**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, 2021

or

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

For the transition period from _________________________ to _________________________

Commission File Number: 001-36790

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

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

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

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

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

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

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

☒ Yes ☐ No

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

☒ Yes ☐ No

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

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

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

☐ Yes ☒ No

As of November 5, 2021, the registrant had 65,576,334 shares of common stock, par value $0.01 per share outstanding.

**PREDICTIVE ONCOLOGY INC.**

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**PREDICTIVE ONCOLOGY INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**

| | September 30, 2021 (unaudited) | December 31, 2020 (audited) |
|---|---|---|
| ASSETS | | |
| Current Assets: | | |
| Cash and Cash Equivalents | $ 41,771,515 | $ 678,332 |
| Accounts Receivable | 275,193 | 256,878 |
| Inventories | 397,976 | 289,535 |
| Prepaid Expense and Other Assets | 595,224 | 289,490 |
| Total Current Assets | 43,039,908 | 1,514,235 |
| | | |
| Fixed Assets, net | 3,810,640 | 3,822,700 |
| Intangibles, net | 3,199,047 | 3,398,101 |
| Lease Right-of-Use Assets | 961,419 | 1,395,351 |
| Other Long-Term Assets | 179,096 | 116,257 |
| Goodwill | - | 2,813,792 |
| Total Assets | $ 51,190,110 | 13,060,436 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts Payable | $ 1,029,545 | $ 1,372,070 |
| Notes Payable – Net of Discounts of $0 and $244,830 | - | 4,431,925 |
| Accrued Expenses and Other Liabilities | 940,892 | 2,588,047 |
| Derivative Liability | 225,498 | 294,382 |
| Deferred Revenue | 152,546 | 53,028 |
| Lease Liability | 637,352 | 597,469 |
| Total Current Liabilities | 2,985,833 | 9,336,921 |
| | | |
| Lease Liability – Net of current portion | 388,473 | 845,129 |
| Other Long-term Liabilities | 30,898 | 235,705 |
| Total Liabilities | 3,405,204 | 10,417,755 |
| | | |
| Stockholders' Equity: | | |
| Preferred Stock, 20,000,000 authorized inclusive of designated below | | |
| Series B Convertible Preferred Stock, $.01 par value, 2,300,000 shares authorized, 79,246 shares outstanding | 792 | 792 |
| Common Stock, $.01 par value, 200,000,000 and 100,000,000 shares authorized, 65,457,484 and 19,804,787 outstanding | 654,575 | 198,048 |
| Additional Paid-in Capital | 167,413,309 | 110,826,949 |
| Accumulated Deficit | (120,283,770) | (108,383,108) |
| | | |
| Total Stockholders' Equity | 47,784,906 | 2,642,681 |
| | | |
| Total Liabilities and Stockholders' Equity | $ 51,190,110 | $ 13,060,436 |

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, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| Revenue | $ 313,663 | $ 480,757 | $ 944,187 | $ 958,484 |
| Cost of goods sold | 110,165 | 175,206 | 350,800 | 353,124 |
| Gross profit | 203,498 | 305,551 | 593,387 | 605,360 |
| | | | | |
| General and administrative expense | 2,061,458 | 2,226,634 | 7,410,208 | 8,266,927 |
| Operations expense | 648,935 | 568,766 | 1,791,543 | 1,638,635 |
| Sales and marketing expense | 172,869 | 121,514 | 447,298 | 518,938 |
| Loss on goodwill impairment | 2,813,792 | 2,997,000 | 2,813,792 | 2,997,000 |
| Total operating loss | (5,493,556) | (5,608,363) | (11,869,454) | (12,816,140) |
| Other income | 58,830 | 44,926 | 144,122 | 97,894 |
| Other expense | (7,413) | (2,147,057) | (244,214) | (3,993,969) |
| Gain on derivative instruments | 4,122 | 1,402,768 | 68,884 | 1,007,794 |
| Gain on notes receivables associated with asset purchase | - | - | - | 1,290,000 |
| Net loss | $ (5,438,017) | $ (6,307,726) | $ (11,900,662) | $ (14,414,421) |
| Deemed dividend | - | 554,287 | - | 554,287 |
| Net loss attributable to common shareholders | $ (5,438,017) | $ (6,862,013) | $ (11,900,662) | $ (14,968,708) |
| Loss per common share basic and diluted | $ (0.08) | $ (0.46) | $ (0.23) | $ (1.51) |
| Weighted average shared used in computation - basic | 65,406,312 | 15,026,789 | 51,272,960 | 9,935,738 |

See Notes to Condensed Consolidated Financial Statements

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

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

**PREDICTIVE ONCOLOGY INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**
**FOR THE THREE AND NINE MONTHS ENDED**
**SEPTEMBER 30, 2020**
**(Unaudited)**

| | 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 12/31/2019** | 79,246 | $ 792 | 3,500,000 | $ 35,000 | 258 | $ 3 | 4,056,652 | $ 40,567 | $ 93,653,667 | $ (82,498,711) | $ 11,231,318 |
| Shares issued pursuant to CEO exchange agreement | | | | | | | 50,000 | 500 | 129,500 | | 130,000 |
| Inducement shares issued pursuant to promissory note extension | | | | | | | 30,000 | 300 | 40,950 | | 41,250 |
| Issuance of shares and prefunded warrants pursuant to March 2020 private placement | | | | | | | 260,000 | 2,600 | 455,223 | | 457,823 |
| Inducement shares issued pursuant to 2020 convertible debt and warrants | | | | | | | 46,875 | 468 | 119,532 | | 120,000 |
| Warrants issued pursuant to 2020 convertible debt | | | | | | | | | 116,951 | | 116,951 |
| Shares issued pursuant to note conversions - bridge loan | | | | | | | 170,000 | 1,700 | 265,628 | | 267,328 |
| Shares issued pursuant to series E preferred stock conversions | | | | | (50) | (1) | 141,191 | 1,412 | (1,411) | | - |
| Shares issued pursuant to Equity Line | | | | | | | 943,000 | 9,430 | 1,860,469 | | 1,869,899 |
| Shares issued to consultant and other | | | | | | | 155,000 | 1,550 | 360,750 | | 362,300 |
| Vesting expense | | | | | | | | | 287,838 | | 287,838 |
| Net loss | | | | | | | | | | (4,529,317) | (4,529,317) |
| **Balance at 03/31/2020** | 79,246 | $ 792 | 3,500,000 | $ 35,000 | 208 | $ 2 | 5,852,718 | $ 58,527 | $ 97,289,097 | $ (87,028,028) | $ 10,355,390 |
| Warrants issued pursuant to 2020 convertible debt | | | | | | | | | 62,373 | | 62,373 |
| Shares issued pursuant to CEO note conversion and accrued interest and exchange agreement | | | | | | | 1,533,481 | 15,335 | 2,177,543 | | 2,192,878 |
| Shares issued pursuant to series E preferred stock conversions | | | | | (208) | (2) | 1,257,416 | 12,574 | (12,572) | | - |
| Shares issued pursuant to series D preferred stock conversions | | | (3,500,000) | (35,000) | | | 350,004 | 3,500 | 31,500 | | - |
| Issuance of shares from | | | | | | | 1,390,166 | 13,902 | (13,148) | | 754 |

| | | | | | | |
|---|---|---|---|---|---|---|
| prefunded warrant exercises | | | | | | |
| Issuance of shares pursuant to May 2020 offering, net | 1,396,826 | 13,968 | 591,949 | | | 605,917 |
| Shares issued in connection with asset purchase agreement | 115,000 | 1,150 | 185,150 | | | 186,300 |

