (0.05)	$ (0.08)	$ (0.25)	$ (0.23)
Weighted average shared used in computation – basic and diluted	78,383,878	65,406,312	71,084,454	51,272,960

See Notes to Condensed Consolidated Financial Statements

PREDICTIVE ONCOLOGY INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE AND NINE MONTHS ENDED
SEPTEMBER 30, 2022
(Unaudited)

	Series B Preferred		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at 12/31/2021	79,246	$ 792	65,614,597	$ 656,146	$ 167,649,028	$ (128,040,282)	$ 40,265,684
Shares issued pursuant to equity line			120,000	1,200	85,685		86,885
Shares issued to consultant & other			171,868	1,719	160,403		162,122
Vesting expense					36,518		36,518
Net loss						(3,370,715)	(3,370,715)
Balance at 03/31/2022	79,246	$ 792	65,906,465	$ 659,065	$ 167,931,634	$ (131,410,997)	$ 37,180,494
Issuance of shares and warrants pursuant to May 2022 Private Offering			12,000,000	120,000	6,387,050		6,507,050
Shares issued pursuant to equity line			195,000	1,950	147,174		149,124
Shares issued to consultant & other			53,662	536	50,134		50,670
Vesting expense					39,383		39,383
Net loss						(10,391,324)	(10,391,324)
Balance at 06/30/2022	79,246	$ 792	78,155,127	$ 781,551	$ 174,555,375	$ (141,802,321)	$ 33,535,397
Shares issued to consultant & other			229,212	2,292	91,708		94,000
Vesting expense			23,134	231	22,734		22,965
Net loss						(4,059,484)	(4,059,484)
Balance at 09/30/2022	79,246	$ 792	78,407,473	$ 784,074	$ 174,669,817	$ (145,861,805)	$ 29,592,878

See Notes to Condensed Consolidated Financial Statements

PREDICTIVE ONCOLOGY INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE AND NINE MONTHS ENDED
SEPTEMBER 30, 2021
(Unaudited)

	Series B Preferred		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at 12/31/2020	79,246	$ 792	19,804,787	$ 198,048	$ 110,826,949	$ (108,383,108)	$ 2,642,681
Shares issued pursuant to agreement with former CEO related to accrued interest			100,401	1,004	142,569		143,573
Issuance of shares and warrants pursuant to Shelf offerings, net			13,488,098	134,881	14,877,611		15,012,492
Issuance of shares and warrants pursuant to February 2021 private placement, net			9,043,766	90,438	15,974,301		16,064,739
Exercise of warrants			5,247,059	52,471	4,442,799		4,495,270
Shares issued pursuant to convertible debt			1,107,544	11,075	502,936		514,011
Shares issued to consultant & other			2,665	27	(4,075)		(4,048)
Vesting expense					565,082		565,082
Net loss						(3,888,713)	(3,888,713)
Balance at 03/31/2021	79,246	$ 792	48,794,320	$ 487,944	$ 147,328,172	$ (112,271,821)	$ 35,545,087
Issuance of shares and warrants pursuant to June 2021 direct placement, net			15,520,911	155,209	19,291,087		19,446,296
Shares issued pursuant to transition agreement with former CEO			400,000	4,000	(4,000)		-
Shares issued pursuant to Equity Line			572,504	5,725	582,865		588,590
Shares issued to consultant & other			47,424	474	48,238		48,802
Vesting expense					33,243		33,243
Net loss						(2,573,932)	(2,573,932)
Balance at 06/30/2021	79,246	$ 792	65,335,159	$ 653,352	$ 167,279,695	$ (114,845,753)	$ 53,088,086
Exercise of warrants			22,000	220	18,370		18,590
Shares issued to consultant & other			77,191	772	97,997		98,769
Vesting expense			23,134	231	17,247		17,478
Net loss						(5,438,017)	(5,438,017)
Balance at 09/30/2021	79,246	$ 792	65,457,484	$ 654,575	$ 167,413,309	$ (120,283,770)	$ 47,784,906

See Notes to Condensed Consolidated Financial Statements

PREDICTIVE ONCOLOGY INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2022	**2021**
Cash flow from operating activities:		
Net loss	$ (17,821,524)	$ (11,900,662)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	980,381	970,488
Vesting expense	102,894	627,329
Amortization of debt discount	-	244,830
Gain on valuation of equity-linked instruments and derivative liability	(107,381)	(68,884)
Equity instruments issued consultant, and other	306,792	143,523
Loss on fixed asset disposal	1,700	5,858
Loss on goodwill impairment	7,231,093	2,813,792
Changes in assets and liabilities:		
Accounts receivable	29,488	(18,315)
Inventories	(106,038)	(108,441)
Prepaid expense and other assets	(39,928)	(313,573)
Accounts payable	(104,503)	(342,525)
Accrued expenses and other liabilities	476,035	(412,952)
Contract liabilities	(64,889)	99,518
Other long-term liabilities	(19,932)	(204,807)
Net cash used in operating activities:	(9,135,812)	(8,464,821)
Cash flow from investing activities:		
Purchase of fixed assets	(361,916)	(714,534)
Loan activities		(55,000)
Acquisition of intangibles	(50,180)	(50,699)
Net cash used in investing activities	(412,096)	(820,233)
Cash flow from financing activities:		
Proceeds from issuance of common stock and warrants, net	6,507,050	50,523,527
Proceeds from exercise of warrants into common stock	-	4,513,860
Repayment of debt	-	(4,162,744)
Payment penalties	-	(1,073,470)
Proceeds from issuance of common stock pursuant to equity line	236,009	588,590
Repurchase of common stock upon vesting of restricted stock units	(4,028)	(11,526)
Net cash provided by financing activities	6,739,031	50,378,237
Net increase (decrease) in cash and cash equivalents	(2,808,877)	41,093,183
Cash and cash equivalents at beginning of period	28,202,615	678,332
Cash and cash equivalents at end of period	$ 25,393,738	$ 41,771,515
Non-cash transactions:		
Shares issued to CEO per agreement related to accrued interest	$ -	$ 143,573
Shares issued pursuant to convertible debt	-	514,011
Cash paid during period for:		
Interest paid on debt	3,754	695,989

See Notes to Condensed Consolidated Financial Statements

NOTE 1 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations and Continuance of Operations

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

The Company operates in four primary business areas. First, we provide drug response prediction services leveraging a unique collection of more than 150,000 tumor samples, categorized by tumor type and powered by artificial intelligence to assist biopharmaceutical companies in the development of new oncology drugs primarily through our wholly owned subsidiary Helomics Holding Corporation® ("Helomics"). Second, we develop tumor-specific in vitro models for oncology drug discovery and research through our newly-acquired wholly-owned subsidiary, zPREDICTA, Inc.®. Third, we offer contract services and research focused on solubility improvements, stability studies, and protein production, primarily with our Soluble Biotech Inc.®, subsidiary. Fourth, we sell and produce the United States Food and Drug Administration ("FDA")-cleared STREAMWAY System® for automated, direct-to-drain medical fluid waste disposal and associated products through our incorporated division Skyline Medical Inc.® ("Skyline").

