

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 March 31, 2021

or

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

For the transition period from _____ to _____

Commission File Number: 001-36790

Predictive Oncology Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

33-1007393

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

2915 Commers Drive, Suite 900

(Address of principal executive offices)

Eagan, Minnesota 55121

(Zip Code)

651-389-4800

(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.01 par value	POAI	Nasdaq Capital Market

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

Yes No

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

Yes No

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

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

Yes No

As of May 7, 2021, the registrant had 49,818,784 shares of common stock, par value \$0.01 per share outstanding.

PREDICTIVE ONCOLOGY INC.

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PREDICTIVE ONCOLOGY INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2021	December 31, 2020
	(unaudited)	(audited)
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 27,299,407	\$ 678,332
Accounts Receivable	264,928	256,878
Inventories	292,824	289,535
Prepaid Expense and Other Assets	344,921	289,490
Total Current Assets	28,202,080	1,514,235
Fixed Assets, net		
Fixed Assets, net	3,975,453	3,822,700
Intangibles, net	3,316,489	3,398,101
Lease Right-of-Use Assets	1,229,773	1,395,351
Other Long-Term Assets	116,257	116,257
Goodwill	2,813,792	2,813,792
Total Assets	\$ 39,653,844	\$ 13,060,436
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	\$ 1,027,000	\$ 1,372,070
Notes Payable – Net of Discounts of \$0 and \$244,830	-	4,431,925
Accrued Expenses and other liabilities	1,277,943	2,588,047
Derivative Liability	198,711	294,382
Deferred Revenue	154,195	53,028
Lease Liability	603,054	597,469
Total Current Liabilities	3,260,903	9,336,921
Lease Liability – Net of current portion	684,756	845,129
Other long-term liabilities	163,098	235,705
Total Liabilities	4,108,757	10,417,755
Stockholders' Equity:		
Preferred Stock, 20,000,000 authorized inclusive of designated below		
Series B Convertible Preferred Stock, \$.01 par value, 2,300,000 shares authorized, 79,246 and 79,246 shares outstanding	792	792
Common Stock, \$.01 par value, 100,000,000 shares authorized, 48,794,320 and 19,804,787 outstanding	487,944	198,048
Additional paid-in capital	147,328,172	110,826,949
Accumulated Deficit	(112,271,821)	(108,383,108)
Total Stockholders' Equity	35,545,087	2,642,681
Total Liabilities and Stockholders' Equity	\$ 39,653,844	\$ 13,060,436

See Notes to Condensed Consolidated Financial Statements

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

	Three Months Ended March 31,	
	2021	2020
Revenue	\$ 280,317	\$ 294,943
Cost of goods sold	97,758	92,657
Gross margin	182,559	202,286
General and administrative expense	3,270,777	2,828,476
Operations expense	574,812	548,753
Sales and marketing expense	114,641	264,409
Total operating loss	(3,777,671)	(3,439,352)
Other income	28,259	3
Other expense	(234,972)	(1,117,075)
Gain on derivative instruments	95,671	27,107
Net loss	<u>\$ (3,888,713)</u>	<u>\$ (4,529,317)</u>
Loss per common share - basic and diluted	\$ (0.11)	\$ (0.93)
Weighted average shares used in computation - basic and diluted	36,513,300	4,866,328

See Notes to Condensed Consolidated Financial Statements

PREDICTIVE ONCOLOGY INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

	Series B Preferred		Series D Preferred		Series E Preferred		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Paid-In Capital	Deficit	
Balance at 12/31/2019	79,246	\$ 792	3,500,000	\$ 35,000	258	\$ 3	4,056,652	\$ 40,567	\$ 93,653,667	\$ (82,498,711)	\$ 11,231,318
Shares issued pursuant to CEO exchange agreement							50,000	500	129,500		130,000
Inducement shares issued pursuant to promissory note extension							30,000	300	40,950		41,250
Issuance of shares and prefunded warrants pursuant to March 2020 private placement, net							260,000	2,600	455,223		457,823
Inducement shares issued pursuant to 2020 convertible debt and warrants							46,875	468	119,532		120,000
Warrants issued pursuant to 2020 convertible debt									116,951		116,951
Shares issued pursuant to note conversions - bridge loan							170,000	1,700	265,628		267,328
Shares issued pursuant to series E preferred stock conversions					(50)	(1)	141,191	1,412	(1,411)		-
Shares issued pursuant to Equity Line							943,000	9,430	1,860,469		1,869,899
Shares issued to consultant and other							155,000	1,550	360,750		362,300
Vesting expense									287,838		287,838
Net loss										(4,529,317)	(4,529,317)
Balance at 03/31/2020	79,246	\$ 792	3,500,000	\$ 35,000	208	\$ 2	5,852,718	\$ 58,527	\$ 97,289,097	\$ (87,028,028)	\$ 10,355,390

PREDICTIVE ONCOLOGY INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE MONTHS ENDED
MARCH 31, 2021
(Unaudited)

	Series B Preferred		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance at 12/31/2020	79,246	\$ 792	19,804,787	\$ 198,048	\$ 110,826,949	\$ (108,383,108)	\$ 2,642,681
Shares issued pursuant to CEO agreement related to accrued interest			100,401	1,004	142,569		143,573
Issuance of shares and warrants pursuant to Shelf offerings, net			13,488,098	134,881	14,877,611		15,012,492
Issuance of shares and warrants pursuant to February 2021 private placement, net			9,043,766	90,438	15,974,301		16,064,739
Exercise of warrants			5,247,059	52,471	4,442,799		4,495,270
Shares issued pursuant to convertible debt			1,107,544	11,075	502,936		514,011
Shares issued to consultant & other			2,665	27	(4,075)		(4,048)
Vesting expense					565,082		565,082
Net loss						(3,888,713)	(3,888,713)
Balance at 03/31/2021	79,246	\$ 792	48,794,320	\$ 487,944	\$ 147,328,172	\$ (112,271,821)	\$ 35,545,087

See Notes to Condensed Consolidated Financial Statements

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

	Three Months Ended	
	March 31,	
	2021	2020
Cash flow from operating activities:		
Net loss	\$ (3,888,713)	\$ (4,529,317)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	321,980	206,580
Vesting expense	565,082	287,838
Common stock issued for consulting and other	(4,048)	362,300
Amortization of debt discount	244,830	448,026
Gain on valuation of equity-linked instruments and derivative liability	(95,671)	(27,107)
Debt extinguishment costs	-	300,000
Equity instruments issued in connection with 2020 convertible debt	-	16,716
Changes in assets and liabilities:		
Accounts receivable	(8,050)	27,278
Inventories	(3,289)	34,473
Prepaid expense and other assets	(55,431)	(62,248)
Accounts payable	(345,070)	(27,121)
Accrued expenses	(82,271)	(14,144)
Deferred revenue	101,167	3,745
Other long-term liabilities	(72,607)	-
Net cash used in operating activities:	<u>(3,322,091)</u>	<u>(2,972,981)</u>
Cash flow from investing activities:		
Purchase of fixed assets	(391,685)	-
Acquisition of intangibles	(1,436)	(32,510)
Net cash used in investing activities:	<u>(393,121)</u>	<u>(32,510)</u>
Cash flow from financing activities:		
Proceeds from debt issuance	-	1,820,000
Proceeds from issuance of common stock and warrants, net	31,077,231	-
Proceeds from exercise of warrants into common stock	4,495,270	-
Repayment of debt	(4,162,744)	(821,916)
Payment premium	(1,073,470)	(84,898)
Proceeds from issuance of common stock pursuant to equity line	-	1,869,899
Issuance of common stock, A, B and prefunded warrants, net	-	3,127,818
Net cash provided by financing activities	<u>30,336,287</u>	<u>5,910,903</u>
Net increase in cash and cash equivalents	26,621,075	2,905,412
Cash and cash equivalents at beginning of period	678,332	150,831
Cash and cash equivalents at end of period	<u>\$ 27,299,407</u>	<u>\$ 3,056,243</u>
Non-cash transactions:		
Bridge loan conversion into common stock	\$ -	\$ 267,328
Shares issued to CEO per agreement related to exchange agreement	-	130,000
Shares issued to CEO per agreement related to accrued interest	143,573	-
Series E preferred stock conversions	-	1,412
Inducement shares issued pursuant to convertible debt	-	103,284
Shares issued pursuant to convertible debt	514,011	-
Inducement shares issued for debt extension	-	41,250
Put and conversion derivative from debt issuance	-	120,921
Warrants issued pursuant to debt issuance	-	116,951

