

# 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, 2023

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-36790

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

<u>Delaware</u>	<u>33-1007393</u>
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
<u>91 43rd Street, Suite 110 Pittsburgh, Pennsylvania</u>	<u>15201</u>
(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 <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input checked="" type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
	Emerging growth company <input type="checkbox"/>

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 6, 2023, the registrant had 4,063,081 shares of common stock, par value \$0.01 per share outstanding. On April 24, 2023, the registrant effected a 1-for-20 reverse stock split. All share amounts and references to stock prices, except par value, have been retroactively restated to reflect the reverse split.

PREDICTIVE ONCOLOGY INC.

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**PART 1. FINANCIAL INFORMATION**

**Item 1. Condensed Consolidated Financial Statements**

**PREDICTIVE ONCOLOGY INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(Unaudited)**

	September 30, 2023	December 31, 2022
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 11,915,048	\$ 22,071,523
Accounts receivable	544,756	331,196
Inventories	439,989	430,493
Prepaid expense and other assets	620,692	526,801
Total current assets	<u>13,520,485</u>	<u>23,360,013</u>
Property and equipment, net	1,392,681	1,833,255
Intangibles, net	259,320	253,865
Lease right-of-use assets	2,870,286	211,893
Other long-term assets	124,096	75,618
Total assets	<u>\$ 18,166,868</u>	<u>\$ 25,734,644</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,168,226	\$ 943,452
Note payable	260,220	-
Accrued expenses and other liabilities	1,810,838	2,229,075
Derivative liability	2,109	13,833
Contract liabilities	374,957	602,073
Lease liability	555,541	94,237
Total current liabilities	<u>4,171,891</u>	<u>3,882,670</u>
Lease liability – net of current portion	2,343,622	86,082
Total liabilities	<u>6,515,513</u>	<u>3,968,752</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 20,000,000 shares authorized inclusive of designated below		
Series B Convertible Preferred Stock, \$.01 par value, 2,300,000 shares authorized, 79,246 shares outstanding as of September 30, 2023 and December 31, 2022	792	792
Common stock, \$.01 par value, 200,000,000 shares authorized, 4,033,293 and 3,938,160 shares outstanding as of September 30, 2023 and December 31, 2022, respectively	40,333	39,382
Additional paid-in capital	175,896,766	175,503,634
Accumulated deficit	<u>(164,286,536)</u>	<u>(153,777,916)</u>
Total stockholders' equity	<u>11,651,355</u>	<u>21,765,892</u>
Total liabilities and stockholders' equity	<u>\$ 18,166,868</u>	<u>\$ 25,734,644</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	\$ 715,056	\$ 455,827	\$ 1,445,061	\$ 1,141,986
Cost of goods sold	106,940	108,151	386,840	351,669
Gross margin	608,116	347,676	1,058,221	790,317
General and administrative expense	2,583,574	3,287,918	7,624,085	8,063,265
Operations expense	842,579	857,130	2,714,139	2,657,314
Sales and marketing expense	336,043	333,377	1,135,383	908,867
Loss on impairment of goodwill	-	-	-	7,231,093
Loss on impairment of property and equipment	-	-	162,905	-
Total operating loss	(3,154,080)	(4,130,749)	(10,578,291)	(18,070,222)
Other income	47,838	63,047	118,618	146,524
Other expense	(60,671)	(2,001)	(60,671)	(5,207)
Gain on derivative instruments	3,463	10,219	11,724	107,381
Net loss	<u>\$ (3,163,450)</u>	<u>\$ (4,059,484)</u>	<u>\$ (10,508,620)</u>	<u>\$ (17,821,524)</u>
Net loss per common share – basic and diluted	\$ (0.78)	\$ (1.04)	\$ (2.63)	\$ (4.95)
Weighted average shares used in computation – basic and diluted	4,031,356	3,919,203	3,998,887	3,602,515

See accompanying notes to unaudited condensed consolidated financial statements.

PREDICTIVE ONCOLOGY INC.  
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
FOR THE THREE AND NINE MONTHS ENDED  
SEPTEMBER 30, 2023  
(Unaudited)

	Series B Preferred		Series F Preferred		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Paid-In Capital	Deficit	
<b>Balance at 12/31/2022</b>	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, net of forfeitures	-	-	-	-	-	-	9,287	-	9,287
Series F Preferred Stock dividend	-	-	79,404	794	-	-	(794)	-	-
Net loss	-	-	-	-	-	-	-	(3,421,802)	(3,421,802)
<b>Balance at 03/31/2023</b>	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, net of forfeitures	-	-	-	-	-	-	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)
<b>Balance at 06/30/2023</b>	79,246	\$ 792	-	\$ -	4,006,301	\$ 40,063	\$175,787,288	\$(161,123,086)	\$14,705,057
Shares issued to consultants and others	-	-	-	-	25,835	258	125,299	-	125,557
Vesting expense, net of forfeitures	-	-	-	-	-	-	(14,300)	-	(14,300)
Shares issued to management for vesting of restricted stock units, net of repurchase to cover withholding tax	-	-	-	-	1,157	12	(1,521)	-	(1,509)
Net loss	-	-	-	-	-	-	-	(3,163,450)	(3,163,450)
<b>Balance at 09/30/2023</b>	79,246	\$ 792	-	\$ -	4,033,293	\$ 40,333	\$175,896,766	\$(164,286,536)	\$11,651,355