The Company had cash and cash equivalents of $25,393,738 as of September 30, 2022 and there was no outstanding debt. The Company believes that its existing capital resources will be sufficient to support its operating plan for the next twelve months and beyond. However, the Company may also seek to raise additional capital to support its growth through additional debt, equity or other alternatives or a combination thereof. The Company currently expects to use cash on hand to fund capital and equipment investments, research and development, potential acquisitions and its operations. The Company believes such sources to be sufficient to fund its requirements over that time.

Coronavirus Outbreak

The current COVID-19 worldwide pandemic has presented substantial public health challenges. In response to the crisis, emergency measures have been imposed by governments worldwide, including mandatory social distancing and the shutdown of non-essential businesses. These measures have adversely impacted the global economy, disrupted global supply chains and created significant volatility and disruption of financial markets. Our business and operations have been and will likely continue to be materially and adversely affected. For example, our contract manufacturer for the STREAMWAY System has been forced to change locations, thereby delaying our order fulfillment for parts. In addition, COVID-19 has impacted the Company's capital and financial resources, including our overall liquidity position and outlook. For instance, our accounts receivable has slowed while our suppliers continue to ask for pre-delivery deposits. Ultimately, the extent of the impact of the COVID-19 pandemic on our future operational and financial performance will depend on, among other matters, the duration and intensity of the pandemic; the level of success of global vaccination efforts; governmental and private sector responses to the pandemic and the impact of such responses on us; and the impact of the pandemic on our employees, customers, suppliers, operations and sales, all of which are uncertain and cannot be predicted. These factors may remain prevalent for a significant period of time even after the pandemic subsides, including due to a continued or prolonged recession in the U.S. or other major economies. Even in areas where "stay-at-home" restrictions, masking and social distancing measures have been lifted and the number of COVID-19 cases have declined, some jurisdictions may re-impose these measures as and if variant strains emerge or cases rise. The impact of the COVID-19 pandemic, as with any adverse public health developments, could have a material adverse effect on our business, results of operations, liquidity or financial condition and heighten or exacerbate risks described in our Annual Report on Form 10-K filed with the SEC on March 31, 2022.

Interim Financial Statements

The Company has prepared the condensed consolidated financial statements and related unaudited financial information in the footnotes in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC") for interim condensed consolidated financial statements. These interim condensed consolidated financial statements reflect all adjustments consisting of normal recurring accruals, which in the opinion of management, are necessary to present fairly the Company's position, the results of its operations, and its cash flows for the interim periods. These interim condensed consolidated financial statements reflect all intercompany eliminations. These interim condensed consolidated financial statements should be read in conjunction with the annual consolidated financial statements and the notes thereto contained in the Annual Report on Form 10-K filed with the SEC on March 31, 2022. The nature of the Company's business is such that the results of any interim period may not be indicative of the results to be expected for the entire year.

Accounting Policies and Estimates

The preparation of condensed 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 condensed consolidated financial statements and during the reporting period. Actual results could materially differ from those estimates.

Cash and cash equivalents

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash. The Company places its cash with high credit quality financial institutions and, by policy, generally limits the amount of credit exposure to any one financial institution. The Company has a credit risk of $6,514,611 for cash amounts held in a single institution that are in excess of amounts issued 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 condensed consolidated balance sheet include amounts billed and currently due from customers. The amounts due are stated at their net estimated realizable value. An allowance for doubtful accounts is maintained to provide for the estimated amount of receivables that will not be collected. The Company reviews customers' credit history before extending unsecured credit and establishes an allowance for uncollectible accounts based upon factors surrounding the credit risk of specific customers, historical trends and other information. Invoices are generally due 30 days after presentation. Accounts receivable over 30 days is generally considered past due. The Company does not accrue interest on past due accounts receivables. Receivables are written off once all collection attempts have failed and are based on individual credit evaluation and specific circumstances of the customer. There was no allowance for doubtful accounts as of both September 30, 2022 and December 31, 2021.

Fair Value Measurements

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

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

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

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

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

The fair value of the Company's investment securities, which consist of cash and cash equivalents, was determined based on Level 1 inputs. The fair value of the Company's derivative liabilities and debt were determined based on Level 3 inputs. The Company generally uses 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 6 – Derivatives*.

Inventories

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

Fixed Assets

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

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

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

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

Long-lived Assets

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

The Company reviews finite-lived identifiable intangible assets for impairment in accordance with ASC 360, *Property, Plant and Equipment*, whenever events or changes in circumstances indicate the carrying amount may not be recoverable. Events or changes in circumstances that indicate the carrying amount may not be recoverable include, but are not limited to, a significant change in the medical device marketplace and a significant adverse change in the business climate in which the Company operates.

Goodwill

In accordance with ASC 350, *Intangibles – Goodwill and Other*, goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the fair value of net assets acquired. Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination. Goodwill is not amortized, but is tested on an annual basis for impairment at the reporting unit level as of December 31, or whenever events or changes in circumstances indicate that the carrying amount may not be fully recoverable.

To determine whether goodwill is impaired, annually or more frequently if needed, the Company performs a multi-step impairment test. The Company first has the option to assess qualitative factors to determine if it is more likely than not that the carrying value of a reporting unit exceeds its estimated fair value. The Company may also elect to skip the qualitative testing and proceed directly to the quantitative testing. When performing quantitative testing, the Company first estimates the fair value of its reporting units using discounted cash flows. To determine fair values, the Company is required to make assumptions about a wide variety of internal and external factors. Significant assumptions used in the impairment analysis include financial projections of free cash flow (including significant assumptions about operations, such as the rate of future revenue growth, capital requirements, and income taxes), and long-term growth rates for determining terminal value and discount rates. Comparative market multiples are used to corroborate the results of the discounted cash flow test. These assumptions require significant judgment. Pursuant to ASU 2017-04, *Simplifying the Test for Goodwill Impairment*, the single step is to determine the estimated fair value of the reporting unit and compare it to the carrying value of the reporting unit, including goodwill. To the extent the carrying amount of goodwill exceeds the implied goodwill, the difference is the amount of the goodwill impairment. The Company also completes a reconciliation between the implied equity valuation prepared and the Company's market capitalization. The majority of the inputs used in the discounted cash flow model are unobservable and thus are considered to be Level 3 inputs. The inputs for the market capitalization calculation are considered Level 1 inputs. See *Note 4 – Intangible Assets and Goodwill*.

Leases – At inception of a contract, a determination is made whether an arrangement meets the definition of a lease. A contract contains a lease if there is an identified asset, and the Company has the right to control the asset. Operating leases are recorded as right-of-use ("ROU") assets with corresponding current and noncurrent operating lease liabilities on our condensed consolidated balance sheets. Financing leases are included within fixed assets with corresponding current within other current liabilities and noncurrent within other long-term liabilities on our condensed 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 condensed 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. Leases are accounted for at a portfolio level when similar in nature with identical or nearly identical provisions and with similar effective dates and lease terms.

