

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

## FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

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:

Predictive Oncology Inc.

(Exact name of registrant as specified in its charter)

Delaware

83-4360734

(State or other jurisdiction of  
incorporation or organization)

(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)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files).

Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

Yes No

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

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. As of November 14, 2019, the registrant had 3,887,956 shares of common stock, par value \$0.01 per share outstanding, adjusted for a one-for-ten reverse stock split effective for trading purposes on October 29, 2019 as described in Note 1 to the unaudited condensed consolidated financial statements under "Nature of Operations and Continuation of Operations". In this report all numbers of shares and per share amounts, as appropriate, have been restated to reflect the reverse stock split.

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PREDICTIVE ONCOLOGY INC.

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

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents	\$ 98,599	\$ 162,152
Accounts Receivable	372,119	232,602
Notes Receivable (inclusive of \$0 and \$452,775 in advances to Helomics; net of \$787,524 and \$0 in allowance for credit losses)	250,000	497,276
Inventories	210,350	241,066
Prepaid Expense and other assets	131,558	318,431
<b>Total Current Assets</b>	<b>1,062,626</b>	<b>1,451,527</b>
Notes Receivable	-	1,112,524
Fixed Assets, net	1,633,750	180,453
Intangibles, net	4,508,433	964,495
Lease Right-of-Use Assets	886,712	-
Goodwill	23,790,290	-
<b>Total Assets</b>	<b>\$ 31,881,811</b>	<b>\$ 3,708,999</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$ 3,762,468	\$ 445,689
Notes Payable –Net of Discounts of \$499,215 and \$1,032,814	4,470,380	1,634,914
Accrued Expenses	1,807,188	1,279,114
Derivative Liability	210,762	272,745
Deferred Revenue	30,638	23,065
Lease Liability – Net of Long-term Portion	500,732	-
<b>Total Current Liabilities</b>	<b>10,782,168</b>	<b>3,655,527</b>
Lease Liability	385,980	-
<b>Total Liabilities</b>	<b>11,168,148</b>	<b>3,655,527</b>
Stockholders' Equity:		
Series E Convertible Preferred Stock, \$.01 par value, 350 shares authorized, 257.7 and 0 shares outstanding (Liquidation value \$2,577,000)	3	-
Series B Convertible Preferred Stock, \$.01 par value, 20,000,000 shares authorized, 79,246 and 79,246 outstanding	792	792
Series D Convertible Preferred Stock, \$.01 par value, 20,000,000 shares authorized, 3,500,000 and 0 outstanding	35,000	-
Common Stock, \$.01 par value, 100,000,000 shares authorized, 3,149,751 and 1,409,175 outstanding	31,497	14,092
Additional paid-in capital	89,590,908	63,146,533
Accumulated Deficit	(68,944,537)	(63,107,945)
<b>Total Stockholders' Equity</b>	<b>20,713,663</b>	<b>53,472</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 31,881,811</b>	<b>\$ 3,708,999</b>

See Notes to Condensed Consolidated Financial Statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue	\$ 522,696	\$ 329,930	\$ 1,064,088	\$ 1,100,108
Cost of goods sold	208,096	83,006	400,202	309,320
Gross margin	314,600	246,924	663,886	790,788
General and administrative expense	2,616,991	762,603	7,425,305	2,708,274
Operations expense	707,414	723,939	2,445,238	1,390,434
Sales and marketing expense	434,955	621,465	1,674,200	1,726,087
Total operating loss	(3,444,760)	(1,861,083)	(10,880,857)	(5,034,007)
Gain on revaluation of cash advances to Helomics	-	-	1,222,244	-
Other income	15,084	-	65,293	-
Other expense	578,836	-	1,967,895	-
Loss on equity method investment	-	645,786	439,637	1,606,294
Gain on revaluation of equity method investment	-	-	6,164,260	-
Net loss	\$ (4,008,512)	\$ (2,506,869)	\$ (5,836,592)	\$ (6,640,301)
Deemed dividend on Series E Convertible Preferred Stock	125,801	-	146,199	-
Net loss attributable to common shareholders per common shares – basic and diluted	<u>\$ (4,134,313)</u>	<u>\$ (2,506,869)</u>	<u>\$ (5,982,791)</u>	<u>\$ (6,640,301)</u>
Loss per common share - basic and diluted	\$ (1.31)	\$ (1.89)	\$ (2.32)	\$ (5.45)
Weighted average shares used in computation - basic and diluted	3,146,609	1,325,261	2,581,014	1,217,829

See Notes to Condensed Consolidated Financial Statements

**PREDICTIVE ONCOLOGY INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**FOR THE THREE AND NINE MONTHS ENDED**  
**SEPTEMBER 30, 2019 AND 2018**  
**(Unaudited)**

	Three Months Ended September 30, 2018								
	Series B Preferred		Common Stock		Additional Paid- In Capital	Accumulated Deficit	Total		
	Shares	Amount	Shares	Amount				\$	\$
Balance at 6/30/2018	79,246	\$ 792	1,208,945	\$ 12,089	\$ 62,247,373	\$ (58,898,476)	\$ 3,361,778		
E Warrant exercises pursuant to S-3 public offering at \$10.00 exercise price per share			5,656	57	56,503		56,560		
Re-priced warrant exercise pursuant to 2016 private investment			25,233	252	252,080		252,332		
Shares issued pursuant to consultant contracts at \$11.80 per share			25,000	250	294,750		295,000		
Shares issued in escrow pursuant to a contract with TumorGenesis at \$11.70 per share			75,000	750	876,750		877,500		
Stock issuable for bridge loan					206,605		206,605		
Warrants issued per bridge loan					143,707		143,707		
Vesting Expense					339,954		339,954		
Net loss						(2,506,869)	(2,506,869)		
Balance at 9/30/2018	79,246	\$ 792	1,339,834	\$ 13,398	\$ 64,417,722	\$ (61,405,345)	\$ 3,026,567		

	Three Months Ended September 30, 2019										
	Series B Preferred		Series D Preferred		Series E Preferred		Common Stock		Additional Paid- In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at 6/30/2019	79,246	\$ 792	3,500,000	\$ 35,000	84.3	\$ 1	3,097,476	\$ 30,975	\$ 87,160,845	\$ (64,936,025)	\$22,291,588
Shares issued pursuant to note conversions - bridge loan							26,573	266	99,734		100,000
Shares issued pursuant to bridge loan agreement							23,858	238	119,136		119,374
Warrants issued pursuant to CEO note payable									14,863		14,863
Exercise of warrants							1,844	18	166		184
Issuance of Series E Preferred shares					173.4	2			1,595,278		1,595,280
Expense warrants for note extension									60,100		60,100
Warrants issued pursuant to promissory note									180,640		180,640
Vesting expense									360,146		360,146
Net loss										(4,008,512)	(4,008,512)
Balance at 9/30/2019	79,246	\$ 792	3,500,000	\$ 35,000	257.7	\$ 3	3,149,751	\$ 31,497	\$ 89,590,908	\$ (68,944,537)	\$20,713,663

	Nine Months Ended September 30, 2018									
	Series C Preferred		Series B Preferred		Common Stock		Additional Paid- in Capital	Accumulated Deficit	Total	
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at 12/31/2017	647,819	\$ 6,479	79,246	\$ 792	694,328	\$ 6,943	\$ 57,442,745	\$ (54,765,045)	\$ 2,691,914	
Preferred conversion to common shares pursuant to private placement agreement	(647,819)	(6,479)			58,975	590	5,889		-	
Shares issued pursuant to S-3 public offering					290,000	2,900	2,752,187		2,755,087	
Investment in Subsidiary pursuant to Helomics 20% acquisition					110,000	1,100	1,041,150		1,042,250	
E Warrant exercises pursuant to S-3 public offering at \$10.00 exercise price per share					14,539	145	145,251		145,396	
Shares issued pursuant to S-3 public offering over-allotment option at \$9.497 exercise price per share					21,525	215	204,206	1	204,422	
Re-priced warrant exercise pursuant to 2016 private investment					50,467	505	504,160		504,665	
Shares issued pursuant to a consultant contract @ 11.80 per share					25,000	250	294,750		295,000	
Shares issued in escrow pursuant to a contract with TumorGenesis @ 11.70 per share					75,000	750	876,750		877,500	
Stock issuable for bridge loan							206,605		206,605	
Warrants issued per bridge loan							143,707		143,707	
Vesting Expense							800,322		800,322	
Net loss								(6,640,301)	(6,640,301)	
Balance at 9/30/2018	-	-	79,246	\$ 792	1,339,834	\$ 13,398	\$ 64,417,722	\$ (61,405,345)	\$ 3,026,567	

	Nine Months Ended September 30, 2019										
	Series B Preferred		Series D Preferred		Series E Preferred		Common Stock		Additional Paid- in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at 12/31/2018	79,246	\$ 792	-	-	-	-	1,409,175	\$ 14,092	\$ 63,146,533	\$ (63,107,945)	\$ 53,472
Investment by CEO							7,813	78	49,922		50,000
Shares issued in forbearance agreement							16,667	166	158,183		158,349
Shares issued pursuant to S-3 public offering							286,375	2,864	2,426,844		2,429,708
Shares issued pursuant to note conversions - bridge loan							82,432	824	337,749		338,573
Shares issued pursuant to bridge loan agreement							23,857	239	119,135		119,374
Warrants issued pursuant to CEO note payable									356,471		356,471
Stock issued for Helomics acquisition			3,500,000	35,000			400,000	4,000	5,573,250		5,612,250
Stock issued to extinguish debt as part of Helomics purchase consideration							863,732	8,637	6,454,672		6,463,309
Issuance of warrants as Helomics purchase consideration									6,261,590		6,261,590
Exercise of warrants							59,700	597	5,373		5,970
Issuance of Series E Preferred Shares					257.7	3			2,338,837		2,338,840
Warrants issued pursuant to promissory note									180,640		180,640
Vesting expense									2,004,366		2,004,366

Issuance of noteholders warrants											177,343		177,343		
Net loss												(5,836,592)	(5,836,592)		
Balance at 9/30/2019	79,246	\$	792	3,500,000	\$	35,000	257.7	\$	3	3,149,751	\$	31,497	\$ 89,590,908	\$ (68,944,537)	\$20,713,663

See Notes to Condensed Consolidated Financial Statements



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

	<b>Nine Months Ended September 30,</b>	
	<b>2019</b>	<b>2018</b>
Cash flow from operating activities:		
Net loss	\$ (5,836,592)	\$ (6,640,301)
Adjustments to reconcile net loss to net cash used in operating activities:		
Recognition of credit loss on notes receivable	787,524	-
Accrued interest revenue	(34,917)	-
Loss on equity method investment	439,637	1,606,294
Gain on revaluation of equity method investment	(6,164,260)	-
Depreciation and amortization	483,631	105,569
Vesting expense	2,004,366	800,322
Equity instruments issued for management and consulting	-	295,000
Amortization of debt discount	1,621,181	-
Gain on valuation of equity-linked instruments	(84,627)	-
Gain on revaluation of cash advances to Helomics	(1,222,244)	-
Debt extinguishment costs	204,750	-
Loss on fixed asset disposal	293	-
Changes in assets and liabilities:		
Accounts receivable	68,252	(101,099)
Inventories	60,638	(13,110)
Prepaid expense and other assets	33,834	70,536
Accounts payable	942,183	268,637
Accrued expenses	751,975	(470,176)
Deferred revenue	7,573	8,643
Net cash used in operating activities:	(5,936,803)	(4,069,685)
Cash flow from investing activities:		
Redemption of certificates of deposit	-	244,971
Advance on notes receivable	(975,000)	(124,774)
Cash received from notes receivable	154,418	-
Cash received in Helomics Acquisition	248,102	-
Purchase of fixed assets	(855)	(169,983)
Acquisition of intangibles	(18,419)	(46,398)
Net cash used in investing activities:	(591,754)	(96,184)
Cash flow from financing activities:		
Proceeds from debt issuance	2,250,000	-
Repayment of debt	(609,514)	-
Proceeds from exercise of warrants into common stock	5,970	650,062
Proceeds from issuance of Series E convertible preferred stock	2,338,840	-
Issuance of common stock	2,479,708	2,959,509
Net cash provided by financing activities	6,465,004	3,609,571
Net decrease in cash and cash equivalents	(63,553)	(556,298)
Cash at beginning of period	162,152	766,189
Cash at end of period	<u>\$ 98,599</u>	<u>\$ 209,891</u>
Non-cash transactions:		
Bridge loan conversion into common stock	\$ 338,573	\$ -
Forbearance settlement bridge loan	503,009	-
Additional warrants issued pursuant to CEO note payable	47,078	-
Warrants issued pursuant to debt issuance	180,640	-
Consideration given for acquisition of Helomics	26,711,791	1,542,250
Shares issued into escrow for TumorGenesis	-	877,500
Bridge loan receivable	-	1,815,000
Conversion of preferred stock to common stock	-	6,479

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. On October 28, 2019, the Company completed a one-for-ten reverse stock split that was effective for trading purposes on October 29, 2019. All numbers of shares and per-share amounts in this report have been adjusted to reflect the reverse stock split (“Reverse Split”).

The Company is a healthcare company that provides personalized medicine solution and medical devices in two main areas: (1) precision medicine, which aims to apply artificial intelligence to personalized medicine and drug discovery; and (2) an environmentally safe system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. The Company also makes ongoing sales of proprietary cleaning fluid and filters to users of its systems.

On April 4, 2019, the Company completed the Helomics Holding Corporation (“Helomics”) acquisition. The Company’s precision medicine services – designed to use artificial intelligence and a comprehensive disease database to improve the effectiveness of cancer therapy – were launched with the Company’s investment in Helomics. Helomics’ precision oncology services are based on its D-CHIP™ diagnostic platform, which combines a database of genomic and drug response profiles from over 149,000 tumors with an artificial intelligence based searchable bioinformatics platform. Once a patient’s tumor is excised and analyzed, the D-CHIP platform compares the tumor profile with its database, and using its extensive drug response data, provides a specific therapeutic roadmap. In addition, the Company’s wholly-owned subsidiary, TumorGenesis Inc., is developing the next generation, patient-derived tumor models for precision cancer therapy and drug development. TumorGenesis Inc., formed during the first quarter of 2018, is presented as part of the unaudited condensed consolidated financial statements (“financial statements”).

The Company has incurred recurring losses from operations and has an accumulated deficit of \$68,944,537. The Company does not expect to generate sufficient operating revenue to sustain its operations in the near-term. Year-to-date the Company has incurred negative cash flows from operations. Although the Company has attempted to curtail expenses, there is no guarantee that the Company will be able to reduce these expenses significantly, and expenses may need to be higher to prepare product lines for broader sales in order to generate sustainable revenues. The Company had cash and cash equivalents of \$98,599 as of September 30, 2019 and needs to raise significant additional capital to meet its operating needs and pay debt obligations coming due. The Company intends to raise these funds through equity or debt financing that may include public offerings, private placements, alternative offerings, or other means. In the third quarter of 2019, the Company raised \$1,562,840 in net proceeds from a private placement of convertible preferred stock and \$25,000 in debt financing from the Company's CEO. The Company also completed a public offering which raised in \$2,811,309 net proceeds in October 2019 (see Note 9). In addition, 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 certain prior conditions. Despite these sources of funding, the Company will need to obtain additional financing in order to fund operations. There is substantial doubt about the Company's ability to continue as a going concern for one year after the date that the financial statements are issued. The accompanying financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

#### **Interim Financial Statements**

The Company has prepared the 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 financial statements. These interim 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 financial statements reflect all intercompany eliminations. These interim financial statements should be read in conjunction with the annual financial statements and the notes thereto contained in the Annual Report on Form 10-K filed with the SEC on April 1, 2019. 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.

#### **Recent Accounting Developments**

The Company has reviewed all recently issued accounting pronouncements and has determined that they are either not applicable or are not expected to have a material impact on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which requires lessees to put most leases on their balance sheets but recognize the expenses on their income statements in a manner similar to current practice. The standard states that a lessee would recognize a lease liability for the obligation to make lease payments and a right-to-use asset for the right to use the underlying asset for the lease term. The standard was effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2018. The Company adopted the standard on January 1, 2019, using the transition relief to the modified retrospective approach, presenting prior year information based on the previous standard. Upon adoption, the Company recognized \$353,007 of lease right-of-use (ROU) assets and liabilities for operating leases on its condensed consolidated balance sheet, of which, \$79,252 were classified as current liabilities. The adoption of ASU 2016-02 did not have a material impact on the Company's consolidated results of operations or cash flows.

#### **Accounting Policies and Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities at the date of the financial statements during the reporting period. Actual results could materially differ from those estimates.

The Company leases facilities under long-term operating leases that are non-cancelable and expire on various dates. At the lease commencement date, lease ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term, which includes all fixed obligations arising from the lease contract. If an interest rate is not explicit in a lease, the Company utilizes its incremental borrowing rate for a period that closely matches the lease term.

See Note 8 – Leases.

#### Cash Equivalents

The Company considers all highly liquid debt instruments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents are stated at cost, which approximates fair value.

#### Fair Value Measurements

Under generally accepted accounting principles as outlined in the FASB's Accounting Standards Codification (ASC) 820, 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. 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 was determined based on Level 1 inputs.