See accompanying notes to unaudited 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	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-In Capital	Deficit	
<b>Balance at 12/31/2021</b>	79,246	\$ 792	3,280,750	\$ 32,808	\$168,272,366	\$(128,040,282)	\$ 40,265,684
Shares issued pursuant to equity line	-	-	6,000	60	86,825	-	86,885
Shares issued to consultants and others	-	-	8,595	86	162,036	-	162,122
Vesting expense, net of forfeitures	-	-	-	-	36,518	-	36,518
Net loss	-	-	-	-	-	(3,370,715)	(3,370,715)
<b>Balance at 03/31/2022</b>	79,246	\$ 792	3,295,345	\$ 32,954	\$168,557,745	\$(131,410,997)	\$ 37,180,494
Issuance of shares and warrants pursuant to May 2022 Private Offering	-	-	600,000	6,000	6,501,050	-	6,507,050
Shares issued pursuant to Equity Line	-	-	9,750	98	149,026	-	149,124
Shares issued to consultants and others	-	-	2,684	27	50,643	-	50,670
Vesting expense, net of forfeitures	-	-	-	-	39,383	-	39,383
Net loss	-	-	-	-	-	(10,391,324)	(10,391,324)
<b>Balance at 06/30/2022</b>	79,246	\$ 792	3,907,779	\$ 39,079	\$175,297,847	\$(141,802,321)	\$ 33,535,397
Shares issued to consultant & other	-	-	11,461	115	93,885	-	94,000
Vesting expense, net of forfeitures	-	-	1,157	12	22,953	-	22,965
Net loss	-	-	-	-	-	(4,059,484)	(4,059,484)
<b>Balance at 09/30/2022</b>	79,246	\$ 792	3,920,397	\$ 39,206	\$175,414,685	\$(145,861,805)	\$ 29,592,878

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<b>Nine Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Cash flow from operating activities:		
Net loss	\$ (10,508,620)	\$ (17,821,524)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	580,976	980,381
Vesting expense	859	102,894
Common stock issued for consulting and other	204,839	306,792
Gain on valuation of equity-linked instruments and derivative liability	(11,724)	(107,381)
Loss on impairment of goodwill	-	7,231,093
Loss on impairment of property and equipment	162,905	-
Loss on property and equipment disposal	903	1,700
Changes in assets and liabilities:		
Accounts receivable	(213,560)	29,488
Inventories	(9,496)	(106,038)
Prepaid expense and other assets	(142,369)	(39,928)
Accounts payable	224,774	(104,503)
Accrued expenses	(169,401)	476,035
Contract liabilities	(227,116)	(64,889)
Other long-term liabilities	-	(19,932)
Net cash used in operating activities:	(10,107,030)	(9,135,812)
Cash flow from investing activities:		
Purchase of property and equipment	(283,648)	(361,916)
Acquisition of intangibles	(26,018)	(50,180)
Net cash used in investing activities:	(309,666)	(412,096)
Cash flow from financing activities:		
Proceeds from issuance of common stock and warrants, net	-	6,507,050
Proceeds from issuance of common stock pursuant to equity line	-	236,009
Repurchase of common stock upon vesting of restricted stock units	-	(4,028)
Proceeds from note payable	364,721	-
Repayment of note payable	(104,500)	-
Net cash provided by financing activities	260,221	6,739,031
Net increase (decrease) in cash and cash equivalents	(10,156,475)	(2,808,877)
Cash and cash equivalents at beginning of period	22,071,523	28,202,615
Cash and cash equivalents at end of period	\$ 11,915,048	\$ 25,393,738
Supplemental disclosure for cash flow information:		
Cash payments for interest	\$ 9,608	\$ 3,754
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 board compensation	189,896	-
Redemption of Series F Preferred Stock	(794)	-
Common stock issued in connection with reverse stock split	253	-
Common stock issued to management upon vesting of restricted stock units	4,934	-

See accompanying notes to unaudited condensed consolidated financial statements.

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

**NOTE 1 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Nature of Operations and Going Concern**

Predictive Oncology Inc. ("Predictive Oncology") is a knowledge-driven company focused on applying artificial intelligence ("AI") to support the development of optimal cancer therapies, which can ultimately lead to more effective treatments and improved patient outcomes. Through AI, Predictive Oncology uses 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.

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

The Company has determined that it will focus its resources on applying AI to support the development of optimal cancer therapies, partnering with biopharma clients to help prioritize drugs for development and identify biomarker-informed indications. Its platform provides a more informed decision tool to select optimal drug/tumor combinations to increase the probability of success during drug development. As a result of this focused approach, the Company has consolidated its brand under the Predictive Oncology name. Going forward, the Company will operate under the Predictive Oncology tradename with laboratory operations in Pittsburgh, Pennsylvania and Birmingham, Alabama. As of January 1, 2023, the Company has changed its reportable segments because of this focused approach.

The Company has three reportable segments that have been delineated by location and specialty: the Pittsburgh segment provides services that include the application of AI using its proprietary biobank of 150,000+ cancer tumor samples. Pittsburgh also utilizes 3D culture models in drug development. The Birmingham segment provides services and research 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 of biologics focused on solubility improvements, stability studies, and protein production. The Eagan (Minnesota) segment consists of the production of the FDA-cleared STREAMWAY System for automated fluid waste management, direct-to-drain medical fluid disposal, and associated products. See *Note 12 – Segments*.

The Company has incurred significant and recurring losses from operations for the past several years and had an accumulated deficit of \$ 164,286,536 as of September 30, 2023. The Company had cash and cash equivalents of \$11,915,048 as of September 30, 2023 and needs to raise significant additional capital to meet its operating needs. The Company's short-term obligations as of September 30, 2023 were \$4,171,891, consisting primarily of aggregate accounts payable and accrued expenses of \$2,979,064 and operating lease obligations of \$555,541. As of September 30, 2023, the Company also had a short-term note payable of \$260,220 that bears interest at an annual percentage rate of 9.25% and long-term operating lease obligations of \$2,343,622 with a weighted average remaining lease term of 4.23 years. The Company does not expect to generate sufficient operating revenue to sustain its operations in the near term. Year-to-date, the Company incurred negative cash flows from operations of \$10,107,030. These conditions raise substantial doubt about the Company's ability to continue as a going concern. 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. 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. Therefore, there is substantial doubt about the Company's ability to continue as a going concern for one year after the date that the financial statements are issued. The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business, and do not include any adjustments that might result from the outcome of this uncertainty.



## **Reverse Stock Split**

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

## **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. 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 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 21, 2023. 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.

## **Reclassifications**

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

## **Cash and Cash Equivalents**

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

## **Receivables**

Receivables are reported at the amount the Company expects to collect on balances outstanding. The Company provides for probable uncollectible amounts through charges to earnings and credits to the valuation allowance based on management's assessment of the status of individual accounts.