See Notes to 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 Continuance of Operations

Predictive Oncology Inc. (the “Company”) was originally incorporated on April 23, 2002 in Minnesota as BioDrain Medical, Inc. Effective August 6, 2013, the Company changed its name to Skyline Medical Inc. Pursuant to an Agreement and Plan of Merger effective December 16, 2013, the Company merged with and into a Delaware corporation with the same name that was its wholly owned subsidiary, with such Delaware corporation as the surviving corporation of the merger. On August 31, 2015, the Company completed a successful offering and concurrent uplisting to the NASDAQ Capital Market. On February 1, 2018, the Company filed with the Secretary of State of Delaware a Certificate of Amendment to its Certificate of Incorporation to change the corporate name from Skyline Medical Inc. to Precision Therapeutics Inc., effective February 1, 2018. Because of this change, the Company’s common stock traded under the ticker symbol “AIPT,” effective February 2, 2018. On June 10, 2019, the Company filed with the Secretary of State of Delaware a Certificate of Amendment to its Certificate of Incorporation to change the corporate name from Precision Therapeutics Inc. to Predictive Oncology Inc., trading under the new ticker symbol “POAI,” effective June 13, 2019. Skyline Medical (“Skyline”) remains as an incorporated division of Predictive Oncology Inc.

The Company is a healthcare company that provides personalized medicine solutions and medical devices in two main areas: (1) precision medicine, which aims to apply artificial intelligence to personalized medicine and drug discovery, primarily through its wholly owned subsidiary Helomics Holding Corporation (“Helomics”) and (2) an environmentally-safe system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care through its incorporated division Skyline. The Company sells proprietary cleaning fluid and filters to users of its systems.

In addition, the Company’s wholly owned subsidiary, TumorGenesis Inc. (“TumorGenesis”), is developing the next generation, patient-derived tumor models for precision cancer therapy and drug development. TumorGenesis is presented as part of the condensed consolidated financial statements and is included in corporate in the Company’s segment reporting.

During the first quarter of 2018, the Company acquired 25% of the capital stock of Helomics Holding Corporation (“Helomics”). On April 4, 2019, the Company completed a forward triangular merger with Helomics Acquisition Inc., a wholly owned subsidiary of the Company and Helomics, acquiring the remaining 75% of the capital stock of Helomics.

The Company had cash and cash equivalents of \$27,299,407 as of March 31, 2021. As of March 31, 2021, there was no outstanding debt. In October 2019, the Company entered into a purchase agreement for an equity line under which it can raise up to \$15,000,000 over a three-year period, subject to market conditions including trading volume and stock price. As of March 31, 2021, there was \$9,789,419 remaining in available balance under the equity line. Additional needs to access this line will be dilutive.

In January and February 2021, the Company received aggregate net proceeds of \$31,077,231 in a series of registered direct offerings and a private placement of equity securities. On March 1, 2021, the Company used \$5,906,802 of the net proceeds from the private placement to pay the remaining principal and interest on the loans originally issued in September 2018, September 2019, and February 2020 and to pay premium due upon such repayment. The remaining net proceeds of the 2021 transactions have been or will be used for working capital.

The Company believes that its existing capital resources will be sufficient to support its operating plan at least through June 30, 2022. However, the Company may also seek to raise additional capital to support its growth through additional debt, equity or other alternatives or a combination thereof. The Company currently expects to use cash on hand to fund capital and equipment investments, research and development, and its operations, over the next twelve months and beyond, and expects such sources to be sufficient to fund its requirements over that time.

Coronavirus Outbreak

In March 2020, the World Health Organization declared the recent spread of COVID-19 to be a global pandemic. In response to the crisis, emergency measures have been imposed by governments worldwide, including mandatory social distancing and the shutdown of non-essential businesses. These measures have adversely impacted the global economy, disrupted global supply chains, and created significant volatility and disruption of financial markets. While it is not currently possible to estimate the duration and severity of the COVID-19 pandemic or the adverse economic impact resulting therefrom, our business and operations have been and will likely continue to be materially and adversely affected. For example, our contract manufacturer for the STREAMWAY® System has been forced to change locations, thereby delaying our order fulfillment for parts. We have also reduced on-site staff at several of our facilities, resulting in delayed production, less efficiency, and our sales staff is unable to visit with hospital administrators who are our customers and potential customers. In addition, COVID-19 has impacted the Company's capital and financial resources, including our overall liquidity position during 2020 and may impact us in the future. For instance, our accounts receivable has slowed while our suppliers continue to ask for pre-delivery deposits. We received a Paycheck Protection Program ("PPP") Loan pursuant to the CARES Act which has helped fund some payroll costs in 2020. During the fourth quarter of 2020, we received forgiveness of the amounts outstanding from the PPP. If COVID-19 continues to spread or the response to contain the virus is unsuccessful, we may continue to experience a material adverse effect on our business, financial condition, results of operations, cash flows and stock price.

Interim Financial Statements

The Company has prepared the condensed consolidated financial statements and related unaudited financial information in the footnotes in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC") for interim condensed consolidated financial statements. These interim condensed consolidated financial statements reflect all adjustments consisting of normal recurring accruals, which in the opinion of management, are necessary to present fairly the Company's position, the results of its operations, and its cash flows for the interim periods. These interim condensed consolidated financial statements reflect all intercompany eliminations. These interim condensed consolidated financial statements should be read in conjunction with the annual consolidated financial statements and the notes thereto contained in the Annual Report on Form 10-K filed with the SEC on March 15, 2021. 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 accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent assets and liabilities at the date of the 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 years' 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 high quality financial institutions and believes its risk of loss is limited due to no 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 for doubtful accounts is maintained to provide for the estimated amount of receivables that will not be collected. The Company reviews customers' credit history before extending unsecured credit and establishes an allowance for uncollectible accounts based upon factors surrounding the credit risk of specific customers, historical trends and other information. Invoices are generally due 30 days after presentation. Accounts receivable over 30 days is generally considered past due. The Company does not accrue interest on past due accounts receivables. Receivables are written off once all collection attempts have failed and are based on individual credit evaluation and specific circumstances of the customer. The allowance for doubtful accounts balance was \$0 as of both March 31, 2021 and December 31, 2020.

Fair Value Measurements

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

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

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

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

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

The fair value of the Company's investment securities, which consist of cash and cash equivalents, was determined based on Level 1 inputs. The fair value of the Company's derivative liabilities and debt were determined based on Level 3 inputs. The Company generally uses the Black Scholes method for determining the fair value of warrants classified as liabilities on a recurring basis. In addition, the Company uses the Monte Carlo method and other acceptable valuation methodologies when valuing the conversion feature and other embedded features classified as derivatives on a recurring basis. See *Note 7 – Derivatives*.