#### Inventories

Inventories are stated at the net realizable value, with cost determined on a first-in, first-out basis. Inventory balances are as follows:

	September 30, 2019	December 31, 2018
Finished goods	\$ 62,696	\$ 58,701
Raw materials	86,413	127,003
Work-In-Process	61,241	55,362
Total	<u>\$ 210,350</u>	<u>\$ 241,066</u>

## 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 and office equipment	3 - 7
Leasehold improvements	2
Manufacturing tooling	3 - 7
Demo equipment	3
Laboratory equipment	4

The Company's fixed assets consist of the following:

	September 30, 2019	December 31, 2018
Computers and office equipment	\$ 504,556	\$ 204,903
Leasehold improvements	188,014	140,114
Manufacturing tooling	108,955	108,955
Demo equipment	73,051	85,246
Laboratory equipment	1,401,210	-
Total	2,275,786	539,218
Less: Accumulated depreciation	642,036	358,765
Total Fixed Assets, Net	<u>\$ 1,633,750</u>	<u>\$ 180,453</u>

The large fluctuation in fixed assets is due to the Helomics acquisition. Upon retirement or sale, the cost and related accumulated depreciation 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.

Depreciation expense was \$130,848 and \$284,150 in the three and nine-month periods ended September 30, 2019 and was \$26,120 and \$59,442 for the three and nine-month periods ended September 30, 2018.

## Intangible 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. The tradename is an indefinite-lived intangible asset and is not amortized. Amortization expense was \$93,421 and \$199,481 in the three and nine-month periods ended September 30, 2019 and was \$38,387 and \$46,127 in the three and nine-month periods ended September 30, 2018. 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 large fluctuation in intangible assets during 2019 was due to the Helomics acquisition.

The components of intangible assets were as follows:

	9/30/2019			12/31/2018		
	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount	Gross Carrying Costs	Accumulated Amortization	Net Carrying Amount
Patents & Trademarks	\$ 336,722	\$ (191,950)	\$ 144,772	\$ 318,304	\$ (182,559)	\$ 135,745
Licensing Fees	877,500	(92,625)	784,875	877,500	(48,750)	828,750
Developed Technology	2,882,000	(72,048)	2,809,952	-	-	-
Customer Relationships	445,000	(74,166)	370,834	-	-	-
Tradename	398,000	-	398,000	-	-	-
Total	<u>\$ 4,939,222</u>	<u>\$ (430,789)</u>	<u>\$ 4,508,433</u>	<u>\$ 1,195,804</u>	<u>\$ (231,309)</u>	<u>\$ 964,495</u>

The following table outlines the estimated future amortization expense related to intangible assets held as of September 30, 2019:

Year ending December 31,	Expense
2019	90,985
2020	363,941
2021	363,941
2022	265,053
2023	215,609
Thereafter	2,810,904
Total	4,110,433

### 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 and represents the future economic benefits that the Company expects to achieve as a result of the acquisition. Goodwill is an indefinite-lived asset and is not amortized. Goodwill is not expected to be deductible for tax purposes. To determine whether goodwill is impaired, annually or more frequently if needed, the Company performs a multi-step impairment test. The Company first assesses 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 must 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, 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. If the fair value is less than the carrying value of the reporting unit, then the implied value of goodwill would be calculated and compared to the carrying amount of goodwill to determine whether goodwill is impaired. The Company did not have goodwill in 2018; therefore, no impairment test was required. Based on qualitative factors as of September 30, 2019, it is more likely than not that goodwill is not impaired. The Company will conduct the 2019 goodwill impairment testing in the fourth quarter of 2019.

### 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 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 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 limitation to the net operating loss. The Company intends to complete a Section 382 analysis in early 2020.

Tax years subsequent to 2015 remain open to examination by federal and state tax authorities.

#### 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.

#### Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash. The Company places its cash with high credit quality financial institutions and, by policy, generally limits the amount of credit exposure to any one financial institution. The Company has no credit risk concentration for cash amounts held in a single institution that are in excess of amounts issued by the Federal Deposit Insurance Corporation.

#### Segments

The Company has five operating segments: domestic sales, international sales, clinical testing revenue, contract research ("CRO") revenue, and D-CHIP, formerly known as diagnostic revenue. The revenues earned in the diagnostic, clinical testing and CRO segments are immaterial to the total revenues earned and are currently represented in corporate/other in the table below. The segment revenues and segment net losses for the three and nine-month periods ended September 30, 2019 are described in the table below. There are significant changes in the Company's assets relating to the Helomics acquisition specifically in the corporate/other segment for intangibles, tangible fixed assets, and goodwill. In 2018, substantially all the Company assets, revenues, and expenses were located or derived from operations in the United States and recorded under the domestic revenue segment.

	Three Months Ended September 30, 2019				Nine Months Ended September 30, 2019			
	Domestic	International	Corporate/Other	Total	Domestic	International	Corporate/Other	Total
<b>Revenue</b>	\$ 455,878	\$ 40,006	\$ 26,812	\$ 522,696	\$ 934,621	\$ 77,051	\$ 52,416	\$ 1,064,088
<b>Segment Loss</b>	\$ (838,742)	\$ (92,398)	\$ (3,077,372)	\$ (4,008,512)	\$ (2,697,338)	\$ (289,492)	\$ (2,849,762)	\$ (5,836,592)

  

	September 30, 2019				December 31, 2018			
	Domestic	International	Corporate/Other	Total	Domestic	International	Corporate/Other	Total
<b>Net Assets</b>	\$ (284,805)	\$ (10,387)	\$ 21,008,855	\$ 20,713,663	\$ 628,451	\$ 41,377	\$ (616,356)	\$ 53,472

## 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 (“FDA”), Clinical Laboratory Improvement Amendments (“CLIA”), and other governmental agencies.

## NOTE 2 – HELOMICS ACQUISITION

The Company acquired 25% of the capital stock of Helomics, in transactions in the first quarter of 2018. On April 4, 2019, (the “Acquisition Date”), 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.

Helomics’ precision medicine services are designed to use artificial intelligence and a comprehensive disease database to improve the effectiveness of cancer therapy. Helomics’ precision oncology services are based on its D-CHIP diagnostic platform, which combines a database of genomic and drug response profiles from over 149,000 tumors with an artificial intelligence based searchable bioinformatics platform. Once a patient’s tumor is excised and analyzed, the D-CHIP platform compares the tumor profile with its database, and using its extensive drug response data, provides a specific therapeutic roadmap.

The acquisition of Helomics was accounted for as a business combination using the acquisition method of accounting. This method requires, among other things, that assets acquired and liabilities assumed be recognized at fair value as of the acquisition date. The fair value for the assets acquired and the liabilities assumed are based on information knowable and determined by management as of the date of this filing. The Company incurred \$656,615 in acquisition costs predominantly in legal and audit expenses.

The fair value of the consideration transferred in the acquisition has five components totaling \$26,711,791. The following table summarizes the acquisition date fair values of assets acquired and liabilities assumed and the consideration transferred:

Value of shares to Helomics shareholders (i)	\$	5,612,250
Value of Helomics notes receivable forgiven (ii)		2,210,381
Value of shares to extinguish debt (iii)		6,463,309
Value of warrants issued (iv)		6,261,591
Gain on revaluation of equity method investment (v)		6,164,260
Fair value of the consideration	\$	26,711,791
Less assets acquired:		
Cash & cash equivalents		248,102
Accounts receivable		207,769
Inventory		17,727
Prepaid expenses		15,321
Fixed assets, net		1,749,080
Intangible assets		3,725,000
Lease right of use assets		780,594
Plus liabilities assumed:		
Accounts payable		2,374,596
Note Payable		303,333
Accrued expenses		363,569
Lease Liability – Net of Long-term Portion		422,126
Lease liability		358,468
Total assets acquired and liabilities assumed		(2,921,501)
Goodwill	\$	23,790,290



(i) Upon the acquisition, all outstanding shares of Helomics stock not already held by the Company were converted into the right to receive a proportionate share of 4,000,000 shares of common stock and 3,500,000 shares of Series D Convertible Preferred Stock of the Company. The fair value of these shares on the date of issuance was \$5,612,250; (ii) the Company forgave notes and interest due from Helomics relating to previous cash advances equaling \$2,210,381; (iii) the Company eliminated debt owed by Helomics to noteholders by issuing 8,637,323 shares of common stock to the noteholders, the value of the shares was \$6,463,309; (iv) the Company issued 14,245,063 warrants in exchange for warrants to purchase 23,741,772 shares of Helomics common stock to the Helomics noteholders agreeing to extinguish or extend their notes. An additional 597,000 warrants were exchanged for warrants held by other parties; the total consideration of all the exchanged warrants was valued by using the Black Scholes method and equaled \$6,261,591; and, (v) as the Company's acquisition of Helomics was a business combination achieved in stages, the initial 25% purchase of Helomics in 2018 was required to be revalued at current fair value on the Acquisition Date. Immediately prior to the Acquisition Date the recorded value of the equity method investment was zero. On the Acquisition Date the Company determined the fair value of the previous equity method investment was \$6,164,260 and recorded a gain for the same amount in order to recognize the investment at its fair value. The gain was calculated as the difference between the implied fair value of the Company's previous equity method investment in Helomics and the recorded book value immediately prior to the acquisition date. The implied fair value was calculated based on the purchase consideration exchanged to acquire the remaining 75% of Helomics and factoring a 10% discount for lack of control.

The fair values of all common and preferred shares issued as consideration in the transaction was determined using the closing bid price of the Company's common stock on April 4, 2019.

The Company did not legally assume the debt extinguished on the day of the acquisition, however three noteholders did not exchange their notes for shares, and the holders agreed to extend such notes, representing \$303,333 in principal, to be due 90 days from the acquisition date. This portion of the debt was assumed by the Company. In order to receive the extension, the Company agreed to issue 583,003 warrants to the noteholders at an exercise price of \$1.00 per share. The warrants were accounted for under the Black Scholes accounting method.

#### *Identifiable Intangible Assets*

The Company acquired intangible assets related to trademarks for the acquired Helomics trade name with an estimated fair market value of \$398,000. The Company expects to employ the Helomics trade name for the foreseeable future. The fair values of the assets were determined by the relief-from-royalty method under the income approach.

The Company acquired intangible assets with a useful life of three years and an estimated value of \$445,000 related to customer relationships stemming from stable and predictable cash flow streams associated with customers. Helomics' customer base includes contract research partnerships with pharmaceutical, diagnostic, biotechnology, and research companies. Helomic's existing customers are all within its CRO services business line. The customer relationships were valued using the with and without method under the income approach.

The Company acquired intangible assets with a useful life of 20 years and an estimated value of \$2,882,000 related to developed technology stemming from the D-CHIP diagnostic platform and underlying tumor database. Since the D-CHIP platform and underlying database was identified as the primary asset, this technology was valued using the multi-period excess earnings method under the income approach.

The acquisition costs related to the intangible assets are presented in legal and accounting expenses within general and administrative expenses in the statement of net loss.

### Goodwill

The \$23,790,290 goodwill represents the excess of the consideration transferred over the fair values of assets acquired and liabilities assumed and represents the future economic benefits and synergies arising from the transaction. None of the goodwill is deductible for income tax purposes. Goodwill was allocated to the three Helomics segments.

### Financial Results

The financial results of Helomics since the acquisition date have been included in the Company's unaudited condensed consolidated statements of net loss for the quarter.

### Pro Forma

The following pro forma information presents the combined results of operations of Predictive Oncology and Helomics as if the acquisition of Helomics had been completed on January 1, 2019, with adjustments to give effect to pro forma events that are directly attributable to the acquisition. The acquisition occurred on April 4, 2019, therefore, there is no difference between the pro-forma and amounts reported herein for the three-month period ended September 30, 2019.

	<b>Nine Months Ended September 30, 2019</b>	
Revenue	\$	1,110,148
Net loss attributable to Predictive	\$	7,249,123

The primary adjustments include the deduction of the original depreciation and amortization and the inclusion of the revalued depreciation and amortization for Helomics tangible and intangible assets. The unaudited pro forma results do not reflect any operating efficiencies or potential cost savings which may result from the consolidation of operations. Accordingly, these unaudited pro forma results are presented for informational purposes only and are not necessarily indicative of what the actual results of operations of the combined company would have been if the acquisition had occurred at the beginning of those respective time periods, nor are they indicative of future results of operations.

There are certain portions of purchase accounting, specifically Section 382 for *Tax Loss Carryforwards*, which take place after a company has undergone a shift in ownership, that the Company has not completed yet and may have a significant impact on the financial statements.

### NOTE 3 – 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. The Company has elected an accounting policy to exclude sales taxes 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, 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: (a) the Company has transferred physical possession of the products, (b) the Company has a present right to payment, (c) the customer has legal title to the products, and (d) 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 is able to 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 subsequent to 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.

#### *Revenue from Clinical Testing*

The Precision Oncology Insights are clinic diagnostic testing comprised of the Company's ChemoFx and BioSpeciFx tests. The ChemoFx test determines how a patient's tumor specimen reacts to a panel of various chemotherapy drugs, while the BioSpeciFx 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 payments terms vary by the agreements reached with insurance carriers and Medicare. The Company's performance obligations are satisfied at one point in time when test reports are delivered. This revenue stream is reported under the clinical revenue segments (see Note 1).

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

The Company recognizes revenue from these patients when contracts as defined in ASC 606, *Revenue from Contracts with Customers* are established at the amount of consideration to which it expects to be entitled or when the Company receives substantially all of the consideration subsequent to the performance obligations being satisfied.

#### *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 CRO revenue segment (see Note 1).

#### *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. As of September 30, 2019, and December 31, 2018, accounts receivable totaled \$372,119 and \$232,602, respectively.

The Company's deferred revenues related primarily to maintenance plans and CRO revenue of \$30,638 and \$23,065 as of September 30, 2019 and December 31, 2018, 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.

#### NOTE 4 – STOCKHOLDERS' EQUITY, STOCK OPTIONS AND WARRANTS

##### *Series D Preferred Shares*

In April 2019, the Company issued 3,500,000 shares of Series D preferred stock to Helomics as part of the acquisition. Each share of Series D preferred stock is subject to automatic conversion, whereby each such share converts automatically on a 10:1 basis into a share of the Company's common stock upon the earlier of (i) the consummation of any fundamental transaction (e.g., a consolidation or merger, the sale or lease of all or substantially all of the assets of Predictive or the purchase, tender or exchange offer of more than 50% of the outstanding shares of voting stock of Predictive) or (ii) the one-year anniversary of the issuance date, which will be April 4, 2020.

##### *Series E Convertible Preferred Stock*

In June through September 2019, the Company entered into a private placement securities purchase agreement with investors for shares of Series E convertible preferred stock for an aggregate purchase price of \$1,734,000 and 2,577,000 in the three and nine-month periods ended September 30, 2019, respectively. During the three and nine-month periods ended September 30, 2019, the Company issued 173.4 and 257.7 preferred shares, respectively. The preferred shares include a contingent beneficial conversion amount of \$182,000 and \$289,936 for shares issued during the three and nine-month periods ended September 30, 2019, respectively, representing the intrinsic value of the shares at the time of issuance. The Company determined the Series E convertible preferred stock should be classified as permanent equity and the Company is accreting the beneficial conversion feature amount to the earliest redemption date of six months after the initial closing of the Series E convertible preferred stock. This offering is now closed. As of September 30, 2019, all shares of the Series E convertible preferred stock issued remain outstanding.

Each Preferred Share Holder shall have the right at the Company's option to be converted into 0.056857% of the issued and outstanding shares of common stock immediately prior to conversion for each share of Series E convertible preferred stock beginning six months after the initial close date of June 13, 2019. On the date that is 12 months after the initial closing date, the Company has the option to convert the preferred shares into common stock upon the same terms and limitations as the above optional conversion.

##### *Net Loss Attributable to common shareholders*

The net loss attributable to common shareholders for the three and nine months ended September 30, 2019, reflects increases for net deemed dividends to Series E convertible preferred shareholders provided in connection with various closings totaling \$2,577,000 of the private placement of Series E convertible preferred stock. The total beneficial conversion feature (BCF) of the Series E convertible preferred stock issued was \$182,000 and \$289,936 for the closing of Series E convertible preferred stock for the three and nine months ended September 30, 2019, respectively.

The Series E convertible preferred stock is not currently redeemable because the contingency has not been met as of September 30, 2019, but it is probable that the preferred stock will be redeemable in the future. The earliest potential redemption based solely on the passage of time is December 13, 2019 and, therefore, the carrying amount of the Series E convertible preferred stock shall be accreted from the commitment date to the redemption price as a deemed dividend. The accretion of the BCF was \$125,801 and \$146,199 for the three and nine months ended September 30, 2019, respectively. Since the Company does not have retained earnings, the amortization of the Series E convertible preferred stock discount was recorded as a deemed dividend through additional paid-in capital and net loss attributable to common shareholders in calculating basic and diluted loss per common share (see Note 7).

##### *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.

### Valuation and accounting for 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.

For grants of stock options and warrants issued during the quarter ended September 30, 2019, the Company used 1.39% to 2.03% risk free interest rate, 0% dividend rate, 82.4% volatility and estimated terms of 5 to 10 years. Value computed using these assumptions ranged from \$3.368 to \$6.527 per share.

