

UNITED STATES
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 June 30, 2024

or

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

For the transition period from _____ to _____

Commission File Number: 001-36790

Predictive Oncology Inc.

(Exact name of registrant as specified in its charter)

Delaware

33-1007393

(State or other jurisdiction of
incorporation or organization)

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

91 43rd Street, Suite 110 Pittsburgh, Pennsylvania Street, Suite 110
Pittsburgh, Pennsylvania

15201

(Address of principal executive offices)

(Zip Code)

(412) 432-1500

(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
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

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

Yes No

As of August 5, 2024, the registrant had 6,666,993 shares of common stock, par value \$0.01 per share outstanding.

PREDICTIVE ONCOLOGY INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

PREDICTIVE ONCOLOGY INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,331,770	\$ 8,728,660
Accounts receivable	387,040	333,697
Inventories	568,215	494,374
Prepaid expense and other assets	597,724	521,700
Total current assets	<u>6,884,749</u>	<u>10,078,431</u>
Property and equipment, net	910,211	1,233,910
Intangibles, net	238,731	252,457
Lease right-of-use assets	2,432,339	2,728,355
Other long-term assets	121,096	124,096
Total assets	<u>\$ 10,587,126</u>	<u>\$ 14,417,249</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,563,023	\$ 1,342,027
Note payable	276,932	150,408
Accrued expenses and other liabilities	1,946,893	1,631,702
Derivative liability	8	1,376
Contract liabilities	269,943	308,091
Lease liability	561,712	517,427
Total current liabilities	<u>4,618,511</u>	<u>3,951,031</u>
Other long-term liabilities	13,661	5,459
Lease liability – net of current portion	1,860,983	2,188,979
Total liabilities	<u>6,493,155</u>	<u>6,145,469</u>
Stockholders' equity:		
Preferred stock, 20,000,000 shares authorized inclusive of designated below		
Series B Convertible Preferred Stock, \$.01 par value, 2,300,000 shares authorized, 79,246 shares outstanding as of June 30, 2024, and December 31, 2023	792	792
Common stock, \$.01 par value, 200,000,000 shares authorized, 5,708,876 and 4,062,853 shares outstanding as of June 30, 2024, and December 31, 2023, respectively	57,089	40,629
Additional paid-in capital	179,198,077	175,992,242
Accumulated deficit	(175,161,987)	(167,761,883)
Total stockholders' equity	<u>4,093,971</u>	<u>8,271,780</u>
Total liabilities and stockholders' equity	<u>\$ 10,587,126</u>	<u>\$ 14,417,249</u>

See accompanying notes to unaudited condensed consolidated financial statements.

PREDICTIVE ONCOLOGY INC.

CONDENSED CONSOLIDATED STATEMENTS OF NET LOSS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	\$ 278,722	\$ 490,110	\$ 698,368	\$ 730,005
Cost of sales	152,968	159,761	340,383	279,900
Gross profit	125,754	330,349	357,985	450,105
Operating expenses:				
General and administrative expense	2,137,189	2,704,527	4,764,265	5,040,511
Operations expense	893,391	993,042	1,995,584	1,871,560
Sales and marketing expense	284,421	429,103	1,024,155	799,340
Loss on impairment of property and equipment	-	162,905	-	162,905
Total operating expenses	3,315,001	4,289,577	7,784,004	7,874,316
Total operating (loss)	(3,189,247)	(3,959,228)	(7,426,019)	(7,424,211)
Other income	9,461	28,552	28,118	70,780
Other expense	(1,834)	-	(3,571)	-
Gain on derivative instruments	359	7,308	1,368	8,261
Net (loss)	\$ (3,181,261)	\$ (3,923,368)	\$ (7,400,104)	\$ (7,345,170)
Net (loss) per common share – basic and diluted	\$ (0.68)	\$ (0.98)	\$ (1.70)	\$ (1.84)
Weighted average shares used in computation – basic and diluted	4,664,771	3,996,512	4,363,812	3,982,384

See accompanying notes to unaudited condensed consolidated financial statements.

PREDICTIVE ONCOLOGY INC.

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
FOR THE THREE AND SIX MONTHS ENDED
JUNE 30, 2024
(Unaudited)

	Series B Preferred		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance at 12/31/2023	79,246	\$ 792	4,062,853	\$ 40,629	\$ 175,992,242	\$(167,761,883)	\$ 8,271,780
Vesting expense, net of forfeitures	-	-	-	-	734	-	734
Net loss	-	-	-	-	-	(4,218,843)	(4,218,843)
Balance at 03/31/2024	79,246	\$ 792	4,062,853	\$ 40,629	\$ 175,992,976	\$(171,980,726)	\$ 4,053,671
Issuance of shares to non-employees	-	-	38,923	389	98,864	-	99,253
Vesting expense, net of forfeitures	-	-	-	-	306	-	306
Issuance of shares pursuant to At-The-Market financing, net of issuance costs	-	-	1,607,100	16,071	3,105,931	-	3,122,002
Net loss	-	-	-	-	-	(3,181,261)	(3,181,261)
Balance at 06/30/2024	79,246	\$ 792	5,708,876	\$ 57,089	\$ 179,198,077	\$(175,161,987)	\$ 4,093,971

See accompanying notes to unaudited condensed consolidated financial statements.