| | Series B Preferred | | Series D Preferred | | Series E Preferred | | Common Stock | | Additional Paid-In | Accumulated | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Capital | Deficit | Total |
| Exercise of warrants and issuance of new warrants June 2020, net | | | | | | | 1,274,826 | 12,748 | 1,682,237 | | 1,694,985 |
| Director compensation | | | | | | | 20,350 | 204 | 34,796 | | 35,000 |
| Vesting expense | | | | | | | | | 134,939 | | 134,939 |
| Net Loss | | | | | | | | | | (3,577,378) | (3,577,378) |
| **Balance at 06/30/20** | 79,246 | $ 792 | - | $ - | - | $ - | 13,190,787 | $ 131,908 | $ 102,163,864 | $ (90,605,406) | $ 11,691,158 |
| Shares issued in connection with asset purchase agreement | | | | | | | 954,719 | 9,547 | 1,460,720 | | 1,470,267 |
| Repricing and Reclassification of warrants issued pursuant to convertible debt | | | | | | | | | 1,865,953 | | 1,865,953 |
| Repricing and Reclassification of June 2020 warrants | | | | | | | | | 803,455 | | 803,455 |
| Exercise of warrants | | | | | | | 122,000 | 1,220 | 190,930 | | 192,150 |
| Share issuance to consultant and other | | | | | | | 2,669 | 26 | 3,005 | | 3,031 |
| Shares issued pursuant to Equity Line | | | | | | | 2,307,000 | 23,070 | 2,336,733 | | 2,359,803 |
| Director Compensation | | | | | | | 16,108 | 161 | 23,839 | | 24,000 |
| Vesting expense and option repricing | | | | | | | | | 134,675 | | 134,675 |
| Net loss | | | | | | | | | | (6,307,726) | (6,307,726) |
| **Balance at 09/30/20** | 79,246 | $ 792 | - | $ - | - | $ - | 16,593,283 | $ 165,932 | $ 108,983,174 | $ (96,913,132) | $ 12,236,766 |

See Notes to Condensed Consolidated Financial Statements

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2021** | **2020** |
| Cash flow from operating activities: | | |
| Net loss | $ (11,900,662) | $ (14,414,421) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 970,488 | 716,595 |
| Vesting expense | 627,329 | 557,452 |
| Amortization of debt discount | 244,830 | 996,271 |
| Gain on valuation of equity-linked instruments and derivative liability | (68,884) | (1,007,794) |
| Debt extinguishment costs | - | 1,996,681 |
| Equity instruments issued in connection with 2020 convertible debt | - | 20,695 |
| Equity instruments issued for management, consultant, and other | 143,523 | 424,331 |
| Gain on note receivable in connection with asset purchase | - | (1,290,000) |
| Loss on fixed asset disposal | 5,858 | 120,577 |
| Loss on goodwill impairment | 2,813,792 | 2,997,000 |
| Changes in assets and liabilities: | | |
| Accounts receivable | (18,315) | (122,003) |
| Inventories | (108,441) | (15,752) |
| Prepaid expense and other assets | (313,573) | (109,060) |
| Accounts payable | (342,525) | (1,438,033) |
| Accrued expenses | (412,952) | 587,937 |
| Deferred revenue | 99,518 | 25,739 |
| Other long-term liabilities | (204,807) | - |
| Net cash provided by operating activities: | (8,464,821) | (9,953,785) |
| | | |
| Cash flow from investing activities: | | |
| Purchase of fixed assets | (714,534) | (114,180) |
| Proceeds from asset sales | - | 133,850 |
| Loan activities | (55,000) | - |
| Acquisition of intangibles | (50,699) | (45,862) |
| Net cash used in investing activities: | (820,233) | (26,192) |
| | | |
| Cash flow from financing activities: | | |
| Proceeds from issuance of common stock, net | 50,523,527 | - |
| Proceeds from debt issuance | - | 2,761,867 |
| Proceeds from exercise of warrants into common stock | 4,513,860 | 1,935,854 |
| Repayment of debt | (4,162,744) | (1,459,973) |
| Proceeds from issuance of common stock pursuant to equity line | 588,590 | 4,229,702 |
| Issuance of common stock, A, B and prefunded warrants, net | - | 5,057,919 |
| Payment penalties | (1,073,470) | (247,327) |
| Repurchase of common stock upon vesting of restricted stock units | (11,526) | - |
| Other financing (security deposit) | - | 25,416 |
| Net cash used in financing activities: | 50,378,237 | 12,303,458 |
| | | |
| Net increase in cash and cash equivalents | 41,093,183 | 2,323,481 |
| Cash and cash equivalents at the beginning of period | 678,332 | 150,831 |
| Cash at the end of period | $ 41,771,515 | $ 2,474,312 |
| | | |
| Non-cash transactions: | | |
| Bridge loan conversion into common stock | - | 267,328 |
| Shares issued pursuant to former CEO note conversion and accrued interest and exchange agreement | - | 2,322,878 |
| Shares issued pursuant to former CEO per agreement related to accrued interest | 143,573 | - |
| Fixed assets sold for accounts receivable | - | 89,207 |
| Put and conversion derivative from debt issuance and modifications | - | 636,563 |
| Series E preferred stock conversions | - | 3 |
| Series D preferred stock conversions | - | 35,000 |
| Inducement shares issued pursuant to convertible debt | 514,011 | 140,555 |
| Fixed assets acquired from common stock | - | 1,470,267 |
| Increase to operating lease right of use asset and lease liability due to new and modified leases | - | 1,417,076 |
| Warrants issued pursuant to debt issuance | - | 179,324 |
| Fixed assets acquired for notes receivable and common stock | - | 1,492,500 |
| | | |
| Cash paid during period for: | | |
| Interest paid on debt | 695,989 | 144,791 |

See Notes to Condensed Consolidated Financial Statements

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

**Nature of Operations and Continuance of Operations**

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

The Company operates in three primary business areas: first, application of artificial intelligence (“AI”) in our precision medicine business, to provide AI-driven predictive models of tumor drug response to improve clinical outcomes for patients and to assist pharmaceutical, diagnostic, and biotech industries in the development of new personalized drugs and diagnostics primarily through its wholly owned subsidiary Helomics Holding Corporation (“Helomics”); second, production of the United States Food and Drug Administration (“FDA”)-cleared STREAMWAY® System for automated, direct-to-drain medical fluid waste disposal and associated products through its incorporated division Skyline and; third, contract services and research focused on solubility improvements, stability studies, and protein production, primarily with our Soluble Biotech subsidiary.

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

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

The Company had cash and cash equivalents of $41,771,515 as of September 30, 2021. As of September 30, 2021, there was no outstanding debt. In October 2019, the Company entered into a purchase agreement for an equity line under which it can raise up to $15,000,000 over a three-year period, subject to market conditions including trading volume and stock price. As of September 30, 2021, there was $9,200,829 remaining in available balance under the equity line. Additional needs to access this line will be dilutive.

In June 2021, the Company completed a direct offering under its shelf registration statement of 15,520,911 shares of common stock and warrants to purchase up to 15,520,911 shares of common stock at a combined offering price of $1.375 per share, for gross proceeds of $21,341,253. The net proceeds have been or will be used for working capital. See Note 6 – Stockholders’ Equity, Stock Options and Warrants.

In January and February 2021, the Company received aggregate net proceeds of $31,077,231 in a series of registered direct offerings and a private placement of equity securities. On March 1, 2021, the Company used $5,906,802 of the net proceeds from the private placement to pay the remaining principal and interest on the loans originally issued in September 2018, September 2019, and February 2020 and to pay premium due upon such repayment. The remaining net proceeds of the 2021 transactions have been or will be used for working capital. See Note 6 – Stockholders’ Equity, Stock Options and Warrants.