Amounts recorded in accounts receivable on the 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 is maintained to provide for the estimated amount of receivables that will not be collected. The Company determines the allowance based on historical experience as well as external business factors expected to impact collectability such as economic factors. The Company reviews customers' credit history before extending unsecured credit and establishes an allowance based upon factors surrounding the credit risk of specific customers, historical trends and other information. Invoices are generally due 30 days after presentation. Accounts receivable over 30 days are generally considered past due. The Company does not accrue interest on past due accounts receivables. Receivables are written off once all collection attempts have failed and are based on individual credit evaluation and specific circumstances of the customer. The allowance for accounts receivable balance was \$0 as of both September 30, 2023 and December 31, 2022.

## 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 were determined based on Level 3 inputs. The Company generally uses the Black Scholes method for determining the fair value of warrants classified as liabilities on a recurring basis. In addition, the Company uses the Monte Carlo method and other acceptable valuation methodologies when valuing the conversion feature and other embedded features classified as derivatives on a recurring basis. See *Note 2 – Fair Value Measurements* and *Note 8 – Derivatives*.

## Inventories

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

## Property and Equipment

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

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

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

Upon retirement or sale of property and equipment, the cost and related accumulated depreciation 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 values of its reporting units using discounted cash flows. To determine fair values, the Company is required to make assumptions about a wide variety of internal and external factors. Significant assumptions used in the impairment analysis include financial projections of free cash flow (including significant assumptions about operations including the rate of future revenue growth, capital requirements, and income taxes), long-term growth rates for determining terminal value and discount rates. Comparative market multiples are used to corroborate the results of the discounted cash flow test. These assumptions require significant judgement. Pursuant to ASU 2017-04, *Simplifying the Test for Goodwill Impairment*, the single step is to determine the estimated fair value of the reporting unit and compare it to the carrying value of the reporting unit, including goodwill. To the extent the carrying amount of goodwill exceeds the implied goodwill, the difference is the amount of the goodwill impairment. The Company also completes a reconciliation between the implied equity valuation prepared and the Company's market capitalization. The majority of the inputs used in the discounted cash flow model are unobservable and thus are considered to be Level 3 inputs. The inputs for the market capitalization calculation are considered Level 1 inputs. See *Note 5 – Intangible Assets*.

## Leases

At inception of a contract, a determination is made whether an arrangement meets the definition of a lease. A contract contains a lease if there is an identified asset, and the Company has the right to control the asset. Operating leases are recorded as right-of-use ("ROU") assets with corresponding current and noncurrent operating lease liabilities on our 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 similar effective dates and lease terms.

## Collaboration Arrangements

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

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

## Revenue Recognition

The Company recognizes revenue when it satisfies a performance obligation by transferring control of the promised goods or services to its customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. 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 of sales of the STREAMWAY System (i.e., hardware), as well as sales of the proprietary cleaning fluid and filters for use with the STREAMWAY System (i.e., disposables), and other related services including maintenance plans. Currently, the Company sells its medical device products directly to hospitals and other medical facilities using employed sales representatives. Purchase orders, which are governed by sales agreements in all cases, state the final terms for unit price, quantity, shipping, and payment terms. The unit price is considered the observable stand-alone selling price for the arrangements. The Company sales agreement, and Terms and Conditions, is a dually executed contract providing explicit criteria supporting the sale of the STREAMWAY System and related products and services. The Company considers the combination of a purchase order and acceptance of its Terms and Conditions to be a customer's contract in all cases.

Product sales for medical devices consist of a single performance obligation that the Company satisfies at a point in time. The Company recognizes product revenue when the following events have occurred: (1) the Company has transferred physical possession of the products, (2) the Company has a present right to payment, (3) the customer has legal title to the products, and (4) the customer bears significant risks and rewards of ownership of the products. Based on the shipping terms specified in the sales agreements and purchase orders, these criteria are generally met when the products are shipped from the Company's facilities ("FOB origin," which is the Company's standard shipping terms). As a result, the Company determined that the customer 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. 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 Eagan reportable segment.

#### *Revenue from Clinical Testing*

Clinic diagnostic testing is comprised of our Tumor Drug Response Testing ("ChemoFx") and Genomic Profiling ("BioSpeciFx") tests. The Tumor Drug Response Testing test determines how a patient's tumor specimen reacts to a panel of various chemotherapy drugs, while the Genomic Profiling test evaluates the expression and/or status of a particular gene related to a patient's tumor specimen. Revenues are recognized when control of the promised goods or services is transferred to customers, in an amount that reflects the consideration 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. Pittsburgh's payments terms vary by the agreements reached with insurance carriers and Medicare. The Company's performance obligations are satisfied at one point in time when test reports are delivered.

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

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

#### *Contract Research Organization ("CRO") and AI-Driven Business*

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 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 based on the standalone-selling price of each distinct good or service in the contract. Advance payments received in excess of revenues recognized are classified as deferred revenue until such time as the revenue recognition criteria have been met. Payment terms are net 30 from the invoice date, which is sent to the customer as the Company satisfies the performance obligation relative to the total expected inputs to the satisfaction of that performance obligation. This revenue stream is reported under the Birmingham and Pittsburgh segments.

#### *Royalty Revenue*

The Company has a collaboration arrangement that includes sales-based royalties, under which our collaboration partners are obligated to pay a royalty that is based on the net sales of their approved drugs. The Company recognizes royalty revenue when the underlying sales occur based on its best estimate of sales of the drugs. To date, the Company has not recognized revenues related to royalties earned under collaboration arrangements.

#### 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 \$544,756 and \$331,196 as of September 30, 2023 and December 31, 2022, respectively. As of December 31, 2021, accounts receivable totaled \$354,196.

The Company's contract liabilities related primarily to 3D services and maintenance plans were \$ 374,957 and \$602,073 as of September 30, 2023 and December 31, 2022, respectively. The Company recognized revenue of \$227,116 during the nine-months ended September 30, 2023 that was included in contract liabilities as of December 31, 2022. As of December 31, 2021, contract liabilities totaled \$186,951.