PREDICTIVE ONCOLOGY INC.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
FOR THE THREE AND SIX MONTHS ENDED
JUNE 30, 2023
(Unaudited)

	Series B Preferred		Series F Preferred		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at 12/31/2022	79,246	\$ 792	-	\$ -	3,938,160	\$ 39,382	\$ 175,503,634	\$ (153,777,916)	\$ 21,765,892
Shares issued to consultants and others	-	-	-	-	31,833	318	200,690	-	201,008
Vesting expense	-	-	-	-	-	-	9,287	-	9,287
Series F Preferred Stock dividend	-	-	79,404	794	-	-	(794)	-	-
Net loss	-	-	-	-	-	-	-	(3,421,802)	(3,421,802)
Balance at 03/31/2023	79,246	\$ 792	79,404	\$ 794	3,969,993	\$ 39,700	\$ 175,712,817	\$ (157,199,718)	\$ 18,554,385
Shares issued to consultants and others	-	-	-	-	10,965	110	68,058	-	68,168
Vesting expense	-	-	-	-	-	-	5,872	-	5,872
Shares issued in connection with reverse stock split	-	-	-	-	25,343	253	(253)	-	-
Series F Preferred Stock redemption	-	-	(79,404)	(794)	-	-	794	-	-
Net loss	-	-	-	-	-	-	-	(3,923,368)	(3,923,368)
Balance at 06/30/2023	79,246	\$ 792	-	\$ -	4,006,301	\$ 40,063	\$ 175,787,288	\$ (161,123,086)	\$ 14,705,057

See accompanying notes to unaudited condensed consolidated financial statements.

PREDICTIVE ONCOLOGY INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,	
	2024	2023
Cash flow from operating activities:		
Net loss	\$ (7,400,104)	\$ (7,345,170)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	326,730	417,989
Vesting expense	1,040	15,159
Common stock issued to non-employees	99,253	79,280
(Gain) on derivative instruments	(1,368)	(8,261)
Loss on impairment of property and equipment	-	162,905
Loss on disposal of property and equipment	20,205	903
Changes in assets and liabilities:		
Accounts receivable	(53,343)	(99,653)
Inventories	(73,841)	36,795
Prepaid expense and other assets	(73,024)	47,090
Accounts payable	220,996	66,109
Accrued expenses and other	329,330	(401,002)
Contract liabilities	(38,148)	25,823
Other long-term liabilities	8,202	-
Net cash (used in) operating activities:	<u>(6,634,072)</u>	<u>(7,002,033)</u>
Cash flow from investing activities:		
Purchase of property and equipment	(9,510)	(279,727)
Acquisition of intangibles	-	(26,018)
Net cash (used in) investing activities:	<u>(9,510)</u>	<u>(305,745)</u>
Cash flow from financing activities:		
Proceeds from issuance of common stock	3,695,848	-
Costs to issue common stock	(573,846)	-
Proceeds from issuance of financing note payable	275,098	-
Repayment of note payable	(150,408)	-
Net cash provided by financing activities	<u>3,246,692</u>	<u>-</u>
Net (decrease) in cash	(3,396,890)	(7,307,778)
Cash and cash equivalents at beginning of period	8,728,660	22,071,523
Cash and cash equivalents at end of period	<u>\$ 5,331,770</u>	<u>\$ 14,763,745</u>
Supplemental disclosure for cash flow information:		
Cash payments for interest	\$ 1,737	\$ -
Non-cash transactions:		
Right-of-use assets obtained in exchange for lease liabilities	\$ -	\$ 2,997,181
Series F Preferred Stock dividend	-	794
Common stock issued to settle accrued board of directors' and advisory boards' compensation	-	189,896
Purchase of property & equipment accrued in accounts payable	-	3,920
Redemption of Series F Preferred Stock	-	794
Common stock issued in connection with reverse stock split	-	253

See accompanying notes to unaudited condensed consolidated financial statements.

PREDICTIVE ONCOLOGY INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations

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

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

The Company operates in three business areas. In its first area, the Company provides optimized, high-confidence drug-response predictions through the application of AI using its proprietary biobank of tumor samples to enable a more informed selection of drug/tumor combinations and increase the probability of success during drug development. The Company also creates and develops tumor-specific 3D cell culture models mimicking the physiological environment of human tissue enabling better-informed decision-making during development. In its second business area, the Company provides services and research using a proprietary self-contained and automated system that conducts high-throughput, self-interaction chromatography screens using additives and excipients commonly included in protein formulations resulting in soluble and physically stable formulations of biologics. The Company’s third business area produces the United States Food and Drug Administration (“FDA”)-cleared STREAMWAY® System and associated products for automated medical fluid waste management and patient-to-drain medical fluid disposal.

The Company has three reportable segments, which have been delineated by location and business area, as further described in *Note 12 – Segments*:

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

Going Concern

These condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. However, substantial doubt about the Company’s ability to continue as a going concern exists.

The Company has incurred significant and recurring losses from operations for the past several years and, as of June 30, 2024, had an accumulated deficit of \$175,161,987. The Company had cash and cash equivalents of \$5,331,770 as of June 30, 2024, and needs to raise significant additional capital to meet its operating needs. The Company had short-term obligations of \$4,618,511 and long-term operating lease obligations of \$1,860,983 as of June 30, 2024. The Company does not expect to generate sufficient operating revenue to sustain its operations in the near term. During the six months ended June 30, 2024, the Company incurred negative cash flows from operations of \$6,634,072. Although the Company has attempted to improve its cash flows from operations by bolstering revenues and continues to seek ways to generate revenue through business development activities, there is no guarantee that the Company will be able to improve its cash flows from operations sufficiently or achieve profitability in the near term. As a result of these conditions, substantial doubt exists about the Company’s ability to continue as a going concern within one year after the date these condensed consolidated financial statements are issued.

The Company is evaluating alternatives to obtain the required additional funding to maintain future operations. These alternatives may include, but are not limited to, equity financing, issuing debt, entering into other financing arrangements, or monetizing operating businesses or assets. These possibilities, to the extent available, may be on terms that result in significant dilution to the Company's existing stockholders or that result in the Company's existing stockholders losing part or all of their investment. Despite these potential sources of funding, the Company may be unable to access financing or obtain additional liquidity when needed or under acceptable terms, if at all. If such financing or adequate funds from operations are not available, the Company would be forced to limit its business activities and the Company could default on existing payment obligations, which would have a material adverse effect on its financial condition and results of operations, and the Company may ultimately be required to cease its operations and liquidate its business. The Company's condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustment relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

Basis of Presentation

The Company has prepared the condensed consolidated financial statements and related unaudited financial information in the notes 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. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These interim condensed consolidated financial statements reflect all adjustments consisting of normal recurring adjustments, 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 28, 2024. 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. Estimates are used in the following areas, among others: variable consideration associated with revenue recognition, stock-based compensation expense, fair value of long-lived assets for impairment analyses, the valuation allowance included in the deferred income tax calculation, accrued expenses, and fair value of derivative liabilities.

