**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**Form 10-Q**

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: September 30, 2020

OR

[  ] TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_\_\_\_\_\_ TO \_\_\_\_\_\_\_\_\_\_

COMMISSION FILE NUMBER **000-53497**

**VIVOS INC**

(Exact name of registrant as specified in its charter)

|  |  |  |
| --- | --- | --- |
| **Delaware** |  | **80-0138937** |
| (State or other jurisdiction of  incorporation or organization) |  | (I.R.S. Employer  Identification No.) |

**719 Jadwin Avenue,**

**Richland, WA 99352**

(Address of principal executive offices, Zip Code)

**(509) 736-4000**

(Registrant’s telephone number, including area code)

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 [X] No [  ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [  ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting 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. (Check one):

|  |  |  |  |
| --- | --- | --- | --- |
|  | Large accelerated filer [  ] | Accelerated filer [  ] |  |
|  |  |  |  |
|  | Non-accelerated filer [X] | Smaller reporting company [X] |  |
|  |  |  |  |
|  |  | Emerging growth company [  ] |  |

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [  ] No [X]

Securities registered pursuant to Section 12(b) of the Act: None

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Title of Each Class** |  | **Trading Symbol** |  | **Name of Each Exchange on which registered** |
|  |  |  |  |  |

As of November 2, 2020, there were 234,700.228 shares of the registrant’s common stock outstanding, 2,552,642 shares of the registrant’s Series A Convertible Preferred Stock outstanding, 1,013,245 of the registrant’s Series B Convertible Preferred Stock outstanding and 385,302 of the registrant’s Series C Convertible Preferred Stock outstanding.

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**PART I – FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **VIVOS INC** | | | | | | | | |
| **BALANCE SHEETS** | | | | | | | | |
| **SEPTEMBER 30, 2020 (UNAUDITED) AND DECEMBER 31, 2019** | | | | | | | | |
|  | | | | | | | | |
|  |  | **SEPTEMBER 30,** | |  |  | **DECEMBER 31,** | |  |
|  |  | **2020** | |  |  | **2019** | |  |
|  |  |  | **(UNAUDITED)** |  |  |  |  |  |
| **ASSETS** |  |  |  |  |  |  |  |  |
| Current Assets: |  |  |  |  |  |  |  |  |
| Cash |  | $ | 14,934 |  |  | $ | 20,381 |  |
| Prepaid expenses |  |  | 42,969 |  |  |  | 23,492 |  |
|  |  |  |  |  |  |  |  |  |
| Total Current Assets |  |  | 57,903 |  |  |  | 43,873 |  |
|  |  |  |  |  |  |  |  |  |
| **TOTAL ASSETS** |  | $ | 57,903 |  |  | $ | 43,873 |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **LIABILITIES AND STOCKHOLDERS’ DEFICIT** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **LIABILITIES** |  |  |  |  |  |  |  |  |
| Current Liabilities: |  |  |  |  |  |  |  |  |
| Accounts payable and accrued expenses |  | $ | 377,483 |  |  | $ | 511,817 |  |
| Related party accounts payable |  |  | 32,110 |  |  |  | 32,110 |  |
| Accrued interest payable |  |  | 94,577 |  |  |  | 93,249 |  |
| Payroll liabilities payable |  |  | 130,000 |  |  |  | 100,000 |  |
| Convertible notes payable, related party, net |  |  | - |  |  |  | 14,500 |  |
| Convertible notes payable, net |  |  | 56,966 |  |  |  | 434,886 |  |
| Promissory notes payable, net of discount |  |  | - |  |  |  | 100,000 |  |
| Related party promissory note |  |  | 237,000 |  |  |  | 237,000 |  |
|  |  |  |  |  |  |  |  |  |
| Total Current Liabilities |  |  | 928,136 |  |  |  | 1,523,562 |  |
|  |  |  |  |  |  |  |  |  |
| **Total Liabilities** |  |  | 928,136 |  |  |  | 1,523,562 |  |
|  |  |  |  |  |  |  |  |  |
| Commitments and contingencies |  |  | - |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |
| **STOCKHOLDERS’ DEFICIT** |  |  |  |  |  |  |  |  |
| Preferred stock, par value, $0.001, 20,000,000 shares authorized, Series A Convertible Preferred, 5,000,000 shares authorized, 2,552,642 shares issued and outstanding, respectively |  |  | 2,553 |  |  |  | 2,553 |  |
| Additional paid in capital - Series A Convertible preferred stock |  |  | 8,870,626 |  |  |  | 8,870,626 |  |
| Series B Convertible Preferred, 5,000,000 shares authorized, 1,013,245 and 1,113,245 shares issued and outstanding, respectively |  |  | 1,013 |  |  |  | 1,113 |  |
| Additional paid in capital - Series B Convertible preferred stock |  |  | 615,295 |  |  |  | 665,195 |  |
| Series C Convertible Preferred, 5,000,000 shares authorized, 385,302 and 821,292 shares issued and outstanding, respectively |  |  | 385 |  |  |  | 821 |  |
| Additional paid in capital - Series C Convertible preferred stock |  |  | 500,507 |  |  |  | 674,457 |  |
| Common stock, par value, $0.001, 950,000,000 shares authorized, 234,700,228 and 184,845,821 issued and outstanding, respectively |  |  | 234,700 |  |  |  | 184,846 |  |
| Additional paid in capital - common stock |  |  | 63,160,706 |  |  |  | 61,721,809 |  |
| Shares to be issued |  |  | - |  |  |  | - |  |
| Accumulated deficit |  |  | (74,256,018 | ) |  |  | (73,601,109 | ) |
|  |  |  |  |  |  |  |  |  |
| **Total Stockholders’ Deficit** |  |  | (870,233 | ) |  |  | (1,479,689 | ) |
|  |  |  |  |  |  |  |  |  |
| **TOTAL LIABILITIES AND STOCKHOLDERS’ DEFICIT** |  | $ | 57,903 |  |  | $ | 43,873 |  |

The accompanying notes are an integral part of these financial statements.

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|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **VIVOS INC** | | | | | | | | | | | | | | | | |
| **CONDENSED STATEMENTS OF OPERATIONS (UNAUDITED)** | | | | | | | | | | | | | | | | |
| **FOR THE NINE AND THREE MONTHS ENDED SEPTEMBER 30, 2020 AND 2019** | | | | | | | | | | | | | | | | |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
|  |  | **NINE MONTHS ENDED** | | | | | |  |  | **THREE MONTHS ENDED** | | | | | |  |
|  |  | **SEPTEMBER 30,** | |  |  | **SEPTEMBER 30,** | |  |  | **SEPTEMBER 30,** | |  |  | **SEPTEMBER 30,** | |  |
|  |  | **2020** | |  |  | **2019** | |  |  | **2020** | |  |  | **2019** | |  |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| **Consulting revenues, net** |  | $ | 7,000 |  |  | $ | 8,000 |  |  | $ | 7,000 |  |  | $ | 8,000 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **OPERATING EXPENSES** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Professional fees |  |  | 170,771 |  |  |  | 356,248 |  |  |  | 59,502 |  |  |  | 87,075 |  |
| Stock based compensation |  |  | 2,176 |  |  |  | 463,917 |  |  |  | - |  |  |  | 457,949 |  |
| Payroll expenses |  |  | 94,029 |  |  |  | 90,000 |  |  |  | 34,029 |  |  |  | 30,000 |  |
| Research and development |  |  | 31,809 |  |  |  | 62,194 |  |  |  | 14,383 |  |  |  | 18,492 |  |
| General and administrative expenses |  |  | 85,482 |  |  |  | 41,067 |  |  |  | 27,526 |  |  |  | 21,691 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Total Operating Expenses |  |  | 384,267 |  |  |  | 1,013,426 |  |  |  | 135,440 |  |  |  | 615,207 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **OPERATING LOSS** |  |  | (377,267 | ) |  |  | (1,005,426 | ) |  |  | (128,440 | ) |  |  | (607,207 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **NON-OPERATING INCOME (EXPENSE)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Interest expense |  |  | (280,642 | ) |  |  | (134,739 | ) |  |  | (7,151 | ) |  |  | (96,271 | ) |
| Other income |  |  | 3,000 |  |  |  | 34,106 |  |  |  | - |  |  |  | 34,106 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Total Non-Operating Income (Expenses) |  |  | (277,642 | ) |  |  | (100,633 | ) |  |  | (7,151 | ) |  |  | (62,165 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **NET LOSS BEFORE PROVISION FOR INCOME TAXES** |  |  | (654,909 | ) |  |  | (1,106,059 | ) |  |  | (135,591 | ) |  |  | (669,372 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Provision for income taxes |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **NET LOSS** |  | $ | (654,909 | ) |  | $ | (1,106,059 | ) |  | $ | (135,591 | ) |  | $ | (669,372 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Net loss per share - basic and diluted** |  | $ | (0.00 | ) |  | $ | (0.01 | ) |  | $ | (0.00 | ) |  | $ | (0.00 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Weighted average common shares outstanding - basic** |  |  | 213,424,420 |  |  |  | 172,437,108 |  |  |  | 234,418,486 |  |  |  | 177,835,282 |  |

The accompanying notes are an integral part of these financial statements.