Inventories

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

Fixed Assets

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

	Years
Computers, software and office equipment	3 - 10
Leasehold improvements (1)	2 - 5
Manufacturing tooling	3 - 7
Laboratory equipment	4 - 6
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 fixed assets, the cost and related accumulated depreciation or amortization are removed from the 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.

The Company concluded there was no impairment of its intangible assets as of December 31, 2020. As a part of the Company's review of the tradename intangible asset associated with its Helomics reportable segment, the Company determined the asset is a finite-lived asset beginning September 30, 2020.

The Company concluded there was no impairment of its finite-lived assets as of December 31, 2020. The Company prepared the undiscounted cash flows per ASC 360. The Company concluded that the undiscounted cash flows of the long-lived assets exceeded the carrying values. As of March 31, 2021, there were no qualitative or quantitative factors indicating an impairment of its other intangible assets.

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.

The Company recognized loss on impairment goodwill during the year ended December 31, 2020 of \$12,876,498. As of March 31, 2021, there were no qualitative or quantitative factors indicating it was more likely than not that the carrying value of a reporting unit exceeds its estimated fair value.

The Company will continue to monitor its reporting units to determine whether events and circumstances warrant further interim impairment testing. Impairment of goodwill is not expected to be deductible for tax purposes. The Company can make no assurances that its goodwill will not be impaired in the future.

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 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.

Revenue Recognition

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

Revenue from Product Sales

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

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

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

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

Revenue from Clinical Testing

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

For service revenues, the Company estimates the transaction price which is the amount of consideration it expects to be entitled to receive in exchange for providing services based on its historical collection experience 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 less consideration than it originally estimated for a contract with a patient, it will account for the change as a decrease to the estimate of the transaction price, provided that such downward adjustment does not result in a significant reversal of cumulative revenue recognized.

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

CRO Revenue

Contract revenues are generally derived from studies conducted with biopharmaceutical and pharmaceutical companies. The specific methodology for revenue recognition is determined on a case-by-case basis according to the facts and circumstances applicable to a given contract. The Company typically uses an input method that recognizes revenue based on the Company's efforts to satisfy the performance obligation relative to the total expected inputs to the satisfaction of that performance obligation. For contracts with multiple performance obligations, the Company allocates the contract's transaction price to each performance obligation on the basis of the standalone-selling price of each distinct good or service in the contract. Advance payments received in excess of revenues recognized are classified as 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 Helomics segment.

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 \$264,928 and \$256,878 as of March 31, 2021 and December 31, 2020, respectively.

The Company's deferred revenues related primarily to maintenance plans of \$154,195 and \$53,028 as of March 31, 2021 and December 31, 2020, respectively.

Practical Expedients

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

Valuation and accounting for stock options and warrants

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

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

	For the three months ended March 31,					
	2021		2020			
	Stock Options					
Expected dividend yield	0.0%		0.0%			
Expected stock price volatility	84.8%		82.6%			
Risk-free interest rate	0.93%	-	1.45%	0.70%	-	1.57%
Expected life (in years)	10		10			
	Warrants					
Expected dividend yield	0.0%		0.0%			
Expected stock price volatility	84.8%		82.6%			
Risk-free interest rate	0.42%	-	0.69%	0.54%	-	0.79%
Expected life (in years)	5	-	5.5	2	-	5.5

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs were \$93,629 and \$129,341 for the three months ended March 31, 2021 and 2020, respectively.

Other Expense

Other expense consisted primarily of interest expense, payment premium, amortization of original issue discounts, and loss on debt extinguishment associated to the Company's notes payable.

Offering Costs

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

Income Taxes

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

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

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

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

Tax years subsequent to 2017 remain open to examination by federal and state tax authorities.

Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company places its cash and cash equivalents with high credit quality financial institutions and, by policy, generally limits the amount of credit exposure to any one financial institution. The Company does not have credit risk due to cash and cash equivalents 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.

Recent Accounting Pronouncements

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

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

Recent Developments

On March 19, 2021, the Company appointed J. Melville Engle, age 71, as its Chief Executive Officer, effective immediately. In addition to being named CEO, Mr. Engle will retain his role of Chairman of the Board. Mr. Engle joined POAI’s Board of Directors in October 2016 and was appointed Chairman of the Board in January 2020.

Dr. Carl Schwartz retired through his resignation as the Chief Executive Officer of the Company effective on March 19, 2021. In connection with the resignation, Dr. Schwartz and the Company simultaneously entered into a Transition and Separation Agreement pursuant to which, among other things, Dr. Schwartz agreed to retire from his employment and resign as a member of the board of directors and to provide certain transition services to the Company in exchange for the issuance to Dr. Schwartz of 100,000 shares of the Company’s common stock on April 1, 2021. In addition, the Company agreed to provide Dr. Schwartz with certain separation benefits and the vesting of restricted stock units previously granted to Dr. Schwartz.

Effective April 21, 2021, the Board of Directors (“Board”) the Company elected Dr. Christina Jenkins, M.D., to the Board, as well as to the Board’s Merger & Acquisition Committee. She was chosen to fill the vacancy created by the retirement of Dr. Carl I. Schwartz. As a Class III Director, Dr. Jenkins’ term will expire at the 2021 annual meeting of the Company’s stockholders. In recognition of the services Dr. Jenkins will provide to the Company as a member of the Board, she was issued 5,000 shares of common stock from the Company’s Amended and Restated 2012 Stock Incentive Plan simultaneously with her election.

The Company has evaluated all of its activities and concluded that no other subsequent events have occurred that would require recognition in the condensed consolidated financial statements or disclosure in the notes to the condensed consolidated financial statements, except as described above and in *Note 11 – Subsequent Events*.

NOTE 2 – INVENTORIES

Inventory balances are as follows:

	As of March 31, 2021	As of December 31, 2020
Finished goods	\$ 96,171	\$ 95,898
Raw materials	141,413	151,366
Work-In-Process	55,240	42,271
Total	<u>\$ 292,824</u>	<u>\$ 289,535</u>

NOTE 3 – FIXED ASSETS

The Company's fixed assets consist of the following:

	As of March 31, 2021	As of December 31, 2020
Computers, software, and office equipment	\$ 3,662,822	\$ 3,638,520
Leasehold improvements	315,296	315,297
Laboratory equipment	1,402,543	1,035,160
Manufacturing tooling	108,956	108,956
Demo equipment	56,614	56,614
Total	5,546,231	5,154,547
Less: Accumulated depreciation	(1,570,778)	(1,331,847)
Total Fixed Assets, Net	<u>\$ 3,975,453</u>	<u>\$ 3,822,700</u>

Depreciation expense was \$238,932 and \$130,075 during the three months ended March 31, 2021 and 2020, respectively.

NOTE 4 – INTANGIBLE ASSETS

The components of intangible assets were as follows:

	As of March 31, 2021			As of December 31, 2020		
	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount
Patents & Trademarks	\$ 402,857	\$ (215,597)	\$ 187,260	\$ 401,421	\$ (211,110)	\$ 190,311
Developed Technology	2,882,000	(288,199)	2,593,801	2,882,000	(252,175)	2,629,825
Customer Relationships	445,000	(296,667)	148,333	445,000	(259,583)	185,417
Tradename	398,000	(10,905)	387,095	398,000	(5,452)	392,548
Total	<u>\$ 4,127,857</u>	<u>\$ (811,368)</u>	<u>\$ 3,316,489</u>	<u>\$ 4,126,421</u>	<u>\$ (728,320)</u>	<u>\$ 3,398,101</u>

Amortization expense was \$83,048 and \$76,505 during the three months ended March 31, 2021 and 2020, respectively.