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, 2017	276,498	\$ 19.95	195,126	\$ 237.40
Issued	109,886	10.13	233,615	10.67
Expired	(19,456)	20.00	(1,071)	1,995.53
Exercised	-	-	(65,006)	10.00
Outstanding at December 31, 2018	366,928	\$ 17.03	362,664	\$ 41.67
Issued	366,120	7.12	1,805,943	9.36
Expired	(19,484)	14.73	(630)	3,258.32
Exercised	-	-	(59,700)	0.10
Outstanding at September 30, 2019	713,564	\$ 11.84	2,108,277	\$ 15.33

Stock-based compensation expense recognized for the three and nine-month periods ended September 30, 2019 was \$360,146 and \$2,004,366, respectively, and for the three and nine-months periods ended September 30, 2018 was \$339,954 and \$800,322, respectively. The Company has \$310,403 of unrecognized compensation expense related to non-vested stock options that are expected to be recognized over the next 16 months.

### NOTE 5 – NOTES RECEIVABLE

The Company has a secured promissory note receivable from CytoBioscience for \$1,112,524, plus interest paid monthly at the per annum rate of (8%) on the principal amount. Unpaid principal and unpaid accrued interest on the note are due and payable on February 28, 2020. In 2019, CytoBioscience and its parent company, InventaBioTech, paid interest in the first quarter due through April 2019. The Company has not received any payments from CytoBioscience since the first quarter. The Company has evaluated the feasibility of repayment, including direct conversations with the CEO and former CEO of CytoBioscience, and has concluded that recovery of the note is in doubt and that it is probable that the Company will be unable to collect all amounts due according to the contractual terms of the receivable. The Company has secured the note with lab equipment originally valued at \$1,290,000. The Company believes it will be able to raise \$250,000 through the sale of this equipment and has recorded a reserve for the difference. The Company obtained a judgement against CytoBioscience and has proceeded with court proceedings to claim the collateral equipment and to attempt to recover the original balance plus interest due under the note.

## NOTE 6 – CONVERTIBLE DEBT AND DERIVATIVE LIABILITY

### *Bridge Loan*

Effective September 28, 2018, the Company issued convertible secured promissory notes to two private investors in the original principal amount of an aggregate \$2,297,727 (the “bridge loan”). The bridge loan was due on September 28, 2019. Effective September 27, 2019, the bridge loan of one investor was paid in full. Also, effective September 27, 2019, the due date of the bridge loan of the other investor was extended to December 31, 2019 in exchange for \$120,000 increase in the principal balance and 15,000 shares of the Company’s common stock. In the third quarter, the remaining investor converted \$100,000 of the principal balance and received 26,573 shares of the Company’s common stock. The outstanding principal balance of the bridge loan as of September 30, 2019 was \$1,878,295.

The bridge loan accrues interest at a rate of 8% per annum. Upon the earlier to occur of an event of default or the filing of certain registration statements, each investor will have the right at any time thereafter to convert all or any part of its bridge loan into shares of the Company’s common stock at a conversion factor that is the lesser of a discounted 20 trading day average price or a set price floor. The number of conversion shares that may be issued is subject to an exchange cap such that the sum of (a) the total number of conversion shares plus (b) the number of inducement shares is limited to an aggregate 267,833 shares.

### *Promissory Note*

Effective September 27, 2019, the Company issued a promissory note with a principal amount of \$847,500 in exchange for an investment of \$700,000. The note is due on March 27, 2020. Pursuant to a security agreement between the Company and the investor, the Company has granted to the investor a security interest in its assets to secure repayment of the note. As additional consideration for the investment, the Company issued an aggregate 8,858 shares of its common stock to the investor plus warrants to acquire up to 68,237 shares of the Company’s common stock at an exercise price of \$6.210 per share. The warrant is exercisable beginning on the sixth month anniversary of the effective date through the fifth-year anniversary thereof. The note accrues interest at a rate of 8% per annum.

### *Derivative Liability*

Management has concluded the bridge loan contains a conversion feature which is an embedded derivative that is required to be bifurcated and separately presented as a liability on the balance sheet. The embedded derivative’s value was determined using discounted stock price for the 20 trading days preceding the balance sheet date, and assuming conversion on that date as management believed it is probable that the bridge loan will be convertible based on management’s expectation that additional financing will be required. The Company recognized an unrealized gain in other expenses on the statements of net loss for the corresponding change in fair value of \$84,627 for the nine-month period ended September 30, 2019. The fair value of the derivative liability as of September 30, 2019 was \$188,118.

The value of the embedded derivative from the bridge loan as well as the derivative included in the note payable agreements with the Company’s CEO (see Note 9) were based upon level 3 inputs – see the Fair Value Caption in Note 1. The table below discloses all changes in value of those derivative liabilities during the nine-month period ended September 30, 2019.

<b>Derivative Liability Balance at December 31, 2018</b>	<b>Derivative Instrument Issued</b>	<b>Gain Recognized to Revalue Derivative Instrument at Fair Value</b>	<b>Adjustments to Derivative Liability for Warrants Issued</b>	<b>Derivative Liability Balance at September 30, 2019</b>
\$ 272,745	69,722	(84,627)	(47,078)	\$ 210,762

## NOTE 7 - LOSS PER SHARE

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

	<u>Three Months Ended September 30</u>		<u>Nine Months Ended September 30</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Numerator:				
Net loss attributable to common shareholders per common share: basic and diluted calculation	\$ (4,134,313)	\$ (2,506,869)	\$ (5,982,791)	\$ (6,640,301)
Denominator:				
Weighted average common shares outstanding-basic	3,146,609	1,325,261	2,581,014	1,217,829
Effect of diluted stock options, warrants and preferred stock (1)	-	-	-	-
Weighted average common shares outstanding-diluted	3,146,609	1,325,261	2,581,014	1,217,829
Loss per common share-basic and diluted	\$ (1.31)	\$ (1.89)	\$ (2.32)	\$ (5.45)

(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:

	<u>Three and Nine Months Ended September 30</u>	
	<u>2019</u>	<u>2018</u>
Options	713,564	344,889
Warrants	2,108,277	331,927
Convertible debt	103,734	504,770
Preferred stock: series B	7,925	7,925
Preferred stock: series D	350,000	-
Preferred stock: series E	461,503	-

## NOTE 8 – LEASES

The Company's corporate offices are located in Eagan, Minnesota. The lease as amended has a three-year term ending January 31, 2021. The Company leases 5,773 square feet at this location, of which 2,945 square feet is used for office space and 2,828 is used for manufacturing.

Skyline Medical Europe's offices are located in Belgium. The Company leases around 2,000 square feet at this location, 750 of which is used for storage and 1,250 for office space. The lease is effective through June 14, 2027.

Helomics' offices are located in Pittsburgh, Pennsylvania. The lease, as amended, has a three-year term ending January 31, 2021. The Company leases 17,417 square feet at this location, of which approximately 1,000 square feet are used for office space and 16,417 square feet is used for laboratory operations. The Company expects that this space will be adequate for its current office and laboratory needs.

Lease expense was \$184,046 and \$367,180 for the three months and nine months ended on September 30, 2019 and \$27,807 and \$64,986 for the three and nine months ended on September 30, 2018, respectively.



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

	September 30, 2019
Weighted average remaining lease term – operating leases in years	3.06
Weighted average discount rate – operating leases	8%

The Company's rent obligation is as follows:

2019	\$ 129,546
2020	519,751
2021	117,722
2022	42,124
2023	42,966
2024 and thereafter	153,278
<b>Total lease payments</b>	<b>1,005,387</b>
Less interest	118,675
<b>Present value of lease liabilities</b>	<b>\$ 886,712</b>

#### NOTE 9 – RELATED PARTY TRANSACTIONS

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

One of the Company's directors, Richard L. Gabriel, is the Chief Operating Officer and serves as a director of GLG Pharma ("GLG"). Another Company director, Tim Krochuk, is on the supervisory board for GLG. The Company and GLG have a partnership agreement with Helomics 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.

On May 1, 2019, Mr. Gabriel executed a one-year contract with renewable three-month periods to continue as Chief Operating Officer for TumorGenesis. Mr. Gabriel will receive \$13,500 in monthly cash payments.

On May 21, 2019, the Company issued a third and restated common stock purchase warrant to Dr. Carl Schwartz, the Company's CEO, for value received in connection with the funding of all or a portion of the purchase price of his second amended and restated promissory note in the principal amount of \$1,620,000. The Company has accounted for the liability to issue more warrants as a derivative liability as the exact number of warrants that will be issued was uncertain at the time of the agreement. The Company issued an additional 3,451 warrants to Dr. Schwartz under the agreement in the third quarter, which reduced the value of the derivative liability by \$14,863. As of September 30, 2019, the recorded derivative liability related to the agreement was \$22,644.

During 2019, Dr. Schwartz advanced \$300,000 to the Company. The loan earns 8% interest per annum. The due date of the loan was amended and the loan is now due December 31, 2019. No additional consideration was given for this extension. The loan is not connected to the previous note payable due to Dr. Schwartz.

#### NOTE 10 – SUBSEQUENT EVENTS

##### *Public Offering*

On October 1, 2019, the Company entered into a placement agency agreement for a public offering in which the Company sold 633,554 shares of the Company's common stock. The offering closed on October 4, 2019. The common stock was sold at a price of \$5.00 per share, resulting in gross proceeds to the Company of \$3,167,769, before deducting placement agent fees and estimated offering expenses. The net offering proceeds to the Company, after deducting the placement agents' fees and other estimated offering expenses payable by the Company, were \$2,811,309.

In addition, the Company granted warrants to the placement agents to purchase up to 63,355 shares of common stock, equal to 10% of the aggregate number of shares of common stock sold in the offering. The warrants have an exercise price of \$6.25.

#### *Reverse Stock Split*

On October 28, 2019, the Company completed a one-for-ten reverse stock split that was effective for trading purposes on October 29, 2019. All numbers of shares and per-share amounts in this report have been adjusted to reflect the reverse split.

#### *Equity Line Arrangement*

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 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.

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

### **Overview**

Predictive Oncology Inc. ("Predictive") 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., effective June 10, 2019. Because of this change, the Company's common stock traded under the new ticker symbol "POAI," effective June 13, 2019. Skyline Medical ("Skyline") remains as an incorporated division of Predictive Oncology Inc. On October 28, 2019, the Company completed a one-for-ten reverse stock split that was effective for trading purposes on October 29, 2019. All numbers of shares and per-share amounts in this report have been adjusted to reflect the reverse split.

Predictive is a healthcare products and services company that has expanded its business to take advantage of emerging areas of the dynamic healthcare market through sales of its products, through its ownership of Helomics Holding Corporation a pioneering Contract Research Organization ("CRO") Services company and through pursuit of other strategic relationships to build value. In the STREAMWAY business, the Company manufactures an environmentally-conscious system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. Since our inception in 2002, the Company has invested significant resources into product development. The Company believes that its success depends upon converting the traditional process of collecting and disposing of infectious fluids from the operating rooms of medical facilities to its wall-mounted Fluid Management System ("System") and use of the Company's proprietary cleaning solution and bifurcated filter. Predictive's CRO services business is committed to improving the effectiveness of cancer therapy using the power of artificial intelligence applied to rich data diseases databases. Predictive has identified the CRO market as a burgeoning sector with significant growth potential. Effective April 4, 2019, Predictive completed the merger with Helomics and, as of then, owned 100% of Helomics. The merger resulted in an issuance of equity securities and has increased the Company's capital needs.

In addition, in 2018, the Company formed a wholly-owned subsidiary, TumorGenesis Inc., to develop the next generation, patient-derived tumor models for precision cancer therapy and drug development.

STREAMWAY products are sold through an experienced direct sales force. The Company had one VP of Sales & Marketing, one VP of International Sales, and two regional sales managers on staff as of September 30, 2019. We had twelve independent distributors in the United States, Canada, and overseas. We incorporated Skyline Medical Europe with an office in Belgium in February 2018 and hired a direct salesperson to cover Germany and France. We have contracted with two General Purchasing Organizations in the United States, Vizient and Intalere, providing customer exposure to more than 10,000 hospitals. The Company has contracted with Alliant Enterprises, LLC, a Service-Disabled Veterans Owned Small Business supplier to the federal government. We have executed contracts with eleven international distributors: Quadromed, a Canadian distributor; MediBridge Sarl, a Swiss distributor; Device Technologies Australia PTY LTD, is an Australian distributor representing us throughout Australia, New Zealand, Fiji and the Pacific Islands; Century Scientific and Equipment Company in Kuwait; Mediurge in Pakistan; Prenit World in India; Sesneber in Saudi Arabia; Winner Scientific in Taiwan; Anifco in Bangladesh; Aras in the United Arab Emirates and Alfaisal Scientific Bureau in Iraq.

Predictive's 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. TumorGenesis intends to develop next generation, patient-derived, ("PDX") tumor models for precision cancer therapy and drug development. This approach is designed to provide a much more relevant model of the patient tumor that may be used for testing of drugs for personalized therapy or for the development of new drugs. Predictive has entered into licensing arrangements with three medical technology companies.

### **Capital Requirements**

Since inception, we have been unprofitable. We incurred net losses of \$4,008,512 and \$5,836,592 for the three and nine months ended September 30, 2019, and net losses of \$2,506,869 and \$6,640,301 for the three and nine months ended September 30, 2018, respectively. As of September 30, 2019, and December 31, 2018, we had an accumulated deficit of \$68,944,537 and \$63,107,945, respectively. We received approval from the FDA in April 2009 to commence sales and marketing activities of the STREAMWAY System and shipped the first system in 2009. However, there was no significant revenue prior to 2011, primarily due to lack of funds to build and ship the product.

We have never generated sufficient revenues to fund our capital requirements. We have funded our operations through a variety of debt and equity instruments. See "Liquidity and Capital Resources – Plan of Financing; Going Concern Qualification" and "Liquidity and Capital Resources – Terms of Financing Transactions" below.

Our future cash requirements and the adequacy of available funds depend on our ability to sell our products and the availability of future financing to fulfill our business plans. We have committed significant capital and management resources to developing our contract research organization business and other new business areas. In addition, we have increased our expenditures to develop the business of our TumorGenesis subsidiary, to pursue a new rapid approach to growing tumors in the laboratory. It is likely that we will make further investments and advances in other businesses as we develop our CRO business and other business models. With completion of the Helomics merger, we expect our operating cash needs will increase significantly. See "Plan of Financing; Going Concern Qualification" below.

As a company, our limited history of operations 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

### Revenue.

	Three Months Ended September 30				Nine Months Ended September 30			
	2019	2018	\$ Difference	% Difference	2019	2018	\$ Difference	% Difference
Revenue	\$ 522,696	\$ 329,930	\$ 192,766	58%	\$ 1,064,088	\$ 1,100,108	\$ (36,020)	-3%

There were 33 sales of STREAMWAY units in the nine months ended September 30, 2019, compared to 35 sales of STREAMWAY units in the comparable 2018 period. Helomics revenue is not material, but we anticipate growth specifically as a result of contracts signed in the third quarter of 2019.

*Cost of sales.* Cost of sales was \$208,096 and \$400,202 in the three and nine months ended September 30, 2019, respectively, and \$83,006 and \$309,320 in the three and nine months ended September 30, 2018, respectively. The gross profit margin was approximately 60% and 62% in the three and nine months ended September 30, 2019, compared to 75% and 72% in the prior year. Our margins decreased in the third quarter of 2019 compared to the 2018 period primarily due to Helomics costs surpassing the revenue earned in the current period.

*General and Administrative expense.* General and administrative expense primarily consists of management salaries, professional fees, consulting fees, travel expense, administrative fees and general office expenses.

General & Administrative (G&A) expenses increased by \$1,854,388 and \$4,717,031 for the three and nine months ended September 30, 2019 compared to the 2018 periods. The increase in the three-month period is primarily due to severance costs incurred in the third quarter of 2019, prepayment charges related to the payment of the bridge loan, as well as increased salaries, taxes and benefits, rent and depreciation and amortization as a result of the combined company. The increase in the nine-month period is primarily due to a combination of increased one-time expenses and initial costs of combining Helomics and the Company. The Company recognized a one-time credit loss on notes receivable from CytoBioscience. Additionally, the Company issued all employees and directors stock options resulting in large vesting expenses. As a result of combining companies, the salaries, taxes and benefits, rent and depreciation and amortization all increased substantially. There were also increases in legal and audit expenditures related to the acquisition.

*Operations expense.* Operations expense primarily consists of expenses related to product development and prototyping and testing in the company's current stage.

Operations expense decreased by \$16,525 in the three months and increased by \$1,054,804 in the nine months ended September 30, 2019 compared to the comparable periods in 2018. The decrease in the three-month period was primarily due to lower consulting costs partially offset by higher salary costs for the combined company. The increase in the nine-month period consisted higher salaries and employee stock option vesting expenses related to operations employees of the combined company.

*Sales and Marketing expense.* Sales and marketing expense consists of expenses required to sell products through independent reps, attendance at trades shows, product literature and other sales and marketing activities.

Sales and marketing expenses decreased by \$186,510 and \$51,887 in the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018. The decrease in the three-month period resulted primarily from lower salaries and other related costs due to a reduction in Skyline sales personnel during the quarter, as well as lower expenditures for trade shows and public relations. The decrease in the nine-month period resulted primarily from decreased expenses for web development, market research, and public relations partially offset by higher salary and benefits costs due to increased sales staff during the first half of the year.