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

**Coronavirus Outbreak**

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

**Interim Financial Statements**

The Company has prepared the condensed consolidated financial statements and related unaudited financial information in the footnotes in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC") for interim condensed consolidated financial statements. These interim condensed consolidated financial statements reflect all adjustments consisting of normal recurring accruals, which in the opinion of management, are necessary to present fairly the Company's position, the results of its operations, and its cash flows for the interim periods. These interim condensed consolidated financial statements reflect all intercompany eliminations. These interim condensed consolidated financial statements should be read in conjunction with the annual consolidated financial statements and the notes thereto contained in the Annual Report on Form 10-K filed with the SEC on March 15, 2021. The nature of the Company's business is such that the results of any interim period may not be indicative of the results to be expected for the entire year.

**Accounting Policies and Estimates**

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

**Reclassifications**

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

**Cash and cash equivalents**

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

**Receivables**

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

Amounts recorded in accounts receivable on the condensed consolidated balance sheet include amounts billed and currently due from customers. The amounts due are stated at their net estimated realizable value. An allowance for doubtful accounts is maintained to provide for the estimated amount of receivables that will not be collected. The Company reviews customers' credit history before extending unsecured credit and establishes an allowance for uncollectible accounts based upon factors surrounding the credit risk of specific customers, historical trends and other information. Invoices are generally due 30 days after presentation. Accounts receivable over 30 days is generally considered past due. The Company does not accrue interest on past due accounts receivables. Receivables are written off once all collection attempts have failed and are based on individual credit evaluation and specific circumstances of the customer. The allowance for doubtful accounts balance was $0 as of both September 30, 2021 and December 31, 2020.

**Fair Value Measurements**

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

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

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

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

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

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

**Inventories**

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

**Fixed Assets**

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

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

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

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

**Long-lived Assets**

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

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

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

The Company concluded there was no impairment of its finite-lived assets as of December 31, 2020. The Company prepared the undiscounted cash flows per ASC 360. The Company concluded that the undiscounted cash flows of the long-lived assets exceeded the carrying values.

The Company concluded there was no impairment of its finite-lived assets as of September 30, 2021. The Company prepared the undiscounted cash flows per ASC 360. The Company concluded that the undiscounted cash flows of the long-lived assets exceeded the carrying values.

**Goodwill**

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

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

**Leases** – At inception of a contract, a determination is made whether an arrangement meets the definition of a lease. A contract contains a lease if there is an identified asset, and the Company has the right to control the asset. Operating leases are recorded as right-of-use ("ROU") assets with corresponding current and noncurrent operating lease liabilities on our condensed consolidated balance sheets. Financing leases are included within fixed assets with corresponding current within other current liabilities and noncurrent within other long-term liabilities on our condensed consolidated balance sheets.

ROU assets represent our right to use an underlying asset for the duration of the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Recognition on the commencement date is based on the present value of lease payments over the lease term using an incremental borrowing rate. Leases with a term of 12 months or less at the commencement date are not recognized on the condensed consolidated balance sheet and are expensed as incurred.

The Company has lease agreements with lease and non-lease components, which are accounted for as a single lease component for all asset classes. Leases are accounted for at a portfolio level when similar in nature with identical or nearly identical provisions and similar effective dates and lease terms.

**Revenue Recognition**

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

*Revenue from Product Sales*

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

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

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

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

*Revenue from Clinical Testing*

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

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

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

*CRO Revenue*

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

*Variable Consideration*

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

*Warranty*

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

*Contract Balances*

The Company records a receivable when it has an unconditional right to receive consideration after the performance obligations are satisfied. Accounts receivable totaled $275,193 and $256,878 as of September 30, 2021 and December 31, 2020, respectively.

The Company's deferred revenues related primarily to maintenance plans of $152,546 and $53,028 as of September 30, 2021 and December 31, 2020, respectively.

*Practical Expedients*

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

**Valuation and accounting for stock options and warrants**

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

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

| | **For the nine months ended September 30,** | |
|---|---|---|
| | **2021** | **2020** |
| | **Stock Options** | |
| Expected dividend yield | 0.0% | 0.0% |
| Expected stock price volatility | 84.8% - 89.6% | 82.6% - 87% |
| Risk-free interest rate | 0.93% - 1.45% | 0.13% - 1.78% |
| Expected life (in years) | 10 | 10 |
| | **Warrants** | |
| Expected dividend yield | 0.0% | 0.0% |
| Expected stock price volatility | 84.8% - 89.6% | 82.6%-87% |
| Risk-free interest rate | 0.42% - 1.04% | 0.135% - 0.79% |
| Expected life (in years) | 3 - 5.5 | 5 - 5.5 |

**Research and Development**

Research and development costs are charged to operations as incurred. Research and development costs were $234,357 and $227,805 for the nine months ended September 30, 2021 and 2020, respectively.

**Other Expense**

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

**Offering Costs**

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

**Income Taxes**

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

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

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

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

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

**Credit Risk**

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash. 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 zero credit risk for cash amounts held in a single institution that are in excess of amounts issued by the Federal Deposit Insurance Corporation.

**Risks and Uncertainties**

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

**Recent Accounting Pronouncements**

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

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

**NOTE 2 – INVENTORIES**

Inventory balances are as follows:

| | As of September 30, 2021 | As of December 31, 2020 |
|---|---|---|
| Finished goods | $ 222,898 | $ 95,898 |
| Raw materials | 161,910 | 151,366 |
| Work-In-Process | 13,168 | 42,271 |
| Total | $ 397,976 | $ 289,535 |

**NOTE 3 – FIXED ASSETS**

The Company's fixed assets consist of the following:

| | As of September 30, 2021 | As of December 31, 2020 |
|---|---|---|
| Computers, software, and office equipment | $ 1,964,329 | $ 1,862,669 |
| Leasehold improvements | 321,796 | 315,297 |
| Laboratory equipment | 3,402,586 | 2,811,012 |
| Manufacturing tooling | 108,955 | 108,955 |
| Demo equipment | 56,614 | 56,614 |
| Total | 5,854,280 | 5,154,547 |
| Less: Accumulated depreciation and amortization | (2,043,640) | (1,331,847) |
| Total Fixed Assets, Net | $ 3,810,640 | $ 3,822,700 |

Depreciation expense was $720,736 and $485,648 during the nine months ended September 30, 2021 and 2020, respectively and $237,742 and $236,599 during the three months ended September 30, 2021 and 2020, respectively.

**NOTE 4 – INTANGIBLE ASSETS AND GOODWILL**

The components of intangible assets were as follows:

| | As of September 30, 2021 | | | As of December 31, 2020 | | |
|---|---|---|---|---|---|---|
| | Gross Carrying Costs | Accumulated Amortization | Net Carrying Amount | Gross Carrying Costs | Accumulated Amortization | Net Carrying Amount |
| Patents & Trademarks | $ 452,119 | $ (225,182) | $ 226,937 | $ 401,421 | $ (211,110) | $ 190,311 |
| Developed Technology | 2,882,000 | (360,249) | 2,521,751 | 2,882,000 | (252,175) | 2,629,825 |
| Customer Relationships | 445,000 | (370,833) | 74,167 | 445,000 | (259,583) | 185,417 |
| Tradename | 398,000 | (21,808) | 376,192 | 398,000 | (5,452) | 392,548 |
| Total | $ 4,177,119 | $ (978,072) | $ 3,199,047 | $ 4,126,421 | $ (728,320) | $ 3,398,101 |

Amortization expense was $249,752 and $230,947 during the nine months ended September 30, 2021 and 2020, respectively and $83,619 and $77,258 during the three months ended September 30, 2021 and 2020, respectively.