The following table outlines the estimated future amortization expense related to intangible assets held as of March 31, 2021:

Year ending December 31,	Expense	
2021	\$	249,182
2022		220,993
2023		183,910
2024		183,910
2025		183,910
Thereafter		2,294,584
Total	\$	3,316,489

NOTE 5 – NOTES PAYABLE

The balances of notes payable were as follows:

	Due Date	As of March 31, 2021		As of December 31, 2020	
Promissory note 2019	March 31, 2021	\$	-	\$	1,490,833
Promissory note 2020	March 31, 2021		-		1,464,146
2018 Investor Loan	March 31, 2021		-		1,721,776
Total Notes Payable, gross			-		4,676,755
Less: Unamortized discount			-		(244,830)
Total Notes Payable, net		\$	-	\$	4,431,925

Promissory Note Conversions

Each investor received the right to convert all or any part of its 2018 Investor loan into shares of the Company's common stock at a conversion factor that is the lesser of a discounted price. The number of conversion shares that may be issued was limited. As of March 31, 2020, the maximum number of conversion shares had been issued, no additional shares were available to be issued related to this conversion option. During the first three months of 2020, the investors converted \$267,328 of the principal balance and received 170,000 shares of the Company's common stock.

Also, the investor in the 2019 and 2020 promissory notes converted \$514,011 of the principal balance and received 1,107,544 shares of the Company's common stock during the first quarter of 2021 through February 15, 2021.

Promissory Note Repayment

On March 1, 2021, the Company used \$5,906,802 of the proceeds of the private placement on February 23, 2021, to repay in full the outstanding principal and interest and applicable premium amounts under the 2018 Investor Loan, the 2019 Promissory Note and the 2020 Promissory Note.

NOTE 6 – STOCKHOLDERS' EQUITY, STOCK OPTIONS AND WARRANTS

Equity Line

On October 24, 2019, the Company entered into an equity purchase agreement with an investor, providing for an equity financing facility. Upon the terms and subject to the conditions in the purchase agreement, the investor is committed to purchase shares having an aggregate value of up to \$15,000,000 of the Company's common stock for a period of up to three years. The Company issued to the investor 104,651 commitment shares at a fair market value of \$450,000 for entering into the agreement. From time to time during the three-year commitment period, provided that the closing conditions are satisfied, the Company may provide the investor with put notices to purchase a specified number of shares subject to certain limitations and conditions and at specified prices, which generally represent discounts to the market price of the common stock. As of March 31, 2021, there was \$9,789,419 of remaining available balance under the equity line, subject to market conditions including trading volume and stock price, and subject to other limitations. See *Note 11 – Subsequent Events*.

2021 Offerings

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

Offering Closing Date	Shares	Sale Price per Share*	Investor Warrants	Exercise Price per Share – Investor Warrants	Placement Agent Warrants	Exercise Price per Share – Placement Agent Warrants	Gross Proceeds of Offering	Net Proceeds of Offering
January 12, 2021 (registered direct)	3,650,840	\$0.842	1,825,420	\$0.80	273,813	\$1.0525	\$3,074,007	\$2,731,766
January 21, 2021 (registered direct)	2,200,000	\$1.00	1,100,000	\$1.00	165,000	\$1.25	\$2,200,000	\$1,932,050
January 26, 2021 (registered direct)	3,414,970	\$1.20	1,707,485	\$1.37	256,123	\$1.50	\$4,097,964	\$3,668,687
February 16, 2021 (registered direct)	4,222,288	\$1.75	2,111,144	\$2.00	316,672	\$2.1875	\$7,389,004	\$6,679,989
February 23, 2021 (private placement)	9,043,766	\$1.95	4,521,883	\$2.00	678,282	\$2.4375	\$17,635,344	\$16,064,739
Total	22,531,864		11,265,932		1,689,890		\$34,396,319	\$31,077,231

* Sale price includes one share and a warrant to purchase one-half share.

2021 Warrant Exercises

During the period January 1, 2021 through March 31, 2021, the holders of outstanding investor warrants have exercised such warrants for the total purchase of 5,247,059 shares at a weighted average exercise price of \$0.86 per share, for total proceeds of \$4,495,270.

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, 2019	766,424	\$ 11.34	2,171,610	\$ 15.26
Issued	319,851	1.03	8,097,468	1.547
Forfeited	(72,728)	10.58	(128,710)	95.11
Exercised	-	-	(2,786,992)	0.79
Outstanding at December 31, 2020	1,013,547	\$ 5.41	7,353,376	\$ 3.76
Issued	10,680	0.69	12,955,822	1.65
Forfeited	(18,078)	9.89	-	-
Exercised	-	-	(5,247,059)	0.86
Outstanding at March 31, 2021	<u>1,006,149</u>	<u>\$ 5.25</u>	<u>15,062,139</u>	<u>\$ 2.96</u>

Stock-based compensation expense recognized for three months ended March 31, 2021 and March 31, 2020 was \$565,082 and \$287,838, respectively. During the three months ended March, \$403,721 of expense related to the modification of the restricted share agreement and acceleration of vesting in connection with the CEO's retirement. The Company has \$7,357 of unrecognized compensation expense related to non-vested stock options that are expected to be recognized over the next 18 months.

NOTE 7 – 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 agent warrants issued in connection with the March 2020 Private Placement was determined to be \$33,654 as of December 31, 2020. The Company recorded a loss on the change in fair value of the placement agent warrants of \$32,507 during the three months ended March 31, 2021. As of March 31, 2021, the fair value of the placement agent warrants was \$66,161.

The fair value of the agent warrants issued in connection with the May 2020 were determined to be \$33,819 and \$65,139 as of December 31, 2020 and March 31, 2021, respectively. The Company recorded a loss on the change in fair value of the agent warrants of \$31,320 during the three months ended March 31, 2021.

The placement agent warrants issued in connection with the June 2020 warrant exercise and issuance had a fair value of \$32,701 and \$67,411 as of December 31, 2020 and March 31, 2021, respectively. The Company recorded a loss on the change in fair value of the agent warrants of \$34,710 during the three months ended March 31, 2021.

The Company concluded the Promissory Note 2020 contained a conversion feature and a put each of which is an embedded derivative and are required to be bifurcated. In accordance with ASC 815, *Derivatives and Hedging*, the Company combined these two embedded derivatives into a single derivative and determined the fair value to record within the derivative liability on the condensed consolidated balance sheet. As of December 31, 2020, the fair value of the derivative liability was \$104,529. As a result of the repayment of the note as of March 1, 2021, the embedded derivative had a fair value of zero prior to the repayment. The Company recorded a gain on the fair value of the derivative of \$104,529 during the three months ended March 31, 2021.

On September 30, 2020, the Promissory Note 2019 was amended. Management concluded the Promissory Note 2019 contained a conversion feature which is an embedded derivative and was required to be bifurcated. In accordance with ASC 815, *Derivatives and Hedging*, the Company determined the fair value to record within the derivative liability on the condensed consolidated balance sheet. As of December 31, 2020, the fair value of the derivative was \$89,680. As a result of the repayment of the note as of March 1, 2021, the embedded derivative had a fair value of zero prior to the repayment. The Company recorded a gain on the fair value of the derivative of \$89,680 during the three months ended March 31, 2021.