Revenue Recognition

The Company recognizes revenue when it satisfies a performance obligation by transferring control of the promised goods or services to its customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Sales taxes are imposed on the Company's sales to nonexempt customers. The Company collects the taxes from the customers and remits the entire amounts to the governmental authorities. Sales taxes are excluded from revenue and expenses.

Revenue from Product Sales

The Company has medical device revenue consisting primarily of sales of the STREAMWAY System, as well as sales of the proprietary cleaning fluid and filters for use with the STREAMWAY System. This revenue stream is reported within the Skyline segment. The Company sells its medical device products directly to hospitals and other medical facilities using employed sales representatives and independent contractors. Purchase orders, which are governed by sales agreements in all cases, state the final terms for unit price, quantity, shipping, and payment terms. The unit price is considered the observable stand-alone selling price for the arrangements. The Company sales agreement, and Terms and Conditions, is a dually executed contract providing explicit criteria supporting the sale of the STREAMWAY System. The Company considers the combination of a purchase order and acceptance of its Terms and Conditions to be a customer's contract in all cases.

Product sales for medical devices consist of a single performance obligation that the Company satisfies at a point in time. The Company recognizes product revenue when the following events have occurred: (1) the Company has transferred physical possession of the products, (2) the Company has a present right to payment, (3) the customer has legal title to the products, and (4) the customer bears significant risks and rewards of ownership of the products. Based on the shipping terms specified in the sales agreements and purchase orders, these criteria are generally met when the products are shipped from the Company's facilities ("FOB origin," which is the Company's standard shipping term). As a result, the Company determined that the customer could direct the use of, and obtain substantially all of the benefits from, the products at the time the products are shipped. The Company may, at its discretion, negotiate different shipping terms with customers which may affect the timing of revenue recognition. The Company's standard payment terms for its customers are generally 30 to 60 days after the Company transfers control of the product to its customer. The Company allows returns of defective disposable merchandise if the customer requests a return merchandise authorization from the Company.

Customers may also purchase a maintenance plan for the medical devices from the Company, which requires the Company to service the STREAMWAY System for a period of one year after the one-year anniversary date of the original STREAMWAY System invoice. The maintenance plan is considered a separate performance obligation from the product sale, is charged separately from the product sale, and is recognized over time (ratably over the one-year period) as maintenance services are provided. A time-elapsed output method is used to measure progress because the Company transfers control evenly by providing a stand-ready service. The Company has determined that this method provides a faithful depiction of the transfer of services to its customers.

All amounts billed to a customer in a sales transaction for medical devices related to shipping and handling, if any, represent revenues earned for the goods provided, and these amounts have been included in revenue. Costs related to such shipping and handling billing are classified as cost of goods sold. This revenue stream is reported under the Skyline reportable segment.

Revenue from Clinical Testing

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

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

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

CRO Revenue

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

Variable Consideration

The Company records revenue from distributors and direct end customers in an amount that reflects the transaction price it expects to be entitled to after transferring control of those goods or services. The Company's current contracts do not contain any features that create variability in the amount or timing of revenue to be earned.

Warranty

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

Contract Balances

The Company records a receivable when it has an unconditional right to receive consideration after the performance obligations are satisfied. Accounts receivable totaled $324,708 and $354,196 as of September 30, 2022 and December 31, 2021, respectively.

The Company's contract liabilities relate to CRO services agreements and maintenance plans and as of September 30, 2022 and December 31, 2021 were $495,365 and $186,951, respectively.

Practical Expedients

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

Valuation and accounting for stock options and warrants

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

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

	For the nine months ended September 30,	
	2022	2021
	Stock Options	
Expected dividend yield	0.0%	0.0%
Expected stock price volatility	86.5% - 92.2%	84.8% - 89.6%
Risk-free interest rate	1.83% - 3.43%	0.93% - 1.45%
Expected life (years)	10	10
	Warrants	
Expected dividend yield	0.0%	0.0%
Expected stock price volatility	92.2%	84.8% - 89.6%
Risk-free interest rate	2.96% - 2.97%	0.42% - 1.04%
Expected life (years)	5 - 5.5	5 - 5.5

Research and Development

Research and development costs are charged to operations expense as incurred. Research and development costs were $116,763 and $234,357 for the nine months ended September 30, 2022 and 2021, respectively.

Other Expense

Other expense for the three and nine months ended September 30, 2021 consisted primarily of interest expense, payment premium, amortization of original issue discounts, and loss on debt extinguishment associated with the Company's notes payable.

Offering Costs

Costs incurred which are direct and incremental to an offering of the Company's securities are deferred and charged against the proceeds of the offering unless such costs are deemed to be insignificant in which case they are expensed as incurred.

Income Taxes

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

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

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

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

Tax years subsequent to 2018 remain open to examination by federal and state tax authorities.

Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash. The Company places its cash with high credit quality financial institutions and, by policy, generally limits the amount of credit exposure to any one financial institution. The Company has a credit risk of $6,514,611 for cash amounts held in a single institution that are in excess of amounts issued by the Federal Deposit Insurance Corporation.

Risks and Uncertainties

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

Recent Accounting Pronouncements

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

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

NOTE 2 – INVENTORIES

Inventory balances are as follows:

	As of September 30, 2022	As of December 31, 2021
Finished goods	$ 333,334	$ 193,287
Raw materials	160,388	183,410
Work-In-Process	-	10,987
Total	$ 493,722	$ 387,684

NOTE 3 – FIXED ASSETS

The Company's fixed assets consist of the following:

	As of September 30, 2022	As of December 31, 2021
Computers, software, and office equipment	$ 539,036	$ 517,488
Leasehold improvements	537,696	428,596
Laboratory equipment	3,685,560	3,456,091
Manufacturing tooling	121,120	121,120
Demo equipment	31,555	56,614
Total	4,914,967	4,579,909
Less: Accumulated depreciation and amortization	(2,712,865)	(2,068,338)
Total Fixed Assets, Net	$ 2,202,102	$ 2,511,571

Depreciation expense was $227,135 and $237,742 for the three months ended September 30, 2022 and 2021, respectively and $669,686 and $720,736 for the nine months ended September 30, 2022 and 2021, respectively.

NOTE 4 – INTANGIBLE ASSETS AND GOODWILL

The components of intangible assets were as follows:

	As of September 30, 2022			As of December 31, 2021			
	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount	Gross Carrying Costs	Accumulated Amortization	Impairment	Net Carrying Amount
Patents & Trademarks	$ 503,495	$ (248,768)	$ 254,727	$ 453,314	$ (230,572)	$ -	$ 222,742
Developed Technology	3,500,000	(298,958)	3,201,042	6,382,000	(432,733)	(2,485,725)	3,463,542
Customer Relationships	200,000	(17,083)	182,917	645,000	(410,000)	(37,083)	197,917
Tradename	80,000	(17,083)	62,917	478,000	(29,343)	(370,740)	77,917
Total	$ 4,283,495	$ (581,892)	$ 3,701,603	$ 7,958,314	$ (1,102,648)	$ (2,893,548)	$ 3,962,118

The impairment loss recognized during the year ended December 31, 2021 adjusted the carrying amount of a long-lived asset. As a result, the gross carrying cost shown as of September 30, 2022 reflects the new cost basis per ASC 360-10-35-20. Amortization expense was $103,805 and $83,619 during the three months ended September 30, 2022 and 2021, respectively and $310,695 and $249,752 during the nine months ended September 30, 2022 and 2021, respectively

The following table outlines the estimated future amortization expense related to intangible assets held as of September 30, 2020:

Year ending December 31,	Expense
2022	$ 207,442
2023	415,194
2024	415,194
2025	413,111
2026	395,194
Thereafter	1,855,468
Total	$ 3,701,603

The Company concluded there was no impairment of its finite-lived assets as of September 30, 2022. The Company prepared the undiscounted cash flows per ASC 360. The Company concluded that the undiscounted cash flows of the long-lived assets exceeded the carrying values.