#### Practical Expedients

The Company has elected the practical expedient not to determine whether contracts with customers contain significant financing components as contracts are generally for less than one year, 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 grant is estimated on the grant date using the Black-Scholes option valuation model with the following assumptions:

	<b>For the nine months ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
	<b>Stock Options</b>	
Expected dividend yield	0.0%	0.0%
Expected stock price volatility	90.8% – 98.2%	86.5% – 92.2%
Risk-free interest rate	3.38% – 3.95%	1.83% – 3.43%
Expected life (years)	10	10
	<b>Warrants</b>	
Expected dividend yield	0.0%	0.0%
Expected stock price volatility	0%	92.2%
Risk-free interest rate	0%	2.96% – 2.97%
Expected life (years)	0	5 – 5.5

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

## Research and Development

Research and development costs are charged to operations as incurred. Research and development costs were \$ 20,671 and \$15,150 for the three months ended September 30, 2023 and 2022, respectively. Research and development costs were \$88,843 and \$116,763 for the nine months ended September 30, 2023 and 2022, respectively.

## Income Taxes

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

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 acquisition of Helomics Corporation ("Helomics") in 2019, there may be significant limitations to the net operating loss. In addition, the current net operating loss carryforwards might be further limited by future issuances of our common stock.

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

## Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash. The Company places its cash with financial institutions and, by policy, generally limits the amount of credit exposure to any one financial institution. As of September 30, 2023, the Company had \$34,853 of credit risk for cash amounts held in a single institution that are in excess of amounts insured by the Federal Deposit Insurance Corporation.

## Risks and Uncertainties

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

The Company is also subject to general economic and geopolitical uncertainties caused by inflation, rising interest rates, supply chain disruptions, tight labor markets, wage inflation, pricing volatility for certain goods and services, banking and financial sector disruptions, instability and volatility in the global markets, disruptions from COVID-19, and geopolitical conflict. The impacts of economic and other global events could have a material adverse effect on our business, results of operations, liquidity or financial condition and heighten or exacerbate risks described in our Annual Report on Form 10-K filed with the SEC on March 21, 2023.

## 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.

## Recently Adopted Accounting Standards

In June 2016, the FASB issued ASU 2016-13, "Financial Instruments – Credit Losses." This ASU added a new impairment model (known as the current expected credit loss ("CECL") model) that is based on expected losses rather than incurred losses. Under the new guidance, an entity recognizes as an allowance its estimate of expected credit losses. The CECL model applies to most debt instruments, trade receivables, lease receivables, financial guarantee contracts, and other loan commitments. The CECL model does not have a minimum threshold for recognition of impairment losses and entities will need to measure expected credit losses on assets that have a low risk of loss. The Company adopted the provisions of ASU 2016-13 on January 1, 2023; the adoption did not have a material impact on our consolidated financial statements.

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

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



## NOTE 2 – FAIR VALUE MEASUREMENTS

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

September 30, 2023	Fair Value	Level 1	Level 2	Level 3
Liabilities:				
Derivatives	\$ 2,109	\$ -	\$ -	\$ 2,109
December 31, 2022	Fair Value	Level 1	Level 2	Level 3
Liabilities:				
Derivatives	\$ 13,833	\$ -	\$ -	\$ 13,833

## NOTE 3 – INVENTORIES

Inventory balances are as follows:

	As of September 30, 2023	As of December 31, 2022
Finished goods	\$ 242,949	\$ 290,616
Raw materials	190,346	133,183
Work-In-Process	6,694	6,694
Total	<u>\$ 439,989</u>	<u>\$ 430,493</u>

## NOTE 4 – PROPERTY AND EQUIPMENT

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

	As of September 30, 2023	As of December 31, 2022
Computers, software, and office equipment	\$ 496,382	\$ 463,292
Leasehold improvements	506,162	535,527
Laboratory equipment	3,661,891	3,559,362
Manufacturing tooling	133,285	121,120
Demo equipment	31,554	31,554
Total	4,829,274	4,710,855
Less: Accumulated depreciation	(3,436,593)	(2,877,600)
Total Property and Equipment, Net	<u>\$ 1,392,681</u>	<u>\$ 1,833,255</u>

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.

Depreciation expense, recorded within general and administrative expenses and operations expenses, was \$ 156,124 and \$227,135 for the three months ended September 30, 2023 and 2022, respectively, and \$560,413 and \$669,686 during the nine months ended September 30, 2023 and 2022, respectively.

## NOTE 5 – INTANGIBLE ASSETS

### Finite-lived Intangible Assets

The components of intangible assets were as follows:

	As of September 30, 2023			As of December 31, 2022			
	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount	Gross Carrying Costs	Accumulated Amortization	Impairment	Net Carrying Amount
Patents & Trademarks	\$ 535,096	\$ (275,776)	\$ 259,320	\$ 509,141	\$ (255,276)	\$ -	\$ 253,865
Developed Technology	-	-	-	3,500,000	(386,459)	(3,113,541)	-
Customer Relationships	-	-	-	200,000	(22,083)	(177,917)	-
Tradename	-	-	-	80,000	(22,083)	(57,917)	-
<b>Total</b>	<b>\$ 535,096</b>	<b>\$ (275,776)</b>	<b>\$ 259,320</b>	<b>\$ 4,289,141</b>	<b>\$ (685,901)</b>	<b>\$ (3,349,375)</b>	<b>\$ 253,865</b>

Amortization expense, recorded within general and administrative expenses, was \$ 6,863 and \$103,805 during the three months ended September 30, 2023 and 2022, respectively, and \$20,563 and \$310,695 during the nine months ended September 30, 2023 and 2022, respectively.

The following table outlines the estimated future amortization expense related to intangible assets held as of September 30, 2023:

Year ending December 31,	Expense
Remainder of 2023	\$ 6,863
2024	27,451
2025	27,451
2026	27,451
2027	27,451
Thereafter	142,653
<b>Total</b>	<b>\$ 259,320</b>

The Company recognized no impairment of its finite-lived intangible assets during the three and nine months ended September 30, 2023 and 2022.

### Goodwill

As of September 30, 2022, the Company concluded that the goodwill acquired in connection with the acquisition of zPREDICTA Inc., the Company's former wholly owned subsidiary, was fully impaired and recognized an impairment loss on goodwill of \$7,231,093 during the nine months then ended. As of September 30, 2023, the cumulative impairment of goodwill recorded was \$7,231,093.