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

Derivative liability balance at December 31, 2019	\$ 50,989
Derivative instrument recognized for A, B and Agent Warrants	2,669,995
Derivative instrument related to Promissory Note 2020	120,921
Gain recognized to revalue derivative instrument at fair value	(27,107)
Derivative liability balance at March 30, 2020	\$ 2,814,798
Derivative liability balance at December 31, 2020	\$ 294,382
Gain recognized to revalue derivative instrument at fair value	(95,671)
Derivative liability balance at March 31, 2021	\$ 198,711

NOTE 8 - LOSS PER SHARE

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

	Three Months Ended	
	March 31,	
	2021	2020
Numerator:		
Net loss attributable to common shareholders per common share: basic and diluted calculation	\$ (3,888,713)	\$ (4,529,317)
Denominator:		
Weighted average common shares outstanding-basic	36,513,300	4,886,328
Effect of diluted stock options, warrants, and preferred stock (1)	-	-
Weighted average common shares outstanding - diluted	36,513,300	4,886,328
Loss per common share-basic and diluted	\$ (0.11)	\$ (0.93)

- (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 Months ended March 31,	
	2021	2020
Options	1,006,419	794,038
Warrants	15,062,139	5,663,594
Convertible debt	-	378,000
Preferred stock: series B	7,925	7,925
Preferred stock: series D	-	350,000
Preferred stock: series E	-	691,159

NOTE 9 – SEGMENTS

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

The Company has three operating segments: Skyline, Helomics and Soluble. 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 months ended March 31, 2021 are included in the table below. All revenues are earned from external customers.

Revenue

	Three Months Ended March 31,	
	2021	2020
Skyline	\$ 264,253	\$ 279,813
Helomics	1,989	15,130
Soluble	14,075	-
Corporate	-	-
Total	\$ 280,317	\$ 294,943

Segment Gain (Loss)

	Three Months Ended March 31,	
	2021	2020
Skyline	\$ (142,558)	\$ (409,844)
Helomics	(1,227,676)	(1,412,465)
Soluble	(249,529)	-
Corporate	(2,268,950)	(2,707,008)
Total	\$ (3,888,713)	\$ (4,529,317)

Assets

	As of March 31, 2021	As of December 31, 2020
Skyline	\$ 872,761	\$ 1,191,439
Helomics	6,872,046	9,773,902
Soluble	1,849,905	1,883,585
Corporate	30,059,132	211,510
Total	\$ 39,653,844	\$ 13,060,436

NOTE 10 – RELATED PARTY TRANSACTIONS

The Audit Committee has the responsibility to review and approve all transactions to which a related party and the Company may be a party prior to their implementation, to assess whether such transactions meet applicable legal requirements.

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

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

NOTE 11 – SUBSEQUENT EVENTS

Equity Line Agreement

Between April 1, 2021 and April 14, 2021, the Company issued 572,504 shares of its common stock valued at \$588,590 pursuant to the equity line.

Resignation of Director

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

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, 2020.

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

- We may not be able to continue operating past June 2022 without additional financing;
- Current 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 the possibility of further impairment of goodwill and risks related to the benefits and costs of acquisition;
- Risks related to our partnerships with other companies, including the need to negotiate the definitive agreements; possible failure to realize anticipated benefits of these partnerships; and costs of providing funding to our partner companies, which may never be repaid or provide anticipated returns;
- Risk that we will be unable to protect our intellectual property or claims that we are infringing on others' intellectual property;
- The impact of competition;
- Acquisition and maintenance of any necessary regulatory clearances applicable to applications of our technology;
- Inability to attract or retain qualified senior management personnel, including sales and marketing personnel;
- Risk that we never become profitable if our product and services are not accepted by potential customers;
- Possible impact of government regulation and scrutiny;
- Unexpected costs and operating deficits, and lower than expected sales and revenues, if any;
- Adverse results of any legal proceedings;
- The volatility of our operating results and financial condition,
- Management of growth;
- Risk that our business and operations will continue to be materially and adversely affected by the COVID-19 pandemic, which has impacted a significant supplier; has resulted in delayed production and less efficiency; and has impacted on our sales efforts, accounts receivable, and terms demanded by suppliers; and may impact financing transactions; and
- Other specific risks that may be alluded to in this report.

All statements, other than statements of historical facts, included in this report regarding our growth strategy, future operations, financial position, estimated revenue or losses, projected costs, prospects and plans, and objectives of management are forward-looking statements. When used in this report, the words "will," "may," "believe," "anticipate," "intend," "estimate," "expect," "project," "plan," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain such identifying words. All forward-looking statements speak only as of the date of this report. We do not undertake any obligation to update any forward-looking statements or other information contained herein. Potential investors should not place undue reliance on these forward-looking statements. Although we believe that our plans, intentions, and expectations reflected in or suggested by the forward-looking statements in this report are reasonable, we cannot assure potential investors that these plans, intentions or expectations will be achieved. We disclose important factors that could cause actual results to differ materially from expectations in the "Risk Factors" section and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2020 and in item 1A of Part II below. These cautionary statements qualify all forward-looking statements attributable to us or persons acting on our behalf.

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

Overview

We operate in three primary business areas: first, application of artificial intelligence (“AI”) in our precision medicine business, to provide AI-driven predictive models of tumor drug response to improve clinical outcomes for patients and to assist pharmaceutical, diagnostic, and biotech industries in the development of new personalized drugs and diagnostics; 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, direct-to-drain medical fluid disposal and associated products.

We have three reportable segments: Helomics, Soluble and Skyline Medical. The Helomics division consists of clinical testing and contract research. Our Soluble division is a provider of soluble and stable formulations for proteins, and our TumorGenesis subsidiary, which is included in corporate, specializes in media that help cancer cells grow and retain their DNA/RNA and proteomic signatures providing researchers with a tool to expand and study cancer cell types found in tumors of the blood and organ systems of all mammals, including humans. Our Skyline Medical segment consists of the STREAMWAY System product sales. Going forward, we have determined that we will focus our resources on the Helomics division and our primary mission of applying AI to precision medicine and drug discovery.

Precision Medicine Business

Our precision medicine business, conducted in our Helomics division, is committed to improving the effectiveness of cancer therapy using our proprietary, multi-omic tumor profiling platform, one-of-a-kind database of historical tumor data, and the power of AI to build predictive models of tumor drug response.

Helomics’ mission is to improve clinical outcomes for patients by partnering with pharmaceutical, diagnostic, and academic organizations to bring innovative clinical products and technologies to the marketplace. Our Patient-centric Drug Discovery using Active Learning asset (PeDAL™) is a unique technology that combines our proprietary, clinically validated patient tumor cell line assay (TruTumor™), a vast knowledgebase of proprietary and public data (TumorSpace™) together with active learning - the active learning allowing the efficient exploration of compound drug responses against a large diverse patient “space”. PeDAL offers researchers the opportunity to bring patient diversity much earlier, efficiently and cost-effectively in the drug discovery process. PeDAL works by iterative cycles of active-learning powered Learn-Predict-Test (L-P-T) to guide the testing of patient-specific compound responses using the TruTumor assay and patient cell lines to build a comprehensive predictive model of patient responses to compounds. This predictive model can then be used to rank compounds by the fraction of patients of certain profiles that respond as well as the set of compounds that provide the best coverage across patients. PeDAL will be used in fee-for-service projects with pharmaceutical companies.

Contract Research Organization (“CRO”) and AI-Driven Business

We believe leveraging our unique, historical database of the drug responses of over 150,000 patient tumors to build AI and data-driven multi-omic predictive models of tumor drug response and outcome will provide actionable insights critical to both new drug development and individualizing patient treatment. Through the course of over 15 years of clinical testing of the responses of patient tumors to drugs, Helomics has amassed a huge proprietary knowledgebase of 150,000 patient cases. This data has been rigorously de-identified and aggregated to build a unique, proprietary model of tumor drug response that we call TumorSpace. The TumorSpace model and its data provide *a priori* knowledge for the machine learning approaches we employ as part of the PeDAL approach.