*Impact of minority investment on net loss.* The Company's net loss for the nine-month period ended September 30, 2019 is \$5,836,592 including a loss on equity method investment of \$439,637 representing a portion of Helomics' net loss from continuing operations of \$1,555,542 and resulted from the Company's ownership of 25% of Helomics' capital stock during the period prior to April 4, 2019; offset by the gain of \$6,164,260 on revaluation of the initial acquisition of Helomics. Commencing with the Merger effective April 4, 2019, the Company owns 100% of the Helomics business, which is included in the Company's consolidated financial statements.

## Liquidity and Capital Resources

### *Cash Flows*

Net cash used in operating activities was \$5,936,803 for the nine months ended September 30, 2019 compared with net cash used of \$4,069,685 for the 2018 period. Cash used in operating activities increased in the 2019 period primarily because of the increase in total operating expenses, which was partially offset by increased accounts payables due to extending payments to vendors and increased accrued expenses.

Cash flows used in investing activities were \$591,754 for the nine months ended September 30, 2019 as compared to \$96,184 of cash flows used for the nine months ended September 30, 2018. Cash used was for cash advances made to Helomics prior to the acquisition but was partially offset by cash received from Helomics on the Acquisition Date.

Net cash provided by financing activities was \$6,465,004 for the nine months ended September 30, 2019 compared to net cash provided of \$3,609,571 for the nine months ended September 30, 2018. The cash provided were proceeds from debt issuance due to the loan we received from the CEO, proceeds of public offerings of units that were completed in the period, and proceeds from the issuance of preferred stock due to a private placement.

### *Capital Resources*

Our cash and cash equivalents balance as of September 30, 2019 and December 31, 2018 was \$98,599 and \$162,152, respectively.

During the three months ended September 30, 2019, the Company raised \$1,595,280 in net proceeds in equity from a private placement of preferred stock, \$700,000 in proceeds of debt financing, and \$25,000 in debt financing from the Company CEO. Subsequent to September 30, 2019, the Company raised \$2,811,309 in net proceeds from a public offering of its common stock.

In the first nine months of 2019, we recognized \$1,064,088 in revenues.

### *Plan of Financing; Going Concern Qualification*

Since our inception, we have incurred significant losses, and our accumulated deficit was \$68,944,537 as of September 30, 2019. We have not achieved profitability and anticipate that we will continue to incur net losses at least through the second quarter of 2020. Our operations from inception have been funded with private placements of convertible debt securities and equity securities, public offerings, and loan agreements.

During 2019, the Company raised capital through a variety of sources. In February 2019, the Company received an additional loan and investment equaling \$1,300,000 from the Company's CEO. On March 1, 2019 the Company closed on a public offering receiving \$1,111,880 in net proceeds. On March 29, 2019 the Company closed on a public offering receiving \$1,053,360 in net proceeds. In June through September 2019 we raised \$2,338,840 in net proceeds from a private placement of convertible preferred stock. In September 2019, we received \$700,000 in proceeds of debt financing from a private investor. Subsequent to September 30, 2019, the company raised \$2,811,309 in net proceeds from a public offering of its common stock.

We had revenues of \$1,064,088 in the nine-month period ended September 30, 2019, but negative operating cash flows of \$5,936,803. Our cash balance was \$98,599 as of September 30, 2019, and our accounts payable and accrued expenses were an aggregate \$5,569,656. Additionally, outstanding debt agreements are all due within one year. This includes secured convertible notes with remaining principal balances of \$1,878,295 due in December 2019 and \$847,500 due in March 2020. Repayment of these notes will include interest at 8% per annum. An additional \$1,920,000 in principal amount of promissory notes payable to our CEO are due in February 2020.

We have committed significant capital and management resources to develop our CRO business and other new business areas, and intend to continue to devote significant resources to the Helomics business and other new businesses in this market. To fund this, we have significantly decreased our salary and benefits expenses, particularly in our Skyline Medical business unit, through reductions in personnel and other measures. We continue to focus on reducing expenses. Our businesses will need to generate significantly more revenue for the Company to sufficiently fund its operations without external financing. There is no assurance that we will be successful in raising sufficient capital. The terms of any such financing will be dilutive to our stockholders. We may also acquire technologies or companies by issuing stock or other equity securities in addition to payment of cash, which may have the result of diluting the investment of our stockholders.

We will attempt to raise these funds through equity or debt financing. In October 2019, the Company entered into a purchase agreement for an equity line under which it can raise up to \$15,000,000, subject to certain prior conditions. The Company will also attempt to raise funds from other sources that may include public offerings, private placements, alternative offerings or other means. If we are successful in securing adequate funding, we plan to make significant capital or equipment investments, and we will also continue to make human resource additions in Helomics over the next 12 months. If such financing or adequate funds from operations are not available, we will be forced to limit our business activities, which will have a material adverse effect on our results of operations and financial condition.

As a result of the above factors, we have concluded that there is substantial doubt about our ability to continue as a going concern. The financial statements have been prepared assuming the Company will continue as a going concern. Furthermore, our independent registered public accounting firm has indicated in their audit opinion, contained in our financial statements included in this Annual Report on Form 10-K within Item 8, that there is substantial doubt about our ability to continue as a going concern.

#### ***Terms of Financing Transactions***

In the second quarter of 2019, Dr. Schwartz advanced the Company an additional \$275,000 in two separate tranches. In July 2019 Dr. Schwartz advanced an additional \$25,000 to the Company. All three advances are consolidated, earning 8% interest per annum, and are due December 31, 2019.

On June 13, 2019, the Company initiated a Series E convertible preferred stock private placement. The Company authorized 350 shares of Series E convertible preferred stock with each share having a liquidation value of \$10,000. Upon liquidation, dissolution or winding up of the Company, the preferred shares shall rank senior to the Series B preferred stock, Series D preferred stock and common stock. There are no dividend rights, and therefore no dividends will accrue on the preferred shares. The Company has sold 257.7 shares of Series E convertible preferred stock for an aggregate purchase price of \$2,577,000 and does not intend to sell any additional shares.

Each holder of Series E preferred stock will have the right to convert each preferred share into 0.056857% of the Company's issued and outstanding shares of common stock immediately prior to conversion, beginning six months after the initial closing date of June 13, 2019. On the date that is twelve months after the initial closing date, the Company has the option to convert the preferred shares into common stock upon the same terms and limitations as the above optional conversion. The Company may redeem the preferred stock on 10 days' notice at 130% of the face value. Prior to redemption, the holders may convert their shares upon the same terms as the optional conversion.

In the event of a change of control of the Company (meaning an acquisition of 30% or more of the Company's issued common shares by a single party/parties acting in concert) before the first anniversary of the final closing, the Company may compel holders to exercise the conversion rights of the Series E preferred shares at a time of the Company's choosing, upon the same terms as the optional conversion.

On October 24, 2019, the Company entered into an equity purchase agreement with an investor, providing for an equity financing facility line. 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 shares for entering into the Purchase Agreement. Under the Purchase Agreement, the investor will not be obligated to purchase shares unless and until certain conditions are met, including a registration statement on Form S-1 being effective which registers the investor's resale of any shares to be purchased by it under the equity line and the commitment shares. 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.

## 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

**Revenue Recognition.** Effective January 1, 2018, we adopted Accounting Standards Update (“ASU”) *No. 2014-09, Revenue from Contracts with Customers (Topic 606)*, which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. The standard’s core principle is that an entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

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. 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, 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 the 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: (a) the Company has transferred physical possession of the products, (b) the Company has a present right to payment, (c) the customer has legal title to the products, and (d) 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 is able to 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 subsequent to 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.

### *Revenue from Clinical Testing*

The Precision Oncology Insights are clinic diagnostic testing comprised of the Company’s ChemoFx and BioSpeciFx tests. The ChemoFx test determines how a tumor specimen reacts to a panel of various chemotherapy drugs, while the BioSpeciFx test evaluates the expression of a particular gene related to a patients’ 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 now generally considered implicit price concessions that are a direct reduction to accounts receivable rather than allowance for doubtful accounts.

The majority of the Company's historical product revenues have been derived from the sales of its diagnostic testing. For revenues, the Company estimates the transaction price which is the amount of consideration it expects to be entitled to receive in exchange for providing services based on its historical collection experience using a portfolio approach as a practical expedient to account for patient contracts as collective groups rather than individually. The Company monitors its estimates of transaction price to depict conditions that exist at each reporting date. If the Company subsequently determines that it will collect more considerations 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's performance obligations are satisfied at one point in time when test reports are delivered. The Company also provides services to patients with whom the Company does not have contracts as defined in ASC 606. The Company recognizes revenue for these patients when contracts as defined in ASC 606 are established at the amount of consideration to which it expects to be entitled or when the Company receives substantially all of the consideration subsequent to the performance obligations being satisfied. This revenue stream is reported under the clinical revenue segments (see Note 1).

#### *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. Advance payments received in excess of revenues recognized are classified as deferred revenue until such time as the revenue recognition criteria have been met. This revenue stream is reported under the CRO revenue segment (see Note 1).

We record receivables when we have an unconditional right to receive consideration after the performance obligations are satisfied. As of September 30, 2019, and December 31, 2018, accounts receivable totaled \$372,119 and \$232,602, respectively.

See "Note 3 – Revenue Recognition," in Notes to Condensed Consolidated Financial Statements of this Quarterly Report on Form 10-Q for further discussion.

**Stock-Based Compensation.** Under ASC 718 stock-based employee compensation cost is recognized using the fair value-based method. ASC 718 requires companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. We use the Black-Scholes option-pricing model which requires the input of significant assumptions including an estimate of the average period of time employees and directors will retain vested stock options before exercising them, the estimated volatility of our common stock price over the expected term, the number of options that will ultimately be forfeited before completing vesting requirements and the risk-free interest rate.

The Company has experienced no significant option exercises in its history. Beginning in 2019, the Company began calculating the estimated volatility used in the Black-Scholes option valuation model based on the trading history of the Company's own stock. Given the limited trading history of the Company's common stock, the Company had previously used the volatility of comparable companies in order to value options and warrants granted in prior years.

When an option or warrant is granted in place of cash compensation for services, we deem the value of the service rendered to be the value of the option or warrant. In most cases, however, an option or warrant is granted in addition to other forms of compensation and its separate value is difficult to determine without utilizing an option pricing model. For that reason we also use the Black-Scholes option-pricing model to value options and warrants granted to non-employees, which requires the input of significant assumptions including an estimate of the average period that investors or consultants will retain vested stock options and warrants before exercising them, the estimated volatility of our common stock price over the expected term, the number of options and warrants that will ultimately be forfeited before completing vesting requirements and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense.



**Notes Receivable.** We review open notes receivable balances for collectability each reporting period. If it is determined that it is probable that we will not collect the full amount due under a note agreement, we record reserves against the note receivable balance in accordance with ASC 310 – *Receivables*. In order to reasonably conclude on the collectability of such balances, we consider the borrower’s current status on payments received, the financial health and other sources of funding available to each borrower, our ability to secure assets collateralized by contractual agreements, as well as other factors.

**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 and represents the future economic benefits that the Company expects to achieve as a result of the acquisition. Purchased goodwill is not expected to be deductible for tax purposes and is not amortized over its indefinite useful life. To determine whether goodwill is impaired, annually or more frequently if needed, the Company performs a multi-step impairment test. The Company may first 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 must 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, 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. If the fair value is less than the carrying value of the reporting unit, then the implied value of goodwill would be calculated and compared to the carrying amount of goodwill to determine whether goodwill is impaired. The Company did not have goodwill in 2018 therefore, no impairment test was required. Based on qualitative factors as of September 30, 2019, it is more likely than not that goodwill is not impaired. The Company will conduct the 2019 goodwill impairment testing in the fourth quarter of 2019.

### **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.

### **Information Regarding Forward-Looking Statements**

This Form 10-Q contains “forward-looking statements” that indicate certain risks and uncertainties related to the Company, many of which are beyond the Company’s control. The Company’s 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:

- The Company will not be able to continue operating without additional financing;
- Current negative operating cash flows;
- The terms of any further financing, which may be highly dilutive and may include onerous terms;
- Risks related to the recent Merger with Helomics; possible failure to realize anticipated benefits of the Merger; costs associated with the Merger may be higher than expected; the Merger may result in the disruption of the Company’s and Helomics’ existing businesses; and distraction of management and diversion of resources; delay in completion of the merger may significantly reduce the expected benefits;

- 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, the obtaining and maintenance of any necessary regulatory clearances applicable to applications of the Company's technology;
- Inability to attract or retain qualified senior management personnel, including sales and marketing personnel;
- Risk that we never become profitable if our product is 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, 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 the Company's 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. The Company does 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 the Company believes that its plans, intentions and expectations reflected in or suggested by the forward-looking statements in this report are reasonable the Company cannot assure potential investors that these plans, intentions or expectations will be achieved. The Company discloses important factors that could cause the Company's actual results to differ materially from its expectations in the "Risk Factors" section and elsewhere our Annual Report on Form 10-K for the year ended December 31, 2018 and in item 1A of Part II below. These cautionary statements qualify all forward-looking statements attributable to the Company or persons acting on its behalf.

Information regarding market and industry statistics contained in this report is included based on information available to the Company that it believes is accurate. It is generally based on academic and other publications that are not produced for purposes of securities offerings or economic analysis. The Company has not reviewed or included data from all sources, and the Company 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. The Company has no obligation to update forward-looking information to reflect actual results or changes in assumptions or other factors that could affect those statements.

### **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 the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Based on their evaluation as of September 30, 2019, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were not effective as of September 30, 2019 for the reasons described below:

Management has determined that the Company has 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 the Company to properly identify and account for new complex transactions. Management has determined that this represents a material weakness in the Company's internal control over financial reporting.

Notwithstanding the material weakness in our internal control over financial reporting, we have concluded that the consolidated financial statements and other financial information included in our annual and quarterly filings fairly present in all material respects our financial condition, results of operations and cash flows as of, and for, the periods presented.

#### *Material Weakness Remediation Activities*

To remediate the material weakness in our internal control over financial reporting described above, we have reevaluated our overall staffing levels within the accounting department, and have hired additional resources with qualifications that include a high level of experience with complex technical accounting transactions and application of U.S. GAAP. The Company has also engaged an external accounting firm to assist with the assessment of new complex transactions. We also plan to re-evaluate the trainings and ongoing professional education that is provided to, and required of, our accounting personnel. Once these processes have been in operation for a sufficient period of time for our management to conclude that the material weakness has been fully remediated and our internal controls over financial reporting are effective, we will consider this material weakness fully addressed.

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

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the three months ended September 30, 2019 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 the risks described below before making an investment decision. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. The following risk factors amend, restate and supplement the risk factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.*

***We will require additional financing to finance operating expenses and fulfill our business plan. Such financing will be dilutive. Our current financing includes secured notes that are due in December 2019. Our independent public accounting firm has indicated in their audit opinion, contained in our financial statements, that they have serious doubts about our ability to remain a going concern.***

We have not achieved profitability and anticipate that we will continue to incur net losses at least through the remainder of fiscal 2019. We had revenues of \$1,411,655 in 2018, but we had negative operating cash flows of \$5,287,956. We had revenues of \$1,064,088 in the first nine months of 2019, but we had negative operating cash flows of \$5,936,803. The Company had cash and cash equivalents of \$98,599 as of September 30, 2019 and we need to raise significant additional capital to meet its operating needs, pay debt obligations coming due, and meet the continued operating needs of Helomics.

The Company has secured convertible notes with remaining principal balances of \$1,878,295 due in December 2019 and \$847,500 due in March 2020. Repayment of these notes will include interest at 8% per annum. An additional \$1,920,000 in principal amount of promissory notes are due in February 2020. As of September 30, 2019, the Company had debt totaling \$4,969,595. Our accounts payable and accrued expenses as of September 30, 2019 were an aggregate \$5,569,656.

Although we are attempting to curtail our expenses, there is no guarantee that we will be able to reduce these expenses significantly, and expenses for some periods may be higher as we prepare our product for broader sales, increase our sales efforts and maintain adequate inventories. Further, Helomics continues to incur negative operating cash flows, and the Helomics business continues to require significant cash resources following the completion of the Merger.

We will require additional funding to finance operating expenses and to invest in our sales organization and new product development and to compete in the international marketplace, as well as to develop the Helomics business and other aspects of our CRO business. We will attempt to raise these funds through equity or debt financing that may include public offerings, private placements, alternative offerings or other means. In October the Company entered into a purchase agreement for an equity line under which it can raise up to \$15,000,000, subject to certain prior conditions. The Company will also attempt to raise funds from other sources that may include public offerings, private placements, alternative offerings, or other means.

If we are successful in securing adequate funding, we plan to make significant capital or equipment investments, and we will also continue to make human resource additions in Helomics over the next 12 months. Such additional financing will be dilutive to existing stockholders, and there is no assurance that such financing will be available upon acceptable terms. If such financing or adequate funds from operations are not available, we will be forced to limit our business activities, which will have a material adverse effect on our results of operations and financial condition.