Note 1 to the annual consolidated financial statements contained in the Annual Report on Form 10-K filed with the SEC on March 28, 2024, describes the significant accounting policies and estimates used in preparation of the consolidated financial statements. There have been no material changes in the Company's significant accounting policies during the six months ended June 30, 2024.

Principles of Consolidation

The Company had two wholly owned subsidiaries, Helomics Corporation and Skyline Medical, Inc. ("Skyline Medical"), as of June 30, 2024, and December 31, 2023, and for the three and six months ended June 30, 2024, and 2023. The condensed consolidated financial statements include the accounts of the Company and these wholly owned subsidiaries after elimination of intercompany transactions and balances as of June 30, 2024, and December 31, 2023, and for the three and six months ended June 30, 2024, and 2023.

Concentration of Credit Risk

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

As of June 30, 2024, accounts receivable from a single customer represented 11% of the Company's total accounts receivable. As of December 31, 2023, accounts receivable from a single customer represented 16% of the Company's total accounts receivable.

Recent Accounting Pronouncements

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

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. This ASU updates reportable segment disclosures by expanding the frequency and extent of segment disclosures. This ASU is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The ASU requires the retrospective adoption method. Management is currently evaluating this ASU to determine its impact on the Company’s disclosures.

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

NOTE 2 – COLLABORATIVE ARRANGEMENTS AND CONTRACTS WITH CUSTOMERS

Collaboration Agreement with Cancer Research Horizons

On March 16, 2023, the Company entered into a Collaboration Agreement (the “CRH Agreement”) with Cancer Research Horizons (“CRH”), pursuant to which the Company used its PEDAL technology to evaluate CRH pre-clinical drug inhibitors of Glutaminase to determine which cancer types and patient populations were most likely to respond to treatment with those compounds (the “Project”). Under the CRH Agreement, both parties retained rights to their respective background intellectual property. Rights to reports, findings, supporting data, and materials (“Project Intellectual Property”) that were generated by the Company pursuant to its performance under the CRH Agreement vested exclusively in CRH. Each party funded its own participation in the Project. Costs incurred to participate in the CRH Agreement were recorded in Cost of sales in the Company’s Consolidated Statement of Net Loss for the year ended December 31, 2023.

Pursuant to the CRH Agreement, the Company shall receive a percentage of net revenue, as defined in the agreement, received by CRH for the commercialization of the CRH Candidates and any CRH Derivatives (each as defined in the CRH Agreement). The percentage of net revenue varies depending on the stage of development. The revenue sharing fees represent variable consideration, which is measured using the expected value method under ASC 606 based on the actual net revenues earned by CRH under Relevant Transfer Agreements (as defined in the CRH Agreement) relating to the CRH Candidates and CRH Derivatives. Due to the uncertainty associated with the timing and amount of revenue sharing fees, the Company concluded that the revenue sharing fees should be fully constrained until such time that Relevant Transfer Agreements have been entered and net revenues have been earned. These estimates will be reassessed at each reporting period. During the six months ended June 30, 2024, and 2023, the Company recognized no revenue under the CRH Agreement.

Contracts with Customers and Contract Balances

The Company records a receivable when it has an unconditional right to receive consideration after the performance obligations are satisfied. As of June 30, 2024, and December 31, 2023, accounts receivable totaled \$387,040 and \$333,697, respectively. The allowance for accounts receivable balance was \$0 as of both June 30, 2024, and December 31, 2023.

During the three months ended June 30, 2024, revenues from three customers were 11%, 11%, and 12% of the Company’s total revenue, respectively. During the six months ended June 30, 2024, revenues from a single customer were 34% of the Company’s total revenue. During the three months ended June 30, 2023, revenues from three customers were 11%, 15%, and 24% of the Company’s total revenue, respectively. During the six months ended June 30, 2023, revenues from three customers were 10%, 12%, and 16% of the Company’s total revenue, respectively.

Advance payments received in excess of revenues recognized are classified as contract liabilities until such time as the revenue recognition criteria have been met. The Company's contract liabilities, related primarily to development of 3D models and STREAMWAY maintenance plans, were \$283,604 and \$313,550 as of June 30, 2024, and December 31, 2023, respectively. During the three and six months ended June 30, 2024, the Company recognized revenue of \$49,165 and \$66,139, respectively, related primarily to deposits for development of 3D models and STREAMWAY maintenance plans that were included in contract liabilities as of December 31, 2023. The Company's contract liabilities as of June 30, 2024, primarily represent its remaining performance obligations. The Company's long-term contract liabilities are reported in Other long-term liabilities in the condensed consolidated balance sheets.