The following table outlines the estimated future amortization expense related to intangible assets held as of September 30, 2021:

| Year ending December 31, | Expense |
|---|---|
| 2021 | $ 83,940 |
| 2022 | 224,511 |
| 2023 | 187,428 |
| 2024 | 187,428 |
| 2025 | 187,428 |
| Thereafter | 2,328,312 |
| Total | $ 3,199,047 |

**Goodwill**

In accordance with ASC 350, *Intangibles – Goodwill and Other*, goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the fair value of net assets acquired. Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination. Goodwill is an indefinite-lived asset and is not amortized. Goodwill is tested for impairment annually at the reporting unit level, or whenever events or circumstances present an indication of impairment.

In the Helomics acquisition, the Company recorded goodwill of $23,790,290. The goodwill was recorded to the Helomics segment which represents a single reporting unit. The Company's annual impairment test as of December 31, 2019 resulted in $8,100,000 of impairment expense related to goodwill.

During the third quarter of 2020, the Company's share price experienced a sustained reduction in trading values. This was also reflective of broader difficulties in the general economic conditions due to the COVID pandemic. Based on our examination of these and other qualitative factors at September 30, 2020, the Company concluded that that potential impairment indicators were present and that an impairment assessment was warranted for goodwill.

In testing goodwill for impairment as of September 30, 2020, the Company performed a quantitative impairment test, including computing the fair value of the Helomics reporting unit and comparing that value to its carrying value. Based upon the Company's quantitative goodwill impairment test, the Company concluded that goodwill was impaired as of September 30, 2020. The quantitative review as of September 30, 2020 resulted in $2,997,000 of impairment expense related to goodwill.

When evaluating the fair value of Helomics reporting unit as of September 30, 2020, the Company used a discounted cash flow model and market comparisons. Key assumptions used to determine the estimated fair value included: (a) expected cash flow for the 20-year period following the testing date (including net revenues, costs of revenues, and operating expenses as well as estimated working capital needs and capital expenditures); (b) an estimated terminal value using a terminal year growth rate of 3.0% determined based on the growth prospects of the reporting unit; and (c) a discount rate of 25% based on management's best estimate of the after-tax weighted average cost of capital. The discount rate included a Company specific risk premium of 10% for risks related to the term of the forecasts.

In testing goodwill for impairment as of December 31, 2020, the Company performed a quantitative impairment test, including computing the fair value of the Helomics reporting unit and comparing that value to its carrying value. Based upon the Company's annual goodwill impairment test, the Company concluded that goodwill was impaired as of the testing date of December 31, 2020. The Company's annual impairment test as of December 31, 2020 resulted in $9,879,458 of impairment expense related to goodwill.

When evaluating the fair value of Helomics reporting unit the Company used a discounted cash flow model. Key assumptions used to determine the estimated fair value as of December 31, 2020 included: (a) expected cash flow for the 10-year period following the testing date (including net revenues, costs of revenues, and operating expenses as well as estimated working capital needs and capital expenditures); (b) an estimated terminal value using a terminal year growth rate of 4.0% determined based on the growth prospects of the reporting unit; and (c) a discount rate of 14.0% based on management's best estimate of the after-tax weighted average cost of capital. The discount rate included a Company specific risk premium of 1.0% for risks related to the term of the forecasts. The Company further used a probability weighting of various forecasts to address forecast risk.

The following tables present changes in the carrying value of goodwill our consolidated balance sheet through December 31, 2020:

| | | |
|---|---|---|
| Goodwill balance at December 31, 2018 | $ | - |
| Acquired | | 23,790,290 |
| Impairment | | (8,100,000) |
| Goodwill balance at December 31, 2019 | $ | 15,690,290 |
| Impairment | | (12,876,498) |
| Goodwill balance at December 31, 2020 | $ | 2,813,792 |

During the third quarter of 2021, the Company concluded that potential impairment indicators were present and that an impairment assessment was warranted for goodwill.

In testing goodwill for impairment as of September 30, 2021, the Company performed a quantitative impairment test, including computing the fair value of the Helomics reporting unit and comparing that value to its carrying value. Based upon the Company's quantitative goodwill impairment test, the Company concluded that goodwill was impaired as of September 30, 2021.

The quantitative review as of September 30, 2021 resulted in $2,813,792 of impairment expense related to goodwill. As of September 30, 2021, the cumulative impairment recorded was $23,790,290.

| | | |
|---|---|---|
| Goodwill balance at December 31, 2020 | $ | 2,813,792 |
| Impairment | | (2,813,792) |
| Goodwill balance at September 30, 2021 | $ | - |

When evaluating the fair value of Helomics reporting unit the Company used a discounted cash flow model and market comparisons. Key assumptions used to determine the estimated fair value included: (a) expected cash flow for the 10-year period following the testing date (including net revenues, costs of revenues, and operating expenses as well as estimated working capital needs and capital expenditures); (b) an estimated terminal value using a terminal year growth rate of 4.0% determined based on the growth prospects of the reporting unit; and (c) a discount rate of 15% based on management's best estimate of the after-tax weighted average cost of capital. The Company further used a probability weighting of various forecasts to address forecast risk.

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

**NOTE 5 – NOTES PAYABLE**

The balances of notes payable were as follows:

| | Due Date | As of September 30, 2021 | As of December 31, 2020 |
|---|---|---|---|
| Promissory note 2019 | March 31, 2021 | $ - | $ 1,490,833 |
| Promissory note 2020 | March 31, 2021 | - | 1,464,146 |
| 2018 Investor Loan | March 31, 2021 | - | 1,721,776 |
| Total Notes Payable, gross | | - | 4,676,755 |
| Less: Unamortized discount | | - | (244,830) |
| Total Notes Payable, net | | $ - | $ 4,431,925 |

*Promissory Note Conversions*

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

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

*Promissory Note Repayment*

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

**NOTE 6 – STOCKHOLDERS' EQUITY, STOCK OPTIONS AND WARRANTS**

*Equity Line*

On October 24, 2019, the Company entered into an equity purchase agreement with an investor, providing for an equity financing facility. Upon the terms and subject to the conditions in the purchase agreement, the investor is committed to purchase shares having an aggregate value of up to $15,000,000 of the Company's common stock for a period of up to three years. The Company issued to the investor 104,651 commitment shares at a fair market value of $450,000 for entering into the agreement. From time to time during the three-year commitment period, provided that the closing conditions are satisfied, the Company may provide the investor with put notices to purchase a specified number of shares subject to certain limitations and conditions and at specified prices, which generally represent discounts to the market price of the common stock. As of September 30, 2021, there was $9,200,829 remaining in available balance under the equity line. Additional needs to access this line will be dilutive.

During the three months ended September, 30, 2021, the Company did not access the equity line. During the nine months ended September 30, 2021, the Company issued 572,504 shares of its common stock valued at $588,590 pursuant to the equity line.

*2021 Offerings*

In June 2021, the Company completed a direct offering under its shelf registration statement of 15,520,911 shares of common stock and warrants to purchase up to 15,520,911 shares of common stock at a combined offering price of $1.375 per share, for gross proceeds of $21,341,253 and net proceeds of $19,446,296. The offering was priced at-the-market under applicable NASDAQ rules. The warrants have an exercise price equal to $1.25 per share, became exercisable on the effective date of the charter amendment, August 17, 2021. These warrants will expire on August 17, 2024.

The Company paid to the placement agent a fee equal to 7.5% of the gross proceeds received by the Company in the offering and a management fee equal to 1% of the gross proceeds received by the Company in the offering and reimbursed the placement agent for $65,000 of non-accountable and out-of-pocket expenses. The Company also agreed to pay the placement agent $15,950 for clearing fees. Also, in connection with the offering, the Company agreed to grant the placement agent, or its designees warrants to purchase an aggregate of up to of 1,164,068 shares of its common stock (which represents 7.5% of the shares sold to investors in the offering) at an exercise price equal to 125% of the offering price of the shares in the offering, or $1.71875. These warrants also became exercisable as of August 17, 2021 and will expire on August 17, 2024.