As a result of the above factors, the Company has concluded that there is substantial doubt about its' ability to continue as a going concern. The financial statements have been prepared assuming the Company will continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Furthermore, our independent registered public accounting firm has indicated in their audit opinion, contained in our financial statements included in this Annual Report on Form 10-K within Item 8, that there is substantial doubt about our ability to continue as a going concern. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

***In connection with developing our CRO business, we have committed and will continue to commit significant capital to investments in early stage companies, all of which may be lost, and which may require us to raise significant additional capital, and our entering into new lines of business will result in significant diversion of management resources, all of which may result in failure of our business.***

We have committed significant capital and management resources to developing our CRO business and other new business areas, and we intend to continue to devote significant capital and management resources to new businesses. In addition, in August 2017, we entered into a merger agreement with CytoBioscience, which was subsequently terminated in November 2017. From July 2017 through November 2017, we advanced \$1,070,000 to CytoBioscience in the form of secured notes, which are still outstanding. The Company has not received any payments from CytoBioscience since the first quarter of 2019. The Company has obtained a judgment against CytoBioscience and has proceeded with court proceedings to claim the collateral equipment and to attempt to recover the original balance plus interest due under the note. Management has concluded that it is probable that the Company will be unable to collect all amounts due according to the contractual terms of the receivable, and the Company has reserved all but \$250,000 of the note. It is possible that we will make further investments and advances in other businesses as we develop our CRO business and other business models. There can be no assurance that any of the outstanding balances of our existing promissory notes or future advances will be repaid. Therefore, we could invest significant capital in other business enterprises with no certainty when or whether we will realize a return on these investments. Investments in cash will deplete our capital resources, meaning that we will be required to raise significant amounts of new capital. There is no assurance that we will be successful in raising sufficient capital, and the terms of any such financing will be dilutive to our stockholders. We may also acquire technologies or companies by issuing stock or other equity securities rather than or in addition to payment of cash, which may have the result of diluting the investment of our stockholders. Further, the energy and resources of our officers and personnel are being substantially diverted to new lines of business, which are unproven. If these businesses are unsuccessful or require too great of a financial investment to be profitable, our business may fail.

***Our limited operating history with respect to our precision medicines services makes evaluation of our business difficult.***

The Company's precision medicine services were launched with the Company's initial investment in Helomics during the first quarter of 2018 and have not generated significant revenue to date. Our ability to implement a successful business plan with respect to precision medicine remains unproven and no assurance can be given that we will ever generate sufficient revenues to sustain our business in the event our STREAMWAY business is unsuccessful. We have a limited operating history which makes it difficult to evaluate our performance. You must consider our prospects in light of these risks and the expenses, technical obstacles, difficulties, market penetration rate and delays frequently encountered in connection with the development of new businesses. These factors include uncertainty as to whether we will be able to:

- Be successful in uncertain markets;
- Respond effectively to competitive pressures;
- Successfully address intellectual property issues of others;
- Protect and expand our intellectual property rights; and
- Continue to develop and upgrade our products.

***The Company's certificate of incorporation, as amended, provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the exclusive forum for certain legal actions between the Company and its stockholders, which could limit the Company's stockholders' ability to obtain a judicial forum viewed by the stockholders as more favorable for disputes with the Company or the Company's directors, officers or employees.***

The Company's certificate of incorporation, as amended, provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director or officer of the corporation to the corporation or the corporation's stockholders, (iii) any action asserting a claim against the corporation arising pursuant to any provision of the General Corporation Law or the corporation's Certificate of Incorporation or Bylaws, or (iv) any action asserting a claim against the corporation governed by the internal affairs doctrine. This choice of forum provision does not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act. Accordingly, our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees.

If a court were to find the choice of forum provision contained in our certificate of incorporation, as amended, to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to the Company's management.

## **STREAMWAY Business Risk Factors**

***Our business is dependent upon proprietary intellectual property rights, which if we were unable to protect, could have a material adverse effect on our business.***

We rely on a combination of patent, trade secret and other intellectual property rights and measures to protect our intellectual property. We currently own and may in the future own or license additional patent rights or trade secrets in the U.S., with non-provisional patents elsewhere in the world that cover certain of our products. We rely on patent laws and other intellectual property laws, nondisclosure and other contractual provisions and technical measures to protect our products and intangible assets. These intellectual property rights are important to our ongoing operations and no assurance can be given that any measure we implement will be sufficient to protect our intellectual property rights. Also, with respect to our trade secrets and proprietary know-how, we cannot be certain that the confidentiality agreements we have entered into with employees will not be breached, or that we will have adequate remedies for any breach. We may lose the protection afforded by these rights through patent expirations, legal challenges or governmental action. If we cannot protect our rights, we may lose our competitive advantage if these patents were found to be invalid in the jurisdictions in which we sell or plan to sell our products. The loss of our intellectual property rights could have a material adverse effect on our business.

***If we become subject to intellectual property actions, this could hinder our ability to deliver our products and services and our business could be negatively impacted.***

We could be subject to legal or regulatory actions alleging intellectual property infringement or similar claims against us. Companies may apply for or be awarded patents or have other intellectual property rights covering aspects of our technologies or businesses. Moreover, if it is determined that our products infringe on the intellectual property rights of third parties, we could be prevented from marketing our products. While we are currently not subject to any material intellectual property litigation, any future litigation alleging intellectual property infringement could be costly, particularly in light of our limited resources. Similarly, if we determine that third parties are infringing on our patents or other intellectual property rights, our limited resources may prevent us from litigating or otherwise taking actions to enforce our rights. Any such litigation or inability to enforce our rights could require us to change our business practices, hinder or prevent our ability to deliver our products and services, and result in a negative impact to our business. Expansion of our business via product line enhancements or new product lines to drive increased growth in current or new markets may be inhibited by the intellectual property rights of our competitors and/or suppliers. Our inability to successfully mitigate those factors may significantly reduce our market opportunity and subsequent growth.

***We face significant competition, including competition from companies with considerably greater resources than ours, and if we are unable to compete effectively with these companies, our market share may decline and our business could be harmed.***

Our industry is highly competitive with numerous competitors ranging from well-established manufacturers to innovative start-ups. A number of our competitors have significantly greater financial, technological, engineering, manufacturing, marketing and distribution resources than we do. Their greater capabilities in these areas may enable them to compete more effectively on the basis of price and production and more quickly develop new products and technologies.

Our competitors include Cardinal Health, Inc., a medical manufacturer and distributor, and Stryker Instruments, a wholly owned subsidiary of Stryker Corporation, which has a leading position in our market. Both of these competitors are substantially larger than our company and are better capitalized than we are.

Companies with significantly greater resources than ours may be able to reverse engineer our products and/or circumvent our intellectual property position. Such action, if successful, would greatly reduce our competitive advantage in the marketplace.

We believe our ability to compete successfully depends on a number of factors, including our technical innovations of unlimited suction and unlimited capacity capabilities, our innovative and advanced research and development capabilities, strength of our intellectual property rights, sales and distribution channels and advanced manufacturing capabilities. We plan to employ these and other elements as we develop our products and technologies, but there are many other factors beyond our control. We may not be able to compete successfully in the future, and increased competition may result in price reductions, reduced profit margins, loss of market share and an inability to generate cash flows that are sufficient to maintain or expand our development and marketing of new products, which could adversely impact the trading price of the shares of our common stock.

***Our business is subject to intense governmental regulation and scrutiny, both in the U.S. and abroad.***

The production, marketing, and research and development of our products is subject to extensive regulation and review by the FDA and other governmental authorities both in the United States and abroad. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record keeping. If we do not comply with applicable regulatory requirements, violations could result in warning letters, non-approvals, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

Periodically, legislative or regulatory proposals are introduced that could alter the review and approval process relating to medical products. It is possible that the FDA will issue additional regulations further restricting the sale of our present or proposed products. Any change in legislation or regulations that govern the review and approval process relating to our current and future products could make it more difficult and costlier to obtain approval for new products, or to produce, market, and distribute existing products.

***If our STREAMWAY System product is not accepted by our potential customers, it is unlikely we will ever become profitable.***

The medical industry has historically used a variety of technologies for fluid waste management. Compared to these conventional technologies, our technology is relatively new, and the number of companies using our technology is limited. The commercial success of our product will depend upon the widespread adoption of our technology as a preferred method by hospitals and surgical centers. In order to be successful, our products must meet the technical and cost requirements for these facilities. Market acceptance will depend on many factors, including:

- the willingness and ability of customers to adopt new technologies;
- our ability to convince prospective strategic partners and customers that our technology is an attractive alternative to conventional methods used by the medical industry;
- our ability to select and execute agreements with effective distributors to market and sell our product; and
- our ability to assure customer use of the Skyline proprietary cleaning solution and in-line filter.

Because of these and other factors, our products may not gain market acceptance or become the industry standard for the health care industry. The failure of such companies to purchase our products would have a material adverse effect on our business, results of operations and financial condition.

***If demand for our product is unexpectedly high, there is no assurance that there will not be supply interruptions or delays.***

We are currently manufacturing the STREAMWAY System, following GMP compliance regulations of the FDA, at our own facility and anticipate the capability of producing the STREAMWAY System in sufficient quantities for future near-term sales. We have contracted with a manufacturing company that can manufacture products at higher volumes. However, if demand for our product is unexpectedly high, there is no assurance that we or our manufacturing partners will be able to produce the product in sufficiently high quantity to satisfy demands. Any supply interruptions or inadequate supply would have a material adverse effect on our results of operations.

***We are dependent on a few key executive officers for our success. Our inability to retain those officers would impede our business plan and growth strategies, which would have a negative impact on our business and the value of an investment.***

Predictive's success depends on the skills, experience and performance of key members of its management team. Predictive heavily depends on its management team: Carl Schwartz, Predictive's Chief Executive Officer ("CEO"), and Bob Myers, Predictive's Chief Financial Officer ("CFO"). Predictive has entered into employment agreements with the CEO and the CFO of the senior management team and may expand the relatively small number of executives in its company. Were Predictive to lose one or more of these key individuals, it would be forced to expend significant time and money in the pursuit of a replacement, which could result in both a delay in the implementation of Predictive's business plan and the diversion of its limited working capital. Predictive can give no assurance that it can find satisfactory replacements for these key individuals at all, or on terms that are not unduly expensive or burdensome to Predictive.

***Our success is dependent on our ability to attract and retain technical personnel, sales and marketing personnel, and other skilled management.***

Our success depends to a significant degree on our ability to attract, retain and motivate highly skilled and qualified personnel. Failure to attract and retain necessary technical, sales and marketing personnel and skilled management could adversely affect our business. If we fail to attract, train and retain sufficient numbers of these highly-qualified people, our prospects, business, financial condition and results of operations will be materially and adversely affected.

***Security breaches, loss of data and other disruptions to Predictive or its third-party service providers could compromise sensitive information related to Predictive's business or prevent Predictive from accessing critical information and expose it to liability, which could adversely affect Predictive's business and reputation.***

Predictive's business requires that Predictive collect and store sensitive data including credit card information, and Predictive's proprietary business and financial information. Predictive faces a number of risks relative to Predictive's protection of, and Predictive's service providers' protection of, this critical information, including loss of access, inappropriate disclosure and inappropriate access, as well as risks associated with Predictive's ability to identify and audit such events. The secure processing, storage, maintenance and transmission of this critical information are vital to Predictive's operations and business strategy, and Predictive devotes significant resources to protecting such information. Although Predictive takes measures to protect sensitive information from unauthorized access or disclosure, Predictive's information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While Predictive has not experienced any such attack or breach, if such event would occur and cause interruptions in Predictive's operations, Predictive's networks would be compromised and the information Predictive stores on those networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Unauthorized access, loss or dissemination could disrupt Predictive's operations, including collecting, processing and preparing company financial information, manage the administrative aspects of Predictive's business and damage Predictive's reputation, any of which could adversely affect Predictive's business. In addition, the interpretation and application of consumer, health-related and data protection laws in the United States are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with Predictive's practices. Complying with these various laws could cause Predictive to incur substantial costs or require Predictive to change its business practices, systems and compliance procedures in a manner adverse to Predictive's business.

***Costs incurred because Predictive is a public company may affect its profitability.***

As a public company, Predictive incurs significant legal, accounting, and other expenses and it is subject to the SEC's rules and regulations relating to public disclosure that generally involve a substantial expenditure of financial resources. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC, requires changes in corporate governance practices of public companies. Full compliance with such rules and regulations requires significant legal and financial compliance costs and makes some activities more time-consuming and costlier, which may negatively impact its financial results. To the extent Predictive's earnings suffer as a result of the financial impact of its SEC reporting or compliance costs, its ability to develop an active trading market for its securities could be harmed.



***Limitations on director and officer liability and indemnification of our officers and directors by us may discourage stockholders from bringing suit against a director.***

Our Certificate of Incorporation and Bylaws provide, with certain exceptions as permitted by governing state law, that a director or officer shall not be personally liable to us or our stockholders for breach of fiduciary duty as a Director, except for acts or omissions which involve intentional misconduct, fraud or knowing violation of law, or unlawful payments of dividends. These provisions may discourage stockholders from bringing suit against a director for breach of fiduciary duty and may reduce the likelihood of derivative litigation brought by stockholders on our behalf against a director. In addition, our certificate of incorporation and bylaws may provide for mandatory indemnification of directors and officers to the fullest extent permitted by governing state law.

***We do not expect to pay dividends for the foreseeable future, and we may never pay dividends; investors must rely on stock appreciation for any return on investment in the Company's common stock.***

We currently intend to retain any future earnings to support the development and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our Board of Directors after taking into account various factors, including but not limited to, our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. In addition, our ability to pay dividends on our common stock may be limited by state law. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize certain returns on their investment. As a result, investors must rely on stock appreciation and a liquid trading market for any return on investment in the Company's common stock.

***Shares eligible for future sale may adversely affect the market.***

From time to time, certain stockholders may be eligible to sell some or all of their shares of common stock pursuant to Rule 144, promulgated under the Securities Act subject to certain limitations. In general, pursuant to Rule 144 as in effect as of the date of this registration statement, a stockholder (or stockholders whose shares are aggregated) who has satisfied the applicable holding period and is not deemed to have been one of our affiliates at the time of sale, or at any time during the three months preceding a sale, may sell their shares of common stock. Any substantial sale, or cumulative sales, of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our securities.

***We expect volatility in the price of our common stock, which may subject us to securities litigation.***

When established, the market for our common stock may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will be more volatile than a seasoned issuer for the indefinite future. In addition, there is no assurance that the price of our common stock will not be volatile. In the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources.

***Our Board of Directors' ability to issue undesignated preferred stock and the existence of anti-takeover provisions may depress the value of our common stock.***

Our authorized capital includes 20 million shares of preferred stock. Of this amount, 18,950 shares have been designated as Series B Convertible Preferred Stock, 1,213,819 shares have been designated as Series C Preferred Stock, 3,500,000 shares have been designated as Series D Convertible Preferred Stock, 350 shares have been designated as Series E convertible stock and the remaining authorized shares are undesignated preferred stock. Our Board of Directors have the power to issue any or all of the shares of undesignated preferred stock, including the authority to establish one or more series and to fix the powers, preferences, rights and limitations of such class or series, without seeking stockholder approval. Further, as a Delaware corporation, we are subject to provisions of the Delaware General Corporation Law regarding "business combinations." We may, in the future, consider adopting additional anti-takeover measures. The authority of our Board of Directors to issue undesignated stock and the anti-takeover provisions of Delaware law, as well as any future anti-takeover measures adopted by us, may, in certain circumstances, delay, deter or prevent takeover attempts and other changes in control of the company not approved by our Board of Directors. As a result, our stockholders may lose opportunities to dispose of their shares at favorable prices generally available in takeover attempts or that may be available under a merger proposal and the market price, voting and other rights of the holders of common stock may also be affected.

***Future sales and issuances of our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.***

We also expect that significant additional capital will be needed in the future to continue our planned operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner, we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. In addition, in the past, we have issued warrants to acquire shares of common stock. To the extent these warrants are ultimately exercised, you will sustain further dilution.

***Acquisitions involve risks that could result in adverse changes to operating results, cash flows and liquidity.***

Predictive intends to make strategic acquisitions in addition to the Merger. However, Predictive may not be able to identify suitable acquisition opportunities or may be unable to obtain the consent of Predictive's stockholders and therefore, may not be able to complete such acquisitions. Predictive may pay for acquisitions with its common stock or with convertible securities, which may dilute shareholders' investment in its common stock or it may decide to pursue acquisitions that investors may not agree with. In connection with potential Predictive's acquisitions, Predictive may agree to substantial earn-out arrangements. To the extent it defers the payment of the purchase price for any acquisition through a cash earn-out arrangement, it will reduce cash flows in subsequent periods. In addition, acquisitions may expose Predictive to operational challenges and risks, including:

- the ability to profitably manage acquired businesses or successfully integrate the operations of acquired businesses, as well as the acquired business's financial reporting and accounting control systems into its existing platforms;
- increased indebtedness and contingent purchase price obligations associated with an acquisition;
- the ability to fund cash flow shortages that may occur if anticipated revenue is not realized or is delayed, whether by general economic or market conditions, or unforeseen internal difficulties;
- the availability of funding sufficient to meet increased capital needs;
- diversion of management's time and attention from existing operations; and
- the ability to retain or hire qualified personnel required for expanded operations.