NOTE 3 – FAIR VALUE MEASUREMENTS

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

June 30, 2024	Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	\$ 4,000,000	\$ 4,000,000	\$ -	\$ -
Liabilities:				
Derivatives	\$ 8	\$ -	\$ -	\$ 8
December 31, 2023				
Liabilities:				
Derivatives	\$ 1,376	\$ -	\$ -	\$ 1,376

NOTE 4 – INVENTORIES

Inventory balances were as follows:

	As of June 30, 2024	As of December 31, 2023
Raw materials	\$ 313,847	\$ 239,998
Work-in-process	-	-
Finished goods	254,368	254,376
Total	<u>\$ 568,215</u>	<u>\$ 494,374</u>

NOTE 5 – PROPERTY AND EQUIPMENT

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

	As of June 30, 2024	As of December 31, 2023
Computers, software, and office equipment	\$ 481,314	\$ 480,882
Leasehold improvements	506,162	506,162
Laboratory equipment	3,605,304	3,670,097
Warehouse and manufacturing equipment	139,763	133,285
Demo equipment	31,554	31,554
Total	<u>4,764,097</u>	<u>4,821,980</u>
Less: Accumulated depreciation	<u>(3,853,886)</u>	<u>(3,588,070)</u>
Total Property and equipment, net	<u>\$ 910,211</u>	<u>\$ 1,233,910</u>

Depreciation expense, recorded within general and administrative expenses, was \$157,302 and \$173,100 for the three months ended June 30, 2024, and 2023, respectively, and \$313,004 and \$404,289 during the six months ended June 30, 2024, and 2023, respectively.

No impairment charges related to property and equipment were incurred during the six months ended June 30, 2024. Due to changes in its future projected cash flows, the Company prepared an undiscounted cash flow for its Birmingham asset group as of June 30, 2023, as required under ASC 360 and determined the carrying amount of the asset group exceeded its estimated undiscounted future cash flows. The Company determined the fair value of the Birmingham asset group using replacement cost and market approaches based on the in-exchange value. The Company recognized an impairment loss of \$162,905 of its property and equipment in the Birmingham operating segment during the second quarter of 2023.

NOTE 6 – INTANGIBLE ASSETS

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

	As of June 30, 2024			As of December 31, 2023		
	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount
Patents & Trademarks	\$ 535,096	\$ (296,365)	\$ 238,731	\$ 535,096	\$ (282,639)	\$ 252,457

Finite-lived intangible assets are amortized over their estimated useful lives. Amortization expense, recorded within general and administrative expenses, was \$6,863 and \$7,035 during the three months ended June 30, 2024, and 2023, respectively, and \$13,726 and \$13,700 during the six months ended June 30, 2024, and 2023, respectively.

Accumulated amortization is included in Intangibles, net in the condensed consolidated balance sheets.

The following table outlines the estimated future amortization expense related to intangible assets held as of June 30, 2024:

Year Ending December 31,	Expense
Remainder of 2024	\$ 13,726
2025	27,451
2026	27,451
2027	27,451
2028	27,451
Thereafter	115,201
Total	<u>\$ 238,731</u>

The Company reviews finite-lived intangible assets for impairment in accordance with ASC 360, whenever events or changes in circumstances indicate the carrying amount may not be recoverable. Events or changes in circumstances that indicate the carrying amount may not be recoverable include, but are not limited to, a significant change in the medical device marketplace and a significant adverse change in the business climate in which the Company operates. No impairment charges related to finite-lived intangible assets were incurred during the six months ended June 30, 2024, and 2023.

NOTE 7 – LEASES

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

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

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

Lease expense under operating lease arrangements, recorded within general and administrative expenses, was \$227,762 and \$220,847 for the three months ended June 30, 2024, and 2023, respectively, and \$455,403 and \$434,862 for the six months ended June 30, 2024, and 2023, respectively.

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

	<u>June 30, 2024</u>	<u>June 30, 2023</u>
Weighted average remaining lease term – operating leases in years	3.53	4.46
Weighted average discount rate – operating leases	12%	12%

The Company's operating lease obligations as of June 30, 2024, which include expected lease extensions that are reasonably certain of renewal, were as follows:

Remainder of 2024	\$	375,487
2025		857,622
2026		803,724
2027		827,909
2028		139,022
Total lease payments		<u>3,003,764</u>
Less: interest		(581,069)
Present value of lease liabilities	\$	<u><u>2,422,695</u></u>

NOTE 8 – NOTE PAYABLE

In June 2023, the Company purchased director and officer insurance policies with a policy period ending June 2024. In July 2023, the Company financed \$364,721 of its total premium by entering into a note payable with a finance provider that required ten monthly installment payments through April 2024. The note was secured by a first priority lien on the financed policies. The short-term note bore interest at an annual percentage rate of 9.25% over the life of the note. As of December 31, 2023, the outstanding balance of the note was \$150,408 including interest. As of June 30, 2024, there was no outstanding balance on the note.

In June 2024, the Company purchased director and officer insurance policies with a policy period ending June 2025 and financed \$275,098 of its total premium by entering into a note payable with a finance provider that required ten monthly installment payments through April 2025. The note was secured by a first priority lien on the financed policies. The short-term note bore interest at an annual percentage rate of 8.00% over the life of the note. As of June 30, 2024, the outstanding balance of the note was \$276,932 including interest.

NOTE 9 – DERIVATIVES

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

The fair value of the placement agent warrants issued in connection with the March 2020 private placement was determined to be \$0 and \$135 as of June 30, 2024, and December 31, 2023, respectively. The Company recorded gains on the change in fair value of the placement agent warrants of \$13 and \$1,900 during the three months ended June 30, 2024, and 2023, respectively, and \$135 and \$2,319 during the six months ended June 30, 2024, and 2023, respectively. The placement agent warrants expire in March 2025.

The fair value of the placement agent warrants issued in connection with the May 2020 offering of securities was determined to be \$0 and \$333 as of June 30, 2024, and December 31, 2023, respectively. The Company recorded gains on the change in fair value of the placement agent warrants of \$57 and \$2,435 during the three months ended June 30, 2024, and 2023, respectively, and \$333 and \$2,770 during the six months ended June 30, 2024, and 2023, respectively. The placement agent warrants expire in May 2025.

The placement agent warrants issued in connection with the June 2020 warrant exercise and issuance had a fair value of \$8 and \$908 as of June 30, 2024, and December 31, 2023, respectively. The Company recorded gains on the change in fair value of the placement agent warrants of \$289 and \$2,973 during the three months ended June 30, 2024, and 2023, respectively, and \$900 and \$3,172 during the six months ended June 30, 2024, and 2023, respectively. The placement agent warrants expire in June 2025.