The goodwill acquired by the Company in connection with the acquisition of Helomics was zero as of both September 30, 2023 and December 31, 2022. The cumulative impairment of goodwill recorded was \$23,790,290.

## **NOTE 6 – 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.

### **Equity Incentive Plan**

The Company has an equity incentive plan, which allows issuance of 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, 2021	53,144	\$ 96.60	1,584,995	\$ 33.20
Issued	1,599	8.40	1,053,136	14.00
Forfeited	(2,013)	17.60	-	-
Expired	(3,677)	208.40	(5,422)	329.60
Cancelled	-	-	(816,272)	30.20
Outstanding at December 31, 2022	49,053	\$ 91.69	1,816,437	\$ 22.60
Issued	1,075	5.45	-	-
Forfeited	(49)	6.18	-	-
Expired	(1,854)	121.24	(9,417)	217.64
Outstanding at September 30, 2023	48,225	\$ 83.58	1,807,020	\$ 21.58

Stock-based compensation expense, net of forfeitures, recognized for the three months ended September 30, 2023 and September 30, 2022 was \$(14,300) and \$26,993, respectively. Stock-based compensation expense recognized for the nine months ended September 30, 2023 and September 30, 2022 was \$859 and \$102,894, respectively. The Company has \$2,833 of unrecognized compensation expense related to unvested stock options that is expected to be recognized over the next 19 months. At September 30, 2023, there were no restricted stock units ("RSUs") outstanding under the plan and the Company has no unrecognized compensation expense related to unvested RSUs.

## NOTE 7 – COLLABORATIVE AGREEMENT

### Collaborative Agreement with Cancer Research Horizons

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

Pursuant to the CRH Agreement, the Company shall receive a percentage of net revenue, as defined in the agreement, received by CRH for the commercialization of the CRH Candidates and any CRH Derivatives. The percentage of net revenue varies depending on the stage of development. As of September 30, 2023, the Company has not recognized any revenue under the CRH Agreement.

## NOTE 8 – DERIVATIVES

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

The fair value of the placement agent warrants issued in connection with the March 2020 private placement was determined to be \$ 293 and \$3,355 as of September 30, 2023 and December 31, 2022, respectively. The Company recorded gains on the change in fair value of the placement agent warrants of \$743 and \$3,308 during the three months ended September 30, 2023 and September 30, 2022, respectively, and \$ 3,062 and \$35,474 during the nine months ended September 30, 2023 and September 30, 2022, respectively. The placement agent warrants expire in March 2025.

The fair value of the placement agent warrants issued in connection with the May 2020 offering of securities was determined to be \$ 576 and \$4,479 as of September 30, 2023 and December 31, 2022, respectively. The Company recorded gains on the change in fair value of the placement agent warrants of \$1,133 and \$3,370 during the three months ended September 30, 2023 and September 30, 2022, respectively, and \$ 3,903 and \$35,421 during the nine months ended September 30, 2023 and September 30, 2022, respectively. The placement agent warrants expire in May 2025.

The placement agent warrants issued in connection with the June 2020 warrant exercise and issuance had a fair value of \$ 1,240 and \$5,999 as of September 30, 2023 and December 31, 2022, respectively. The Company recorded gains on the change in fair value of the placement agent warrants of \$1,587 and \$3,541 during the three months ended September 30, 2023 and September 30, 2022, respectively, and \$ 4,759 and \$36,486 during the nine months ended September 30, 2023 and September 30, 2022, respectively. The placement agent warrants expire in June 2025.

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

<b>Derivative liability balance at December 31, 2021</b>	<b>\$</b>	<b>129,480</b>
Gain recognized to revalue derivative instrument at fair value		(1,908)
<b>Derivative liability balance at March 31, 2022</b>	<b>\$</b>	<b>127,572</b>
Gain recognized to revalue derivative instrument at fair value		(95,254)
<b>Derivative liability balance at June 30, 2022</b>	<b>\$</b>	<b>32,318</b>
Gain recognized to revalue derivative instrument at fair value		(10,219)
<b>Derivative liability balance at September 30, 2022</b>	<b>\$</b>	<b>22,099</b>
<b>Derivative liability balance at December 31, 2022</b>	<b>\$</b>	<b>13,833</b>
Gain recognized to revalue derivative instrument at fair value		(953)
<b>Derivative liability balance at March 31, 2023</b>	<b>\$</b>	<b>12,880</b>
Gain recognized to revalue derivative instrument at fair value		(7,308)
<b>Derivative liability balance at June 30, 2023</b>	<b>\$</b>	<b>5,572</b>
Gain recognized to revalue derivative instrument at fair value		(3,463)
<b>Derivative liability balance at September 30, 2023</b>	<b>\$</b>	<b>2,109</b>

#### NOTE 9 – LOSS PER SHARE

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
Numerator:				
Net loss attributable to common stockholders: basic and diluted calculation	\$ (3,163,450)	\$ (4,059,485)	\$ (10,508,620)	\$ (17,821,524)
Denominator:				
Weighted average common shares outstanding - basic	4,031,356	3,919,203	3,998,887	3,602,515
Effect of diluted stock options, warrants, and preferred stock (1)	-	-	-	-
Weighted average common shares outstanding - diluted	4,031,356	3,919,203	3,998,887	3,602,515
Loss per common share - basic and diluted	\$ (0.78)	\$ (1.04)	\$ (2.63)	\$ (4.95)

- (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 Nine Months Ended September 30,	
	2023	2022
Options	48,225	51,082
Restricted Stock Units	-	24,167
Warrants	1,807,020	1,819,927
Series B Convertible Preferred Stock	16	16

There were 79,246 shares of Series B Convertible Preferred Stock outstanding as of September 30, 2023 and September 30, 2022. In total, the 79,246 shares of Series B Convertible Preferred Stock were convertible to 16 shares of common stock as of September 30, 2023 and September 30, 2022 due to the cumulative effect of reverse stock splits.

#### NOTE 10 – LEASES

The Company's corporate offices and other offices are located in Pittsburgh, Pennsylvania. Upon expiration of previous leases for office space and laboratory operations, the Company entered into two new leases for office space and laboratory operations on January 4, 2023. The leases each have an approximate five-year term ending February 28, 2028 and the Company recorded corresponding ROU assets and liabilities of \$ 2,922,365.