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**VIVOS INC**

**STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT**

**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2020 (UNAUDITED) AND DECEMBER 31, 2019**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | |  |  |  | |  |  | **Additional** | |  |  |  | |  |  |  | |  |  | **Additional** | |  |  |  | |  |  |  | |  |  | **Additional** | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
|  |  |  | |  |  |  | |  |  | **Paid-In** | |  |  |  | |  |  |  | |  |  | **Paid-In** | |  |  |  | |  |  |  | |  |  | **Paid-In** | |  |  |  | | | | | |  |  | **Additional** | |  |  |  | |  |  |  | |  |  |  | |  |
|  |  | **Series A Preferred** | | | | | |  |  | **Capital - Series A** | |  |  | **Series B Preferred** | | | | | |  |  | **Capital - Series B** | |  |  | **Series C Preferred** | | | | | |  |  | **Capital - Series C** | |  |  | **Common Stock** | | | | | |  |  | **Paid-In Capital -** | |  |  | **Shares to be** | |  |  | **Accumulated** | |  |  |  | |  |
|  |  | **Shares** | |  |  | **Amount** | |  |  | **Preferred** | |  |  | **Shares** | |  |  | **Amount** | |  |  | **Preferred** | |  |  | **Shares** | |  |  | **Amount** | |  |  | **Preferred** | |  |  | **Shares** | |  |  | **Amount** | |  |  | **Common** | |  |  | **Issued** | |  |  | **Deficit** | |  |  | **Total** | |  |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| Balance - December 31, 2018 |  |  | 2,552,642 |  |  | $ | 2,553 |  |  | $ | 8,870,626 |  |  |  | 3,305,755 |  |  | $ | 3,306 |  |  | $ | 1,876,768 |  |  |  | - |  |  | $ | - |  |  | $ | - |  |  |  | 163,445,736 |  |  | $ | 163,446 |  |  | $ | 60,132,139 |  |  | $ | - |  |  | $ | (71,991,012 | ) |  | $ | (942,174 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cash |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 100,000 |  |  |  | 100 |  |  |  | 49,900 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 1,250,000 |  |  |  | 1,250 |  |  |  | 48,750 |  |  |  | - |  |  |  | - |  |  |  | 100,000 |  |
| Conversion of preferred stock into common stock |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (524,218 | ) |  |  | (525 | ) |  |  | (209,163 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 6,552,725 |  |  |  | 6,553 |  |  |  | 203,135 |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Conversion of Series B Preferred into Series C Preferred |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (821,292 | ) |  |  | (821 | ) |  |  | (674,457 | ) |  |  | 821,292 |  |  |  | 821 |  |  |  | 674,457 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Warrants issued with notes payable (discount) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 28,721 |  |  |  | - |  |  |  | - |  |  |  | 28,721 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 3,792 |  |  |  | - |  |  |  | - |  |  |  | 3,792 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (236,382 | ) |  |  | (236,382 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - March 31, 2019 |  |  | 2,552,642 |  |  |  | 2,553 |  |  |  | 8,870,626 |  |  |  | 2,060,245 |  |  |  | 2,060 |  |  |  | 1,043,048 |  |  |  | 821,292 |  |  |  | 821 |  |  |  | 674,457 |  |  |  | 171,248,461 |  |  |  | 171,249 |  |  |  | 60,416,537 |  |  |  | - |  |  |  | (72,227,394 | ) |  |  | (1,046,043 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Conversion of preferred stock into common stock |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (517,000 | ) |  |  | (517 | ) |  |  | (206,283 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 6,462,500 |  |  |  | 6,462 |  |  |  | 200,338 |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Adjustment for fractional shares in reverse split |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (140 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Warrants issued with notes payable (discount) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 12,592 |  |  |  | - |  |  |  | - |  |  |  | 12,592 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 2,176 |  |  |  | - |  |  |  | - |  |  |  | 2,176 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (200,305 | ) |  |  | (200,305 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - June 30, 2019 |  |  | 2,552,642 |  |  |  | 2,553 |  |  |  | 8,870,626 |  |  |  | 1,543,245 |  |  |  | 1,543 |  |  |  | 836,765 |  |  |  | 821,292 |  |  |  | 821 |  |  |  | 674,457 |  |  |  | 177,710,821 |  |  |  | 177,711 |  |  |  | 60,631,643 |  |  |  | - |  |  |  | (72,427,699 | ) |  |  | (1,231,580 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accounts payable |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 562,500 |  |  |  | 563 |  |  |  | 21,937 |  |  |  | - |  |  |  | - |  |  |  | 22,500 |  |
| Services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 312,500 |  |  |  | 312 |  |  |  | 12,188 |  |  |  | - |  |  |  | - |  |  |  | 12,500 |  |
| Warrants issued with notes payable (discount) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 95,437 |  |  |  | - |  |  |  | - |  |  |  | 95,437 |  |
| Warrants issued for extension of notes payable |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 25,656 |  |  |  | - |  |  |  | - |  |  |  | 25,656 |  |
| Options issued for settlement of accounts payable |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 33,829 |  |  |  | - |  |  |  | - |  |  |  | 33,829 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 457,949 |  |  |  | - |  |  |  | - |  |  |  | 457,949 |  |
| BCF recognized on convertible notes |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 59,957 |  |  |  | - |  |  |  | - |  |  |  | 59,957 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (669,372 | ) |  |  | (669,372 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - September 30, 2019 |  |  | 2,552,642 |  |  |  | 2,553 |  |  |  | 8,870,626 |  |  |  | 1,543,245 |  |  |  | 1,543 |  |  |  | 836,765 |  |  |  | 821,292 |  |  |  | 821 |  |  |  | 674,457 |  |  |  | 178,585,821 |  |  |  | 178,586 |  |  |  | 61,338,596 |  |  |  | - |  |  |  | (73,097,071 | ) |  |  | (1,193,124 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accounts payable |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 500,000 |  |  |  | 500 |  |  |  | 20,900 |  |  |  | - |  |  |  | - |  |  |  | 21,400 |  |
| Conversion of preferred stock into common stock |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (430,000 | ) |  |  | (430 | ) |  |  | (171,570 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 5,375,000 |  |  |  | 5,375 |  |  |  | 166,625 |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Conversion of restricted stock units into common stock |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 385,000 |  |  |  | 385 |  |  |  | (385 | ) |  |  | - |  |  |  | - |  |  |  | - |  |
| Warrants issued with notes payable (discount) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 14,299 |  |  |  | - |  |  |  | - |  |  |  | 14,299 |  |
| Warrants issued in settlement of litgation |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 18,500 |  |  |  | - |  |  |  | - |  |  |  | 18,500 |  |
| Options issued for settlement of payables |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 14,812 |  |  |  | - |  |  |  | - |  |  |  | 14,812 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 148,462 |  |  |  | - |  |  |  | - |  |  |  | 148,462 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (504,038 | ) |  |  | (504,038 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - December 31, 2019 |  |  | 2,552,642 |  |  |  | 2,553 |  |  |  | 8,870,626 |  |  |  | 1,113,245 |  |  |  | 1,113 |  |  |  | 665,195 |  |  |  | 821,292 |  |  |  | 821 |  |  |  | 674,457 |  |  |  | 184,845,821 |  |  |  | 184,846 |  |  |  | 61,721,809 |  |  |  | - |  |  |  | (73,601,109 | ) |  |  | (1,479,689 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cash |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 6,870 |  |  |  | - |  |  |  | 6,870 |  |
| Note conversions |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 526,113 |  |  |  | - |  |  |  | 526,113 |  |
| Redemption of preferred stock in convertible note agreement |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (100,000 | ) |  |  | (100 | ) |  |  | (49,900 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (50,000 | ) |
| Conversion of preferred stock into common stock |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (435,990 | ) |  |  | (436 | ) |  |  | (173,950 | ) |  |  | 5,449,875 |  |  |  | 5,449 |  |  |  | 168,937 |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Warrants issued with notes payable (discount) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 28,482 |  |  |  | - |  |  |  | - |  |  |  | 28,482 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 77,883 |  |  |  | - |  |  |  | - |  |  |  | 77,883 |  |
| Share adjustmnet |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (62 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (360,231 | ) |  |  | (360,231 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - March 31, 2020 |  |  | 2,552,642 |  |  |  | 2,553 |  |  |  | 8,870,626 |  |  |  | 1,013,245 |  |  |  | 1,013 |  |  |  | 615,295 |  |  |  | 385,302 |  |  |  | 385 |  |  |  | 500,507 |  |  |  | 190,295,634 |  |  |  | 190,295 |  |  |  | 61,997,111 |  |  |  | 532,983 |  |  |  | (73,961,340 | ) |  |  | (1,250,572 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cash |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 18,440,000 |  |  |  | 18,440 |  |  |  | 479,440 |  |  |  | (6,870 | ) |  |  | - |  |  |  | 491,010 |  |
| Note conversions/settlements |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 24,112,742 |  |  |  | 24,113 |  |  |  | 626,931 |  |  |  | (526,113 | ) |  |  | - |  |  |  | 124,931 |  |
| Warrants purchased for cash |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 6,900 |  |  |  | - |  |  |  | - |  |  |  | 6,900 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 2,176 |  |  |  | - |  |  |  | - |  |  |  | 2,176 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (159,087 | ) |  |  | (159,087 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - June 30, 2020 |  |  | 2,552,642 |  |  | $ | 2,553 |  |  | $ | 8,870,626 |  |  |  | 1,013,245 |  |  | $ | 1,013 |  |  | $ | 615,295 |  |  |  | 385,302 |  |  | $ | 385 |  |  | $ | 500,507 |  |  |  | 232,848,376 |  |  | $ | 232,848 |  |  | $ | 63,112,558 |  |  | $ | - |  |  | $ | (74,120,427 | ) |  | $ | (784,642 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Note conversions/settlements |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 1,851,852 |  |  |  | 1,852 |  |  |  | 48,148 |  |  |  | - |  |  |  | - |  |  |  | 50,000 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (135,591 | ) |  |  | (135,591 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - September 30, 2020 |  |  | 2,552,642 |  |  | $ | 2,553 |  |  | $ | 8,870,626 |  |  |  | 1,013,245 |  |  | $ | 1,013 |  |  | $ | 615,295 |  |  |  | 385,302 |  |  | $ | 385 |  |  | $ | 500,507 |  |  |  | 234,700,228 |  |  | $ | 234,700 |  |  | $ | 63,160,706 |  |  | $ | - |  |  | $ | (74,256,018 | ) |  | $ | (870,233 | ) |