TumorSpace model provides a significant competitive advantage to our business offerings. PeDAL’s unique patient and tumor-centric AI-driven approach can rapidly and cost-effectively screen hundreds of compounds in thousands of tumor cell lines, and gain valuable information about off-target effects and deliver:

- A ranked list of drug candidates by responsiveness
- Sets of drug candidates that provide maximum patient coverage
- Biomarker profiles of patients that respond to specific drug candidates

PeDAL also can deliver drug candidates targeted at a specific patient profile as early as the hit-to-lead stage of discovery, significantly increasing the chance of clinical success, leading to a dramatic improvement in both the success, time, and cost of your oncology discovery programs. The AI-driven models will, once validated, also provide clinical decision support to help oncologists individualize treatment.

Our CRO/AI business leverages our core competence in profiling the drug response of patient tumors. Our large knowledgebase of tumor drug response and other data, together with proven AI, has created a unique capability for oncology drug discovery that allows for the highly efficient screening of drug responses from thousands of diverse, well-characterized patient primary tumor cell lines. This novel disruptive patient-centric approach is ideally suited to the early part of drug discovery (especially hit-to-lead, lead optimization, and pre-clinical), resulting in better prioritization of compounds and better coverage of patient diversity. This will dramatically improve the chances of successfully translating discoveries, resulting in lowered costs, shortened timelines, and most importantly enhanced “speed-to-patient” for new therapies.

Our CRO services business applies PeDAL to address a range of needs from discovery through clinical and translational research, to clinical trials and diagnostic development and validation as noted below:

Research

- Biomarker discovery
- Drug discovery
- Drug-repurposing

Development

- Patient enrichment & selection for trials
- Clinical trial optimization
- Adaptive trials

Clinical Decision Support

- Patient stratification
- Treatment selection

We believe this market segment has significant growth potential and we believe we are differentiated from traditional CRO’s and other precision medicine and AI companies through these unique assets:

- Clinically validated TruTumor platform;
- TumorSpace model of over 150,000 tumor cases;
- Experienced AI team and AI platform; and
- Ability to access outcome data going back over ten years for over 120,000 of the tumor cases in our database.

Clinical Testing

Via our Helomics subsidiary, we offer a group of clinically relevant, cancer-related tumor profiling and biomarker tests for gynecological cancers that determine how likely the patient is to respond to various types of chemotherapy and which therapies might be indicated by relevant tumor biomarkers.

Clinical testing is comprised of Tumor Drug Response Testing (formerly ChemoFx) and Genomic Profiling (formerly BioSpeciFx) tests. The Tumor Drug Response Testing determines how a patient’s tumor specimen responds to a panel of various chemotherapy drugs, while the Genomic Profiling evaluates the expression of specific genes, or biomarkers, in the patient’s tumor. Our proprietary TruTumor tumor platform provides us with the ability to work with actual live tumor cells to study the unique biology of the patient’s tumor in order to understand how the patient responds to treatment.

Testing involves obtaining tumor tissue during biopsy or surgery which is then sent to our Clinical Laboratory Improvement Amendments (“CLIA”) certified laboratory using a special collection kit. Tumor Drug Response Testing is a fresh tissue platform that uses the patient’s own live tumor cells to help physicians identify effective treatment options for each gynecologic cancer patient.

Genomic Profiling offers a select group of clinically relevant protein expression and genetic mutation tests associated with drug response and disease prognosis. Physicians can select biomarkers for testing from carefully chosen panels of relevant tests, intuitively organized by cancer pathway and tumor type. Results for these tests are presented in a clear, easy to understand format, including summaries of the clinical relevance of each marker.

Soluble Biotech

Our subsidiary, Soluble Biotech Inc. (“Soluble”), focuses on contract services and research focused on solubility improvements, stability studies, and protein production and operates the assets of Soluble Therapeutics and BioDtech, which the Company acquired in May 2020. Specifically, Soluble provides optimized FDA-approved formulations for vaccines, antibodies, and other protein therapeutics in a faster and lower cost basis to its customers. In addition, Soluble enables protein degradation studies, which is a new and, based on current projections, potentially substantial line of business for the Company.

The primary assets of Soluble are our automated High Throughput Self-Interaction Chromatography (HSC™). HSC is a self-contained, automated system that conducts high-throughput, self-interaction chromatography screens on FDA approved excipients for protein formulations. Our technology measures second virial coefficient (B22 value) of protein-protein interactions to identify excipients that promote protein solubility in solutions. The data generated from HSC screens are analyzed by a proprietary predictive algorithm to identify the optimal combination(s) of buffers, pH, and excipients, resulting in increased solubility and physical stability of proteins. Several of our clients have seen ten-fold and hundred-fold increases in their protein’s solubility while maintaining physical stability. For biopharmaceutical clients this means faster development times and quicker progression of molecules into the clinic. For academic collaborators, this means further progression of biochemical and biology studies necessary to advance fundamental research in areas of unmet medical need.

In addition, Soluble provides comprehensive protein stability analysis. Analysis via time-dependent shelf-life studies and forced degradation studies designed to quickly determine which of the FDA approved additives that will improve the solubility and stability of proteins in solutions. Services include pre-formulation development, formulation stability assessment, and biophysical characterization which evaluate variables including pH, temperature, humidity, light, oxidizing agents, and mechanical stress to determine the most promising additives, formulation of B22 values and confirmation on conformation stability. We provide clients with a list of the most promising additives from a set of over 40 different additives that can increase the solubility and stability of protein formulations.

Soluble also offers protein solubility kits that allow rapid identification of soluble formulations. We provide four different kits to fulfill customer solubility requirements. The kits are in 96-well format and provide the tools and methods to compare relative solubility across 88 common formulations (with 8 controls). Soluble kits utilize a simple mix and spin protocol that quickly evaluates aggregation behavior as a function of pH, salt, and additives costing significantly less than if manually determined. In addition, we provide innovative technologies for bacterial detection and removal in therapeutic proteins that continue to be a significant issue in the pharmaceutical field.

Soluble also offers technically superior products for the bioresearch and bioprocess markets, which are designed exclusively for the detection, neutralization and removal of endotoxin. Our products offer the scientist the ability to eliminate the effects of endotoxin contamination by neutralization and/or removal and to achieve unparalleled accuracy in endotoxin detection, especially in complex samples such as recombinant proteins and blood products. These products address all of the concerns of the endotoxin market and eliminates common critical issues associated with current methods.

TumorGenesis

Our subsidiary, TumorGenesis, is pursuing a new rapid approach to growing tumors in the laboratory, which essentially “fools” the cancer cells into thinking they are still growing inside the patient. We have also announced a proposed joint venture with GLG Pharma focused on using their combined technologies to bring personalized medicines and testing to ovarian and breast cancer patients, especially those who present with ascites fluid (over one-third of patients). TumorGenesis is focused on providing the best media for the right cancer cell and during the first quarter of 2021, launched web-based distribution of media products for ovarian and breast cancers.

Skyline Medical – The STREAMWAY System

Sold through our subsidiary, Skyline Medical Inc. (“Skyline Medical”), the STREAMWAY System is a wall-mounted fully automated system that disposes of an unlimited amount of suction fluid providing uninterrupted performance for physicians while virtually eliminating healthcare workers’ exposure to potentially infectious fluids collected during surgical and other patient procedures. Antiquated manual fluid handling methods that require hand carrying and emptying filled fluid canisters present both an exposure risk and potential liability. Conversely, the STREAMWAY System is designed to: 1) reduce overhead costs to hospitals and surgical centers; 2) improve compliance with the Occupational Safety and Health Administration (“OSHA”) and other regulatory agency safety guidelines; 3) improve efficiency in the operating room and radiology and endoscopy departments, thereby leading to greater profitability; and 4) provide greater environmental stewardship by helping to eliminate the approximately 50 million potentially disease-infected canisters that go into landfills each year in the United States.