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

The Company has an additional office in Birmingham, Alabama, which is used for office space, warehousing and laboratory operations. The lease is effective through August 25, 2025.

Lease expense, recorded within general and administrative expenses, was \$ 230,390 and \$183,924 for the three months ended September 30, 2023 and September 30, 2022, respectively, and \$665,252 and \$536,156 for the nine months ended September 30, 2023 and September 30, 2022, respectively.

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

	September 30, 2023
Weighted average remaining lease term – operating leases in years	4.23
Weighted average discount rate – operating leases	12%

The Company's operating lease obligations as of September 30, 2023 are as follows:

Remainder of 2023	\$	209,506
2024		887,424
2025		857,622
2026		803,724
2027		827,909
Thereafter		139,022
Total lease payments		3,725,207
Less: interest		(826,044)
Present value of lease liabilities	\$	<u>2,899,163</u>

#### NOTE 11 – 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 requires ten monthly installment payments through April 2024. The note is secured by a first priority lien on the financed policies. The short-term note bears interest at an annual percentage rate of 9.25% over the life of the note. As of September 30, 2023, the outstanding balance of the note was \$260,220 including interest.

## NOTE 12 – SEGMENTS

The Company has determined that it will focus its resources on applying AI to support the development of optimal cancer therapies, partnering with biopharma clients to help prioritize drugs for development and identify biomarker-informed indications. Its platform provides an informed decision tool to select optimal drug/tumor combinations to increase the probability of success during drug development. As a result of this focused approach, the Company has consolidated its brand under the Predictive Oncology name. Going forward, the Company will operate under the Predictive Oncology tradename with laboratory operations in Pittsburgh, Pennsylvania and Birmingham, Alabama. As of January 1, 2023, the Company changed its reportable segments because of this focused approach. The Company has retrospectively revised the reported segment information for all periods presented for consistency.

The Company has three reportable segments that have been delineated by location and specialty: the Pittsburgh segment provides services that include the application of AI using its proprietary biobank of 150,000+ cancer tumor samples. Pittsburgh also utilizes 3D culture models in drug development. The Birmingham segment provides services and research 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 of biologics focused on solubility improvements, stability studies, and protein production. The Eagan (Minnesota) segment consists of the production of the United States Food and Drug Administration ("FDA")-cleared STREAMWAY System for automated fluid waste management, direct-to-drain medical fluid disposal, and associated products.

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.

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, 2023 and 2022 are included in the table below. zPREDICTA Inc. was merged with Predictive Oncology Inc. at the end of 2022 and is now reported as part of the Pittsburgh operating segment. All revenues are earned from external customers.

### Revenue

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Pittsburgh	\$ 417,096	\$ 172,637	\$ 441,567	\$ 266,642
Eagan	259,530	253,751	866,535	809,875
Birmingham	38,430	29,439	136,959	64,580
Corporate	-	-	-	889
Total	\$ 715,056	\$ 455,827	\$ 1,445,061	\$ 1,141,986

## Segment Loss

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Pittsburgh	\$ (674,952)	\$ (1,076,508)	\$ (3,428,644)	\$ (10,891,767)
Eagan	(189,031)	(109,408)	(756,115)	(259,444)
Birmingham	(415,083)	(407,622)	(1,483,222)	(1,206,550)
Corporate	(1,884,384)	(2,465,946)	(4,840,639)	(5,463,763)
Total	\$ (3,163,450)	\$ (4,059,484)	\$ (10,508,620)	\$ (17,821,524)

## Assets

	As of September 30,	As of December 31,
	2023	2022
Pittsburgh	\$ 3,422,462	\$ 1,055,228
Eagan	1,336,101	946,394
Birmingham	1,116,990	1,353,434
Corporate	12,291,315	22,379,588
Total	\$ 18,166,868	\$ 25,734,644

## 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, 2022.

This Form 10-Q contains "forward-looking statements" that are subject to 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 risk factors that may cause actual results to differ from forward-looking statements include:

- Our ability to be able 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 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 disruptions caused by COVID-19 as well as general economic and geopolitical uncertainties; 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, 2022 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

Predictive Oncology Inc. (“Predictive Oncology”) is a knowledge-driven company focused on applying artificial intelligence (“AI”) to support the development of optimal cancer therapies, which can ultimately lead to more effective treatments and improved patient outcomes. Through AI, Predictive Oncology uses a 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 success. The Company offers a suite of solutions for oncology drug development from early discovery to clinical trials.

We operate in three primary business areas: first, along the drug discovery continuum (i) the application of AI for optimized, high-confidence drug-response predictions within a large experimental space that enables a more informed selection of drug/tumor combinations to increase the probability of success during development and (ii) the creation and development of tumor-specific 3D cell culture models; second, contract services and research focused on solubility improvements, stability studies, and protein production, and; third, production of the United States Food and Drug Administration (“FDA”)-cleared STREAMWAY System for automated fluid waste management, direct-to-drain medical fluid disposal and associated products.

We have determined that we will focus our resources on applying AI to support the development of optimal cancer therapies, partnering with biopharma clients to help prioritize drugs for development and identify biomarker-informed indications. Our platform provides a more informed decision tool to select optimal drug/tumor combinations to increase the probability of success during drug development. As a result of this focused approach, we have consolidated our brand under the Predictive Oncology name. Going forward, we will operate under the Predictive Oncology tradename with laboratory operations in Pittsburgh, Pennsylvania and Birmingham, Alabama. As of January 1, 2023, we have changed in our reportable segments because of this focused approach.

We have three reportable segments that have been delineated by location and specialty: our Pittsburgh segment provides services that include the application of AI using its proprietary biobank of 150,000+ cancer tumor samples. Pittsburgh also utilizes 3D culture models in drug development. Our Birmingham segment provides services and research 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 of biologics focused on solubility improvements, stability studies, and protein production. Our Eagan (Minnesota) segment consists of the production of the United States Food and Drug Administration ("FDA")-cleared STREAMWAY System for automated fluid waste management, direct-to-drain medical fluid disposal, and associated products.