The accompanying notes are an integral part of these financial statements.

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| **VIVOS INC** |
| **STATEMENTS OF CASH FLOWS** |
| **FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2020 AND 2019 (UNAUDITED)** |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **2020** | |  |  | **2019** | |  |
| **CASH FLOW FROM OPERTING ACTIVIITES** |  |  |  |  |  |  |  |  |
| Net loss |  | $ | (654,909 | ) |  | $ | (1,106,059 | ) |
| Adjustments to reconcile net loss to net cash used in operating activities |  |  |  |  |  |  |  |  |
| Amortization of convertible debt discount |  |  | 53,527 |  |  |  | 66,969 |  |
| Amortization of BCF discount |  |  | 6,187 |  |  |  | 16,327 |  |
| Common stock issued for services |  |  | - |  |  |  | 12,500 |  |
| Stock options and warrants for services |  |  | 2,176 |  |  |  | 489,573 |  |
| Forgiveness of debt |  |  | - |  |  |  | (34,106 | ) |
| Warrants issued for interest expense |  |  | 77,883 |  |  |  | - |  |
| Exchange premium in conversion of notes |  |  | 98,508 |  |  |  | - |  |
| **Changes in assets and liabilities** |  |  |  |  |  |  |  |  |
| Prepaid expenses and other assets |  |  | (19,477 | ) |  |  | (27,528 | ) |
| Accounts payable and accrued expenses |  |  | (134,334 | ) |  |  | (101,620 | ) |
| Accounts payable and accrued expenses from related party |  |  | - |  |  |  | 15,100 |  |
| Payroll liabilities |  |  | 30,000 |  |  |  | 68,549 |  |
| Accrued interest |  |  | 30,212 |  |  |  | 16,339 |  |
| Total adjustments |  |  | 144,682 |  |  |  | 522,103 |  |
|  |  |  |  |  |  |  |  |  |
| **Net cash used in operating activities** |  |  | (510,227 | ) |  |  | (583,956 | ) |
|  |  |  |  |  |  |  |  |  |
| **CASH FLOWS FROM FINANCING ACTIVITES** |  |  |  |  |  |  |  |  |
| Proceeds from related party notes payable |  |  | - |  |  |  | 187,000 |  |
| Redemption of preferred stock |  |  | (50,000 | ) |  |  | - |  |
| Proceeds from sale of preferred stock |  |  | - |  |  |  | 50,000 |  |
| Proceeds from sale of common stock |  |  | - |  |  |  | 50,000 |  |
| Proceeds from sale of common stock and warrants |  |  | 504,780 |  |  |  | - |  |
| Proceeds from convertible debt |  |  | 100,000 |  |  |  | - |  |
| Proceeds from promnissory notes |  |  | - |  |  |  | 450,000 |  |
| Payment of notes payable |  |  | (50,000 | ) |  |  | - |  |
| **Net cash provided by financing activities** |  |  | 504,780 |  |  |  | 737,000 |  |
|  |  |  |  |  |  |  |  |  |
| **NET INCREASE (DECREASE) IN CASH** |  |  | (5,447 | ) |  |  | 153,044 |  |
|  |  |  |  |  |  |  |  |  |
| **CASH  - BEGINNING OF PERIOD** |  |  | 20,381 |  |  |  | 5,494 |  |
|  |  |  |  |  |  |  |  |  |
| **CASH - END OF PERIOD** |  | $ | 14,934 |  |  | $ | 158,538 |  |
|  |  |  |  |  |  |  |  |  |
| **CASH PAID DURING THE PERIOD FOR:** |  |  |  |  |  |  |  |  |
| Interest expense |  | $ | 13,442 |  |  | $ | 4,000 |  |
|  |  |  |  |  |  |  |  |  |
| Income taxes |  | $ | - |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |
| **SUPPLEMENTAL INFORMATION - NON-CASH INVESTING AND FINANCING ACTIVITIES:** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Conversion of preferred stock into common stock |  | $ | 174,386 |  |  | $ | 416,487 |  |
| Conversion of convertible preferred B into convertible preferred C |  | $ | - |  |  | $ | 675,278 |  |
| Recognition of debt discount at inception of  notes payable |  | $ | 28,482 |  |  | $ | 136,750 |  |
| Conversion of notes payable and accrued interest into common stock |  | $ | 701,044 |  |  | $ | - |  |
| Recognition of BCF discount at inception of notes payable |  | $ | - |  |  | $ | 59,957 |  |
| Common stock issued in settlement of accounts payable |  | $ | - |  |  | $ | 22,500 |  |
| Stock options issued in settlement of accounts payable |  | $ | - |  |  | $ | 33,829 |  |
| Reclassification of notes payable and accrued interest into common stock |  | $ | - |  |  | $ | 15,000 |  |

The accompanying notes are an integral part of these financial statements.

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**Vivos Inc.**

**Notes to Condensed Financial Statements**

**(Unaudited)**

**NOTE 1: BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES**

The accompanying condensed financial statements of Vivos Inc. (the “*Company*”) have been prepared without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and disclosures required by accounting principles generally accepted in the United States have been condensed or omitted pursuant to such rules and regulations. These condensed financial statements reflect all adjustments that, in the opinion of management, are necessary to present fairly the results of operations of the Company for the period presented. The results of operations for the six months ended June 30, 2020, are not necessarily indicative of the results that may be expected for any future period or the fiscal year ending December 31, 2020 and should be read in conjunction with the Company’s Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on April 28, 2020.

Effective June 28, 2019, FINRA approved the Company’s reverse 1 for 8 stock-split. The reverse stock split will enable the Company to issue additional shares now that there is availability to do so. All share and per-share figures herein have been restated to take effect for this reverse stock-split.