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

Derivative liability balance as of December 31, 2022	\$ 13,833
(Gain) recognized to revalue derivative instrument at fair value	(953)
Derivative liability balance as of March 31, 2023	\$ 12,880
(Gain) recognized to revalue derivative instrument at fair value	(7,308)
Derivative liability balance as of June 30, 2023	\$ 5,572
Derivative liability balance as of December 31, 2023	\$ 1,376
(Gain) recognized to revalue derivative instrument at fair value	(1,009)
Derivative liability balance as of March 31, 2024	\$ 367
(Gain) recognized to revalue derivative instrument at fair value	(359)
Derivative liability balance as of June 30, 2024	\$ 8

NOTE 10 – STOCKHOLDERS' EQUITY, STOCK OPTIONS AND WARRANTS

Series F Preferred Stock Dividend and Reverse Stock Split

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

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

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

Redemption of Series F Preferred Stock

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

At The Market Offering

On May 3, 2024, the Company entered into an ATM Sales Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), to sell shares of the Company's common stock, par value \$0.01 per share (the "Shares"), having an aggregate sales price of up to \$3,696,000, from time to time, through an "at the market offering" program pursuant to which Wainwright will act as sales agent. Subject to the terms and conditions of the Sales Agreement, Wainwright is permitted to sell the Shares by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Sales Agreement provides that Wainwright will be entitled to compensation for its services of 3.0% of the gross sales price of all shares sold through Wainwright under the Sales Agreement. As of June 30, 2024, the Company has sold 1,607,100 shares of common stock at an average price of approximately \$2.30 per share, resulting in aggregate gross proceeds of approximately \$3,696,000.

Equity Incentive Plan

The Company's Amended and Restated 2012 Stock Incentive Plan (the "2012 Plan") allows for the issuance of incentive and non-qualified stock options, stock appreciation rights, stock awards, restricted stock, restricted stock units ("RSUs") and performance awards to employees, directors, and consultants of the Company, where permitted under the plan. The exercise price for each stock option is determined by the market price on the date of issuance. Vesting requirements are determined by the Board of Directors when granted and currently range from immediate to three years. Options outstanding under this plan have a contractual life of ten years.

ASC 718, *Compensation – Stock Compensation* ("ASC 718"), requires that a company that issues equity as compensation record compensation expense that corresponds to the estimated cost of those equity grants. ASC 718 requires companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model or other acceptable means.

Valuation and Accounting for Stock Options and Warrants

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

During the three and six months ended June 30, 2024, there were no options or warrants granted. The fair value of each stock option grant was estimated on the grant date using the Black-Scholes option valuation model with the following assumptions:

	Six Months Ended June 30,	
	2024	2023
	Stock Options	
Expected dividend yield	-	0.0%
Expected stock price volatility	-	90.8% -91.6%
Risk-free interest rate	-	3.38% -3.72%
Expected life (in years)	-	10

Stock Options and Warrants Granted by the Company

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

	Stock Options		Warrants	
	Number of Shares	Average Exercise Price	Number of Shares	Average Exercise Price
Outstanding as of December 31, 2023	47,664	\$ 82.23	1,806,589	\$ 21.52
Issued	-	-	-	-
Forfeited	(233)	4.67	-	-
Expired	(1,019)	105.99	(77,285)	33.86
Outstanding as of June 30, 2024	46,412	\$ 82.09	1,729,304	\$ 20.97

Stock-based compensation expense, net of forfeitures, recognized for the three months ended June 30, 2024, and 2023, was \$307 and \$5,872, respectively. Stock-based compensation expense, net of forfeitures, recognized for the six months ended June 30, 2024, and 2023, was \$1,040 and \$15,159, respectively. Stock-based compensation expense is recorded within each of the captions comprising Operating expenses. The Company has \$182 of unrecognized compensation expense related to unvested stock options that is expected to be recognized over the next 10 months.

NOTE 11 – LOSS PER SHARE

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
Net (loss) attributable to common stockholders: basic and diluted calculation	\$ (3,181,261)	\$ (3,923,368)	\$ (7,400,104)	\$ (7,345,170)
Denominator:				
Weighted average common shares outstanding - basic	4,664,771	3,996,512	4,363,812	3,982,384
Effect of diluted stock options, warrants, and preferred stock (1)	-	-	-	-
Weighted average common shares outstanding - diluted	4,664,771	3,996,512	4,363,812	3,982,384
(Loss) per common share - basic and diluted	\$ (0.68)	\$ (0.98)	\$ (1.70)	\$ (1.84)

- (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:

	Three and Six Months Ended June 30,	
	2024	2023
Options	46,412	48,037
RSUs	-	2,500
Warrants	1,729,304	1,812,379
Preferred stock: Series B	16	16

NOTE 12 – SEGMENTS

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

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

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

All revenues are earned from external customers.

The tables below summarize the Company’s segment reporting as of June 30, 2024, and December 31, 2023, and for the three and six months ended June 30, 2024, and 2023.