Goodwill

Goodwill for our zPREDICTA operating segment was zero as of September 30, 2022 and $6,857,790 as of December 31, 2021. The change in value of goodwill from December 31, 2021 and September 30, 2022 was the result of identification of an immaterial error in the fair value of the acquired contract liabilities. The Company identified this error during the second quarter of 2022 and recorded an adjustment to increase the acquired goodwill and increase the contract liability by $373,303.

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

The Company evaluated the materiality of these errors both qualitatively and quantitatively in accordance with Staff Accounting Bulletin ("SAB") No. 99, Materiality and SAB No. 108, Considering the Effects of Prior Year Misstatements in Current Year Financial Statements, and determined the effect of these corrections was not material to the consolidated financial statements as of and for the year ended December 31, 2021 nor for the quarterly period ended June 30, 2022.

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

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

Pro Forma

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

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

Helomics reporting unit

The goodwill for our Helomics operating segment was zero as of both September 30, 2022 and December 31, 2021, and the cumulative impairment losses are $23,790,290.

zPREDICTA reporting unit

As of September 30, 2022, the cumulative impairment recorded was $7,231,093.

Goodwill balance at December 31, 2021	$ 6,857,790
Adjustment to fair value	373,303
Impairment	(7,231,093)
Goodwill balance at June 30, 2022	$ -
Impairment	-
Goodwill balance at September 30, 2022	$ -

When evaluating the fair value of the zPREDICTA reporting unit, the Company used a discounted cash flow model and market comparisons. Key assumptions used to determine the estimated fair value included: (a) expected cash flow for the 10-year period following the testing date (including net revenues, costs of revenues, and operating expenses as well as estimated working capital needs and capital expenditures) and (b) an estimated terminal value using a terminal year growth rate of 4.0% determined based on the growth prospects of the reporting unit. The Company further used a probability weighting of various forecasts to address forecast risk The Company used an estimated discount rate of 65% based on management's best estimate and considering the Company's current market capitalization.

The majority of the inputs used in the discounted cash flow model are unobservable and thus are considered to be Level 3 inputs. The inputs for the market capitalization calculation are considered Level 1 inputs. Goodwill is not expected to be deductible for tax purposes.

NOTE 5 – STOCKHOLDERS' EQUITY, STOCK OPTIONS AND WARRANTS

May 2022 Offerings

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

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

In each case, the Company paid to the placement agent an aggregate fee equal to 7.5% of the aggregate gross proceeds received by the Company in the offering and a management fee equal to 1% of the aggregate gross proceeds received by the Company in the offering and provided the placement agent expense allowance of $65,000 for non-accountable and other out-of-pocket expenses. In addition, the Company granted to the placement agent or its assigns warrants to purchase 7.5% of the shares sold to investors in the offering at an exercise price equal to 125% of the price of the shares in the transaction, or $0.75 per share, with a term of five years (the “Agent Warrants”). The Agent Warrants become exercisable six months after issuance.

Equity Line

On October 24, 2019, the Company entered into an equity purchase agreement with an investor, providing for an equity financing facility. Upon the terms and subject to the conditions in the purchase agreement, the investor is committed to purchase shares having an aggregate value of up to $15,000,000 of the Company’s common stock for a period of up to three years. The Company issued to the investor 104,651 commitment shares at a fair market value of $450,000 for entering into the agreement. From time to time during the three-year commitment period, provided that the closing conditions are satisfied, the Company may provide the investor with put notices to purchase a specified number of shares subject to certain limitations and conditions and at specified prices, which generally represent discounts to the market price of the common stock. As of September 30, 2022, there was $8,877,820 remaining in available balance under the equity line. In connection with the May 2022 offerings, the Company agreed not to access the remaining balance for a period of one year after the closing date, or May 18, 2022. Additional issuances under this line will be dilutive. During the nine months ended September 30,2022, the Company issued 315,000 shares of its common stock valued at $236,009 pursuant to the equity line.

Equity Incentive Plan

The Company has an equity incentive plan, which allows the Company to issue incentive and non-qualified stock options to employees, directors, and consultants of the Company, where permitted under the plan. The exercise price for each stock option is determined by the Board of Directors. Vesting requirements are determined by the Board of Directors when granted and currently range from immediate to three years. Options under this plan have terms ranging from three to ten years.

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

	Stock Options		Warrants	
	Number of Shares	Average Exercise Price	Number of Shares	Average Exercise Price
Outstanding at December 31, 2020	1,013,547	$ 5.41	7,353,376	$ 1.99
Issued	147,230	1.06	29,640,801	1.44
Forfeited	(92,593)	8.64	-	-
Expired	-	-	(25,233)	10.00
Exercised	(5,313)	0.74	(5,269,059)	0.86
Outstanding at December 31, 2021	1,062,871	$ 4.83	31,699,885	$ 1.66
Issued	16,410	0.49	21,062,714	0.70
Expired	(45,760)	16.06	(47,744)	23.82
Forfeited	(11,897)	1.09	-	-
Modified	-	-	(16,325,433)	1.51
Outstanding at September 30, 2022	1,021,624	$ 4.45	36,389,422	$ 0.74

Stock-based compensation expense recognized for the three months ended September 30, 2022 and 2021 was $26,993 and $29,004, respectively. Stock-based compensation expense recognized for nine months ended September 30, 2022 and 2021 was $102,894 and $627,329, respectively The Company has $17,033 of unrecognized compensation expense related to non-vested stock options that is expected to be recognized over the next 20 months and $42,070 of unrecognized compensation expense related to non-vested restricted stock units that is expected to be recognized over the next 15 months. At September 30, 2022, there were 483,333 RSUs outstanding under the plan.

NOTE 6 – DERIVATIVES

Certain warrants issued to placement agents were determined to be a derivative liability due to specific features of the warrants which could, in particular circumstances, result in the holder receiving the Black Scholes value of the outstanding warrants in the same type of consideration as the common stockholders. As a result, in those circumstances, the amount of consideration would differ from that provided to holders of common stock, therefore, the warrants were classified as a liability.

The fair value of the agent warrants issued in connection with the March 2020 private placement was determined to be $41,336 as of December 31, 2021. The Company recorded a gain on the change in fair value of the placement agent warrants of $35,474 during the nine months ended September 30, 2022 and a loss on the change in fair value of the placement agent warrants of $41,326 during the nine months ended September 30, 2021. As of September 30, 2022, the fair value of the placement agent warrants was $5,862.