In April of 2017, the Company filed a Certificate of Merger with the Delaware Division of Corporations in order to merge the Company’s wholly-owned subsidiary, IsoPet Solutions Corporation, with and into the Company. The Company therefore no longer prepares Consolidated Financial Statements.

The Company is a radiation oncology medical device company engaged in the development of its yttrium-90 based brachytherapy device RadioGel™ for the treatment of non-resectable tumors. A prominent team of radiochemists, scientists and engineers, collaborating with strategic partners, including national laboratories, universities and private corporations, lead the Company’s development efforts. The Company’s overall vision is to globally empower physicians, medical researchers and patients by providing them with new isotope technologies that offer safe and effective treatments for cancer.

The Company’s current focus is on the development of its RadioGel™ device. RadioGel™ is an injectable particle-gel, for brachytherapy radiation treatment of cancerous tumors in people and animals. RadioGel™ is comprised of a hydrogel, or a substance that is liquid at room temperature and then gels when reaching body temperature after injection into a tumor. In the gel are small, one micron, yttrium-90 phosphate particles (“*Y-90*”). Once injected, these inert particles are locked in place inside the tumor by the gel, delivering a very high local radiation dose. The radiation is beta, consisting of high-speed electrons. These electrons only travel a short distance so the device can deliver high radiation to the tumor with minimal dose to the surrounding tissue. Optimally, patients can go home immediately following treatment without the risk of radiation exposure to family members. Since Y-90 has a half-life of 2.7 days, the radioactively drops to 5% of its original value after ten days.

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The Company’s lead brachytherapy products, including RadioGel™, incorporate patented technology developed for Battelle Memorial Institute (“*Battelle*”) at Pacific Northwest National Laboratory, a leading research institute for government and commercial customers. Battelle has granted the Company an exclusive license to patents covering the manufacturing, processing and applications of RadioGel™ (the “*Battelle License*”). Other intellectual property protection includes proprietary production processes and trademark protection in 17 countries. The Company plans to continue efforts to develop new refinements on the production process, and the product and application hardware, as a basis for future patents.

The Company is currently focusing on obtaining approval from the Food and Drug Administration (*“FDA”*) to market and sell RadioGel™ as a Class II medical device. The Company first requested FDA approval of RadioGel™ in June 2013, at which time the FDA classified RadioGel™ as a medical device. The Company then followed with a 510(k) submission which the FDA responded, in turn, with a request for a physician letter of substantial equivalence and a reformatted 510(k) summary, which the Company provided in January 2014.

In February 2014, the FDA ruled the device as not substantially equivalent due to a lack of a predicate device and it was therefore classified as a Class III device. Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory review, control and oversight. Class III devices must typically be approved by the FDA before they are marketed. Class II devices represent lower risk devices than Class III and require fewer regulatory controls to provide reasonable assurance of the device’s safety and effectiveness. In contrast, Class I devices are deemed to be lower risk than Class II or III and are therefore subject to the least regulatory controls.

The Company is currently developing test plans to address issues raised by the FDA in connection with the Company’s previous submissions regarding RadioGel™, including developing specific test plans and specific indication of use. The Company intends to request that the FDA grant approval to re-apply for *de novo* classification of RadioGel™, which would reclassify the device from a Class III device to a Class II device, further simplifying the path to FDA approval. In the event the FDA denies the Company’s application and subsequently determines during the de novo review that RadioGel™ cannot be classified as a Class I or Class I1 device, the Company will then need to submit a pre-market approval application to obtain the necessary regulatory approval as a Class III device. *See also* Business – Regulatory History in Part I of the Annual Report on Form 10-K (“*Annual Report*”) filed April 28, 2020 for a discussion regarding the Company’s application for FDA approval of RadioGel™.

**IsoPet Solutions**

The Company’s IsoPet Solutions division was established in May 2016 to focus on the veterinary oncology market, namely engagement of university veterinarian hospital to develop the detailed therapy procedures to treat animal tumors and ultimately use of the technology in private clinics. The Company has worked with three different university veterinarian hospitals on IsoPet® testing and therapy. Washington State University treated five cats for feline sarcoma and served to develop the procedures which are incorporated in our label. They concluded that the product was safe and effective in killing cancer cells. Colorado State University demonstrated the CT and PET-CT imaging of IsoPet®. A contract was signed with University of Missouri to treat canine sarcomas and equine sarcoids starting in November 2017.

The dogs were treated for canine soft tissue sarcoma. Response evaluation criteria in solid tumors (“*RECIST*”) is a set of published rules that define when tumors in cancer patients improve (respond), stay the same (stabilize), or worsen (progress) during treatment. The criteria were published by an international collaboration including the European Organisation for Research and Treatment of Cancer (EORTC), National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group.

The testing at the University of Missouri met its objective to demonstrate the safety of IsoPet®. Using its advanced CT and PET equipment it was able to demonstrate that the dose calculations were accurate and that the injections perfused into the cell interstices and did not stay concentrated in a bolus. This results in a more homogeneous dose distribution. There was insignificant spread of Y-90 outside the points of injection demonstrating the effectiveness of the particles and the gel to localize the radiation with no spreading to the blood or other organs nor to urine or fecal material. This confirms that IsoPet® is safe for same day therapy.

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The effectiveness of IsoPet® for life extension was not the prime objective, but it resulted in valuable insights. Of the cases one is still cancer-free but the others eventually recurred since there was not a strong focus on treating the margins. The University of Missouri has agreed to become a regional center to administer IsoPet® therapy and will incorporate the improvements suggested by the testing program.

The Company anticipates that future profits, if any, will be derived from direct sales of RadioGel™ (under the name IsoPet®) and related services, and from licensing to private medical and veterinary clinics in the U.S. and internationally. The Company intends to report the results from the IsoPet® Solutions division as a separate operating segment in accordance with GAAP.

Commencing in July 2019, the Company recognized its first commercial sale of IsoPet®. A doctor brought his cat with a re-occurrent spindle cell sarcoma tumor on his face. The cat had previously received external beam therapy, but now the tumor was growing rapidly. He was given a high dose of 400Gy with heavy therapy at the margins. This sale met the revenue recognition requirements under ASC 606 as the performance obligation was satisfied. The Company completed sales for an additional four animals that received the IsoPet® during 2019.

Our plan is to incorporate the data assembled from our work with Isopet® in animal therapy to support the Company’s efforts in the development of our RadioGel™ device candidate, including obtaining approval from the *FDA* to market and sell RadioGel™ as a Class II medical device. RadioGel™ is an injectable particle-gel for brachytherapy radiation treatment of cancerous tumors in people and animals. RadioGel™ is comprised of a hydrogel, or a substance that is liquid at room temperature and then gels when reaching body temperature after injection into a tumor. In the gel are small, one micron, yttrium-90 phosphate particles (“*Y-90*”). Once injected, these inert particles are locked in place inside the tumor by the gel, delivering a very high local radiation dose. The radiation is beta, consisting of high-speed electrons. These electrons only travel a short distance so the device can deliver high radiation to the tumor with minimal dose to the surrounding tissue. Optimally, patients can go home immediately following treatment without the risk of radiation exposure to family members. Since Y-90 has a half-life of 2.7 days, the radioactivity drops to 5% of its original value after ten days.

The Company’s lead brachytherapy products, including RadioGel™, incorporate patented technology developed for Battelle Memorial Institute (“*Battelle*”) at Pacific Northwest National Laboratory, a leading research institute for government and commercial customers. Battelle has granted the Company an exclusive license to patents covering the manufacturing, processing and applications of RadioGel™ (the “*Battelle License*”). This exclusive license is to terminate upon the expiration of the last patent included in this agreement (January 2022). Other intellectual property protection includes proprietary production processes and trademark protection in 17 countries. The Company plans to continue efforts to develop new refinements on the production process, and the product and application hardware, as a basis for future patents.

**Use of Estimates**

The preparation of financial statements in accordance with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates the Company considers include criteria for stock-based compensation expense, and valuation allowances on deferred tax assets. Actual results could differ from those estimates.

**Financial Statement Reclassification**

Certain account balances from prior periods have been reclassified in these financial statements so as to conform to current period classifications.

**Cash Equivalents**

For the purposes of the statement of cash flows, the Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents.

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**Inventory**

Inventory is reported at the lower of cost or market, determined using the first-in, first-out basis, or net realizable value. All inventories consisted of finished goods. The Company has no inventory for the nine-months ended September 30, 2020 and for the year ended December 31, 2019.