We also manufacture and sell two disposable products required for the operation of the STREAMWAY System: a bifurcated dual port procedure filter with tissue trap and a single use bottle of cleaning solution. The STREAMWAY disposables are a critical component of our business model. Recurring revenues from the sale of the disposables are expected to be significantly higher over time than the revenues from the initial sale of the unit. We have exclusive distribution rights to the disposable solution.

We have been granted patents for the STREAMWAY System in the United States, Canada and Europe. We distribute our STREAMWAY products to medical facilities where bodily and irrigation fluids produced during medical procedures must be contained, measured, documented, and disposed.

Skyline Medical operated with reduced personnel and associated operating costs in 2020. By streamlining our production, the Company maximized efficiency while attaining similar revenue to 2019. Throughout the year we continued to receive indications of interest from several parties for the possible acquisition of the Skyline division, as well as other partnership initiatives. We continue to operate the Skyline Medical business by continually improving our strategic opportunities, while focusing our resources on our precision medicine business.

Capital Requirements

Since inception, we have been unprofitable. We incurred net losses of \$3,888,713 and \$4,529,317 for the three months ended March 31, 2021 and March 31, 2020, respectively. As of March 31, 2021, and December 31, 2020, we had an accumulated deficit of \$112,271,821 and \$108,383,108, respectively.

We have never generated sufficient revenues to fund our capital requirements. From 2009 through 2018, we built the Skyline Medical business, building a national sales network and international sales. However, the Skyline Medical business has never reached profitability. In 2017, we determined to diversify our business by investing in ventures in the precision medicine business, including making significant loans and investments in early-stage companies. These activities led to the acquisition of Helomics in April 2019, which accelerated our capital needs further. We have funded our operations through a variety of debt and equity instruments. See “Liquidity and Capital Resources – Liquidity and Plan of Financing” below.

Our future cash requirements and the adequacy of available funds depend on our ability to generate revenues from our Helomics segment; to continue to sell our Skyline Medical products and attempt to reach profitability in the Skyline Medical business and the availability of future financing to fulfill our business plans. See “Liquidity and Plan of Financing” below.

Our limited history of operations, especially in our precision medicine business, and our change in the emphasis of our business, 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-month periods ended March 31, 2021 and March 31, 2020

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020	Difference
Revenue	\$ 280,317	\$ 294,943	\$ (14,626)
Cost of goods sold	97,758	92,657	(5,101)
General and administrative expense	3,270,777	2,828,476	(442,301)
Operations expense	574,812	548,753	(26,059)
Sales and marketing expense	114,641	264,409	149,768

Revenue. We recorded revenue of \$280,317 and \$294,943 in the three months ended March 31, 2021 and 2020, respectively. We sold a net of 3 and 5 STREAMWAY System units during the three months ended March 31, 2021 and 2020, respectively. During the three months ended March 31, 2021 and 2020, all revenue was derived from the Skyline Medical business except for \$1,989 and \$15,130 in Helomics revenues, respectively and \$14,075 during the three months ended March 31, 2021 in the Soluble reportable segment.

Cost of goods sold. Cost of sales was \$97,758 in the three months ended March 31, 2021 and \$92,657 in the three months ended March 31, 2020, respectively. The gross profit margin was approximately 65% in the three months ended March 31, 2021 compared to 69% in the prior year. Our margins decreased in the current year as costs were higher. Exclusive of Helomics, gross profit margin related to the Skyline Medical business was 71% in the three months ended March 31, 2021 and approximately 77% in the three months ended March 31, 2020.

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

G&A expense increased by \$442,301 for the three months ended March 31, 2021 compared to 2020. The increase was primarily due to an increase of severance and share-based compensation associated with the retirement of our CEO, increased depreciation due to newly acquired assets placed in service during the first quarter of 2021 and increased audit and related fees. These increases were offset by declines in expenses related to share-based compensation for awards made in 2020 and other share-based payments as well as lower franchise taxes.

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

Operations expense increased by \$26,059 to \$574,812 in the three months ended March 31, 2021 compared to 2020. The increase was primarily due to higher costs related to staff and higher AI computing costs.

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

Sales and marketing expense decreased by \$149,768 to \$114,641 in the three months ended March 31, 2021. Such expenses related almost exclusively to the Skyline Medical business. The decrease in 2021 was a direct result of the strategic decision focus on the precision medicine business and reduce the emphasis on expenditures in the Skyline Medical business. These factors decreased our expenses for public relations and salary and travel costs for sales staff.

Other income. We earned other income of \$28,259 in the three months ended March 31, 2021 compared to \$3 in the comparable period in 2020. Other income included interest and dividend income.

Other expense. We incurred other expense of \$234,972 in the three months ended March 31, 2021 compared to \$1,117,075 in the comparable period in 2020. Other expense in 2020 consisted primarily of net interest expense, payment premium, amortization of original issue discounts, and loss on debt extinguishment related to our notes payable.

Gain on derivative instruments. We incurred a gain of \$95,671 in the three months ended March 31, 2021 compared to \$27,107 in the comparable period in 2020.

Liquidity and Capital Resources

Cash Flows

Net cash used in operating activities was \$3,322,091 and \$2,972,981 for the three months ended March 31, 2021 and March 31, 2020, respectively. Cash used in operating activities increased in the 2021 period primarily because of the increase in cash used for working capital and the additional costs related to the Helomics and Soluble Biotech business.

Cash flows used in investing activities were \$393,121 for the three months ended March 31, 2021 and cash flows used in investing activities was \$32,510 for the three months ended March 31, 2020, respectively. Cash used in the three months ended March 31, 2021 was from the acquisition of fixed assets and cash used to maintain our intangible assets. Cash used in the three months ended March 31, 2020 was for the acquisition of intangible assets.

Net cash provided by financing activities was \$30,336,287 and \$5,910,903 for the three months ended March 31, 2021 and March 31, 2020, respectively. The cash provided in the three months ended March 31, 2021 was primarily due to proceeds from issuance of common stock, warrant exercises and issuances related to various transactions, and proceeds from the issuance common stock pursuant to the equity line agreement, each discussed below in “Financing Transactions”.

Liquidity and Plan of Financing

We have incurred a net loss in each of our annual periods since our inception. We incurred a net loss of \$3,888,713 for the three months ended March 31, 2021. On March 31, 2021, we had \$27,299,407 in cash and cash equivalents. In addition to our cash, we also have access to additional capital through our \$15,000,000 equity line with a remaining available balance of \$9,789,419 as of March 31, 2021, subject to market conditions including trading volume and stock price, and subject to other limitations. See *Note 11 – Subsequent Events*.

Since our inception, we have received net proceeds from the sale of our common stock (through our initial public offering and subsequent public offerings, including at-the-market offerings) which have funded our operations. We maintain additional access to capital through our active shelf registration statement which allows for the sale of various equity or debt instruments up to an aggregate amount of \$250,000,000 subject to availability and certain limitations.

We believe that our existing capital resources will be sufficient to support our operating plan through at least June 30, 2022. If we anticipate that our actual results will differ from our operating plan, we believe we have sufficient capabilities to enact cost savings measures to preserve capital. We may also seek to raise additional capital to support our growth through the incurrence of additional debt, the sale of equity or other alternatives (including asset sales) or a combination thereof.

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.

Equity Line

On October 24, 2019, the Company entered into an equity purchase agreement with an investor, providing for an equity financing facility. Upon the terms and subject to the conditions in the purchase agreement, the investor is committed to purchase shares having an aggregate value of up to \$15,000,000 of the Company’s common stock for a period of up to three years. The Company issued to the investor 104,651 commitment shares at a fair market value of \$450,000 for entering into the agreement. From time to time during the three-year commitment period, provided that the closing conditions are satisfied, the Company may provide the investor with put notices to purchase a specified number of shares subject to certain limitations and conditions and at specified prices, which generally represent discounts to the market price of the common stock. As of March 31, 2021, there was \$9,789,419 of remaining available balance under the equity line, subject to market conditions including trading volume and stock price, and subject to other limitations. See *Note 11 – Subsequent Events*.