	Three Months Ended June 30, 2024				
	Pittsburgh	Birmingham	Eagan	Corporate	Total
Revenue	\$ 67,255	\$ 20,813	\$ 190,654	\$ -	\$ 278,722
Depreciation and amortization	(31,408)	(123,714)	(7,224)	(1,819)	(164,165)
Segment loss	\$ (1,010,978)	\$ (459,012)	\$ (265,580)	\$ (1,445,691)	\$ (3,181,261)

	Six Months Ended June 30, 2024				
	Pittsburgh	Birmingham	Eagan	Corporate	Total
Revenue	\$ 72,113	\$ 31,822	\$ 594,433	\$ -	\$ 698,368
Depreciation and amortization	(63,505)	(244,508)	(15,047)	(3,670)	(326,730)
Segment loss	\$ (2,207,043)	\$ (924,174)	\$ (455,156)	\$ (3,813,731)	\$ (7,400,104)

	June 30, 2024				
	Pittsburgh	Birmingham	Eagan	Corporate	Total
Assets	\$ 2,968,289	\$ 696,017	\$ 1,140,234	\$ 5,782,586	\$ 10,587,126

Three Months Ended June 30, 2023

	Pittsburgh	Birmingham	Eagan	Corporate	Total
Revenue	\$ 13,844	\$ 84,880	\$ 391,386	\$ -	\$ 490,110
Depreciation and amortization	(31,945)	(136,194)	(9,973)	(2,023)	(180,135)
Segment loss	\$ (1,594,587)	\$ (585,443)	\$ (281,687)	\$ (1,461,651)	\$ (3,923,368)

Six Months Ended June 30, 2023

	Pittsburgh	Birmingham	Eagan	Corporate	Total
Revenue	\$ 24,471	\$ 98,529	\$ 607,005	\$ -	\$ 730,005
Depreciation and amortization	(143,767)	(253,794)	(16,751)	(3,677)	(417,989)
Segment loss	\$ (2,753,692)	\$ (1,068,139)	\$ (567,084)	\$ (2,956,255)	\$ (7,345,170)

December 31, 2023

	Pittsburgh	Birmingham	Eagan	Corporate	Total
Assets	\$ 3,263,270	\$ 981,914	\$ 1,390,031	\$ 8,782,034	\$ 14,417,249

NOTE 13 – SUBSEQUENT EVENTS**Warrant Inducement Transaction**

On July 25, 2024, the Company entered into definitive agreements with certain of its existing warrant holders for the exercise of warrants to purchase an aggregate of 958,117 shares of its common stock having a current exercise price of \$14.00 originally issued in February 2021, June 2021 and May 2022, at a reduced exercise price of \$1.32 per share. The gross proceeds to the Company from the exercise of the existing warrants were approximately \$1.26 million, prior to deducting placement agent fees and transaction expenses payable by the Company.

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

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

Strategic Cost Savings Initiative

On July 25, 2024, the Company’s Board of Directors approved a plan to implement a strategic cost savings initiative, primarily related to the consolidation of the operations of the Company’s Birmingham laboratory into its Pittsburgh laboratory. The Company began implementing the cost savings initiative in August 2024 and continues to review its progress and effectiveness, including the impact of the changes on the Company’s operating segments and the full financial effect on our consolidated financial statements.

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, 2023.

This Quarterly Report on Form 10-Q contains “forward-looking statements” that are management’s present expectations of future events. Actual results could differ materially and adversely from those anticipated in such forward-looking statements as a result of certain factors, including but not limited to those set forth below and elsewhere in this report, many of which are beyond our control. Important factors that may cause actual results to differ from forward-looking statements include:

- Our ability to continue operating beyond twelve months without additional financing;
- Continued negative operating cash flows;
- Our capital needs to accomplish our goals, including any further financing, which may be highly dilutive and may include onerous terms;
- Risks related to recent and future acquisitions, including risks related to the benefits and costs of acquisition;
- Risks related to our partnerships with other companies, including the need to negotiate the definitive agreements; possible failure to realize anticipated benefits of these partnerships; and costs of providing funding to our partner companies, which may never be repaid or provide anticipated returns;
- Risks related to the initiation, formation, or success of our collaboration arrangements, commercialization activities and product sales levels by our collaboration partners and future payments that may come due to us under these arrangements,
- Risk that we will be unable to protect our intellectual property or claims that we are infringing on others’ intellectual property;
- The impact of competition;
- Acquisition and maintenance of any necessary regulatory clearances applicable to applications of our technology;
- Inability to attract or retain qualified senior management personnel, including sales and marketing personnel;
- Risk that we never become profitable if our products and services are not accepted by potential customers;
- Possible impact of government regulation and scrutiny;
- Unexpected costs and operating deficits, and lower than expected sales and revenues, if any;
- Adverse results of any legal proceedings;
- The volatility of our operating results and financial condition,
- Management of growth;
- Risk that our business and operations could be materially and adversely affected by disruptions caused by economic and geopolitical uncertainties as well as epidemics or pandemics; and
- Other specific risks that may be alluded to in this report.

All statements, other than statements of historical facts, included in this report regarding our growth strategy, future operations, financial position, estimated revenue or losses, projected costs, prospects and plans, and objectives of management are forward-looking statements. When used in this report, the words “will,” “may,” “believe,” “anticipate,” “intend,” “estimate,” “expect,” “project,” “plan,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain such identifying words. All forward-looking statements speak only as of the date of this report. We do not undertake any obligation to update any forward-looking statements or other information contained herein. Potential investors should not place undue reliance on these forward-looking statements. Although we believe that our plans, intentions, and expectations reflected in or suggested by the forward-looking statements in this report are reasonable, we cannot assure potential investors that these plans, intentions or expectations will be achieved. We disclose important factors that could cause actual results to differ materially from expectations in the “Risk Factors” section and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2023, 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.

Overview

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

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

We operate in three business areas. In our first area, we provide optimized, high-confidence drug-response predictions through the application of AI using our proprietary biobank of tumor samples to enable a more informed selection of drug/tumor combinations and increase the probability of success during development. We also create and develop tumor-specific 3D cell culture models mimicking the physiological environment of human tissue enabling better-informed decision-making during development. In our second business area, we provide services and research using a proprietary self-contained and automated system that conducts high-throughput, self-interaction chromatography screens using additives and excipients commonly included in protein formulations resulting in soluble and physically stable formulations of biologics. Our third business area produces the United States Food and Drug Administration (“FDA”)-cleared STREAMWAY® System and associated products for automated medical fluid waste management and patient-to-drain medical fluid disposal.