**Fair Value of Financial Instruments**

Fair value of financial instruments requires disclosure of the fair value information, whether or not recognized in the balance sheet, where it is practicable to estimate that value. As of September 30, 2020 and December 31, 2019, the balances reported for cash, prepaid expenses, accounts receivable, accounts payable, and accrued expenses, approximate the fair value because of their short maturities.

Fair value is defined as 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. Accounting Standards Codification (“*ASC*”) Topic 820 established a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). These tiers include:

Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets;

Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and

Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

The Company measures certain financial instruments including options and warrants issued during the period at fair value on a recurring basis.

**Derivative Liabilities and Beneficial Conversion Feature**

The Company evaluates its convertible debt, options, warrants or other contracts, if any, to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for in accordance with ASC Topic 815, Accounting for Derivative Instruments and Hedging Activities (“*ASC 815*”) as well as related interpretations of this standard and Accounting Standards Update 2017-11, which was adopted by the Company effective January 1, 2018. In accordance with this standard, derivative instruments are recognized as either assets or liabilities in the balance sheet and are measured at fair values with gains or losses recognized in earnings. Embedded derivatives that are not clearly and closely related to the host contract are bifurcated and are recognized at fair value with changes in fair value recognized as either a gain or loss in earnings.

The result of this accounting treatment is that the fair value of the derivative instrument is marked-to-market each balance sheet date and with the change in fair value recognized in the statement of operations as other income or expense.

Upon conversion, exercise or cancellation of a derivative instrument, the instrument is marked to fair value at the date of conversion, exercise or cancellation than that the related fair value is removed from the books. Gains or losses on debt extinguishment are recognized in the statement of operations upon conversion, exercise or cancellation of a derivative instrument after any shares issued in such a transaction are recorded at market value.

The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Instruments that become a derivative after inception are recognized as a derivative on the date they become a derivative with the offsetting entry recorded in earnings.

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The Company determines the fair value of derivative instruments and hybrid instruments, considering all of the rights and obligations of each instrument, based on available market data using a binomial model, adjusted for the effect of dilution, because it embodies all of the requisite assumptions (including trading volatility, estimated terms, dilution and risk-free rates) necessary to fair value these instruments. For instruments in default with no remaining time to maturity the Company uses a one-year term for their years to maturity estimate unless a sooner conversion date can be estimated or is known. Estimating fair values of derivative financial instruments requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques (such as Black-Scholes model) are highly volatile and sensitive to changes in the trading market price of our common stock.

The Company accounts for the beneficial conversion feature on its convertible instruments in accordance with ASC 470-20. The Beneficial Conversion Feature (“BCF”) is normally characterized as the convertible portion or feature that provides a rate of conversion that is below market value or in the money when issued. The Company records a BCF when these criteria exist, when issued. BCFs that are contingent upon the occurrence of a future event are recorded when the contingency is resolved.

To determine the effective conversion price, the Company first allocates the proceeds received to the convertible instrument, and then use those allocated proceeds to determine the effective conversion price. The intrinsic value of the conversion option should be measured using the effective conversion price for the convertible instrument on the proceeds allocated to that instrument.

The accounting for a BCF requires that the BCF be recognized by allocating the intrinsic value of the conversion option to additional paid in capital, resulting in a discount to the convertible instrument. This discount should be accreted from the date on which the BCF is first recognized through the earliest conversion date for instruments that do not have a stated redemption date.

**Fixed Assets**

Fixed assets are carried at the lower of cost or net realizable value. Production equipment with a cost of $2,500 or greater and other fixed assets with a cost of $1,500 or greater are capitalized. Major betterments that extend the useful lives of assets are also capitalized. Normal maintenance and repairs are charged to expense as incurred. When assets are sold or otherwise disposed of, the cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized in operations.

Depreciation is computed using the straight-line method over the following estimated useful lives:

|  |  |
| --- | --- |
| Production equipment: | 3 to 7 years |
| Office equipment: | 2 to 5 years |
| Furniture and fixtures: | 2 to 5 years |

Leasehold improvements and capital lease assets are amortized over the shorter of the life of the lease or the estimated life of the asset.

Management of the Company reviews the net carrying value of all of its equipment on an asset by asset basis whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. These reviews consider the net realizable value of each asset, as measured in accordance with the preceding paragraph, to determine whether impairment in value has occurred, and the need for any asset impairment write-down.

**License Fees**

License fees are stated at cost, less accumulated amortization. Amortization of license fees is computed using the straight-line method over the estimated economic useful life of the assets.

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Effective March 2012, the Company entered into an exclusive license agreement with Battelle Memorial Institute regarding the use of its patented RadioGel™ technology. This license agreement originally called for a $17,500 nonrefundable license fee and a royalty based on a percent of gross sales for licensed products sold; the license agreement also contains a minimum royalty amount to be paid each year starting with 2013. The license agreement was most recently amended on December 20, 2018, and pursuant to the amendment the maintenance fee schedule was updated for minimum royalties, as well as the increase in royalties from one percent (1%) to two percent (2%), then on October 8, 2019 to reduce the fee back to one percent (1%).

Future minimum royalties for the years ended December 31 are noted below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Minimum** | |  |
|  |  | **Royalties per** | |  |
| **Calendar Year** |  | **Calendar Year** | |  |
| 2020 |  | $ | 10,000 |  |
| 2021 |  |  | 10,000 |  |
| 2022 |  |  | 4,000 |  |
| Total |  | $ | 24,000 |  |

The Company periodically reviews the carrying values of capitalized license fees and any impairments are recognized when the expected future operating cash flows to be derived from such assets are less than their carrying value.

The 2020 fee was paid in January 2020.

**Patents and Intellectual Property**

While patents are being developed or pending, they are not being amortized. Management has determined that the economic life of the patents to be ten years and amortization, over such 10-year period and on a straight-line basis will begin once the patents have been issued and the Company begins utilization of the patents through production and sales, resulting in revenues.

The Company evaluates the recoverability of intangible assets, including patents and intellectual property on a continual basis. Several factors are used to evaluate intangibles, including, but not limited to, management’s plans for future operations, recent operating results and projected and expected undiscounted future cash flows.

There have been no such capitalized costs in the nine-months ended June 30, 2020 and 2019, respectively. However, a patent was filed on July 1, 2019 (No. 1811.191) filed by Michael Korenko and David Swanberg and assigned to the Company based on the Company’s proprietary particle manufacturing process. The timing of this filing was important given the Company’s plans to make IsoPet® commercially available, which it did on or about July 9, 2019. This additional patent protection will strengthen the Company’s competitive position. It is the Company’s intention to further extend this patent protection to several key countries within one year, as permitted under international patent laws and treaties.

**Revenue Recognition**

In May 2014, the Financial Accounting Standards Board (“F*ASB*”) issued Accounting Standard Update (“*ASU*”) No. 2014-09, Revenue from Contracts with Customers (Topic 606). This standard provides a single set of guidelines for revenue recognition to be used across all industries and requires additional disclosures. The updated guidance introduces a five-step model to achieve its core principal of the entity recognizing revenue to depict the transfer of goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company adopted the updated guidance effective January 1, 2018 using the full retrospective method.

Under ASC 606, in order to recognize revenue, the Company is required to identify an approved contract with commitments to preform respective obligations, identify rights of each party in the transaction regarding goods to be transferred, identify the payment terms for the goods transferred, verify that the contract has commercial substance and verify that collection of substantially all consideration is probable. The adoption of ASC 606 did not have an impact on the Company’s operations or cash flows.

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The Company recognized revenue as they (i) identified the contracts with ach customer; (ii) identified the performance obligation in each contract; (iii) determined the transaction price in each contract; (iv) were able to allocate the transaction price to the performance obligations in the contract; and (v) recognized revenue upon the satisfaction of the performance obligation. Upon the sales of the product to complete the procedures on the animals, the Company recognized revenue as that was considered the performance obligation.

All revenue generated during the nine months ended September 30, 2020 and year ended December 31, 2019 related to sales of product.

**Loss Per Share**

The Company accounts for its loss per common share by replacing primary and fully diluted earnings per share with basic and diluted earnings per share. Basic loss per share is computed by dividing loss available to common stockholders (the numerator) by the weighted-average number of common shares outstanding (the denominator) for the period, and does not include the impact of any potentially dilutive common stock equivalents since the impact would be anti-dilutive. The computation of diluted earnings per share is similar to basic earnings per share, except that the denominator is increased to include the number of additional common shares that would have been outstanding if potentially dilutive common shares had been issued. For the given periods of loss, of the periods ended in the nine months ended September 30, 2020 and 2019, the basic earnings per share equals the diluted earnings per share.