Completing acquisitions may require significant management time and financial resources because Predictive may need to assimilate widely dispersed operations with different corporate cultures. In addition, acquired companies may have liabilities that it failed to or were unable to discover in the course of performing due diligence investigations. Predictive cannot assure the shareholders' that the indemnification granted by sellers of acquired companies will be sufficient in amount, scope or duration to fully offset the possible liabilities associated with businesses or properties it assumes upon consummation of an acquisition. Predictive may learn additional information about its acquired businesses that could have a material adverse effect on Predictive, such as unknown or contingent liabilities and liabilities related to compliance with applicable laws. Any such liabilities, individually or in the aggregate, could have a material adverse effect on its business. Failure to successfully manage the operational challenges and risks associated with, or resulting from, acquisitions could adversely affect Predictive's results of operations, cash flows and liquidity. Borrowings or issuances of convertible securities associated with these acquisitions may also result in higher levels of indebtedness, which could adversely impact Predictive's ability to service its debt within the scheduled repayment terms.

***Predictive may fail to prevent further defaults under the Amended and Restated Notes, which could result in material penalties and acceleration of the Amended and Restated Notes, and the Investor could assert its rights as a secured creditor.***

Effective February 7, 2019, Predictive entered into a Forbearance Agreement with the Investor in connection with (1) the Investor claims that Predictive failed to timely comply with the requirements of a registration rights agreement with the Investor and (2) a default resulting from Predictive's failure to obtain stockholder approval on or before December 31, 2018 for Predictive's then-pending Merger with Helomics. Under the Forbearance Agreement, Predictive issued an aggregate of 11,667 shares to the Investor, and a total of \$242,386 was added to the principal amount of Predictive's indebtedness to the Investor. Interest on the Amended and Restated Note accrued at a default rate of 18% beginning as of November 15, 2018 and continuing through the date of the Default Cure (as defined below).

Under the Forbearance Agreement, if (a) Predictive obtained shareholder approval of the then-pending merger with Helomics by March 31, 2019, (b) Predictive maintains the effectiveness of its currently effective registration statement on Form S-3 that registers the resale of certain shares that we issued to the Investor as an inducement for its investment, and (c) there are no other defaults under the Amended and Restated Note and related documents, then the above default will be considered cured (the "Default Cure"), the Amended and Restated Notes would not be accelerated and no additional default penalties would be paid. If Predictive failed to satisfy these conditions, the forbearance would terminate, the Amended and Restated Notes would have accelerated, and the Investor may have asserted all of its rights. The Company believes that, as a result of the effectiveness of such registration statement on February 13, 2019 and the stockholder approval of the Merger on March 22, 2019, the Default Cure has been achieved. However, there can be no assurance that there will not be additional defaults under terms of the Amended and Restated Note. Upon a default, among other things, the Amended and Restated Note becomes immediately due and payable, Predictive is required to pay to the holder 135% (plus an additional 5% per each additional event of default) multiplied by the then outstanding balance of the Amended and Restated Note plus default interest at 18%. Further, the Investor has a security interest in substantially all of Predictive's assets and those of Helomics. In the event of a default, we may attempt to refinance the payment of the balance of the Amended and Restated Note and applicable penalties; however, there is no assurance that such refinancing will be available. Therefore, defaults on the Amended and Restated Note would have a material adverse effect on our financial condition, including the Investor's rights to seize our assets or those of Helomics in the event we cannot satisfy our obligations under the Amended and Restated Note.

***Predictive's ability to obtain and/or utilize financing to fund our ongoing operations may be limited by the terms of certain outstanding Promissory Notes***

On September 27, 2019, the Company entered into an amendment to the L2 Note. Under the amendment, the maturity date of the L2 Note was extended from September 28, 2019 to December 31, 2019. In exchange for such extension, the outstanding principal amount of the L2 Note was increased by \$120,000, such that, as of the effective date of the amendment, the outstanding principal amount owed under the L2 Note is \$1,789,104. Under the amendment, through October 15, 2019, L2 waived its rights under the L2 Note to have the L2 Note repaid from the proceeds of any financing consummated by the Company. In exchange for such waiver, the Company issued 15,000 shares of common stock to the holder.

After October 15, 2019, if Predictive receives cash proceeds from any source other than (i) sales of our products or (ii) the first \$2,000,000 of proceeds from securities offering transactions, Predictive is required to inform L2 of such receipt. L2 will have the right to require that Predictive apply up to 50% of such proceeds to repay outstanding amounts owed under the L2 Note. As a result, proceeds from future securities offering transactions will likely be subject to L2's repayment right. The aforementioned criteria may negatively impact Predictive's ability to obtain financing from securities offering transactions until repayment or conversion of the L2 Note. To the extent we are able to obtain such financing, this arrangement may limit Predictive's ability to use the proceeds thereof to fund its operations. If we are unable to obtain financing or use the proceeds to fund its operations, Predictive will be forced to limit its business activities, which will have a material adverse effect on Predictive's results of operations and financial condition.

## **Risks Related to the Merger with Helomics Holding Corporation (the “Merger”) completed on April 4, 2019**

***Completion of the Merger and the Exchange Offer resulted in the issuance of a large number of our shares and warrants, which significantly diluted and will significantly further dilute the percentage of stock held by existing holders of our common stock.***

On the effective date of the Merger, we issued 400,000 shares of our common stock and 3,500,000 shares of Series D Preferred Stock to holders of Helomics capital stock. This issuance is in addition to the 110,000 shares of Predictive common stock previously issued to Helomics as consideration for Predictive’s prior acquisition of a twenty percent ownership interest in Helomics; these 110,000 shares remained outstanding and were distributed to holders of Helomics capital stock. Each share of Predictive Series D Preferred Stock is convertible on a 10:1 basis of Predictive common stock starting one year after issuance, subject to adjustment. In connection with the Merger, Predictive offered the following offer (the “Exchange Offer”) to holders of certain promissory notes of Helomics that were issued to investors (the “Helomics Notes Payable”) and accompanying warrants to purchase Helomics common stock (the “Helomics Warrants”): the exchange of (a) one share of our common stock for each \$1.00 of principal and accrued and unpaid interest outstanding of the tendered Helomics Notes Payable held by each holder as of the effective time of the Merger, and (b) a warrant to purchase shares of our common stock at an exercise price of \$1.00 per share (a “Predictive Warrant”) for each of the Helomics Warrants held by such holders, at a ratio of 0.6 Predictive Warrants for each 1.0 Helomics Warrant. Ultimately, we issued such holders: (1) 863,732 additional shares of our common stock, (2) 1,424,506 warrants to purchase our Common Stock at an exercise price of \$10.00 per share and (3) 59,700 warrants to purchase common stock at an exercise price of \$0.10 per share. Conversion of the Series D Preferred Stock and exercise of such warrants will significantly further dilute the percentage of stock held by existing holders of our common stock.

***Costs associated with the Merger are difficult to estimate, may be higher than expected, and may harm the financial results of the combined company.***

Both Predictive and Helomics incurred substantial direct transaction costs associated with the Merger, and Predictive will incur additional costs associated with consolidation and integration of operations. If the total costs of the Merger exceed estimates, or the benefits of the Merger do not exceed the total costs of the Merger, Predictive’s consolidated financial results could be adversely affected.

***The Merger may result in disruption of Predictive’s existing business, distraction of management and diversion of other resources.***

The integration of Predictive’s and Helomics’ operations may divert management time and resources from the main historical businesses of both companies. After the Merger, management will likely be required to spend significant time integrating Predictive’s and Helomics’ operations. This diversion of time and resources could cause the combined business to suffer.

***Predictive’s ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code and may be subject to further limitation because of prior or future offerings of Predictive’s stock or other transactions.***

Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended (the “Code”) contain rules that limit the ability of a company that undergoes an ownership change, which is generally an increase in the ownership percentage of certain stockholders in the stock of a company by more than 50% over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change, as defined by Section 382 of the Code, occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term tax-exempt rate and the value of the company’s stock immediately before the ownership change. The Merger will result in such an ownership change. As a result, Predictive will not be able to use its pre-Merger losses or credit carryovers or certain built-in losses to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383 of the Code, which may result in the expiration of a portion of Predictive’s tax attributes before utilization.

***If Predictive is required to write down goodwill and other intangible assets, Predictive's financial condition and operating results would be negatively affected.***

When Predictive acquires a business, a substantial portion of the purchase price of the acquisition is allocated to goodwill and other identifiable intangible assets. The amount of the purchase price which is allocated to goodwill and other intangible assets is determined by the excess of the purchase price over the net identifiable assets acquired. For example, when Predictive acquired Helomics, it acquired intangible assets with an estimated value of \$3,725,000, and \$23,790,290 in goodwill represented the excess of the consideration transferred over the fair values of assets acquired and liabilities assumed and represents the future economic benefits arising from other assets acquired that could not be individually identified and separately recognized. Predictive tests intangible assets and goodwill for impairment at least annually. Under current accounting standards, if Predictive determines that intangible assets or goodwill are impaired, Predictive will be required to write down these assets. Any write-downs Predictive may be required to record would adversely affect Predictive's financial condition and operating results.

***Predictive will incur significantly increased costs as a result of the completion of the Merger.***

In the periods following the completion of the Merger, Predictive's operating expenses are likely to increase significantly as Helomics continues to develop and grow its business. These increases are most likely to be in the areas of sales and marketing, compensation and research and product development. There also may be increases in legal, accounting, insurance and compliance costs. As a result, the combined company is expected to report operating losses until Helomics can significantly increase its revenues. This may have a material adverse impact on the market price of Predictive common stock following the Merger. Additionally, the integration of the operations of Predictive and Helomics may result in unanticipated costs, which may be higher than expected and could have a material adverse effect on the combined company's financial condition and operating results.

***The combined company will not be able to continue operating without additional financing.***

Both Predictive and Helomics have been operating at a loss. In order to continue operating and remain a going concern, the combined company will need to obtain additional financing, either through borrowings, public offerings, private offerings, or some type of business combination (e.g., merger, buyout, etc.), and there can be no assurance that it will be successful in such pursuits with terms satisfactory to management and Predictive's board of directors. In the past, both companies have actively pursued a variety of funding sources including private offerings and have consummated certain transactions in order to address their respective capital requirements. Predictive recently completed a private offering of securities and loaned a portion of the proceeds to Helomics. However, the combined company anticipates the need for additional capital beyond the recent offering and may not be able to acquire such additional funding. Accordingly, if the combined company is unable to generate adequate cash from operations, and if it is unable to find sources of funding, it may be necessary for it to sell one or more lines of business or all or a portion of its assets, enter into a business combination, reduce or eliminate operations, liquidate assets, or seek relief through a filing under the U.S. Bankruptcy Code. These possibilities, to the extent available, may be on terms that result in significant dilution to the combined company's existing shareholders or that result in its existing shareholders losing all of their investment in the combined company.

***Predictive may fail to realize the anticipated benefits of the Merger.***

The success of the Merger will depend, in part, on Predictive's ability to realize the anticipated growth opportunities and synergies from combining Predictive and Helomics. The integration of Predictive and Helomics will be a time consuming and expensive process and may disrupt their operations if it is not completed in a timely and efficient manner. In addition, Predictive may not achieve anticipated synergies or other benefits of the Merger. Following the Merger, Predictive and Helomics must operate as a combined organization utilizing common information and communication systems, operating procedures, financial controls and human resources practices. The combined company may encounter the following integration difficulties, resulting in costs and delays:

- failure to successfully manage relationships with customers and other important relationships;
- failure of customers to continue using the services of the combined company;
- difficulties in successfully integrating the management teams and employees of Predictive and Helomics;
- challenges encountered in managing larger operations;
- losses of key employees;
- failure to manage the growth and growth strategies of Predictive and Helomics;
- diversion of the attention of management from other ongoing business concerns;
- incompatibility of technologies and systems;
- impairment charges incurred to write down the carrying amount of intangible assets generated as a result of the Merger; and
- incompatibility of business cultures.

If the combined company's operations after the Merger do not meet the expectations of existing or prospective customers of Predictive and Helomics, then these customers and prospective customers may cease doing business with the combined company altogether, which would harm its results of operations, financial condition and business prospects. If the management team is not able to develop strategies and implement a business plan that successfully addresses these difficulties, Predictive may not realize the anticipated benefits of the Merger.

**Risk Relating to the Acquisition of Helomics**

***Helomics molecular diagnostics business has limited revenue, and Helomics expects to incur net losses for the foreseeable future and Helomics may never achieve or sustain profitability.***

The revenue generated from Helomics' molecular diagnostics business was \$297,465, for the year ended December 31, 2018 and for the same fiscal period, Helomics' molecular diagnostics business had operating losses of \$5.2 million. Although Helomics expects the revenue generated from Helomics' molecular diagnostics business to grow in the future, there can be no assurance that Helomics will achieve revenue sufficient to offset expenses. Additionally, Helomics is engaged in activities to expand and diversify its revenue base. Helomics expects that a significant portion of Helomics revenue will come from certain service efforts being offered to pharmaceutical, diagnostic and biotech companies as well as academic institutions. Helomics' business may never achieve or sustain profitability, and Helomics' failure to achieve and sustain profitability in the future could have a material adverse effect on Helomics' business, financial condition and results of operations.

***Helomics has a limited operating history as a molecular diagnostics company, which may make it difficult to evaluate the success of Helomics' business to date and to assess Helomics' future viability.***

Helomics has operated as a molecular diagnostics company since the beginning of 2017. Helomics is building a new business foundation which may make it difficult to evaluate the success of Helomics' business to date and to assess its future viability.

***If one or more significant payors stops providing reimbursement or decreases the amount of reimbursement for Helomics' molecular diagnostic tests, Helomics' revenue could decline.***

Although Helomics has entered into contracts with certain third-party payors which establish in-network allowable rates of reimbursement for its molecular diagnostic tests, payors may suspend or discontinue reimbursement at any time, may require or increase co-payments from patients, or may reduce the reimbursement rates paid to Helomics. Any such actions could have a negative effect on Helomics' revenue.

***If payors do not provide reimbursement, rescind or modify their reimbursement policies or delay payments for Helomics' tests, or if Helomics is unable to successfully negotiate additional reimbursement contracts, Helomics' commercial success could be compromised.***

Physicians may not order Helomics' tests unless payors reimburse a substantial portion of the test price. There is uncertainty concerning third-party reimbursement of any test incorporating new molecular diagnostic technology. Reimbursement by a payor may depend on a number of factors, including a payor's determination that tests such as Helomics' molecular diagnostic tests are: (a) not experimental or investigational; (b) pre-authorized and appropriate for the patient; (c) cost-effective; (d) supported by peer-reviewed publications; and (e) included in clinical practice guidelines. Since each payor makes its own decision as to whether to establish a policy or enter into a contract to reimburse Helomics' tests, seeking these approvals is a time-consuming and costly process. Also, payor consolidation is underway and creates uncertainty as to whether coverage and contracts with existing payors will remain in effect. Finally, commercial payors may tie their allowable rates to Medicare rates, and should Medicare reduce their rates, Helomics may be negatively impacted. If Helomics fails to establish broad adoption of and reimbursement for its molecular diagnostic tests, or if Helomics is unable to maintain existing reimbursement from payors, its ability to generate revenue could be harmed and this could have a material adverse effect on Helomics' business, financial condition and results of operations.

***Helomics may experience limits on its revenue if physicians decide not to order its molecular diagnostic tests.***

If Helomics is unable to create or maintain demand for its molecular diagnostic tests in sufficient volume, it may not become profitable. To generate demand, Helomics will need to continue to educate physicians and the medical community on the value and benefits of its molecular diagnostic tests in order to change clinical practices through published papers, presentations at scientific conferences and one-on-one education by Helomics' internal sales force. In addition, Helomics' ability to obtain and maintain adequate reimbursement from third-party payors will be critical to generating revenue. In many cases, practice guidelines in the United States have recommended therapies or surgery to determine if a patient's condition is malignant or benign. Accordingly, physicians may be reluctant to order a diagnostic test that may suggest surgery is unnecessary. In addition, Helomics' molecular diagnostic tests are performed at Helomics' laboratories rather than by a pathologist in a local laboratory, so pathologists may be reluctant to support Helomics' molecular diagnostic tests. In addition, guidelines for the diagnosis and treatment of thyroid nodules may change to recommend another type of treatment protocol, and these changes may result in medical practitioners deciding not to use Helomics' molecular diagnostic tests. These facts may make physicians reluctant to convert to using Helomics' molecular diagnostic tests, which could limit Helomics' ability to generate revenue and achieve profitability which could have a material adverse effect on its business, financial condition and results of operations.

***Helomics may experience limits on its revenue if patients decide not to use its molecular diagnostic tests.***

Some patients may decide not to use Helomics' molecular diagnostic tests due to price, all or part of which may be payable directly by the patient if the patient's insurer denies reimbursement in full or in part. Many insurers seek to shift more of the cost of healthcare to patients in the form of higher co-payments or premiums. In addition, the current economic environment in the United States has and may continue to result in the loss of healthcare coverage. Implementation of provisions of the Patient Protection and Affordable Care Act, or PPACA (also known as the Affordable Care Act) also resulted in the loss of health insurance, and increases in premiums and reductions in coverage, for some patients. These events may result in patients delaying or forgoing medical checkups or treatment due to their inability to pay for Helomics' test, which could have an adverse effect on Helomics' revenue.