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

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

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

*2021 Warrant Exercises*

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

*Equity Incentive Plan*

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

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

| | **Stock Options** | | **Warrants** | |
|---|---|---|---|---|
| | **Number of Shares** | **Average Exercise Price** | **Number of Shares** | **Average Exercise Price** |
| Outstanding at December 31, 2019 | 766,424 | $ 11.34 | 2,171,610 | $ 15.26 |
| Issued | 319,851 | 1.03 | 8,097,468 | 1.55 |
| Forfeited | (72,728) | 10.58 | (128,710) | 95.11 |
| Exercised | - | - | (2,786,992) | 0.79 |
| Outstanding at December 31, 2020 | 1,013,547 | $ 5.41 | 7,353,376 | $ 3.76 |
| Issued | 60,680 | 1.08 | 29,640,801 | 1.44 |
| Forfeited | (61,467) | 9.27 | - | - |
| Exercised | - | - | (5,269,059) | 0.86 |
| Outstanding at September 30, 2021 | 1,012,760 | $ 5.02 | 31,725,118 | $ 2.08 |

Under the equity incentive plan, the Company is also authorized to issue restricted stock, restricted stock units ("RSUs") and other awards specified under the plan. On August 10, 2021, the stockholders approved an amendment to the Amended and Restated 2012 Stock Incentive Plan to increase the reserve of shares of common stock authorized for issuance thereunder by 1,500,000, to 3,250,000. During the nine-months ended September 30, 2021, the Company issued 450,000 RSUs under the plan which have market, performance and service vesting conditions through January 1, 2024. During the nine-months ended September 30, 2021, 333,334 RSUs became vested, resulting in the issuance of the same number of shares of common stock. At September 30, 2021, there were 516,666 RSUs outstanding under the plan.

Stock-based compensation expense recognized for three months ended September 30, 2021 and September 30, 2020 was $29,004 and $134,675, respectively. Stock-based compensation expense recognized for nine months ended September 30, 2021 and September 30, 2020 was $627,329 and $557,452, respectively. The Company has $7,357 of unrecognized compensation expense related to non-vested stock options that is expected to be recognized over the next 23 months and $122,162 of unrecognized compensation expense related to non-vested restricted stock units that is expected to be recognized over the next 27 months.

Dr. Carl Schwartz retired through his resignation as the Chief Executive Officer of the Company effective on March 19, 2021. In connection with the resignation, Dr. Schwartz and the Company simultaneously entered into a Transition and Separation Agreement pursuant to which, among other things, Dr. Schwartz agreed to retire from his employment and resign as a member of the board of directors and to provide certain transition services to the Company in exchange for the issuance to Dr. Schwartz of 100,000 shares of the Company's common stock on April 1, 2021. In addition, the Company agreed to provide Dr. Schwartz with certain separation benefits and the vesting of 300,000 restricted stock units previously granted to Dr. Schwartz.

On August 17, 2021, at the reconvened special meeting of the stockholders of the Company, the stockholders approved an increase in the number of authorized shares of Company common stock from 100,000,000, to 200,000,000.

**NOTE 7 – DERIVATIVES**

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

The fair value of the agent warrants issued in connection with the March 2020 private placement certain accredited investors for the sale of the Company's common stock was determined to be $33,654 as of December 31, 2020. The Company recorded a loss on the change in fair value of the placement agent warrants of $41,326 during the nine months ended September 30, 2021. As of September 30, 2021, the fair value of the placement agent warrants was $74,980.

The fair value of the agent warrants issued in connection with the May 2020 offering were determined to be $73,765 and $33,819 as of September 30, 2021 and December 31, 2020, respectively. The Company recorded a loss on the change in fair value of the agent warrants of $39,946 during the nine months ended September 30, 2021.

The placement agent warrants issued in connection with the June 2020 warrant exercise and issuance had a fair value of $76,752 and $32,701 as of September 30, 2021 and December 31, 2020, respectively. The Company recorded a loss on the change in fair value of the agent warrants of $44,051 during the nine months ended September 30, 2021.

The Company concluded the promissory note issued on February 5, 2020 contained a conversion feature and a put each of which is an embedded derivative and are required to be bifurcated. In accordance with ASC 815, *Derivatives and Hedging*, the Company combined these two embedded derivatives into a single derivative and determined the fair value to record within the derivative liability on the condensed consolidated balance sheet. As of December 31, 2020, the fair value of the derivative liability was $104,529. As a result of the repayment of the note as of March 1, 2021, the embedded derivative had a fair value of zero prior to the repayment. The Company recorded a gain on the fair value of the derivative of $104,529 during the nine months ended September 30, 2021.

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

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

| | | |
|---|---|---|
| **Derivative liability balance at December 31, 2019** | **$** | **50,989** |
| Derivative instrument recognized for A, B and Agent Warrants | | 2,669,995 |
| Derivative instrument related to Promissory Note 2020 | | 120,921 |
| Gain recognized to revalue derivative instrument at fair value | | (27,107) |
| **Derivative liability balance at March 30, 2020** | **$** | **2,814,798** |
| Derivative instrument recognized for May 2020 Warrants | | 1,324,184 |
| Derivative instrument recognized for June 2020 Warrants | | 1,749,721 |
| Derivative instrument related to Promissory Note 2020 | | 20,542 |
| Reclassification of Warrant liabilities to Equity on exercise | | (1,701,756) |
| Loss recognized to revalue derivative instrument at fair value | | 422,081 |
| **Derivative liability balance at June 30, 2020** | **$** | **4,629,570** |
| Gain recognized to revalue derivative instrument at fair value | | (1,402,768) |
| Reclassification of Warrant liabilities to Equity | | (2,669,408) |
| Derivative instrument related to September 30 debt amendments | | 495,100 |
| **Derivative liability balance at September 30, 2020** | **$** | **1,052,494** |
| Gain recognized to revalue derivative instrument at fair value | | (758,112) |
| **Derivative liability balance at December 31, 2020** | **$** | **294,382** |
| Gain recognized to revalue derivative instrument at fair value | | (95,671) |
| **Derivative liability balance at March 31, 2021** | **$** | **198,711** |
| Loss recognized to revalue derivative instrument at fair value | | 30,909 |
| **Derivative liability balance at June 30, 2021** | **$** | **229,620** |
| Gain recognized to revalue derivative instrument at fair value | | (4,122) |
| **Derivative liability balance at September 30, 2021** | **$** | **225,498** |

**NOTE 8 - LOSS PER SHARE**

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| Numerator: | | | | |
| Net loss attributable to common shareholders per common share: basic and diluted calculation | $ (5,438,017) | $ (6,862,013) | $ (11,900,662) | $ (14,968,708) |
| | | | | |
| Denominator: | | | | |
| Weighted average common shares outstanding-basic (1) | 65,406,312 | 15,026,789 | 51,272,960 | 9,935,738 |
| Effect of diluted stock options, warrants, and preferred stock (2) | - | - | - | - |
| Weighted average common shares outstanding - diluted | 65,406,312 | 15,026,789 | 51,272,960 | 9,935,738 |
| Loss per common share-basic | $ (0.08) | $ ( 0.46) | $ (0.23) | $ (1.51) |
| Loss per common share- diluted | $ (0.08) | $ ( 0.46) | $ (0.23) | $ (1.51) |

(1) The following is a summary of the number of underlying shares outstanding at the end of the respective periods that have been excluded from the diluted calculations because the effect on loss per common share would have been anti-dilutive:

| | Nine Months ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| Options | 1,012,760 | 836,655 |
| Warrants | 31,725,118 | 7,257,883 |
| RSU | 516,666 | - |
| Convertible debt | - | 3,319,903 |
| Preferred stock: series B | 79,246 | 79,246 |