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

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

On July 25, 2024, our board of directors approved a plan to implement a strategic cost savings initiative, primarily related to the consolidation of the operations of our Birmingham laboratory into our Pittsburgh laboratory. We began implementing the cost savings initiative in August 2024 and continue to review its progress and effectiveness, including the impact of the changes on our operating segments as described immediately above. In particular, we anticipate that our three segments will be reduced to two in future reporting periods with the closure of our Birmingham laboratory. The initiative is expected to reduce the Company’s run rate for cash used in operating activities by approximately 20% annually when fully implemented in Q4 2024.

Capital Requirements

Since inception, we have been unprofitable. We incurred net losses of \$7,400,104 and \$7,345,170 for the six months ended June 30, 2024, and 2023, respectively. As of June 30, 2024, and December 31, 2023, we had an accumulated deficit of \$175,161,987 and \$167,761,883, respectively.

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

Our future cash requirements and the adequacy of available funds depend on our ability to generate revenues from our oncology businesses located in Pittsburgh and Birmingham; our ability to continue to sell our Skyline Medical products and services and to reach profitability in all our businesses; and the availability of future financing to fulfill our business plans. See “Liquidity and Capital Resources – Liquidity and Plan of Financing; Going Concern” below.

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

Results of Operations

Comparison of three and six months ended June 30, 2024, and 2023

	Three Months Ended June 30,			Six Months Ended June 30,		
	2024	2023	Difference	2024	2023	Difference
Revenue	\$ 278,722	\$ 490,110	\$ (211,388)	\$ 698,368	\$ 730,005	\$ (31,637)
Cost of sales	152,968	159,761	\$ 6,793	340,383	279,900	(60,483)
General and administrative expense	2,137,189	2,704,527	\$ 567,338	4,764,265	5,040,511	276,246
Operations expense	893,391	993,042	\$ 99,651	1,995,584	1,871,560	(124,024)
Sales and marketing expense	284,421	429,103	\$ 144,682	1,024,155	799,340	(224,815)

Revenue. We recorded revenue of \$278,722 and \$490,110 in the three months ended June 30, 2024, and 2023, respectively. Revenue in the three months ended June 30, 2024, and 2023, was primarily derived from the Eagan operating segment. The decrease in revenue from the comparative period was primarily due to a change in sales mix with decreased sales of STREAMWAY systems in the three months ended June 30, 2024.

We recorded revenue of \$698,368 and \$730,005 in the six months ended June 30, 2024, and 2023, respectively. Revenue in the six months ended June 30, 2024, was primarily derived from the Eagan operating segment. The decrease in revenue from the comparative period was primarily due to a change in sales mix with decreased sales related to biologics in our Birmingham operating segment during the six months ended June 30, 2024.

Cost of sales. Cost of sales was \$152,968 and \$159,761 in the three months ended June 30, 2024, and 2023, respectively. The gross profit margin was approximately 45% and 67% in the three months ended June 30, 2024, and 2023, respectively. The decline in gross profit margin for the three months ended June 30, 2024, was primarily due to increased labor costs and a change in sales mix with decreased sales of STREAMWAY systems.

Cost of sales was \$340,383 and \$279,900 in the six months ended June 30, 2024, and 2023, respectively. The gross profit margin was approximately 51% and 62% in the six months ended June 30, 2024, and 2023, respectively. The decline in gross profit margin for the six months ended June 30, 2024, was primarily due to increased labor costs.

General and administrative expense. General and administrative (“G&A”) expense primarily consists of management salaries, professional fees, consulting fees, administrative fees, and general office expenses. G&A expense decreased by \$567,338 to \$2,137,189 in the three months ended June 30, 2024, compared to \$2,704,527 in the comparable period in 2023. The decrease was primarily due to decreased employee compensation and decreased investor relations costs, offset by increased consultant fees.

G&A expense decreased by \$276,246 to \$4,764,265 in the six months ended June 30, 2024, compared to \$5,040,511 in the comparable period in 2023. The decrease was primarily due to decreased employee compensation and decreased investor relations costs, offset by increased audit fees and consultant fees.

Operations expense. Operations expense primarily consists of expenses related to product development and prototyping and testing. Operations expense decreased by \$99,651 to \$893,391 in the three months ended June 30, 2024 compared to \$993,042 in the comparable period in 2023. The decrease was primarily due to decreased cloud computing expenses related to our Pittsburgh operating segment.

Operations expense increased by \$124,024 to \$1,995,584 in the six months ended June 30, 2024, compared to \$1,871,560 in the comparable period in 2023. The increase was primarily due to higher employee compensation.

Sales and marketing expense. Sales and marketing expenses consist of expenses required to market and sell our products including staff-related expenses for individuals performing this work. Sales and marketing expense decreased by \$144,682 to \$284,421 in the three months ended June 30, 2024, compared to \$429,103 in the comparable period in 2023. The decrease was primarily due to lower employee compensation including sales commissions.

Sales and marketing expense increased by \$224,815 to \$1,024,155 in the six months ended June 30, 2024, compared to \$799,340 in the comparable period in 2023. The increase was primarily due to severance related to a former executive.

Loss on impairment of property and equipment. We recorded no losses on impairment of property and equipment during the three and six months ended June 30, 2024. We recorded a loss on impairment of property and equipment of \$162,905 during the three and six months ended June 30, 2023. We prepared an undiscounted cash flow for our Birmingham asset group as of June 30, 2023, to evaluate long-lived assets, then completed a fair value assessment which resulted in the impairment and allocated the impairment to the assets of the affected asset group. Please see *Note 5 – Property and Equipment* to our unaudited condensed consolidated financial statements for further information.

Other income. We earned other income of \$9,461 during the three months ended June 30, 2024, compared to \$28,552 in the comparable period in 2023. We earned other income of \$28,118 during the six months ended June 30, 2024, compared to \$70,780 in the comparable period in 2023. Other income in all periods primarily consisted of interest income.