## Capital Requirements

Since inception, we have been unprofitable. We incurred net losses of \$10,508,620 and \$17,821,524 for the nine months ended September 30, 2023, and September 30, 2022, respectively. As of September 30, 2023, and December 31, 2022, we had an accumulated deficit of \$164,286,536 and \$153,777,916, 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; Going Concern Qualification" 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 drug discovery 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 Qualification" 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 nine months ended September 30, 2023 and September 30, 2022

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	Difference	2023	2022	Difference
Revenue	\$ 715,056	\$ 455,827	\$ 259,229	\$ 1,445,061	\$ 1,141,986	\$ 303,075
Cost of goods sold	106,940	108,151	1,211	386,840	351,669	(35,171)
General and administrative expense	2,583,574	3,287,918	704,344	7,624,085	8,063,265	439,180
Operations expense	842,579	857,130	14,551	2,714,139	2,657,314	(56,825)
Sales and marketing expense	336,043	333,377	(2,666)	1,135,383	908,867	(226,516)

**Revenue.** We recorded revenue of \$715,056 and \$455,827 in the three months ended September 30, 2023 and 2022, respectively, and \$1,445,061 and \$1,141,986 in the nine months ended September 30, 2023 and 2022, respectively. Revenue in the three months ended September 30, 2023 was primarily derived from the Pittsburgh operating segment related to development of tumor-specific 3D cell culture models, while revenue in the three months ended September 30, 2022 was primarily derived from the Eagan operating segment. The Pittsburgh operating segment contributed revenues of \$417,096 and \$172,637 in the three months ended September 30, 2023 and September 30, 2022, respectively, while the Eagan operating segment contributed \$259,530 and \$253,751 in the three months ended September 30, 2023 and September 30, 2022, respectively. Revenue in the nine months ended September 30, 2023 and September 30, 2022 was primarily derived from the Eagan operating segment, which contributed \$866,535 and \$809,875 for the nine months ended September 30, 2023 and September 30, 2022, respectively.

*Cost of goods sold.* Cost of sales was \$106,940 and \$386,840 in the three and nine months ended September 30, 2023 compared to \$108,151 and \$351,669 in the three and nine months ended September 30, 2022. The gross profit margin was approximately 85% and 73% in the three and nine months ended September 30, 2023 compared to 76% and 69% in the three and nine months ended September 30, 2022. The improvement in gross profit margins for both periods was primarily due to a change in sales mix to higher margin contracted services primarily provided by our Pittsburgh and Birmingham operating segments.

*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 decreased by \$704,344 to \$2,583,574 in the three months ended September 30, 2023 compared to \$3,287,918 in the comparable period in 2022. G&A expense decreased by \$439,180 to \$7,624,085 in the nine months ended September 30, 2023 compared to \$8,063,265 in the comparable period in 2022. The decreases in both periods were primarily due to decreased severance to former employees as well as decreased depreciation and amortization expenses due to fully depreciated assets and prior period impairments, offset by increased fees for investor relations and advisory boards as well as rent and other general and administrative expenses.

*Operations expense.* Operations expense primarily consists of expenses related to product development and prototyping and testing. Operations expense decreased by \$14,551 to \$842,579 in the three months ended September 30, 2023 compared to \$857,130 in the comparable period in 2022. The decrease was primarily due to decreased consultant fees and decreased spending on tools, calibration, and testing in Eagan.

Operations expense increased by \$56,825 to \$2,714,139 in the nine months ended September 30, 2023 compared to \$2,657,314 in the comparable period in 2022. The increase in the nine-month period was driven primarily by higher cloud computing expenses related to our Pittsburgh operating segment, which were offset by decreases in expenses related to the closure of the offices of the Company's former wholly-owned subsidiaries.

*Sales and marketing expense.* Sales and marketing expense consists of expenses required to sell products through attendance at trade shows, product literature and other sales and marketing activities. Sales and marketing expense increased by \$2,666 to \$336,043 in the three months ended September 30, 2023 compared to \$333,377 in the comparable period in 2022. Sales and marketing expense increased by \$226,516 to \$1,135,383 in the nine months ended September 30, 2023 compared to \$908,867 in the comparable period in 2022. The increases in both periods were primarily due to the increase in marketing and business development staff hired after September 30, 2022.

*Loss on impairment of property and equipment.* We recorded a loss on impairment of property and equipment of \$162,905 during the nine months ended September 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 4 – Property and Equipment* to our unaudited condensed consolidated financial statements for further information.

*Other income.* We earned other income of \$47,838 in the three months ended September 30, 2023 compared to \$63,047 in the comparable period in 2022 and earned other income of \$118,617 in the nine months ended September 30, 2023 compared to \$146,524 in the comparable period in 2022. Other income is primarily interest income.

*Other expense.* We incurred other expense of \$60,671 in the three and nine months ended September 30, 2023 compared to \$2,001 in the three months ended September 30, 2022 and \$5,207 in the nine months ended September 30, 2022. The increase was primarily due to the write off of a note receivable deemed uncollectible.

*Gain on derivative instruments.* We recorded a gain of \$3,463 in the three months ended September 30, 2023 compared to \$10,219 in the comparable period in 2022 and recorded a gain of \$11,724 in the nine months ended September 30, 2023 compared to \$107,381 in the comparable period in 2022 related to the change in fair value of the derivative.

## **Liquidity and Capital Resources**

### **Cash Flows**

Net cash used in operating activities was \$10,107,030 and \$9,135,812 for the nine months ended September 30, 2023 and September 30, 2022, respectively. Cash used in operating activities increased in the 2023 period primarily because of the increase in operating expenses and changes in working capital.

Net cash used in investing activities was \$309,666 and \$412,096 for the nine months ended September 30, 2023 and September 30, 2022, respectively. Cash used in investing activities decreased in the 2023 period primarily due to a decrease in the acquisition of fixed assets.

Net cash provided by financing activities was \$260,221 and \$6,739,031 for the nine months ended September 30, 2023 and September 30, 2022, 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 while the cash provided in the nine months ended September 30, 2023 primarily related to proceeds from financing insurance premiums over the insured period with a short-term note payable.