The following represent common stock equivalents that could be dilutive in the future as of September 30, 2020 and December 31, 2019, which include the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | September 30, 2020 | |  |  | December 31, 2019 | |  |
| Convertible debt |  |  | 2,419 |  |  |  | 10,914,782 |  |
| Preferred stock |  |  | 20,672,640 |  |  |  | 27,372,515 |  |
| Common stock options |  |  | 34,524,580 |  |  |  | 34,524,580 |  |
| Common stock warrants |  |  | 43,956,847 |  |  |  | 31,286,847 |  |
| Total potential dilutive securities |  |  | 99,156,486 |  |  |  | 104,098,724 |  |

**Research and Development Costs**

Research and developments costs, including salaries, research materials, administrative expenses and contractor fees, are charged to operations as incurred. The cost of equipment used in research and development activities which has alternative uses is capitalized as part of fixed assets and not treated as an expense in the period acquired. Depreciation of capitalized equipment used to perform research and development is classified as research and development expense in the year computed.

The Company incurred $31,809 and $62,194 research and development costs for the nine months ended September 30, 2020, and 2019, respectively, all of which were recorded in the Company’s operating expenses noted on the statements of operations for the nine months then ended.

**Advertising and Marketing Costs**

Advertising and marketing costs are expensed as incurred except for the cost of tradeshows which are deferred until the tradeshow occurs. During the nine months ended September 30, 2020 and 2019, the Company incurred $6,182 and $0, respectively, in advertising and marketing costs.

**Shipping and Handling Costs**

Shipping and handling costs are expensed as incurred and included in cost of materials.

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**Contingencies**

In the ordinary course of business, the Company is involved in legal proceedings involving contractual and employment relationships, product liability claims, patent rights, and a variety of other matters. The Company records contingent liabilities resulting from asserted and unasserted claims against it, when it is probable that a liability has been incurred and the amount of the loss is reasonably estimable. The Company discloses contingent liabilities when there is a reasonable possibility that the ultimate loss will exceed the recorded liability. Estimated probable losses require analysis of multiple factors, in some cases including judgments about the potential actions of third-party claimants and courts. Therefore, actual losses in any future period are inherently uncertain. The Company has entered into various agreements that require them to pay certain fees to consultants and/or employees that have been fully accrued for as of September 30, 2020 and December 31, 2019.

**Income Taxes**

To address accounting for uncertainty in tax positions, the Company clarifies the accounting for income taxes by prescribing a minimum recognition threshold that a tax position is required to meet before being recognized in the financial statements. The Company also provides guidance on de-recognition, measurement, classification, interest, and penalties, accounting in interim periods, disclosure and transition.

The Company files income tax returns in the U.S. federal jurisdiction. The Company did not have any tax expense for the nine months ended September 30, 2020 and 2019. The Company did not have any deferred tax liability or asset on its balance sheet on September 30, 2020 and December 31, 2019.

Interest costs and penalties related to income taxes, if any, will be classified as interest expense and general and administrative costs, respectively, in the Company’s financial statements. For the nine months ended September 30, 2020 and 2019, the Company did not recognize any interest or penalty expense related to income taxes. The Company believes that it is not reasonably possible for the amounts of unrecognized tax benefits to significantly increase or decrease within the next twelve months.

**Stock-Based Compensation**

The Company recognizes compensation costs to employees under FASB ASC Topic 718, Compensation – Stock Compensation. Under FASB ASC Topic. 718, companies are required to measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Share based compensation arrangements include stock options, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. As such, compensation cost is measured on the date of grant at their fair value. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant.

In May 2017, the FASB issued ASU 2017-09, “Compensation - Stock Compensation.” The update provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in ASC Topic 718. An entity shall account for the effects of a modification described in ASC paragraphs 718-20-35-3 through 35-9, unless all the following are met: (1) The fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified; (2) The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified; and (3) The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The provisions of this update become effective for annual periods and interim periods within those annual periods beginning after December 15, 2017. The Company’s adoption of this guidance on January 1, 2018 did not have a material impact on the Company’s results of operations, financial position and related disclosures.

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In June 2018, the FASB issued ASU No. 2018-07 “Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.” These amendments expand the scope of Topic 718, Compensation - Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The ASU supersedes Subtopic 505-50, Equity - Equity-Based Payments to Non-Employees. The guidance is effective for public companies for fiscal years, and interim fiscal periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, but no earlier than a company’s adoption date of Topic 606, Revenue from Contracts with Customers. The adoption of this standard did not have a material impact on its financial statements. The Company has determined that no amounts had to be revalued upon adoption of this amendment.

**Recent Accounting Pronouncements**

In August, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2020-06, Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity’s Own Equity (Subtopic 815-40), Accounting for Convertible Instruments and Contract’s in an Entity’s Own Equity. The ASU simplifies accounting for convertible instruments by removing major separation models required under current GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. The ASU simplifies the diluted net income per share calculation in certain areas. The ASU is effective for annual and interim periods beginning after December 31, 2021, and early adoption is permitted for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company is currently evaluating the impact that this new guidance will have on its financial statements.

The Company does not discuss recent pronouncements that are not anticipated to have an impact on or are unrelated to its financial condition, results of operations, cash flows or disclosures.

**NOTE 2: GOING CONCERN**

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As shown in the accompanying financial statements, the Company has suffered recurring losses and used significant cash in support of its operating activities and the Company’s cash position is not sufficient to support the Company’s operations. Research and development of the Company’s brachytherapy product line has been funded with proceeds from the sale of equity and debt securities as well as a series of grants. The Company requires funding of approximately $1.5 to $2.0 million annually to maintain current operating activities.

The Company’s stock offering under Regulation A+ was qualified by the Securities and Exchange Commission (“SEC”) on June 3, 2020 and have issued the first tranche of shares under the Regulation A+ on June 10, 2020. The intent is to raise up to $4,050,000 over the next 12-18 months, which may be completed in separate closings.

The Company intends to use the proceeds generated from the sale of shares under Regulation A+ as follows:

For the animal therapy market:

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|  | ● | Fund the effort to communicate the benefits of IsoPet® to the veterinary community and the pet parents. |
|  | ● | Conduct additional clinical studies to generate more data for the veterinary community |
|  | ● | Subsidize some IsoPet® therapies, if necessary, to ensure that all viable candidates are treated. |
|  | ● | Assist a new regional clinic with their license and certification training. |

For the human market:

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|  | ● | Enhance the pedigree of the Quality Management System. |
|  | ● | Complete the pre-clinical testing that has been previously defined and report the bulk of the results to the FDA in a pre-submission meeting. |
|  | ● | Use the feedback from that meeting to write the IDE (Investigational Device Exemption), which is required to initiate clinical trials. |

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The Company received $497,880 which were deposited into the Company’s accounts between April and June 2020. Following the clearance of the Regulation A+ offering by the SEC on June 3, 2020, the common shares for these proceeds were issued. In addition, the Company exchanged their outstanding convertible notes payable of $525,000, $27,536 in accrued interest and $98,508 in an exchange premium stipulated in the note agreements into shares of common stock through September 30, 2020.

Over the next 12 to 24 months, the Company believes it will cost approximately $5.0 million to $10.0 million to: (1) fund the FDA approval process and initial deployment of the brachytherapy products, and (2) initiate regulatory approval processes outside of the United States. The continued deployment of the brachytherapy products and a worldwide regulatory approval effort will require additional resources and personnel. The principal variables in the timing and amount of spending for the brachytherapy products in the next 12 to 24 months will be the FDA’s classification of the Company’s brachytherapy products as Class II or Class III devices (or otherwise) and any requirements for additional studies which may possibly include clinical studies. Thereafter, the principal variables in the amount of the Company’s spending and its financing requirements would be the timing of any approvals and the nature of the Company’s arrangements with third parties for manufacturing, sales, distribution and licensing of those products and the products’ success in the U.S. and elsewhere. The Company intends to fund its activities through strategic transactions such as licensing and partnership agreements or additional capital raises.

Following receipt of required regulatory approvals and financing, in the U.S., the Company intends to outsource material aspects of manufacturing, distribution, sales and marketing. Outside of the U.S., the Company intends to pursue licensing arrangements and/or partnerships to facilitate its global commercialization strategy.

In the longer-term, subject to the Company receiving adequate funding, regulatory approval for RadioGel™ and other brachytherapy products, and thereafter being able to successfully commercialize its brachytherapy products, the Company intends to consider resuming research efforts with respect to other products and technologies intended to help improve the diagnosis and treatment of cancer and other illnesses.