Other expense. We incurred other expense of \$1,834 during the three months ended June 30, 2024, compared to no other expense in the comparable period in 2023. We incurred other expense of \$3,571 during the six months ended June 30, 2024, compared to no other expense in the comparable period in 2023. Other expense in 2024 consisted primarily of interest expense.

Gain on derivative instruments. We recorded a gain of \$359 in the three months ended June 30, 2024, compared to \$7,308 in the comparable period in 2023. We recorded a gain of \$1,368 in the six months ended June 30, 2024, compared to \$8,261 in the comparable period in 2023. These gains related to the change in fair value of the derivative.

Liquidity and Capital Resources

Cash Flows

Net cash used in operating activities was \$6,634,072 and \$7,002,033 for the six months ended June 30, 2024, and 2023, respectively. Cash used in operating activities decreased in the 2024 period primarily because of changes in working capital.

Net cash used in investing activities was \$9,510 and \$305,745 for the six months ended June 30, 2024, and 2023, respectively. Cash used in investing activities decreased in the 2024 period primarily due to a decrease in fixed asset purchases during the six months ended June 30, 2024, as compared to the same period in 2023.

Net cash provided by financing activities was \$3,246,692 and \$0 for the six months ended June 30, 2024, and 2023, respectively. The cash provided in the six months ended June 30, 2024, was primarily due to proceeds from the issuance of common stock pursuant to the ATM offering completed in May 2024.

Liquidity and Plan of Financing; Going Concern

We have incurred significant and recurring losses from operations for the past several years and, as of June 30, 2024, had an accumulated deficit of \$175,161,987. We had cash and cash equivalents of \$5,331,770 as of June 30, 2024, and need to raise significant additional capital to meet our operating needs. We had short-term obligations of \$4,618,511 and long-term operating lease obligations of \$1,860,983 as of June 30, 2024. We do not expect to generate sufficient operating revenue to sustain our operations in the near term. During the six months ended June 30, 2024, we incurred negative cash flows from operations of \$6,634,072. Although we have attempted to improve our cash flows from operations by bolstering revenues and continue to seek ways to generate revenue through business development activities, there is no guarantee that we will be able to improve our cash flows from operations sufficiently or achieve profitability in the near term. As a result of these conditions, substantial doubt exists about our ability to continue as a going concern within one year after the date our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q are issued.

We are evaluating alternatives to obtain the required additional funding to maintain future operations. These alternatives may include, but are not limited to, equity financing, issuing debt, entering into other financing arrangements, or monetizing operating businesses or assets. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing stockholders or that result in our existing stockholders losing part or all of their investment. Despite these potential sources of funding, we may be unable to access financing or obtain additional liquidity when needed or under acceptable terms, if at all. If such financing or adequate funds from operations are not available, we would be forced to limit our business activities and we could default on existing payment obligations, which would have a material adverse effect on our financial condition and results of operations, and may ultimately be required to cease our operations and liquidate our business. Our condensed consolidated financial statements as of and for the three and six months ended June 30, 2024, included in this Quarterly Report on Form 10-Q, have been prepared assuming we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

Financing Transactions

We have primarily funded our operations through a combination of debt and equity instruments including short-term borrowings, and a variety of debt and equity offerings. We have no off-balance sheet transactions.

On May 3, 2024, the Company entered into an ATM Sales Agreement (the “Sales Agreement”) with H.C. Wainwright & Co., LLC (“Wainwright”), to sell shares of the Company’s common stock, par value \$0.01 per share (the “Shares”), having an aggregate sales price of up to \$3,696,000, from time to time, through an “at the market offering” program pursuant to which Wainwright will act as sales agent. Subject to the terms and conditions of the Sales Agreement, Wainwright is permitted to sell the Shares by methods deemed to be an “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Sales Agreement provides that Wainwright will be entitled to compensation for its services of 3.0% of the gross sales price of all shares sold through Wainwright under the Sales Agreement. As of June 30, 2024, the Company has sold 1,607,100 shares of common stock at an average price of approximately \$2.30 per share, resulting in aggregate gross proceeds of approximately \$3,696,000.

There were no financing transactions during the six months ended June 30, 2023.

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.

Management, with the participation of our Chief Executive Officer and Interim Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as of June 30, 2024. Based on that evaluation, our Chief Executive Officer and Interim Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective as of June 30, 2024.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the six months ended June 30, 2024, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities from time to time. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially affect our results of operations, cash flows or financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management attention and resources and other factors.

Based on information readily available, as of the end of the period covered by this Quarterly Report on Form 10-Q, there are no pending legal proceedings that, in the opinion of management, are likely to result in a material adverse effect on our financial position, results of operations or cash flows.

ITEM 1A. RISK FACTORS

As of the date of this Quarterly Report on Form 10-Q, there have been no material changes to our risk factors from those disclosed under “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 28, 2024.

In addition to the information set forth in this 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, 2023, 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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the six months ended June 30, 2024, there were no sales of our securities that were not registered under the Securities Act.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
<u>31.1*</u>	<u>Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>31.2*</u>	<u>Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>32.1**</u>	<u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith

** Furnished herewith

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: August 13, 2024

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

Date: August 13, 2024

By: /s/ Josh Blacher
Josh Blacher
Interim Chief Financial Officer

**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: August 13, 2024

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

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

I, Josh Blacher, 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: August 13, 2024

/s/ Josh Blacher

Josh Blacher

Interim Chief Financial Officer

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 June 30, 2024 as filed with the Securities and Exchange Commission (the "Report"), I, Raymond F. Vennare, Chief Executive Officer (Principal Executive Officer) and, I, Josh Blacher, Interim Chief Financial Officer (Principal Financial Officer) of the Company, hereby certify as of the date hereof, solely for purposes of § 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1350, that to the best of my knowledge:

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

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

Date: August 13, 2024

/s/ Raymond F. Vennare

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

Date: August 13, 2024

/s/ Josh Blacher

Josh Blacher
Interim Chief Financial Officer
(Principal Financial Officer)