### **Liquidity and Plan of Financing; Going Concern**

We have incurred significant and recurring losses from operations for the past several years and had an accumulated deficit of \$164,286,536 as of September 30, 2023. We had cash and cash equivalents of \$11,915,048 as of September 30, 2023 and need to raise significant additional capital to meet our operating needs. Our short-term obligations as of September 30, 2023 were \$4,171,891, consisting primarily of aggregate accounts payable and accrued expenses of \$2,979,064 and operating lease obligations of \$555,541. As of September 30, 2023, we also had a short-term note payable of \$260,220 that bears interest at an annual percentage rate of 9.25% and long-term operating lease obligations of \$2,343,622 with a weighted average remaining lease term of 4.23 years. We do not expect to generate sufficient operating revenue to sustain our operations in the near term. Year-to-date, we incurred negative cash flows from operations of \$10,107,030. Although we have attempted to improve our operating margin by bolstering revenues and curtailing expenses, and continue to seek ways to generate revenue through business development activities, there is no guarantee that we will be able to improve our operating margin sufficiently or achieve profitability in the near term. These conditions raise substantial doubt about our ability to continue as a going concern. 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. 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. Therefore, there is substantial doubt about our ability to continue as a going concern for one year after the date that the financial statements are issued. The condensed consolidated financial statements included in this report have been prepared assuming we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business, and do not include any adjustments that might result from the outcome of this uncertainty.

### **Financing Transactions**

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

### **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, 2023, 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, 2023 due to the material weaknesses in internal control over financial reporting described below.

*Material Weaknesses in Internal Controls.* In connection with the evaluation of the Company's internal control over financial reporting as described above, management has identified the following deficiencies in our control environment in the current period that constitute material weaknesses in the Company's internal control over financial reporting. Therefore, there was a risk that a potential material misstatement of the consolidated financial statements could occur without being prevented or detected on a timely basis.

Management did not maintain effective information technology general controls in the areas of user access management, administrative user access, and segregation of duties within its financial information systems and other financial reporting controls that are relevant to the Company's preparation of financial statements. As a result of those segregation of duties deficiencies, the related manual business process controls were determined to be ineffective.

The material weakness first reported in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 continued to exist as of September 30, 2023. Management determined that we have not maintained adequate accounting resources with a sufficient understanding of accounting principles generally accepted in the United States of America ("U.S. GAAP") to allow us to properly identify and account for new complex transactions.

Notwithstanding the material weaknesses in our internal control over financial reporting, we have concluded that the condensed 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.* In response to the material weakness, management, with oversight of the Audit Committee of the Company's Board of Directors, has begun the process of, and is committed to, designing and implementing effective measures to strengthen our internal controls over financial reporting and remediate the material weakness. Our planned internal control remediation efforts include:

- Management is evaluating logical access, including administrative user access, and eliminating known segregation of duties conflicts.
- Management has designed and is in the process of implementing periodic logical access review controls to monitor user access and proper segregation of duties.
- Management has reevaluated our overall staffing levels within the accounting department and during the second quarter of 2023 we hired additional resources with qualifications that include a high level of experience with complex technical accounting transactions and application of U.S. GAAP.

Once the above actions and 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. We are committed to the continuous improvement of our internal control over financial reporting and will continue to diligently review our internal control over financial reporting.

## **Changes in Internal Control Over Financial Reporting**

Except for the changes described above, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the three months ended September 30, 2023 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, 2022, filed with the SEC on March 21, 2023, except as described below.

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

We have incurred significant and recurring losses from operations for the past several years and had an accumulated deficit of \$164,286,536 as of September 30, 2023. We had cash and cash equivalents of \$11,915,048 as of September 30, 2023 and need to raise significant additional capital to meet our operating needs. Our short-term obligations as of September 30, 2023 were \$4,171,891, consisting primarily of aggregate accounts payable and accrued expenses of \$2,979,064 and operating lease obligations of \$555,541. As of September 30, 2023, we also had a short-term note payable of \$260,220 that bears interest at an annual percentage rate of 9.25% and long-term operating lease obligations of \$2,343,622 with a weighted average remaining lease term of 4.23 years. We do not expect to generate sufficient operating revenue to sustain our operations in the near term. Year-to-date, we incurred negative cash flows from operations of \$10,107,030. Although we have attempted to improve our operating margin by bolstering revenues and curtailing expenses, and continue to seek ways to generate revenue through business development activities, there is no guarantee that we will be able to improve our operating margin sufficiently or achieve profitability in the near term. These conditions raise substantial doubt about our ability to continue as a going concern. 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. 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. Therefore, there is substantial doubt about our ability to continue as a going concern for one year after the date that the financial statements are issued. The condensed consolidated financial statements for the quarter ended September 30, 2023 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.

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

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

Further, the cost and time needed to discover drug candidates is difficult to predict, and our efforts may not result in the discovery and development of commercially viable therapies, drugs, or clinical treatments. Our estimates of our defined patient populations available for study and treatment may be lower than expected, which could adversely affect our or our partners' ability to conduct clinical trials and may also adversely affect the size of any market for therapies, drugs or treatments we may license for commercialization. Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new drugs as quickly or cost effectively as expected and therefore we may not be able to commercialize our approach as expected at this time.

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

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

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

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

In addition to the foregoing risks, and the other 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, 2022 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 Forms 8-K or 10-K.

During the nine months ended September 30, 2023, 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

Exhibit Number	Description
<a href="#"><u>31.1*</u></a>	<a href="#"><u>Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
<a href="#"><u>31.2*</u></a>	<a href="#"><u>Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
<a href="#"><u>32.1**</u></a>	<a href="#"><u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
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: November 13, 2023

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

Date: November 13, 2023

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: November 13, 2023

/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 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 13, 2023

/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 September 30, 2023 as filed with the Securities and Exchange Commission (the "Report"), I, Raymond F. Vennare, Chief Executive Officer (Principal Executive Officer) and, I, Josh Blacher, Interim Chief Financial Officer (Principal Financial Officer) of the Company, hereby certify as of the date hereof, solely for purposes of § 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1350, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: November 13, 2023

/s/ Raymond F. Vennare

Raymond F. Vennare  
Chief Executive Officer

Date: November 13, 2023

/s/ Josh Blacher

Josh Blacher  
Interim Chief Financial Officer