**NOTE 9 – SEGMENTS**

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

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

***Revenue***

| | Three Months Ended, September 30, | | Nine Months Ended, September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| **Skyline** | $ 282,675 | $ 471,054 | $ 853,063 | $ 924,605 |
| **Helomics** | 2,164 | 9,703 | 11,314 | 33,879 |
| **Soluble** | 27,653 | - | 76,639 | - |
| **Corporate** | 1,171 | - | 3,171 | - |
| **Total** | $ 313,663 | $ 480,757 | $ 944,187 | $ 958,484 |

***Segment Loss***

| | Three Months Ended, September 30, | | Nine Months Ended, September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| **Skyline** | $ (102,850) | $ (42,275) | $ (378,490) | $ (1,024,786) |
| **Helomics** | (3,739,275) | (4,138,459) | (6,024,129) | (7,346,236) |
| **Soluble** | (352,324) | (282,150) | (840,790) | (397,887) |
| **Corporate** | (1,243,568) | (1,844,842) | (4,657,253) | (5,645,512) |
| **Total** | $ (5,438,017) | $ (6,307,726) | $ (11,900,662) | $ (14,414,421) |

*Assets*

| | As of September 30, 2021 | As of December 31, 2020 |
|---|---|---|
| **Skyline** | $ 860,408 | $ 1,191,439 |
| **Helomics** | 6,184,782 | 9,773,902 |
| **Soluble** | 1,690,018 | 1,883,585 |
| **Corporate** | 42,454,902 | 211,510 |
| **Total** | $ 51,190,110 | $ 13,060,436 |

**NOTE 10 – RELATED PARTY TRANSACTIONS**

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

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

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

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

**NOTE 11 – SUBSEQUENT EVENTS**

*Equity Line Agreement:* During the fourth quarter of 2021 through November 10, 2021 the Company issued 75,000 shares of its common stock valued at $87,000 pursuant to the equity line.

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

The following discussion and analysis should be read together with our unaudited condensed consolidated financial statements and related notes thereto set forth in this Quarterly Report on Form 10-Q as well as our Annual Report on Form 10-K for the year ended December 31, 2020.

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

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

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

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

**Overview**

We operate in three primary business areas: first, application of artificial intelligence ("AI") in our precision medicine business, to provide AI-driven predictive models of tumor drug response to improve clinical outcomes for patients and to assist pharmaceutical, diagnostic, and biotech industries in the development of new personalized drugs and diagnostics; second, contract services and research focused on solubility improvements, stability studies, and protein production; and third, production of the United States Food and Drug Administration ("FDA")-cleared STREAMWAY® System for automated, direct-to-drain medical fluid disposal and associated products.

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

**Precision Medicine Business**

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

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

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

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

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

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

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

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

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

Research

- Biomarker discovery
- Drug discovery
- Drug-repurposing

Development

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

Clinical Decision Support

- Patient stratification
- Treatment selection

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

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

*Clinical Testing*

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

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

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

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

**Soluble Biotech**

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

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

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

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

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

**TumorGenesis**

Our subsidiary, TumorGenesis, is pursuing a new rapid approach to growing tumors in the laboratory, which essentially "fools" the cancer cells into thinking they are still growing inside the patient. TumorGenesis is focused on providing the best media for the right cancer cell and, during the first quarter of 2021, launched web-based distribution of media products for ovarian and breast cancers.

**Skyline Medical – The STREAMWAY System**

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

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

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

We operate the Skyline Medical business by continually improving our strategic opportunities, while focusing our resources on our precision medicine business.

**Capital Requirements**

Since inception, we have been unprofitable. We incurred net losses of $5,438,017 and $6,307,726 for the three months ended September 30, 2021 and September 30, 2020, respectively. As of September 30, 2021, and December 31, 2020, we had an accumulated deficit of $120,283,770 and $108,383,108, respectively.

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

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

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

**Recent Developments**

Effective September 13, 2021, our Board of Directors (“Board”) elected Raymond F. Vennare to the Board. He was chosen to fill the vacancy created by the resignation of Richard Gabriel in May 2021. As a Class III Director, Mr. Vennare’s term will expire at the 2021 annual meeting of our stockholders. In recognition of the services Mr. Vennare will provide to us as a member of the Board, he was issued 5,000 shares of common stock from our Amended and Restated 2012 Stock Incentive Plan simultaneously with his election.

At their special meeting on August 10, 2021, as reconvened on August 17, 2021, our stockholders took the following actions:

i. The stockholders approved an amendment to the Amended and Restated 2012 Stock Incentive Plan (the "Amended and Restated Plan") to increase the reserve of shares of common stock authorized for issuance thereunder by 1,500,000, to 3,250,000 (the "Plan Proposal").

ii. The stockholders approved the issuance of additional shares of common stock, in accordance with Nasdaq Listing Rule 5635(d), pursuant to a previously approved equity line of credit arrangement (the "Equity Line Proposal").

iii. The stockholders ratified the appointment of Baker Tilly US, LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2021 (the "Auditor Proposal").

iv. The stockholders approved a proposal to adjourn the Special Meeting, if necessary, to solicit additional proxies for approval of an amendment to our certificate of incorporation to increase the number of authorized shares of our common stock from 100,000,000, to 200,000,000 (the "Charter Proposal"), the Plan Proposal, the Equity Line Proposal and/or the Auditor Proposal, as applicable, in the event that there are not sufficient votes at the time of the Special Meeting to approve any such proposal.

v. The stockholders approved an increase in the number of authorized shares of our common stock from 100,000,000, to 200,000,000.

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

Dr. Carl Schwartz retired through his resignation as the Chief Executive Officer effective on March 19, 2021. In connection with the resignation, Dr. Schwartz and we simultaneously entered into a Transition and Separation Agreement pursuant to which, among other things, Dr. Schwartz agreed to retire from his employment and resign as a member of the board of directors and to provide certain transition services to us in exchange for the issuance to Dr. Schwartz of 100,000 shares of our common stock on April 1, 2021. In addition, we agreed to provide Dr. Schwartz with certain separation benefits and the vesting of 300,000 restricted stock units previously granted to Dr. Schwartz.

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

**Results of Operations**

***Comparison of three and nine months ended September 30, 2021 and September 30, 2020***

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2021 | 2020 | Difference | 2021 | 2020 | Difference |
| Revenue | $ 313,663 | $ 480,757 | $ (167,094) | $ 944,187 | $ 958,484 | $ (14,297) |
| Cost of goods sold | 110,165 | 175,206 | 65,041 | 350,800 | 353,124 | 2,324 |
| General and administrative expense | 2,061,458 | 2,226,634 | 165,176 | 7,410,208 | 8,266,927 | 856,719 |
| Operations expense | 648,935 | 568,766 | (80,169) | 1,791,543 | 1,638,635 | (152,908) |
| Sales and marketing expense | 172,869 | 121,514 | (51,355) | 447,298 | 518,938 | 71,640 |

*Revenue*. We recorded revenue of $313,663 and $480,757 in the three months ended September 30, 2021 and 2020, respectively. We sold a net of 3 and 15 STREAMWAY System units during the three months ended September 30, 2021 and 2020, respectively.

We recorded revenue of $944,187 and $958,484 in the nine months ended September 30, 2021 and 2020, respectively. During the nine months ended September 30, 2021 and 2020, most of our revenue was derived from the Skyline Medical business and also included $11,314 and $33,879 in Helomics revenues, respectively and $76,639 during the nine months ended September 30, 2021 in the Soluble reportable segment. There were 10 and 21 sales of STREAMWAY units in the nine months ended September 30, 2021 and 2020 respectively.

*Cost of goods sold.* Cost of sales was $110,165 and $350,800 in the three and nine months ended September 30, 2021 and $175,206 and $353,124 in the three and nine months ended September 30, 2020, respectively. The gross profit margin was approximately 65% and 63% in the three and nine months ended September 30, 2021 compared to 64% and 63% in the prior year. Our margins increased in the three-month period in the current year as costs were lower. Exclusive of Helomics, gross profit margin related to the Skyline Medical business was approximately 68% in the nine months ended September 30, 2021 and 72% in the nine months ended September 30, 2020.