The fair value of the agent warrants issued in connection with the May 2020 registered offering were determined to be $7,225 and $42,646 as of September 30, 2022 and December 31, 2021, respectively. The Company recorded a gain on the change in fair value of the placement agent warrants of $35,421 during the nine months ended September 30, 2022 and a loss on the change in fair value of the agent warrants of $39,946 during the nine months ended September 30, 2021.

The placement agent warrants issued in connection with the June 2020 warrant exercise and issuance had a fair value of $9,012 and $45,498 as of September 30, 2022 and December 31, 2021, respectively. The Company recorded a recorded a gain on the change in fair value of the placement agent warrants of $36,486 during the nine months ended September 30, 2022 and loss on the change in fair value of the agent warrants of $44,051 during the nine months ended September 30, 2021.

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

Derivative liability balance at December 31, 2020	**$ 294,382**
Gain recognized to revalue derivative instrument at fair value	(95,671)
Derivative liability balance at March 31, 2021	**$ 198,711**
Gain recognized to revalue derivative instrument at fair value	30,909
Derivative liability balance at June 30, 2021	**$ 229,620**
Derivative liability balance at December 31, 2021	**$ 129,480**
Gain recognized to revalue derivative instrument at fair value	(1,908)
Derivative liability balance at March 31, 2022	**$ 127,572**
Gain recognized to revalue derivative instrument at fair value	(95,254)
Derivative liability balance at June 30, 2022	**$ 32,318**
Gain recognized to revenue derivative instrument at fair value	(10,219)
Derivative liability balance at September 30, 2022	**$ 22,099**

NOTE 7 - LOSS PER SHARE

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Numerator:				
Net loss attributable to common shareholders per common share: basic and diluted calculation	$ (4,059,484)	$ (5,438,017)	$ (17,821,524)	$ (11,900,662)
Denominator:				
Weighted average common shares outstanding-basic (1)	78,383,878	65,406,312	71,084,454	51,272,960
Effect of diluted stock options, warrants, and preferred stock (2)	-	-	-	-
Weighted average common shares outstanding - diluted	78,383,878	65,406,312	71,084,454	51,272,960
Loss per common share-basic	$ (0.05)	$ (0.08)	$ (0.25)	$ (0.23)
Loss per common share- diluted	$ (0.05)	$ (0.08)	$ (0.25)	$ (0.23)

(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:

	Nine Months ended September 30,	
	2022	**2021**
Options	1,021,624	1,012,760
RSU	483,333	516,666
Warrants	36,389,422	31,725,118
Preferred stock: series B	79,246	79,246

NOTE 8 – SEGMENTS

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

The Company has four reportable segments: Helomics, zPREDICTA, Soluble and Skyline. See discussion of revenue recognition in Note 1 – Summary of Significant Accounting Policies for a description of the products and services recognized in each segment. The segment revenues and segment net losses for the three and nine months ended September 30, 2022 and 2021 are included in the table below. All revenues are earned from external customers.

Revenue

	Three Months Ended September 30,		Nine Months Ended, September 30,	
	2022	**2021**	**2022**	**2021**
Helomics	$ 1,821	$ 2,164	$ 5,543	$ 11,314
Soluble	29,439	27,653	64,580	76,639
zPREDICTA	170,816	-	261,099	
Skyline	253,751	282,675	809,875	853,063
Corporate	-	1,171	889	3,171
Total	$ 455,827	$ 313,663	$ 1,141,986	$ 944,187

Segment Gain (Loss)

	Three Months Ended September 30,		Nine Months Ended, September 30,	
	2022	**2021**	**2022**	**2021**
Helomics	$ (916,113)	$ (3,739,275)	$ (2,902,182)	$ (6,024,129)
Soluble	(407,622)	(352,324)	(1,206,550)	(840,790)
zPREDICTA	(160,395)	-	(7,989,585)	-
Skyline	(109,408)	(102,850)	(259,444)	(378,490)
Corporate	(2,465,946)	(1,243,568)	(5,463,763)	(4,657,253)
Total	$ (4,059,484)	$ (5,438,017)	$ (17,821,524)	$ (11,900,662)

Assets

	As of September 30, 2022	As of December 31, 2021
Helomics	$ 1,061,545	$ 1,802,792
Soluble	1,559,917	1,742,445
zPREDICTA	3,815,513	10,782,568
Skyline	15,046,253	906,977
Corporate	11,682,981	28,536,489
Total	$ 33,166,209	$ 43,771,271

NOTE 9 – RELATED PARTY TRANSACTIONS

The Audit Committee has the responsibility to review and approve all transactions to which a related party and the Company may be a party prior to their implementation, to assess whether such transactions meet applicable legal requirements. There are no material related party transactions during the three and nine months ended September 30, 2022.

One of the Company's former directors, Richard L. Gabriel, is the Chief Operating Officer of GLG Pharma ("GLG") and serves as a director of that firm. The Company and GLG have a partnership agreement for the purpose of bringing together their proprietary technologies to build out personalized medicine platform for the diagnosis and treatment of women's cancer. There has been no revenue or expenses generated by this partnership to date.

Richard L. Gabriel was also contracted as the Chief Operating Officer for TumorGenesis. Through April 1, 2019, Mr. Gabriel received $12,000 per month pursuant to a renewable six-month contract. On May 1, 2019, Mr. Gabriel executed a one-year contract with renewable three-month periods to continue as the Chief Operating Officer for TumorGenesis, receiving $13,500 in monthly cash payments.

Effective May 1, 2021, Richard Gabriel resigned as a member of the Company's Board of Directors. Mr. Gabriel's resignation is in connection with his assuming a management position with the Company, and not due to any disagreements with the Company on any of our operations, policies or practices.

NOTE 10 – RETIREMENT OF CHIEF EXECUTIVE OFFICER

On September 15, 2022, J. Melville Engle announced that he will retire as the Chief Executive Officer of the Company and as Chairman and a member of the Company's board of directors, effective October 31, 2022. To ensure an orderly transition of his responsibilities, the Company and Mr. Engle entered into a Transition and Separation Agreement dated September 15, 2022 (the "Transition Agreement") pursuant to which Mr. Engle will continue to serve as Chief Executive Officer until October 31, 2022. The Transition Agreement provides for, among other things, the payment of certain separation benefits to Mr. Engle following termination of his employment, contingent upon Mr. Engle signing, delivering and not rescinding or revoking a general release of claims in favor of the Company, including $524,400 in severance pay, which amount is equal to one year of Mr. Engle's base salary, a pro-rata bonus for 2022 in the amount of $139,000, and accelerated vesting of 300,000 restricted stock units previously granted to Mr. Engle as part of the Company's 2021 Long-Term Incentive Plan. As of September 30, 2022. $741,505 is included within Accrued expenses and other liabilities in the Company's balance sheet for this liability.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read together with our unaudited condensed consolidated financial statements and related notes thereto set forth in this Quarterly Report on Form 10-Q as well as our Annual Report on Form 10-K for the year ended December 31, 2021.