2021 Offerings

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

Offering Closing Date	Shares	Sale Price per Share*	Investor Warrants	Exercise Price per Share – Investor Warrants	Placement Agent Warrants	Exercise Price per Share – Placement Agent Warrants	Gross Proceeds of Offering	Net Proceeds of Offering
January 12, 2021 (registered direct)	3,650,840	\$0.842	1,825,420	\$0.80	273,813	\$1.0525	\$3,074,007	\$2,731,766
January 21, 2021 (registered direct)	2,200,000	\$1.00	1,100,000	\$1.00	165,000	\$1.25	\$2,200,000	\$1,932,050
January 26, 2021 (registered direct)	3,414,970	\$1.20	1,707,485	\$1.37	256,123	\$1.50	\$4,097,964	\$3,668,687
February 16, 2021 (registered direct)	4,222,288	\$1.75	2,111,144	\$2.00	316,672	\$2.1875	\$7,389,004	\$6,679,989
February 23, 2021 (private placement)	9,043,766	\$1.95	4,521,883	\$2.00	678,282	\$2.4375	\$17,635,344	\$16,064,739
Total	22,531,864		11,265,932		1,689,890		\$34,396,319	\$31,077,231

* Sale price includes one share and a warrant to purchase one-half share.

2021 Warrant Exercises

During the period January 1, 2021 through March 31, 2021, the holders of outstanding investor warrants have exercised such warrants for the total purchase of 5,247,059 shares at a weighted average exercise price of \$0.86 per share, for total proceeds of \$4,495,269.

Off-Balance Sheet Arrangements

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

Accounting Standards and Recent Accounting Developments

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

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Not required.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), defines the term “disclosure controls and procedures” as those controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Based on their evaluation as of March 31, 2021, 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 March 31, 2021 for the reasons described below:

Management has 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. We have determined that this represents a material weakness in our internal control over financial reporting.

Notwithstanding the material weakness in our internal control over financial reporting, we have concluded that the 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

To remediate the material weakness in our internal control over financial reporting described above, we have reevaluated our overall staffing levels within the accounting department and during the fourth quarter of 2019 hired additional resources with qualifications that include a high level of experience with complex technical accounting transactions and application of U.S. GAAP. In the first quarter of 2020, we also engaged an external accounting consultant to assist with the assessment of new complex transactions, which has been ongoing to date. We have completed internal control remediation testing utilizing an external consulting company. We have also re-evaluated the training and ongoing professional education that is provided to, and required of, our accounting personnel.

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.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the three months ended March 31, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. Legal Proceedings

None

ITEM 1A. Risk Factors

In addition to the other information set forth in the Quarterly Report on Form 10-Q, the reader should carefully consider the risks included in Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 before making an investment decision. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. The reader should also carefully consider these risk factors.

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

Information regarding sales of unregistered securities during the prior year periods covered hereby has been included in previous reports on Form 8-K or 10-K. The following is a summary of our transactions during the period beginning January 1, 2021 involving sales of our securities that were not registered under the Securities Act:

On April 16, 2021, we issued 8,814 shares of common stock for payment of \$10,400 for professional research services.

None of the securities described above were registered under the Securities Act of 1933, as amended at the time of sale, and therefore may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. For these issuances, we relied on the exemption from federal registration under Section 4(a)(2) of the Securities Act and/or Rule 506 promulgated thereunder, based on our belief that the offer and sale of such securities has not and will not involve a public offering.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

Not applicable.

ITEM 6. Exhibits

See the attached exhibit index.

SIGNATURES:

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

PREDICTIVE ONCOLOGY INC.

Date: May 12, 2021

By: /s/ J. Melville Engle
J. Melville Engle
Chief Executive Officer

Date: May 12, 2021

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

EXHIBIT INDEX

Exhibit Number	Description
4.1	Form of Common Stock Purchase Warrant dated January 12, 2021 (1) Exhibit 4.1
4.2	Form of Common Stock Purchase Warrant dated January 21, 2021 (2) Exhibit 4.2
4.3	Form of Common Stock Purchase Warrant dated January 26, 2021 (3) Exhibit 4.3
4.4	Form of Placement Agent Warrant to H.C. Wainwright & Co., LLC or its designees in connection with certain financing transactions in 2020 and 2021 (4) Exhibit 4.4
4.5	Form of Common Stock Purchase Warrant dated February 16, 2021 (5) Exhibit 4.5
4.6	Form of Common Stock Purchase Warrant dated February 22, 2021 (6) Exhibit 4.6
10.1	Form of Securities Purchase Agreement dated January 8, 2021, by and between Predictive Oncology Inc. and certain Purchasers (1) Exhibit 10.1
10.2	Form of Securities Purchase Agreement dated January 19, 2021, by and between Predictive Oncology Inc. and certain Purchasers (2) Exhibit 10.2
10.3	Form of Securities Purchase Agreement dated January 21, 2021, by and between Predictive Oncology Inc. and certain Purchasers (3) Exhibit 10.3
10.4	Form of Securities Purchase Agreement dated February 10, 2021, by and between Predictive Oncology Inc. and certain Purchasers (4) Exhibit 10.4
10.5	Form of Securities Purchase Agreement dated February 18, 2021, by and between Predictive Oncology Inc. and certain Purchasers (5) Exhibit 10.5
10.6	Form of Registration Rights Agreement dated February 18, 2021, by and between Predictive Oncology Inc. and certain Purchasers (6) Exhibit 10.6
10.7	Transition and Separation Agreement by and between Carl I. Schwartz and the Company (8) Exhibit 10.7
10.8	Agreement and Release by and between Carl I. Schwartz and the Company (8) Exhibit 10.8
10.9	Offer Letter to J. Melville Engle dated March 19, 2021 (8) Exhibit 10.9
10.10	Employment Agreement effective March 19, 2021 by and between J. Melville Engle and the Company (9) Exhibit 10.10
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith

- (1) Filed on January 12, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (2) Filed on January 21, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (3) Filed on January 26, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (4) Filed on January 29, 2021 as an exhibit to our Registration Statement on Form S-1 and incorporated herein by reference
- (5) Filed on February 12, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (6) Filed on February 22, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (7) Filed on March 15, 2021 as an exhibit to our Registration Statement on Form S-3 and incorporated herein by reference.
- (8) Filed on March 23, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (9) Filed on April 7, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

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

I, J. Melville Engle, 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: May 12, 2021

/s/ J. Melville Engle

J. Melville Engle
Chief Executive Officer

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

I, Bob Myers, certify that:

1. I have reviewed the quarterly report on Form 10-Q of Predictive Oncology Inc.;
2. Based on my knowledge, this report does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements in light of the circumstances under which some statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report (that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting); and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date May 12, 2021

/s/ Bob Myers

Bob Myers
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 March 31, 2021 as filed with the Securities and Exchange Commission (the "Report"), I, Carl Schwartz, Chief Executive Officer (Principal Executive Officer) and, I, Bob Myers, Chief Financial Officer (Principal Financial Officer) of the Company, hereby certify as of the date hereof, solely for purposes of § 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1350, that to the best of my knowledge:

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

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

Date: May 12, 2021

/s/ J. Melville Engle

J. Melville Engle
Chief Executive Officer

Date: May 12, 2021

/s/ Bob Myers

Bob Myers
Chief Financial Officer