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

G&A expense decreased by $165,176 for the three months ended September 30, 2021 compared to 2020. This was primarily due to a decrease in costs driven by approximately $187,500 due to decrease in long-term bonuses, $111,644 decrease in share-based compensation for awards made in 2020, and approximately $53,716 decrease in professional fees including legal and audit support and decrease in investor relations expenses of $92,958, offset by an increase in other staff related expenses of $77,159 and increased board related expenses of $72,788, as well as others.

G&A expenses decreased by $856,719 for the nine months ended September 30, 2021 compared to 2020. The decrease was primarily due to a decrease in share-based compensation for employees and investors, lower use, franchise and sales taxes, and a decrease in professional fees including legal and audit support fees, partially offset by an increase of related to severance associated with the retirement of our CEO and higher depreciation due to new assets placed in service in 2021.

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

Operations expense increased by $80,169 to $648,935 in the three months ended September 30, 2021 compared to 2020 and increased by $152,908 to $1,791,543 in the nine months ended September 30, 2021 compared to 2020. The increase was primarily due to higher costs related to staff and higher AI computing costs, partially offset by lower consulting expenses.

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

Sales and marketing expense increased by $51,355 to $172,869 in the three months ended September 30, 2021 compared to $121,514 in the comparable period in 2020, such expenses related almost exclusively to the Skyline Medical business and corporate expenses for website development. The increase in 2021 was a direct result of advertising and promotion including website development, market research and trade shows, offset by lower commissions expenditures in the Skyline Medical business. Sales and Marketing decreased by $71,640 to $447,298 in the nine months ended September 30, 2021 compared to 2020. The nine-month decrease was driven by decreased staff related expenses, partially offset by increases in other advertising and marketing expenses.

*Other income.* We earned other income of $58,830 in the three months ended September 30, 2021 compared to $44,926 in the comparable period in 2020 and earned other income of $144,122 in the nine months ended September 30, 2021, compared to $97,894 in the comparable in 2020. Other income included interest and dividend income.

*Other expense.* We incurred other expense of $7,413 in the three months ended September 30, 2021 compared to $2,147,057 in the comparable period in 2020 and incurred other expense of $244,214 in the nine months ended September 30, 2021, compared to $3,993,969 in the comparable period in 2020. Other expense in 2021 consisted primarily of net interest expense, payment premium, amortization of original issue discounts, and loss on debt extinguishment related to our notes payable. Net interest expense was significantly lower in both periods due to the repayment of our remaining debt in the first quarter of 2021.

*Loss on derivative instruments.* We incurred a gain of $4,122 in the three months ended September 30, 2021 compared to a gain of $1,402,768 in the comparable period in 2020 and incurred gains of $68,884 in the nine months ended September 30, 2021, compared to gains of $1,007,794 in the comparable period in 2020 primarily related to the changes in fair market value on derivatives.

*Loss on goodwill impairment.* We incurred an impairment charge on goodwill of $2,813,792 and $2,997,000, during the three and nine months ended September 30, 2021 and September 30, 2020, respectively. The Company performs a goodwill assessment using a qualitative approach to identify and consider the significance of relevant key factors, events, and circumstances that affect the fair value of each of our reporting units. The Company's goodwill relates to the Helomics operating segment and none of the Company's other operating segments. The Company made its qualitative evaluation considering, among other things, general macroeconomic conditions, industry and market considerations, cost factors, overall financial performance and other relevant entity-specific events.

Based upon the goodwill impairment test, the Company concluded that goodwill was impaired as of the testing date. Pursuant to Accounting Standards Update No, 2017-04, Simplifying the Test for Goodwill Impairment, the single step is to determine the estimated fair value of our reporting unit and compare it to the carrying value of the reporting unit, including goodwill. To the extent the carrying amount of goodwill exceeds the implied goodwill, the difference is the amount of the goodwill impairment. The quantitative review resulted in $2,813,792 of impairment charges related to our goodwill. Our goodwill at September 30, 2021 following the impairment was zero.

**Liquidity and Capital Resources**

***Cash Flows***

Net cash used in operating activities was $8,464,821 and $9,953,785 for the nine months ended September 30, 2021 and September 30, 2020, respectively. Cash used in operating activities decreased in the 2021 period primarily because of the decrease in cash used for working capital and the lower operating costs related to the Helomics and Skyline business.

Cash flows used in investing activities were $820,233 for the nine months ended September 30, 2021 and cash flows used by investing activities was $26,192 for the nine months ended September 30, 2020, respectively. Cash used in the nine months ended September 30, 2021 was from the acquisition of fixed assets and cash used to maintain our intangible assets. Cash used in the nine months ended September 30, 2020 was for the acquisition of intangible assets.

Net cash provided by financing activities was $50,378,237 and $12,303,458 for the nine months ended September 30, 2021 and September 30, 2020, respectively. The cash provided in the nine months ended September 30, 2021 was primarily due to proceeds from issuance of common stock and warrants in six financing transactions and the exercise of warrants by investors, in addition to proceeds from the issuance of common stock pursuant to the equity line agreement, offset by the repayment of outstanding debt, each discussed below in "Financing Transactions".

***Liquidity and Plan of Financing***

We have incurred a net loss in each of our annual periods since our inception. We incurred a net loss of $11,900,662 for the nine months ended September 30, 2021. On September 30, 2021, we had $41,771,515 in cash. In addition to our cash, we also have access to additional capital through our $15,000,000 equity line with a remaining available balance of $9,200,829, subject to requirements for market conditions including trading volume and stock price, and subject to other limitations.

Since our inception, we have received net proceeds from the sale of our common stock (through our initial public offering and subsequent public offerings, including at-the-market offerings) which have funded our operations. We maintain additional access to capital through our active shelf registration statement which allows for the sale of various equity or debt instruments up to an aggregate amount of approximately $207,000,000 subject to availability and certain limitations.

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

***Financing Transactions***

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

*Equity Line*

On October 24, 2019, the Company entered into an equity purchase agreement with an investor, providing for an equity financing facility. Upon the terms and subject to the conditions in the purchase agreement, the investor is committed to purchase shares having an aggregate value of up to $15,000,000 of the Company's common stock for a period of up to three years. The Company issued to the investor 104,651 commitment shares at a fair market value of $450,000 for entering into the agreement. From time to time during the three-year commitment period, provided that the closing conditions are satisfied, the Company may provide the investor with put notices to purchase a specified number of shares subject to certain limitations and conditions and at specified prices, which generally represent discounts to the market price of the common stock. As of September 30, 2021, there was $9,200,829 of remaining available balance under the equity line, subject to shareholder approval required for additional purchases, as well as requirements for market conditions including trading volume and stock price, and subject to other limitations. During the nine months ended September 30, 2021, the Company issued 572,504, shares of its common stock valued at $588,590 pursuant to the equity line.

*2021 Offerings*

In June 2021, the Company completed a direct offering, under its shelf registration statement of 15,520,911 shares of common stock and warrants to purchase up to 15,520,911 shares of common stock at a combined offering price of $1.375 per share, for gross proceeds of $21,341,253 and net proceeds of $19,446,296. The offering was priced at-the-market under applicable NASDAQ rules. The warrants have an exercise price equal to $1.25 per share, are exercisable on the effective date of an increase in the number of shares of the Company's authorized common stock and will expire three years after the initial exercise date. The purchase agreement contained customary representations and warranties and agreements of the Company and the Purchasers and customary indemnification rights and obligations of the parties. The Company agreed to hold a special meeting of shareholders on or prior to August 15, 2021 for the purpose of obtaining the Authorized Share Approval.