This Form 10-Q contains "forward-looking statements" that indicate certain risks and uncertainties, many of which are beyond our control. Actual results could differ materially and adversely from those anticipated in such forward-looking statements as a result of certain factors, including those set forth below and elsewhere in this report. Important factors that may cause actual results to differ from projections include:

- Our history of operating losses;
- Current negative operating cash flows;
- Our capital needs to accomplish our goals, , and the adequacy of available funds, including our ability to access the capital markets, our ability to obtain additional equity funding from current or new stockholders to fund our business operations and/or future growth plans, and the dilutive effect that raising equity capital would have on the relative equity ownership of our existing investors;
- Risks related to recent and future acquisitions, including the possibility of further impairment of goodwill and risks related to the benefits and costs of acquisition;
- Risks related to our partnerships with other companies, including the need to negotiate the definitive agreements; possible failure to realize anticipated benefits of these partnerships; and costs of providing funding to our partner companies, which may never be repaid or provide anticipated returns;
- Risk that we will be unable to protect our intellectual property or claims that we are infringing on others' intellectual property;
- The impact of competition;
- Acquisition and maintenance of any necessary regulatory clearances applicable to applications of our technology;
- Inability to attract or retain qualified senior management personnel, including sales and marketing personnel;
- Risk that we never become profitable if our product and services are not accepted by potential customers;

- Possible impact of government regulation and scrutiny;
- Unexpected costs and operating deficits, and lower than expected sales and revenues, if any;
- Adverse results of any legal proceedings;
- The volatility of our operating results and financial condition;
- Management of growth;
- Risk that our business and operations will continue to be materially and adversely affected by the COVID-19 pandemic, which has impacted a significant supplier; has resulted in delayed production and less efficiency; and has impacted on our sales efforts, accounts receivable, and terms demanded by suppliers; and may impact financing transactions; 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 our Annual Report on Form 10-K for the year ended December 31, 2021 and in item 1A of Part II below. These cautionary statements qualify all forward-looking statements attributable to us or persons acting on our behalf.

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

Overview

We operate in four primary business areas. First, we provide drug response prediction services leveraging a unique collection of more than 150,000 tumor samples, categorized by tumor type and powered by artificial intelligence to assist biopharmaceutical companies in the development of new oncology drugs primarily through our wholly owned subsidiary Helomics Holding Corporation® (“Helomics”). Second, we develop tumor-specific in vitro models for oncology drug discovery and research through our newly acquired wholly-owned subsidiary, zPREDICTA, Inc.®. Third, we offer contract services and research focused on solubility improvements, stability studies, and protein production, primarily with our Soluble Biotech Inc.®, subsidiary. Fourth, we sell and produce the United States Food and Drug Administration (“FDA”)-cleared STREAMWAY System® for automated, direct-to-drain medical fluid waste disposal and associated products through our incorporated division Skyline Medical Inc. (“Skyine”).

We have four reportable segments: Helomics, zPREDICTA, Soluble and Skyline. The Helomics segment includes clinical testing and contract research services that include the application of AI. Our zPREDICTA segment specializes in organ-specific disease models that provide 3D reconstruction of human tissues accurately representing each disease state and mimicking drug response enabling accurate testing of anticancer agents. Our Soluble segment provides services using a self-contained, automated system that conducts high-throughput, self-interaction chromatography screens, using additives and excipients commonly included in protein formulations resulting in soluble and physically stable formulations for biologics. Our Skyline segment consists of the STREAMWAY System product sales, and our TumorGenesis subsidiary is included within corporate. Going forward, we have determined that we will focus our resources on the Helomics and zPREDICTA segments and our primary mission statements to accelerate patient-centric drug discovery to improve patient outcomes in cancer treatment, harnessing the power of AI, and to develop tumor-specific 3D cell culture models that provide accurate 3D reconstruction of human tissues representing each cancer disease state.

Capital Requirements

Since inception, we have been unprofitable. We incurred net losses of $4,059,484 and $5,438,017 for the three months ended September 30, 2022, and September 30, 2021, respectively. As of September 30, 2022, and December 31, 2021, we had an accumulated deficit of $145,861,805 and $128,040,282, respectively.

We have never generated sufficient revenues to fund our capital requirements. Since 2017, we have diversified our business by investing in ventures, including making significant loans and investments in early-stage companies. These activities led to the acquisition of Helomics in April 2019, the purchase of the assets of three businesses in 2020 and the acquisition of zPREDICTA in November 2021, each of which have accelerated our capital needs. We have funded our operations through a variety of debt and equity instruments. See "Liquidity and Capital Resources – Liquidity and Plan of Financing" and "Liquidity and Capital Resources – Financing Transactions" below.

Our future cash requirements and the adequacy of available funds depend on our ability to generate revenues from our Helomics, Soluble and zPREDICTA segments; our ability to continue to sell our Skyline Medical products and to reach profitability in the Skyline Medical business and the availability of future financing to fulfill our business plans. See "Liquidity and Capital Resources – Liquidity and Plan of Financing" below.

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

Results of Operations

Comparison of three and nine months ended September 30, 2022 and September 30, 2021

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	**2021**	**Difference**	**2022**	**2021**	**Difference**
Revenue	$ 455,827	$ 313,663	$ 142,164	$ 1,141,986	$ 944,187	$ 197,799
Cost of goods sold	108,151	110,165	2,014	351,669	350,800	(869)
General and administrative expense	3,287,918	2,061,458	(1,226,460)	8,063,265	7,410,208	(653,057
Operations expense	857,130	648,935	(208,195)	2,657,314	1,791,543	865,771
Sales and marketing expense	333,377	172,869	(160,508)	908,867	447,298	461,569

Revenue. We recorded revenue of $455,827 and $313,663 in the three months ended September 30, 2022 and 2021, respectively. We sold a net of 2 and 3 STREAMWAY System units during the three months ended September 30, 2022 and 2021, respectively.

We recorded revenue of $1,141,986 and $944,187 in the nine months ended September 30, 2022 and 2021, respectively. Revenue was primarily derived from the Skyline business. The nine months ended September 30, 2022 also included $261,099 from our zPREDICTA division. The Soluble reportable segment recorded $64,580 and $76,639 during the nine months ended September 30, 2022 and 2021 and there was an additional $5,543 and $11,314 from our Helomics reportable segment during the nine months ended September 30, 2022 and 2021, respectively. There were 7 and 10 sales of STREAMWAY units in the nine months ended September 30, 2022 and 2021 respectively.

Cost of goods sold. Cost of sales was $108,151 and $351,669 in the three and nine months ended September 30, 2022 and $110,165 and $350,800 in the three and nine months ended September 30, 2021, respectively. The gross profit margin was approximately 76% and 69% in the three and nine months ended September 30, 2022 compared to 65% in both of the prior year periods. Our margins increased in the three months ended September 30, 2022 due to a larger portion of revenue being generated from our CRO services from our zPREDICTA subsidiary. Our margins decreased in the nine-month period in the current year as costs were higher, specifically related to disposables.

General and administrative expense. General and administrative ("G&A") expense primarily consists of management salaries, professional fees, consulting fees, travel expense, administrative fees, and general office expenses.