Based on the Company’s financial history since inception, the Company’s independent registered public accounting firm has expressed substantial doubt as to the Company’s ability to continue as a going concern. The Company has limited revenue, nominal cash, and has accumulated deficits since inception. If the Company cannot obtain sufficient additional capital, the Company will be required to delay the implementation of its business strategy and may not be able to continue operations.

The Company has been impacted from the effects of COVID-19. The Company’s headquarters are in Northeast Washington however there focus of the animal therapy market has been the Northwestern sector of the United States, the initial epicenter of the COVID-19 outbreak in the United States. In addition to a slow down in the marketing of the services, the volatility of the stock market has contributed to a lack of funds that ordinarily may have been available to the Company. The Company is hopeful that by the end of 2020 into the first quarter of 2021, they will be allowed to continue their marketing to the animal therapy market and attempt to increase the exposure to their product and generate revenue accordingly.

The financial statements do not include any adjustments relating to the recoverability and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company’s continuation as a going concern is dependent upon its ability to generate sufficient cash flow to meet its obligations on a timely basis and ultimately to attain profitability. The Company plans to seek additional funding to maintain its operations through debt and equity financing and to improve operating performance through a focus on strategic products and increased efficiencies in business processes and improvements to the cost structure. There is no assurance that the Company will be successful in its efforts to raise additional working capital or achieve profitable operations. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As of September 30, 2020, the Company has $14,934 cash on hand. There are currently commitments to vendors for products and services purchased that will necessitate liquidation of the Company if it is unable to raise additional capital. The current level of cash is not enough to cover the fixed and variable obligations of the Company. The Company was able to execute the following transactions to improve their balance sheet and decrease the liabilities incurred and increase their cash flow:

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|  | ● | In November 2019, the Company had its Regulation A+ initially qualified by the SEC for an offering up to 150 million shares of common stock. On April 30, 2020, the Company filed a post-effective Amendment, which was qualified by the SEC on June 3, 2020. |
|  |  |  |
|  | ● | During the Company’s second and third fiscal quarters, the Company secured approximately $300,000 in convertible promissory notes, which have subsequently been converted into shares of common stock and raised approximately $500,000 from the sales of common stock under the Regulation A+.. |
|  |  |  |
|  | ● | The Company recognized initial sales of IsoPet®. |

Assuming the Company is successful in the Company’s sales/development effort, it believes that it will be able to raise additional funds through strategic agreements or the sale of the Company’s stock to either current or new stockholders. There is no guarantee that the Company will be able to raise additional funds or to do so at an advantageous price.

The financial statements do not include any adjustments relating to the recoverability and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company’s continuation as a going concern is dependent upon its ability to generate sufficient cash flow to meet its obligations on a timely basis and ultimately to attain profitability. The Company plans to seek additional funding to maintain its operations through debt and equity financing and to improve operating performance through a focus on strategic products and increased efficiencies in business processes and improvements to the cost structure. There is no assurance that the Company will be successful in its efforts to raise additional working capital or achieve profitable operations. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**NOTE 3: FIXED ASSETS**

Fixed assets consist of the following at September 30, 2020 (unaudited) and December 31, 2019:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | September 30, 2020 |  |  |  | December 31, 2019 |  |
| Production equipment |  | $ | - |  |  | $ | - |  |
| Less accumulated depreciation |  |  | (- | ) |  |  | (- | ) |
|  |  | $ | - |  |  | $ | - |  |

There is no depreciation expense for the above fixed assets for the nine months ended September 30, 2020 and 2019, respectively. In June 2019, the Company sold the one piece of equipment still held for $0. The basis of this piece of equipment was also $0, resulting in no gain or loss on the sale.

**NOTE 4: RELATED PARTY TRANSACTIONS**

**Related Party Convertible Notes Payable**

As of September 30, 2020 and December 31, 2019, the Company had the following related party convertible notes outstanding:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | September 30, 2020 | | | | | |  |  | December 31, 2019 | | | | | |  |
|  |  | Principal | |  |  | Accrued  Interest | |  |  | Principal | |  |  | Accrued  Interest | |  |
| September 2019 $15,000 Note, 8% interest, due January 2020 |  | $ | - |  |  | $ | - |  |  | $ | 15,000 |  |  | $ | 321 |  |
| Other related party notes |  |  | - |  |  |  | 1,054 |  |  |  | - |  |  |  | 1,054 |  |
| March 2017 $332,195 Note, 10% interest, due May 2017 |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Total Convertible Notes Payable, Net |  | $ | - |  |  | $ | 1,054 |  |  | $ | 15,000 |  |  | $ | 1,375 |  |
| Less: Debt Discount |  |  | - |  |  |  | - |  |  |  | (500 | ) |  |  | - |  |
|  |  | $ | - |  |  | $ | 1,054 |  |  | $ | 14,500 |  |  | $ | 1,375 |  |

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In March 2017, the Company combined Outstanding Notes owed to a director and major stockholder, along with $51,576 of accrued interest payable, into one promissory note (the “*Related Party Note*”). The Related Party Note accrues interest at a rate of 10% and was due and payable on December 31, 2017. The note holder agreed to an extension of the due date until May 9, 2018. On August 9, 2018 the Company entered into a Path Forward and Restructuring Agreement whereby this Convertible Note would convert at a conversion price of $0.032 per share concurrently with a funding of at least $500,000 (the “*Qualified Financing*”). The Qualified Financing occurred on October 10, 2018 at which time this note was fully converted into 6,250,000 shares of Company common stock, 385,302 Series B Convertible Preferred shares of the Company, and 5,533,138 warrants that are exercisable into common shares with an exercise price of $0.08. The Company valued this transaction at a price of $0.104 per share as the conversion occurred October 19, 2018 upon board approval.

The Company has outstanding accrued interest in the amount of $1,054 from old related party notes that the principal had been paid off in full.

The Company from time to time receives non-interest bearing advancers from its Chief Executive Officer that are due on demand. During the year ended December 31, 2019, the Company received $20,000 in advances and repaid $5,000 of these and had $15,000 outstanding at September 24, 2019. On September 24, 2019, these advances were converted into a convertible note at 8% interest which matures January 15, 2020. Interest on this note for the period ended December 31, 2019 amounted to $321, and this amount is accrued at December 31, 2019. The Chief Executive Officer received 150,000 warrants when the advances were converted into this convertible note payable. The Company recognized a discount on the convertible note of $3,721 as a result of the warrants which are being amortized over the life of the note through January 15, 2020. The Company is in default of this note. As a result of the default, the interest rate charged was changed to 12.5% through conversion of this note in April 2020.

Interest expense for the nine months ended September 30, 2020 and 2019 on the related party convertible notes payable amounted to $298 and $0, respectively.

**Related Party Notes Payable**

As of September 30, 2020 and December 31, 2019, the Company had the following related party notes outstanding:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | September 30, 2020 | | | | | |  |  | December 31, 2019 | | | | | |  |
|  |  | Principal | |  |  | Accrued  Interest | |  |  | Principal | |  |  | Accrued  Interest | |  |
| January 2019 $60,000 Note, 8% interest, due January 2020 |  | $ | 60,000 |  |  | $ | 8,065 |  |  | $ | 60,000 |  |  | $ | 4,472 |  |
| March 2019 $48,000 Note, 8% interest, due March 2020 |  |  | 48,000 |  |  |  | 5,802 |  |  |  | 48,000 |  |  |  | 2,927 |  |
| April 2019 $29,000 Note, 8% interest, due April 2020 |  |  | 29,000 |  |  |  | 3,296 |  |  |  | 29,000 |  |  |  | 1,559 |  |
| July 2019 $50,000 Note 8% interest, due July 2020 |  |  | 50,000 |  |  |  | 4,951 |  |  |  | 50,000 |  |  |  | 1,956 |  |
| November 2019 $50,000 Note 8% interest, due November 2020 |  |  | 50,000 |  |  |  | 3,388 |  |  |  | 50,000 |  |  |  | 393 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Total Related Party Notes Payable, Net |  | $ | 237,000 |  |  | $ | 25,502 |  |  | $ | 237,000 |  |  | $ | 11,307 |  |

On January 24, 2019 the Company entered into a note payable with a trust related to one of the Company’s directors in the amount of $60,000. The note is for a one-year period which was to mature January 24, 2020 and bears interest at an annual rate of 8.00%. The Company is in default of this note.