***If Helomics' sales efforts are less successful than anticipated, its business expansion plans, including its service offerings, could suffer and its ability to generate revenues could be diminished. In addition, Helomics has limited history selling its molecular diagnostics tests on a direct basis and Helomics' limited history makes forecasting difficult.***

If Helomics' sales efforts are not successful, or new additions to its sales initiatives fail to gain traction among customers, Helomics may not be able to increase market awareness and sales of its molecular diagnostic tests or its service offerings. If Helomics fails to establish its molecular diagnostic tests in the marketplace, it could have a negative effect on its ability to sell subsequent molecular diagnostic tests and hinder the desired expansion of its business. Helomics has limited historical experience forecasting the direct sales of its molecular diagnostics products and service offerings. Helomics' ability to produce product quantities that meet customer demand is dependent upon its ability to forecast accurately and plan production and processing accordingly.

***Helomics relies on sole suppliers for some of the materials used in its molecular diagnostic tests, and it may not be able to find replacements or transition to alternative suppliers in a timely manner.***

Helomics relies on sole suppliers for certain materials that it uses to perform its molecular diagnostic tests. Helomics also purchases reagents used in its molecular diagnostic tests from sole-source suppliers. While Helomics has developed alternate sourcing strategies for these materials and vendors, Helomics cannot be certain whether these strategies will be effective or the alternative sources will be available in a timely manner. If these suppliers can no longer provide Helomics with the materials it needs to perform its molecular diagnostic tests, if the materials do not meet its quality specifications, or if it cannot obtain acceptable substitute materials, an interruption in molecular diagnostic test processing could occur. Any such interruption may directly impact Helomics' revenue and cause it to incur higher costs.

***Helomics may experience problems in scaling its operations, or in delays or reagent and supply shortages that could limit the growth of its revenue.***

If Helomics encounters difficulties in scaling its operations as a result of, among other things, quality control and quality assurance issues and availability of reagents and raw material supplies, it will likely experience reduced sales of its molecular diagnostic tests, increased repair or re-engineering costs, and defects and increased expenses due to switching to alternate suppliers, any of which would reduce Helomics' revenues and gross margins. Although Helomics attempts to match its capabilities to estimates of marketplace demand, to the extent demand materially varies from Helomics' estimates, Helomics may experience constraints in its operations and delivery capacity, which could adversely impact revenue in a given fiscal period. Should Helomics' need for raw materials and reagents used in its molecular diagnostic tests fluctuate, Helomics could incur additional costs associated with either expediting or postponing delivery of those materials or reagents.

***If Helomics is unable to support demand for its molecular diagnostic tests or any of its future tests or solutions, Helomics' business could suffer.***

As demand for Helomics' molecular diagnostic tests grow, Helomics will need to continue to scale its testing capacity and processing technology, to expand its customer service, billing and systems processes and to enhance its internal quality assurance program. Helomics will also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of its molecular diagnostic tests. Helomics cannot guarantee that increases in scale, related improvements and quality assurance will be implemented successfully or that appropriate personnel will be available. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing tests or inability to meet demand. There can be no assurance that Helomics will be able to perform its testing on a timely basis at a level consistent with demand, or that Helomics' efforts to scale its operations will not negatively affect the quality of test results. If Helomics encounters difficulty meeting market demand or quality standards its reputation could be harmed, and its future prospects and business could suffer, causing a material adverse effect on Helomics' business, financial condition and results of operations.

***If Helomics is unable to compete successfully, Helomics may be unable to increase or sustain its revenue or achieve profitability.***



Helomics competes with physicians and the medical community who use traditional diagnostic methods. In many cases, practice guidelines in the United States have recommended therapies or surgery to determine if a patient's condition is malignant or benign. As a result, Helomics believes it will need to continue to educate physicians and the medical community on the value and benefits of its molecular diagnostic tests in order to change clinical practices. In addition, Helomics faces competition from other companies that offer diagnostic tests. It is also possible that Helomics faces future competition from laboratory-developed tests, or LDTs, developed by commercial laboratories such as Quest and/or other diagnostic companies developing new molecular diagnostic tests or technologies. Furthermore, Helomics may be subject to competition as a result of the new, unforeseen technologies that can be developed by Helomics' competitors in its diagnostic tests space.

To compete successfully Helomics must be able to demonstrate, among other things, that its molecular diagnostic test results are accurate and cost effective, and Helomics must secure a meaningful level of reimbursement for its tests. Many of Helomics' potential competitors have stronger brand recognition and greater financial capabilities than Helomics does. Others may develop tests with a lower price than Helomics that could be viewed by physicians and payors as functionally equivalent to Helomics' molecular diagnostic tests or offer a test at prices designed to promote market penetration, which could force Helomics to lower the price of its molecular diagnostic tests and affect its ability to achieve and maintain profitability. If Helomics is unable to compete successfully against current and future competitors, it may be unable to increase market acceptance of its molecular diagnostic tests and overall sales, which could prevent Helomics from increasing its revenue or achieving profitability and cause the market price of its common stock to decline. As Helomics adds new molecular diagnostic tests and services, it will face many of these same competitive risks for these new molecular diagnostic tests and services.

Developing new molecular diagnostic tests involves a lengthy and complex process, and Helomics may not be able to commercialize on a timely basis, or at all, other molecular diagnostic tests Helomics is developing. Developing new molecular diagnostic tests and solutions will require Helomics to devote considerable resources to research and development. Helomics may face challenges obtaining sufficient numbers of samples to validate a newly acquired or developed molecular diagnostic test. In order to develop and commercialize new molecular diagnostic tests, Helomics needs to:

- expend significant funds to conduct substantial research and development;
- conduct successful analytical and clinical studies;
- scale Helomics' laboratory processes to accommodate new molecular diagnostic tests; and
- build the commercial infrastructure to market and sell new molecular diagnostic tests.

Typically, few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, Helomics may abandon development of a molecular diagnostic test or Helomics may be required to expend considerable resources repeating clinical studies, which would adversely affect the timing for generating revenue from such test. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study or if Helomics fails to sufficiently demonstrate analytical validity, Helomics might choose to abandon the development of the molecular diagnostic test, which could harm its business. In addition, competitors may develop and commercialize new competing molecular diagnostic tests faster than Helomics or at a lower cost, which could have a material adverse effect on Helomics' business, financial condition and results of operations.

***If Helomics is unable to develop or acquire molecular diagnostic tests to keep pace with rapid technological, medical and scientific change, its operating results and competitive position could be affected.***

Recently, there have been numerous advances in technologies relating to diagnostics, particularly diagnostics that are based on genomic information. These advances require Helomics to continuously develop its technology and to work to develop new solutions to keep pace with evolving standards of care. Helomics' solutions could become obsolete unless it continually innovates and expands its product offerings to include new clinical applications. If Helomics is unable to develop or acquire new molecular diagnostic tests or to demonstrate the applicability of its molecular diagnostic tests for other diseases, Helomics' sales could decline and its competitive position could be harmed.

***If the United States Food and Drug Administration (“FDA”) begins to enforce regulation of Helomics’ molecular diagnostic tests, Helomics could incur substantial costs and delays associated with trying to obtain pre-market clearance or approval and costs associated with complying with post-market requirements.***

Clinical laboratory tests like Helomics’ molecular diagnostic tests are regulated under CLIA as well as by applicable state laws. Most Laboratory Developed Tests (“LDTs”) are currently not subject to the FDA’s, regulation (although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation). In October 2014, the FDA issued two draft guidance documents: “Framework for Regulatory Oversight of Laboratory Developed Tests”, which provides an overview of how the FDA would regulate LDTs through a risk-based approach, and “FDA Notification and Medical Device Reporting for Laboratory Developed Tests”, which provides guidance on how the FDA intends to collect information on existing LDTs, including adverse event reports. On January 13, 2017, the FDA also issued a discussion paper on LDTs. Pursuant to the Framework for Regulatory Oversight draft guidance, LDT manufacturers would be subject to medical device registration, listing, and adverse event reporting requirements. The risk-based classification considers the LDT’s intended use, technological characteristics, and the risk to patients if the LDT were to fail. The FDA has indicated in its guidance that screening devices for malignant cancers are LDTs of higher concern to the FDA and for which enforcement of pre-market and post-market review requirements would likely commence before other LDT types.

Pursuant to the Framework for Regulatory Oversight draft guidance, LDT manufacturers would be required to either submit a pre-market application and receive the FDA’s approval before an LDT may be marketed or submit a pre-market notification in advance of marketing. These requirements would be phased in, starting with higher risk LDTs, following the issuance of the FDA’s final guidance on this topic, which the FDA has identified as a priority. The draft guidance provides that LDTs that are already marketed at the time the final guidance is issued would not be withdrawn from the market during the FDA’s review process. There is no timeframe within which the FDA must issue its final guidance, but issuance of this final guidance has been identified among a list of the FDA’s priorities for 2016. As of the date of the filing of this proxy statement/prospectus/information statement, the FDA has not issued its final guidance. How the final guidance would affect Helomics’ business is not yet known. Helomics cannot provide any assurance that the FDA regulation will not be required in the future for its tests, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated, or guidance could be issued by the FDA which may result in increased regulatory burdens for Helomics to continue to offer its molecular diagnostic tests or to develop and introduce new tests. Helomics cannot predict the timing or content of future legislation enacted, regulations promulgated, or guidance issued regarding LDTs, or how it will affect Helomics’ business.

If pre-market review is required by the FDA or if Helomics decides to voluntarily pursue the FDA’s pre-market review of Helomics’ tests, there can be no assurance that Helomics’ molecular diagnostic tests or any tests Helomics may develop or acquire in the future will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with Helomics’ current claims or adequate to support continued adoption of and reimbursement for its tests. If pre-market review is required, Helomics’ business could be negatively impacted as a result of commercial delay that may be caused by the new requirements. The cost of conducting clinical trials and otherwise developing data and information to support pre-market applications may be significant. If Helomics is required to submit applications for its currently-marketed tests, Helomics may be required to conduct additional studies, which may be time-consuming and costly and could result in Helomics’ currently-marketed tests being withdrawn from the market. If Helomics’ tests are allowed to remain on the market but there is uncertainty in the marketplace about its tests, if Helomics is required by the FDA to label them investigational, or if labeling claims the FDA allows Helomics to make are limited, orders may decline, and reimbursement may be adversely affected. Continued compliance with the FDA’s regulations would increase the cost of conducting Helomics’ business, and subject Helomics to heightened regulation by the FDA and penalties for failure to comply with these requirements. Helomics cannot predict the timing or form of any such guidance or regulation, or the potential effect on Helomics’ existing molecular diagnostic tests or Helomics’ tests in development, or the potential impact of such guidance or regulation on Helomics’ business, financial condition and results of operations.

***If Helomics fails to comply with Federal, State and foreign laboratory licensing requirements, Helomics could lose the ability to perform its tests or experience disruptions to Helomics’ business.***

Helomics is subject to Clinical Laboratory Improvement Amendments (“CLIA”), a Federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management and quality assurance. CLIA certification is also required in order for Helomics to be eligible to bill Federal and State healthcare programs, as well as many private third-party payors, for its molecular diagnostic tests. To renew these certifications, Helomics is subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of Helomics’ clinical reference laboratories. Helomics is also required to maintain State licenses to conduct testing in its Pittsburgh, Pennsylvania laboratories. Pennsylvania laws require that Helomics maintain a license and establish standards for the day-to-day operation of Helomics’ clinical reference laboratory in Pittsburgh, Pennsylvania. In addition, Helomics’ Pittsburgh and New Haven laboratories are required to be licensed on a test-specific basis by certain other states. If Helomics were unable to obtain or lose its CLIA certificate or State licenses for its laboratories, whether as a result of revocation, suspension or limitation, Helomics would no longer be able to perform its molecular diagnostic tests, which could have a material adverse effect on Helomics’ business, financial condition and results of operations. If Helomics were to lose its licenses issued by the States in which Helomics is required to hold licenses, Helomics would not be able to test specimens from those States. New molecular diagnostic tests Helomics may develop may be subject to new approvals by governmental bodies, and Helomics may not be able to offer its new molecular diagnostic tests to patients in such jurisdictions until such approvals are received.

***Complying with numerous statutes and regulations pertaining to Helomics’ molecular diagnostics business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.***

Helomics is subject to regulation by both the Federal government and the States in which Helomics conducts its molecular diagnostics business, including:

- The Food, Drug and Cosmetic Act, as supplemented by various other statutes;
- The Prescription Drug Marketing Act of 1987, the amendments thereto, and the regulations promulgated thereunder and contained in 21 C.F.R. Parts 203 and 205, or the PDMA;
- CLIA and State licensing requirements;
- Manufacturing and promotion laws;
- Medicare billing and payment regulations applicable to clinical laboratories;
- The Federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a Federal healthcare program;
- The Federal Stark physician self-referral law (and state equivalents), which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition;
- The Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, and amendments made in 2013 to HIPAA under the Health Information Technology for Economic and Clinical Health Act, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- The Federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- The Federal False Claims Act, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;

- Other Federal and State fraud and abuse laws, prohibitions on self-referral, fee-splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payor, including private insurers;
- The prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- The rules regarding billing for diagnostic tests reimbursable by the Medicare program, which prohibit a physician or other supplier from marking up the price of the technical component or professional component of a diagnostic test ordered by the physician or other supplier and supervised or performed by a physician who does not “share a practice” with the billing physician or supplier; and
- State laws that prohibit other specified practices related to billing such as billing physicians for testing that they order, waiving coinsurance, co-payments, deductibles, and other amounts owed by patients, and billing a State Medicaid program at a price that is higher than what is charged to other payors.

Helomics has implemented policies and procedures designed to comply with these laws and regulations. Helomics periodically conducts internal reviews of its compliance with these laws. Helomics’ compliance is also subject to governmental review. The growth of Helomics’ business may increase the potential of violating these laws, regulations or Helomics’ internal policies and procedures. The risk of Helomics being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Violations of Federal or State regulations may incur investigation or enforcement action by the FDA, Department of Justice, State agencies, or other legal authorities, and may result in substantial civil, criminal, or other sanctions. Any action brought against Helomics for violation of these or other laws or regulations, even if Helomics successfully defend against it, could cause Helomics to incur significant legal expenses and divert Helomics’ managements’ attention from the operation of its business. If Helomics’ operations are found to be in violation of any of these laws and regulations, Helomics may be subject to civil and criminal penalties, damages and fines, Helomics could be required to refund payments received by it, Helomics could face possible exclusion from Medicare, Medicaid and other Federal or State healthcare programs and Helomics could even be required to cease its operations. Any of the foregoing consequences could have a material adverse effect on Helomics’ business, financial condition and results of operations.

***If Helomics uses hazardous materials in a manner that causes contamination or injury, Helomics could be liable for resulting damages.***

Helomics is subject to Federal, State and local laws, rules and regulations governing the use, discharge, storage, handling and disposal of biological material, chemicals and waste. Helomics cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, Helomics could be held liable for any resulting damages, remediation costs and any related penalties or fines, and any liability could exceed Helomics’ resources or any applicable insurance coverage Helomics may have. The cost of compliance with these laws and regulations may become significant, and Helomics’ failure to comply may result in substantial fines or other consequences, and either could have a significant impact on Helomics’ operating results.

***Security breaches, loss of data and other disruptions to Helomics or its third-party service providers could compromise sensitive information related to Helomics’ business or prevent Helomics from accessing critical information and expose it to liability, which could adversely affect Helomics’ business and reputation.***

Helomics’ business requires that Helomics and its third-party service providers collect and store sensitive data, including legally protected health information, personally identifiable information about patients, credit card information, and Helomics’ proprietary business and financial information. Helomics faces a number of risks relative to Helomics’ protection of, and Helomics’ service providers’ protection of, this critical information, including loss of access, inappropriate disclosure and inappropriate access, as well as risks associated with Helomics’ ability to identify and audit such events. The secure processing, storage, maintenance and transmission of this critical information are vital to Helomics’ operations and business strategy, and Helomics devotes significant resources to protecting such information. Although Helomics takes measures to protect sensitive information from unauthorized access or disclosure, Helomics’ information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While Helomics has not experienced any such attack or breach, if such event would occur and cause interruptions in Helomics’ operations, Helomics’ networks would be compromised and the information Helomics stores on those networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Unauthorized access, loss or dissemination could disrupt Helomics’ operations, including Helomics’ ability to process tests, provide test results, bill payors or patients, process claims, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about Helomics’ solution and other patient and physician education and outreach efforts, manage the administrative aspects of Helomics’ business and damage Helomics’ reputation, any of which could adversely affect Helomics’ business. In addition, the interpretation and application of consumer, health-related and data protection laws in the United States are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with Helomics’ practices. Complying with these various laws could cause Helomics to incur substantial costs or require Helomics to change its business practices, systems and compliance procedures in a manner adverse to Helomics’ business.

***If Helomics is sued for product liability or errors and omissions liability, Helomics could face substantial liabilities that exceed its resources.***

The marketing, sale and use of Helomics' molecular diagnostic tests could lead to product liability claims if someone were to allege that the molecular diagnostic test failed to perform as it was designed. Helomics may also be subject to liability for errors in the results Helomics provides to physicians or for a misunderstanding of, or inappropriate reliance upon, the information Helomics provides. A product liability or errors and omissions liability claim could result in substantial damages and be costly and time consuming for Helomics to defend. Although Helomics maintains product liability and errors and omissions insurance, Helomics cannot be certain that its insurance would fully protect it from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of such claims. Any product liability or errors and omissions liability claim brought against Helomics, with or without merit, could increase its insurance rates or prevent it from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to Helomics' reputation or cause Helomics to suspend sales of its products and solutions. The occurrence of any of these events could have a material adverse effect on Helomics' business, financial condition and results of operations.