G&A expense increased by $1,226,460 for the three months ended September 30, 2022 compared to 2021. The increase was primarily due to higher employee related expenses due to acquisition of the zPREDICTA reportable segment, costs associated with the consolidation of our TumorGenesis division to Pittsburgh and the retirement of our CEO, offset by other costs due to changes in headcount. Other increases were driven by higher professional and outside services.

G&A expenses increased by $653,057 for the nine months ended September 30, 2022 compared to 2021. The increase was primarily due to expenses associated with the retirement of our CEO, offset by lower professional fees for legal and investor relations services, offset by increased corporate insurance expenses and employee related expenses due to increased headcount including the acquisition of the zPREDICTA reportable segment.

Operations expense. Operations expense primarily consists of expenses related to product development and prototyping and testing.

Operations expense increased by $208,195 to $857,130 in the three months ended September 30, 2022 compared to 2021 and increased by $865,771 to $2,657,314 in the nine months ended September 30, 2022 compared to 2021. The increase was primarily due to higher staff related expenses including the increased headcount at our zPREDICTA reportable segment, partially offset by lower research and development expenses.

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

Sales and marketing expense increased by $160,508 to $333,377 in the three months ended September 30, 2022 compared to $172,869 in the comparable period in 2021. Such expenses in 2021 related almost entirely to our corporate marketing and business development staffing and sales support for our Skyline business. The increase in 2022 was a direct result of the increases in marketing and business development staff in 2022. Sales and Marketing increased by $461,569 to $908,867 in the nine months ended September 30, 2022 compared to 2021. The increase was driven by increased staff related expenses and other advertising and marketing expenses.

Loss in Goodwill Impairment. We recognized no goodwill impairment charge for the three months ended September 30, 2022 compared to a goodwill impairment charge of $2,813,792 for the comparable period in 2021. We recognized a goodwill impairment charge of $7,231,093 related to the zPREDICTA segment during the nine months ended September 30, 2022 compared to goodwill impairment charge of $2,813,792 related to the Helomics segment during the comparable period in 2021.

Other income. We earned other income of $63,047 in the three months ended September 30, 2022 compared to $58,830 in the comparable period in 2021 and earned other income of $146,524 in the nine months ended September 30, 2022, compared to $144,122 in the comparable in 2021. Other income included interest and dividend income.

Other expense. We incurred other expense of $2,001 in the three months ended September 30, 2022 compared to $7,413 in the comparable period in 2021 and other expense of $5,207 in the nine months ended September 30, 2022 compared to $244,214 in the comparable period in 2021. Other expense in 2022 consisted primarily of net interest expense. Net interest expense was significantly lower in the nine-month period due to the repayment of our remaining debt in the first quarter of 2021.

Gain on derivative instruments. We recorded a gain of $10,219 in the three months ended September 30, 2022 compared to a gain of $4,122 in the comparable period in 2021 and incurred gains of $107,381 in the nine months ended September 30, 2022, compared to gains of $68,884 in the comparable period in 2021 related to the changes in fair market value on derivatives.

Liquidity and Capital Resources

Cash Flows

Net cash used in operating activities was $9,135,812 and $8,464,821 for the nine months ended September 30, 2022 and September 30, 2021, respectively. Cash used in operating activities increased in the 2022 period primarily because of the increase in cash used for working capital and higher operating costs.

Cash flows used in investing activities was $412,096 and $820,233 for the nine months ended September 30, 2022 and September 30, 2021, respectively. Cash used in these periods was from the acquisition of fixed assets and cash used to maintain our intangible assets.

Net cash provided by financing activities was $6,739,031 and $50,378,237 for the nine months ended September 30, 2022 and September 30, 2021, respectively. The cash provided in the nine months ended September 30, 2022 was primarily due to proceeds from the issuance of common stock and warrants in connection with the May 2022 offering and the issuance of common stock pursuant to the equity line agreement. The cash provided in the nine months ended September 30, 2021 was primarily due to proceeds from issuance of common stock and warrants in six financing transactions and the exercise of warrants by investors, in addition to proceeds from the issuance of common stock pursuant to the equity line agreement, offset by the repayment of outstanding debt.

Liquidity and Plan of Financing

We have incurred a net loss in each of our annual periods since our inception. We incurred a net loss of $17,821,524 for the nine months ended September 30, 2022. On September 30, 2022, we had $25,393,738 in cash. In addition to our cash, we also have access to additional capital through our $15,000,000 equity line with a remaining available balance of $8,877,820, subject to requirements for market conditions including trading volume and stock price, and subject to other limitations. In connection with the May 2022 offerings, we agreed not to access the remaining balance under the equity line for a period of one year after the closing date, or May 18, 2023.

Since our inception, we have received net proceeds from the sale of our common stock (through our initial public offering and subsequent public offerings, including at-the-market offerings) which have funded our operations. We believe that our existing capital resources will be sufficient to support our operating plan for the next twelve months and beyond. If we anticipate that our actual results will differ from our operating plan, we believe we have sufficient capabilities to enact cost savings measures to preserve capital. We may also seek to raise additional capital to support our growth through the incurrence of additional debt, the sale of equity or other alternatives (including asset sales) or a combination thereof. Such additional capital may not be available on terms acceptable to us or at all. If we raise funds by issuing equity or equity-linked securities, the ownership of some or all of our stockholders will be diluted, and the holders of new equity securities may have priority rights over our existing stockholders. If adequate funds are not available, we may be required to curtail operations significantly or obtain funds by entering into agreements on unattractive terms. Our inability to raise capital could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, the recent decline in economic activity caused by events such as the armed conflict between Russia and Ukraine and by the COVID pandemic, together with the deterioration and/or volatility of the credit and capital markets, could have an adverse impact on potential sources of future financing.

Financing Transactions

We have funded our operations through a combination of debt and equity instruments including short-term borrowings, and a variety of debt and equity offerings.

May 2022 Offerings

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

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

In each case, the Company paid to the placement agent an aggregate fee equal to 7.5% of the aggregate gross proceeds received by the Company in the offering and a management fee equal to 1% of the aggregate gross proceeds received by the Company in the offering and provided the placement agent expense allowance of $65,000 for non-accountable and other out-of-pocket expenses. In addition, the Company granted to the placement agent or its assigns warrants to purchase 7.5% of the shares sold to investors in the offering at an exercise price equal to 125% of the price of the shares in the transaction, or $0.75 per share, with a term of five years (the "Agent Warrants"). The Agent Warrants become exercisable six months after issuance.