The Company paid to the placement agent a fee equal to 7.5% of the gross proceeds received by the Company in the offering and a management fee equal to 1% of the gross proceeds received by the Company in the offering and reimbursed the placement agent for $65,000 of non-accountable and out-of-pocket expenses. The Company also agreed to pay the placement agent $15,950 for clearing fees. Also, in connection with the offering, the Company agreed to grant the placement agent, or its designees, warrants to purchase an aggregate of up to of 1,164,068 shares of its common stock (which represents 7.5% of the shares sold to investors in the offering) at an exercise price equal to 125% of the offering price of the shares in the offering, or $1.71875. These warrants also became exercisable as of August 17, 2021 and will expire on August 17, 2024.

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

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

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

*2021 Warrant Exercises*

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

**Off-Balance Sheet Arrangements**

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

**Accounting Standards and Recent Accounting Developments**

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

**ITEM 3. Quantitative and Qualitative Disclosures About Market Risk**

Not required.

## ITEM 4. Controls and Procedures

*Evaluation of Disclosure Controls and Procedures*

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

Based on their evaluation as of September 30, 2021, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective as of September 30, 2021.

*Material Weakness Remediation Activities*

Management had previously determined that we had not maintained adequate accounting resources with a sufficient understanding of accounting principles generally accepted in the United States of America (“U.S. GAAP”) to allow us to properly identify and account for new complex transactions. To remediate the material weakness in our internal control over financial reporting described above, we have reevaluated our overall staffing levels within the accounting department and during the fourth quarter of 2019 hired additional resources with qualifications that include a high level of experience with complex technical accounting transactions and application of U.S. GAAP. In the first quarter of 2020, we also engaged an external accounting consultant to assist with the assessment of new complex transactions, which has been ongoing to date. We have completed internal control remediation testing utilizing an external consulting company. We have improved reporting procedures, and we have also re-evaluated the training and ongoing professional education that is provided to, and required of, our accounting personnel.

*Remediation of Material Weakness*

During the second quarter of 2021, we tested and adopted changes to our internal control over financial reporting related to our remediation efforts described above that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on the actions taken, as well as the evaluation of the design and operating effectiveness of the new controls, we determined that the material weakness has been remediated as of June 30, 2021.

*Changes in Internal Control Over Financial Reporting*

There were no other changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the nine months ended September 30, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# PART II. OTHER INFORMATION

## ITEM 1. Legal Proceedings

None

## ITEM 1A. Risk Factors

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

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

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

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

On August 30, 2021, we issued 4,505 shares of common stock for payment of $5,000 for professional research services.

On October 11, 2021, we issued 3,760 shares of common stock for payment of $5,000 for professional research services.

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

**ITEM 3. Defaults Upon Senior Securities**

None.

**ITEM 4. Mine Safety Disclosures**

Not applicable.

**ITEM 5. Other Information**

Not applicable.

**ITEM 6. Exhibits**

See the attached exhibit index.

**SIGNATURES:**

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

| | |
|---|---|
| | **PREDICTIVE ONCOLOGY INC.** |
| Date: November 10, 2021 | By: /s/ J. Melville Engle |
| | J. Melville Engle |
| | Chief Executive Officer |
| Date: November 10, 2021 | By: /s/ Bob Myers |
| | Bob Myers |
| | Chief Financial Officer |

## EXHIBIT INDEX

| Exhibit Number | Description |
|---|---|
| 3.1 | Certificate of Incorporation (1) Exhibit 3.1 |
| 3.2 | Certificate of Amendment to Certificate of Incorporation to effect reverse stock split and reduction in authorized share capital filed with the Delaware Secretary of State on October 20, 2014 (2) Exhibit 3.2 |
| 3.3 | Certificate of Amendment to Certificate of Incorporation regarding increase in share capital, filed with the Delaware Secretary of State on July 24, 2015 (3) Exhibit 3.3 |
| 3.4 | Certificate of Amendment to Certificate of Incorporation to increase authorized share capital, filed with the Delaware Secretary of State on September 16, 2016 (6) Exhibit 3.4 |
| 3.5 | Certificate of Amendment to Certificate of Incorporation to effect reverse stock split and reduction in authorized share capital, fled with the Delaware Secretary of State on October 26, 2016 (7) Exhibit 3.5 |
| 3.6 | Certificate of Amendment to Certificate of Incorporation regarding increase in share capital, filed with the Delaware Secretary of State on January 26, 2017 (8) Exhibit 3.6 |
| 3.7 | Certificate of Amendment to Certificate of Incorporation to effect reverse stock split, filed with the Delaware Secretary of State on January 2, 2018 (10) Exhibit 3.7 |
| 3.8 | Certificate of Amendment to Certificate of Incorporation to effect name change, filed with the Delaware Secretary of State on February 1, 2018 (4) Exhibit 3.8 |
| 3.9 | Certificate of Amendment to Certificate of Incorporation to increase authorized share capital and establish a classified Board of Directors (11) Exhibit 3.9 |
| 3.10 | Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (5) Exhibit 3.10 |
| 3.11 | Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (9) Exhibit 3.11 |
| 3.12 | Certificate of Amendment to Certificate of Incorporation dated March 22, 2019 (12) Exhibit 3.12 |
| 3.13 | Certificate of Designation Of Preferences, Rights And Limitations of Series D Convertible Preferred Stock (16) Exhibit 3.13 |
| 3.14 | Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock Effective June 13, 2019 (14) Exhibit 3.14 |
| 3.15 | Certificate of Amendment of Certificate of Incorporation (13) Exhibit 3.15 |
| 3.16 | Certificate of Amendment of Certificate of Incorporation (15) Exhibit 3.16 |
| 3.17 | Certificate of Amendment to Certificate of Incorporation dated August 17, 2021 (17) Exhibit 3.17 |
| 10.1 | Amended And Restated 2012 Stock Incentive Plan effective August 10, 2021 (18) Exhibit 10.1 |
| 31.1* | Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1* | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) |

* Filed herewith

(1) Filed on December 19, 2013 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(2) Filed on October 24, 2014 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(3) Filed on June 30, 2015 as an appendix to our Information Statement on Schedule 14C and incorporated herein by reference.

(4) Filed on February 6, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(5) Filed on August 20, 2015 as an exhibit to our Registration Statement on Form S-1 (File No. 333-198962) and incorporated herein by reference.

(6) Filed on September 16, 2016 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(7) Filed on October 27, 2016 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(8) Filed on January 27, 2017 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(9) Filed on November 29, 2017 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(10) Filed on January 2, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(11) Filed on October 4, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(12) Filed on March 22, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(13) Filed on June 13, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference

(14) Filed on June 19, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference

(15) Filed on October 28, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference

(16) Filed on April 1, 2020 as an exhibit to our Annual Report on Form 10-K and incorporated herein by reference

(17) Filed on August 19, 2021 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(18) Filed on September 2, 2021 as an exhibit to our Registration Statement on Form S-8 and incorporated herein by reference

**Exhibit 31.1**

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

I, J. Melville Engle, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2021

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

**Exhibit 31.2**

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

I, Bob Myers, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date November 10, 2021

/s/ Bob Myers
Bob Myers
Chief Financial Officer

**Exhibit 32.1**

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

In connection with the Quarterly Report on Form 10-Q of Predictive Oncology Inc. (the “Company”) for the quarter ended September 30, 2021 as filed with the Securities and Exchange Commission (the “Report”), I, J. Melville Engle, 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.

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|---|---|
| Date: November 10, 2021 | /s/ J. Melville Engle<br>J. Melville Engle<br>Chief Executive Officer |
| Date: November 10, 2021 | /s/ Bob Myers<br>Bob Myers<br>Chief Financial Officer |