***Billing for Helomics' diagnostic solutions is complex, and Helomics must dedicate substantial time and resources to the billing process to be paid for its molecular diagnostic tests.***

Billing for clinical laboratory testing services is complex, time consuming and expensive. Depending on the billing arrangement and applicable law, Helomics bills various payors, including Medicare, insurance companies and patients, all of which have different billing requirements. To the extent laws or contracts require Helomics to bill patient co-payments or co-insurance, Helomics must also comply with these requirements. Helomics may also face increased risk in its collection efforts, including write-offs of doubtful accounts and long collection cycles, which could have a material adverse effect on Helomics' business, results of operations and financial condition. Among others, the following factors make the billing process complex:

- differences between the list price for Helomics' molecular diagnostic tests and the reimbursement rates of payors;
- compliance with complex Federal and State regulations related to billing Medicare;
- disputes among payors as to which party is responsible for payment;
- differences in coverage among payors and the effect of patient co-payments or co-insurance;
- differences in information and billing requirements among payors;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

As Helomics introduces new molecular diagnostic tests, it will need to add new codes to the billing process as well as to Helomics' financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect Helomics' revenue and cash flow. Additionally, Helomics' billing activities require it to implement compliance procedures and oversight, train and monitor its employees, challenge coverage and payment denials, assist patients in appealing claims, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. These billing complexities, and the related uncertainty in obtaining payment for Helomics' diagnostic solution, could negatively affect Helomics' revenue and cash flow, Helomics' ability to achieve profitability, and the consistency and comparability of Helomics' results of operations.

***Helomics relies on a third-party to process and transmit claims to payors, and any delay in either could have an adverse effect on Helomics' revenue.***

Helomics relies on a third-party provider to provide overall processing of claims and to transmit the actual claims to payors based on the specific payor billing format. If claims for Helomics' molecular diagnostic tests are not submitted to payors on a timely basis, or if Helomics is required to switch to a different provider to handle claim submissions, Helomics may experience delays in its ability to process these claims and receipt of payments from payors, which could have a material adverse effect on Helomics' business, financial condition and results of operations.

***Enacted healthcare reform legislation may increase Helomics' costs, impair Helomics' ability to adjust its pricing to match any such increased costs, and therefore could materially and adversely affect its business, financial condition and results of operations.***

PPACA entails sweeping healthcare reforms with staggered effective dates from 2010 through 2018, although certain of these effective dates have been delayed by action of the current administration. While some guidance has been issued under PPACA over the past several years, many provisions in PPACA require the issuance of additional guidance from the U.S. Department of Labor, the Internal Revenue Service, the U.S. Department of Health & Human Services, and State governments. This reform includes, but is not limited to: the implementation of a small business tax credit; required changes in the design of Helomics' healthcare policy including providing insurance coverage to part-time workers working on average thirty (30) or more hours per week; "grandfathering" provisions for existing policies; "pay or play" requirements; a "Cadillac plan" excise tax; and specifically required "essential benefits," that must be included in "qualified plans," which benefits include coverage for laboratory tests.

Effective January 1, 2014, each State was required to participate in the PPACA marketplace and make health insurance coverage available for purchase by eligible individuals through a website. While these websites were subject to significant administrative issues leading up to their inception dates (and, in some cases, thereafter), it is currently estimated that in excess of 11 million individuals nationwide had enrolled in health insurance coverage through these exchanges as of the end of 2015. It is unclear, however, how many of these individuals are becoming insured after previously not having health insurance coverage, versus maintaining their plans purchased on the exchanges in 2014 or switching from other health insurance plans.

PPACA also requires "Applicable Manufacturers" to disclose to the Secretary of the Department of Health & Human Services drug sample distributions and certain payments or transfers of value to covered recipients (physicians and teaching hospitals) on an annual basis. "Applicable Manufacturers" and "Applicable Group Purchasing Organizations" must also disclose certain physician ownership or investment interests. The data submitted will ultimately be made available on a public website. Based upon the structure of Helomics' relationship with its clients, Helomics may be included in the definition of "Applicable Manufacturer" for purposes of the disclosure requirements or may provide services that include the transfer of drug samples and/or other items of value to covered recipients. As such, Helomics may be required to disclose or provide information that is subject to disclosure. There may be certain risks and penalties associated with the failure to properly make such disclosures, including but not limited to the specific civil liabilities set forth in PPACA, which allows for a maximum civil monetary penalty per "Applicable Manufacturer" of \$1,150,000 per year. There may be additional risks and claims made by third parties derived from an improper disclosure that are difficult to ascertain at this time.

While PPACA may increase the number of patients who have insurance coverage, its cost containment measures could also adversely affect reimbursement for any of Helomics' molecular diagnostic tests. Cost control initiatives also could decrease the price that Helomics' receives for any molecular diagnostic tests Helomics may develop in the future. If Helomics' molecular diagnostic tests are not considered cost-effective or if Helomics is unable to generate adequate third-party reimbursement for the users of its molecular diagnostic tests, then Helomics may be unable to maintain revenue streams sufficient to realize its targeted return on investment for its molecular diagnostic tests.

Helomics is currently unable to determine the long-term, direct or indirect impact of such legislation on its business. Since the effect of many of the provisions of PPACA may not be determinable for a number of years, Helomics does not expect PPACA to have a material adverse impact on its near-term results of operations. However, healthcare reform as mandated and implemented under PPACA and any future Federal or State mandated healthcare reform could materially and adversely affect its business, financial condition and operations by increasing Helomics' operating costs, including its costs of providing health insurance to Helomics' employees, decreasing Helomics' revenue, impeding Helomics' ability to attract and retain customers, requiring changes to Helomics' business model, or causing Helomics to lose certain current competitive advantages.

***Changes in governmental regulation could negatively impact Helomics' business operations and increase its costs.***

The pharmaceutical, biotechnology and healthcare industries are subject to a high degree of governmental regulation. Significant changes in these regulations affecting Helomics' business could result in the imposition of additional restrictions on Helomics' business, additional costs to Helomics in providing Helomics' molecular diagnostic tests to its customers or otherwise negatively impact Helomics' business operations. Changes in governmental regulations mandating price controls and limitations on patient access to Helomics' products could also reduce, eliminate or otherwise negatively impact Helomics' sales.

***If Helomics does not increase its revenues and successfully manage the size of its operations, Helomics' business, financial condition and results of operations could be materially and adversely affected.***

The majority of Helomics' operating expenses are personnel-related costs such as employee compensation and benefits, reagents and disposable supplies as well as the cost of infrastructure to support Helomics' operations, including facility space and equipment. Helomics continuously reviews its personnel to determine whether they are fully utilizing their services. If Helomics is unable to achieve revenue growth in the future or fail to adjust its cost infrastructure to the appropriate level to support its revenues, Helomics' business, financial condition and results of operations could be materially and adversely affected.

***If Helomics research and development (R&D) efforts for its TruTumor and D-CHIP artificial intelligence platform take longer than expected the commercial revenues from the service offerings that use these platforms could also be delayed.***

Helomics CRO business offers various services to pharma, diagnostics and biotech companies. These services use its TruTumor Patient derived tumor platform and its D-CHIP AI platform. These platforms are the subject of active R&D to further improve and validate them for commercial use in order to help Helomics' clients in their drug discovery, biomarker and clinical trial activities. Helomics could face delays in this R&D, for example; Helomics may not be able to secure access to and approval to use clinical data from academic hospital partners required to validate the D-CHIP platform in a timely manner; clinical testing volume (number of specimens coming to Helomics for testing) may not grow sufficiently to drive data generation for D-CHIP as well as further development of the TruTumor platform; patient consent to use the patient's data and tumor material for R&D may not be sufficient to support Helomics R&D; Helomics may not be able to attract and retain the appropriately qualified staff to perform the necessary R&D. Helomics has a limited operating history with the CRO and Informatics business which makes it difficult to forecast the revenue of these business units. While Helomics is committed to the buildout of both the CRO and D-CHIP services for the long term, the company cannot predict at this time, with any certainty, the future viability of either business unit.

***If Helomics' information technology and communications systems fail or Helomics experiences a significant interruption in its operation, its reputation, business and results of operations could be materially and adversely affected.***

The efficient operation of Helomics' business is dependent on Helomics' information technology and communications systems. The failure of these systems to operate as anticipated could disrupt its business and result in decreased revenue and increased overhead costs. In addition, Helomics does not have complete redundancy for all of its systems and its disaster recovery planning cannot account for all eventualities. Helomics' information technology and communications systems, including the information technology systems and services that are maintained by third party vendors, are vulnerable to damage or interruption from natural disasters, fire, terrorist attacks, malicious attacks by computer viruses or hackers, power loss or failure of computer systems, Internet, telecommunications or data networks. If these systems or services become unavailable or suffer a security breach, Helomics may expend significant resources to address these problems, and Helomics' reputation, business and results of operations could be materially and adversely affected.

***If Helomics is unable to protect its intellectual property effectively, Helomics' business would be harmed.***

Helomics relies on patent protection as well as trademark, trade secret and other intellectual property rights protection and contractual restrictions to protect Helomics' proprietary technology. If Helomics' fails to protect its intellectual property, third parties may be able to compete more effectively against it and Helomics may incur substantial litigation costs in its attempts to recover or restrict use of its intellectual property. While Helomics applies for patents covering its products and technologies and uses thereof, Helomics may fail to apply for patents on important products and technologies in a timely fashion or at all, or Helomics may fail to apply for patents in relevant jurisdictions. Others could seek to design around Helomics' current or future patented technologies. Helomics may not be successful in defending any challenges made against Helomics' patents or patent applications. Any successful third-party challenge to Helomics' patents could result in the unenforceability or invalidity of such patents and increased competition to Helomics' business. The outcome of patent litigation can be uncertain and any attempt by Helomics to enforce its patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert Helomics' efforts and attention from other aspects of its business.

Monitoring unauthorized disclosure is difficult, and Helomics does not know whether the steps Helomics has taken to prevent such disclosure are, or will be, adequate. If Helomics were to enforce a claim that a third-party had illegally obtained and was using its trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. Further, competitors could willfully infringe Helomics' intellectual property rights, design around its protected technology or develop their own competitive technologies that arguably fall outside of Helomics' intellectual property rights. Others may independently develop similar or alternative products and technologies or replicate any of Helomics' products and technologies. If Helomics' intellectual property does not adequately protect it against competitors' products and methods, Helomics' competitive position could be adversely affected, as could Helomics' business and the results of its operations. To the extent Helomics' intellectual property offers inadequate protection, or is found to be invalid or unenforceable, Helomics would be exposed to a greater risk of competition. If Helomics' intellectual property does not provide adequate coverage of its competitors' products, Helomics' competitive position could be adversely affected, as could its overall business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

***Helomics may be involved in litigation related to intellectual property, which could be time-intensive and costly and may adversely affect its business, operating results or financial condition.***

Helomics may receive notices of claims of direct or indirect infringement or misappropriation or misuse of other parties' proprietary rights from time to time and some of these claims may lead to litigation. Helomics cannot assume that it will prevail in such actions, or that other actions alleging misappropriation or misuse by Helomics of third-party trade secrets, infringement by Helomics of third-party patents and trademarks or other rights, or the validity of Helomics' patents, trademarks or other rights, will not be asserted or prosecuted against it. Helomics might not have been the first to make the inventions covered by each of Helomics' pending patent applications and Helomics might not have been the first to file patent applications for these inventions. No assurance can be given that other patent applications will not have priority over Helomics' patent applications. If third parties bring these proceedings against Helomics' patents, Helomics could incur significant costs and experience management distraction. Litigation may be necessary for Helomics to enforce its patents and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to Helomics, and Helomics might not be able to obtain licenses to technology that it requires on acceptable terms or at all. In addition, if Helomics resorts to legal proceedings to enforce its intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if Helomics were to prevail. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on Helomics' business, financial condition and operating results.



In the event of a successful claim of infringement against Helomics, Helomics may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling its products. Helomics may not be able to obtain these licenses on acceptable terms, if at all. Helomics could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect Helomics' financial results. In addition, Helomics' agreements with some of its customers, suppliers or other entities with whom Helomics' does business require it to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. If Helomics is required or agrees to defend or indemnify third parties in connection with any infringement claims, Helomics could incur significant costs and expenses that could have a material adverse effect on Helomics' business, financial condition, and results of operations.

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

On June 13, 2019, the Company initiated a Series E convertible preferred stock ("Series E Stock") private placement. The Company has sold 257.7 shares of Series E Convertible Preferred Stock for an aggregate purchase price of \$2,577,000 and does not intend to sell any additional shares. Each holder of Series E Stock shall have the right to convert each share of Series E Stock into 0.056857% of the issued and outstanding shares of common stock immediately prior to conversion (rounded down to the nearest whole share) for each share of Series E Convertible Preferred Stock, beginning six months after the initial closing date of June 13, 2019. On the date that is 12 months after the initial closing date, the Company has the option to convert the shares of Series E Stock into common stock upon the same terms and limitations as the above optional conversion. The Series E Stock was subject to certain limitations required under the NASDAQ Marketplace Rules; however, these limitations are no longer in effect for purposes of conversion, because the Company's stockholders approved the removal of these limitations on October 23, 2019.

On September 27, 2019, the Company issued a promissory note to an investor in the original principal amount of \$847,500 in exchange for an investment of \$700,000. As additional consideration for the investment, the Company issued an aggregate 8,857 shares of its common stock to the Investor plus a warrant to acquire up to 68,237 shares of the Company's common stock at an exercise price of \$6.21 per share.

On September 27, 2019, the Company entered into an amendment to a secured note originally dated September 28, 2018 issued to L2 Capital, LLC, under which the maturity date of the note was extended. In connection with the amendment, the Company issued 15,000 shares of common stock to the holder.

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, the Company relied on the exemption from federal registration under Section 4(a)(2) of the Securities Act and/or Rule 506 promulgated thereunder, based on the Company's 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: November 15, 2019

By: /s/ Carl Schwartz  
Carl Schwartz  
Chief Executive Officer

Date: November 15, 2019

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

## EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Description</b>
1.1	Placement Agency Agreement with Dawson James Securities, Inc. and Paulson Investment Company, LLC dated October 1, 2019 (1) <a href="#">Exhibit 1.1</a>
3.1	Certificate of Amendment to Certificate of Incorporation to effect reverse stock split, filed with the Delaware Secretary of State on October 25, 2019 (2) <a href="#">Exhibit 3.1</a>
4.1	Common Stock Purchase Warrant issued to Oasis Capital, LLC dated September 27, 2019 (3) <a href="#">Exhibit 4.1</a>
4.2	Form of Common Stock Purchase Warrant dated October 1, 2019 (1) <a href="#">Exhibit 4.2</a>
10.1	Form of Securities Purchase Agreement for purchase of Series E. Convertible Preferred Stock (4) <a href="#">Exhibit 10.1</a>
10.2	Securities Purchase Agreement by and between registrant and Oasis Capital, LLC dated September 27, 2019 (3) <a href="#">Exhibit 10.2</a>
10.3	Senior Secured Promissory Notes issued to Oasis Capital, LLC dated September 27, 2019 (3) <a href="#">Exhibit 10.3</a>
10.4	Security Agreement by and between registrant and Oasis Capital, LLC dated September 27, 2019 (3) <a href="#">Exhibit 10.4</a>
10.5	Amendment #1 to the Amended and restated Senior Secured Promissory Note Originally Issued on September 28, 2018 by and between registrant and L2 Capital, LLC, dated September 27, 2019 (3) <a href="#">Exhibit 10.5</a>
10.6	Equity Purchase Agreement by and between the Company and Oasis Capital, LLC dated October 24, 2019 (5) <a href="#">Exhibit 10.6</a>
10.7	Registration Rights Agreement by and between the Company and Oasis Capital, LLC dated October 24, 2019 (5) <a href="#">Exhibit 10.7</a>
<a href="#">31.1*</a>	<a href="#">Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
<a href="#">31.2*</a>	<a href="#">Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
<a href="#">32.1*</a>	<a href="#">Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS*	XBRL Instance Document**
101.SCH*	XBRL Extension Schema Document**
101.CAL*	XBRL Extension Calculation Linkbase Document**
101.DEF*	XBRL Extension Definition Linkbase Document**
101.LAB*	XBRL Extension Labels Linkbase Document**
101.PRE*	XBRL Extension Presentation Linkbase Document**

\* Filed herewith

- (1) Filed on October 10, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference
- (2) Filed on October 28, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (3) Filed on September 30, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (4) Filed on July 11, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.
- (5) Filed on October 25, 2019 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, Carl Schwartz, 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 principals;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2019

/s/ Carl Schwartz  
Carl Schwartz  
Chief Executive Officer

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**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 principals;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) (that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date November 15, 2019

/s/ Bob Myers  
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Bob Myers  
Chief Financial Officer

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

In connection with the Quarterly Report on Form 10-Q of Predictive Oncology Inc. (the "Company") for the quarter ended September 30, 2019 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: November 15, 2019

/s/ Carl Schwartz  
Carl Schwartz  
Chief Executive Officer

Date: November 15, 2019

/s/ Bob Myers  
Bob Myers  
Chief Financial Officer

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