2021 Offerings

In January and February 2021, the Company completed a series of five offerings, all of which were priced at-the-market under applicable NASDAQ rules. The first four offerings were registered direct offerings of common stock under its shelf registration statement, and in each such case, in a concurrent private placement, the Company also issued such investors one warrant to purchase common stock for each two shares purchased in the transaction. Following those four offerings, the Company completed a private placement of common stock, with each investor receiving one warrant to purchase common stock for each two shares purchased in the transaction. In June 2021, the Company completed a registered direct offering of common stock and warrants. The warrants became exercisable on the effective date of an increase in the number of shares of the Company's authorized common stock, which occurred on August 17, 2021, and expire three years after the initial exercise date. In each case, each such investor warrant is exercisable immediately upon issuance and will expire five and one-half years from the issue date. In each case, the Company paid to the placement agent an aggregate fee equal to 7.5% of the aggregate gross proceeds received by the Company in the offering and a management fee equal to 1% of the aggregate gross proceeds received by the Company in the offering and reimbursed the placement agent for certain non-accountable and out-of-pocket expenses. In addition, the Company granted to the placement agent, or its assigns warrants to purchase 7.5% of the shares sold to investors in the offering at an exercise price equal to 125% of the price of the shares in the transaction, with a term of five years for the registered direct offerings (three years for the June 2021 offering) or five and one-half years for the private placement.

These 2021 offerings were as follows:

Offering Closing Date	Shares of Common Stock	Sale Price per Share*	Investor Warrants	Exercise Price per Share – investor Warrants	Placement Agent Warrants	Exercise Price per Share – Placement Agent Warrants	Gross Proceeds of Offering	Net Proceeds of Offering
January 12, 2021 (registered direct)	3,650,840	$ 0.842	1,825,420	$ 0.80	273,813	$ 1.0525	$ 3,074,007	$ 2,731,767
January 21, 2021 (registered direct)	2,200,000	$ 1.00	1,100,000	$ 1.00	165,000	$ 1.25	$ 2,200,000	$ 1,932,050
January 26, 2021 (registered direct)	3,414,970	$ 1.20	1,707,485	$ 1.20	256,123	$ 1.50	$ 4,097,964	$ 3,668,687
February 16, 2021 (registered direct)	4,222,288	$ 1.75	2,111,144	$ 2.00	316,672	$ 2.1875	$ 7,389,004	$ 6,679,989
February 23, 2021 (private placement)	9,043,766	$ 1.95	4,521,883	$ 2.00	678,282	$ 2.4375	$ 17,635,344	$ 16,064,739
June 16, 2021 (registered direct)	15,520,911	$ 1.375	15,520,911	$ 1.25	1,164,068	$ 1.71875	$ 21,341,252	$ 19,446,296
Total	38,052,775		26,786,843		2,853,958		$ 55,737,571	$ 50,523,528

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

Secured Notes and Repayment in Full

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

2021 Warrant Exercises

During the period January 1, 2021 through September 30, 2021, the holders of outstanding investor warrants have exercised such warrants for the total purchase of 5,269,059 shares at a weighted average exercise price of $0.86 per share, for total proceeds of $4,513,860.

Equity Line

On October 24, 2019, the Company entered into an equity purchase agreement with an investor, providing for an equity financing facility. Upon the terms and subject to the conditions in the purchase agreement, the investor is committed to purchase shares having an aggregate value of up to $15,000,000 of the Company’s common stock for a period of up to three years. The Company issued to the investor 104,651 commitment shares at a fair market value of $450,000 for entering into the agreement. From time to time during the three-year commitment period, provided that the closing conditions are satisfied, the Company may provide the investor with put notices to purchase a specified number of shares subject to certain limitations and conditions and at specified prices, which generally represent discounts to the market price of the common stock. As of September 30, 2022, there was an available balance of $8,877,820 under the equity line. In connection with the May 2022 offerings, the Company agreed not to access the remaining balance for a period of one year after the closing date, or May 18, 2022. Additional issuances under this line will be dilutive. During the nine months ended September 30, 2022, the Company issued 315,000 shares of its common stock valued at $236,009 pursuant to the equity line.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet activities as defined in Item 303(a)(4) of Regulation S-K.

Accounting Standards and Recent Accounting Developments

See *Note 1 - Summary of Significant Accounting Policies* to the unaudited, Condensed Consolidated Financial Statements of this Quarterly Report on Form 10-Q for a discussion of recent accounting developments.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Not required.

ITEM 4. Controls and Procedures

Evaluation of 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.

Based on their evaluation as of September 30, 2022, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were not effective as of September 30, 2022 due to the material weakness in internal controls regarding adequate accounting resources, as described below.

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

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

Changes in Internal Control Over Financial Reporting

There were no other changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the nine months ended September 30, 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. Legal Proceedings

None

ITEM 1A. Risk Factors

In addition to the other information set forth in the Quarterly Report on Form 10-Q, the reader should carefully consider the risks included in Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 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 reader should also carefully consider these risk factors.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

Information regarding sales of unregistered securities during the prior year periods covered hereby has been included in previous reports on Form 8-K or 10-K. The following is a summary of our transactions during the nine months ended September 30, 2022 involving sales of our securities that were not registered under the Securities Act:

During the nine months ended September 30, 2022, we issued an aggregate of 29,346 shares of common stock for an aggregate payment of $25,000 for professional research services.

The sale of the above securities was exempt from registration under the Securities Act of 1933, as amended, in reliance on the exemption from federal registration under Section 4(a)(2) of the Securities Act and/or Rule 506 promulgated thereunder, based on our belief that the offer and sale of such securities has not and will not involve a public offering. The recipient of the securities in the transaction represented its intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in the transaction.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

Not applicable.

ITEM 6. Exhibits

See the attached exhibit index.

SIGNATURES:

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PREDICTIVE ONCOLOGY INC.

Date: November 10, 2022

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

Date: November 10, 2022

By: /s/ Bob Myers
Bob Myers
Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
3.1	Amendment to Second Amended and Restated Bylaws of Predictive Oncology Inc., dated September 9, 2022 (Filed on September 14, 2022 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference). Exhibit 3.1
3.2	Second Amended and Restated Bylaws effective as of September 9, 2022 (Filed on September 30, 2022 as an exhibit to our Registration Statement on Form S-1 and incorporated herein by reference). Exhibit 3.2
10.1	Amended and Restated Employment Agreement, effective as of August 1, 2022, by and between Julia Kirshner and Predictive Oncology Inc. (Filed on July 26, 2022 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference). Exhibit 10.1
10.2	Transition and Separation Agreement dated September 15, 2022 by and between J. Melville Engle and Predictive Oncology Inc. (Filed on September 16, 2022 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference). Exhibit 10.2
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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
** Furnished herewith

Exhibit 31.1

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

I, Raymond F. Vennare, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Predictive Oncology Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2022

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

Exhibit 31.2

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

I, Bob Myers, certify that:

1. I have reviewed the quarterly report on Form 10-Q of Predictive Oncology Inc.;

2. Based on my knowledge, this report does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements in light of the circumstances under which some statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report (that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date November 10, 2022

/s/ Bob Myers
Bob Myers
Chief Financial Officer

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Predictive Oncology Inc. (the "Company") for the quarter ended September 30, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Raymond F. Vennare, Chief Executive Officer (Principal Executive Officer) and, I, Bob Myers, Chief Financial Officer (Principal Financial Officer) of the Company, hereby certify as of the date hereof, solely for purposes of § 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1350, that to the best of my knowledge:

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

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

Date: November 10, 2022

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

Date: November 10, 2022

/s/ Bob Myers
Bob Myers
Chief Financial Officer