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On March 27, 2019 the Company entered into a note payable with a trust related to one of our directors in the amount of $48,000. The note is for a one-year period maturing March 27, 2020 and bears interest at an annual rate of 8%. The Company is in default of this note. On April 29, 2019 the Company entered into a note payable with a trust related to one of our directors in the amount of $29,000. The Company is in default of this note. On July 5, 2019 the Company entered into a note payable with a trust related to one of our directors in the amount of $50,000. The note is for a one-year period maturing July 5, 2020 and bears interest at an annual rate of 8%. On November 25, 2019 the Company entered into a note payable with a trust related to one of our directors in the amount of $50,000. The note is for a one-year period maturing November 25, 2020 and bears interest at an annual rate of 8%. Interest expense for these notes for the nine months ended September 30, 2020 and 2019 was $14,194 and $7,155, respectively and accrued interest at September 30, 2020 is $25,502.

The Company borrowed $87,000 in the nine months ended September 30, 2020 from its CEO and repaid these amounts in full.

**Related Party Payables**

The Company periodically receives advances for operating funds from related parties or has related parties make payments on the Company’s behalf. As a result of these activities the Company had related party payables of $32,110 and $32,110 as of September 30, 2020 and December 31, 2019, respectively.

**Preferred and Common Shares Issued to Officers and Directors**

The Company’s Chairman converted the Series B Convertible Preferred Shares into Series C Convertible Preferred Shares and as of April 2020, the 385,302 shares that are issued in the Series C Convertible Preferred Stock are all to the Chairman.

In April 2020, effective March 31, 2020, the Company converted the $15,000 convertible note payable along with $619 in accrued interest and an exchange premium of $3,124 into 694,178 shares of common stock. This was part of the Regulation A+. These shares were issued on June 10, 2020 following the qualification of the Regulation A+.

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**NOTE 5: CONVERTIBLE NOTES PAYABLE**

As of September 30, 2020 and December 31, 2019, the Company had the following convertible notes outstanding:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | September 30, 2020 | | | | | |  |  | December 31, 2019 | | | | | |  |
|  |  | Principal | |  |  | Accrued Interest | |  |  | Principal | |  |  | Accrued Interest | |  |
| July and August 2012 $1,060,000 Notes convertible into common stock at $4.60 per share, 12% interest, due December 2013 and January 2014 |  | $ | 45,000 |  |  | $ | 44,031 |  |  | $ | 45,000 |  |  |  | 39,998 |  |
| May through October 2015 $605,000 Notes convertible into preferred stock at $1 per share, 8-10% interest, due September 30, 2015 |  |  | - |  |  |  | 17,341 |  |  |  | - |  |  |  | 17,341 |  |
| October through December 2015 $613,000 Notes convertible into preferred stock at $1 per share, 8% interest, due June 30, 2016, net of debt discount of $0 and $560,913, respectively |  |  | - |  |  |  | 5,953 |  |  |  | - |  |  |  | 5,953 |  |
| January through March 2016 $345,000 Notes convertible into preferred stock at $1 per share, 8% interest, due June 30, 2016 |  |  | - |  |  |  | 696 |  |  |  | - |  |  |  | 696 |  |
| May 2019 $60,000 Note convertible into common shares at $0.04 per share, 8% interest, due October 30, 2019 |  |  | - |  |  |  | - |  |  |  | 60,000 |  |  |  | 3,264 |  |
| July 2019 $50,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | - |  |  |  | - |  |  |  | 50,000 |  |  |  | 1,880 |  |
| September 2019 $50,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | - |  |  |  | - |  |  |  | 50,000 |  |  |  | 1,235 |  |
| September 2019 $38,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | - |  |  |  | - |  |  |  | 38,000 |  |  |  | 939 |  |
| September 2019 $25,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | - |  |  |  | - |  |  |  | 25,000 |  |  |  | 612 |  |
| September 2019 $50,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | - |  |  |  | - |  |  |  | 50,000 |  |  |  | 1,213 |  |
| September 2019 $50,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | - |  |  |  | - |  |  |  | 50,000 |  |  |  | 1,202 |  |
| September 2019 $37,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | - |  |  |  | - |  |  |  | 37,000 |  |  |  | 833 |  |
| December 2019 $50,000 Note convertible into common shares at $0.04 per share, 8% interest, due March 31, 2020 |  |  | - |  |  |  | - |  |  |  | 50,000 |  |  |  | - |  |
| January 2020 $100,000 Note convertible into common shares at $0,04 per share, 8% interest, due March 31, 2020 |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Penalties on notes in default |  |  | 11,966 |  |  |  | - |  |  |  | 10,618 |  |  |  | - |  |
| Total Convertible Notes Payable, Net |  | $ | 56,966 |  |  | $ | 68,021 |  |  | $ | 465,618 |  |  | $ | 75,166 |  |
| Less: BCF Discount |  |  | (- | ) |  |  | - |  |  |  | (6,187 | ) |  |  | - |  |
| Less: Debt Discount |  |  | (- | ) |  |  | - |  |  |  | (24,545 | ) |  |  | - |  |
|  |  | $ | 56,966 |  |  | $ | 68,021 |  |  | $ | 434,886 |  |  | $ | 75,166 |  |

Interest expense for the nine months ended September 30, 2020 and 2019 on the convertible notes payable amounted to $19,783 and $7,509, respectively.

The May 2017 notes totaling $3,136,506, $2,419,240 after debt discounts, had a December 2017 due date which was extended to May 2018.

The Company entered into a $50,000 convertible promissory note dated May 31, 2019, that was to mature October 30, 2019. The convertible promissory note bears interest at a rate of 8%, The convertible promissory note is convertible into shares of common stock at a price of $0.032 per share. Upon the closing of an equity financing pursuant to an effective registration statement with gross proceeds to the Company totaling at least $250,000 exclusive of any exchanges (“Qualified Financing”), the outstanding principal amount of this convertible promissory note together with all accrued and unpaid interest shall be exchanged into such securities as are issued in the Qualified Financing at a rate of 1.20. Upon an exchange, the Payee shall be granted all rights afforded to an investor in the Qualified Financing. The $10,000 contingent exchange amount is classified as original issue discount and will be amortized over the life of the convertible promissory note. The convertible promissory noteholder received 625,000 warrants at an exercise price of $0.04 per share, that have a term of two years. The warrants were valued at $12,592 and represent a debt discount, which were amortized over the life of the convertible promissory note.

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The Company entered into $300,000 in convertible promissory notes in July and September 2019, that were to mature January 15, 2020. The convertible promissory notes bear interest at a rate of 8%, The convertible promissory notes are convertible into shares of common stock at a price of $0.04 per share. Upon the closing of an equity financing pursuant to an effective registration statement with gross proceeds to the Company totaling at least $250,000 exclusive of any exchanges (“Qualified Financing”), the outstanding principal amount of this convertible promissory notes together with all accrued and unpaid interest shall be exchanged into such securities as are issued in the Qualified Financing at a rate of 1.20. Upon an exchange, the Payee shall be granted all rights afforded to an investor in the Qualified Financing. The convertible promissory noteholders received 3,000,000 warrants at an exercise price ranging between $0.06 and $0.08 per share (amended to $0.045 per share), that have a term of two years. The warrants were valued at $91,716 and represent a debt discount, which will be amortized over the life of the convertible promissory notes. In addition, the Company recognized a beneficial conversion feature discount to the notes of $59,957 that is being amortized over the life of the notes. For the nine months ended September 30, 2020 and 2019, the Company recognized $6,187 and $0, in amortization of the BCF discount.

Prior to the conversion of these notes, the Company was in default of these notes. As a result of the default, the interest rate charged was changed to 12.5% up through the conversion of these notes.

The Company entered into $50,000 in a convertible promissory note on December 31, 2019, that matures March 31, 2020. The convertible promissory notes bear interest at a rate of 8%, The convertible promissory note is convertible into shares of common stock at a price of $0.04 per share. Upon the closing of an equity financing pursuant to an effective registration statement with gross proceeds to the Company totaling at least $250,000 exclusive of any exchanges (“Qualified Financing”), the outstanding principal amount of this convertible promissory notes together with all accrued and unpaid interest shall be exchanged into such securities as are issued in the Qualified Financing at a rate of 1.20. Upon an exchange, the Payee shall be granted all rights afforded to an investor in the Qualified Financing. The convertible promissory noteholders received 625,000 warrants at an exercise price of $0.06 per share (amended to $0.045 per share), that have a term of two years. The warrants were valued at $14,299 and represent a debt discount, which will be amortized over the life of the convertible promissory note. This note was converted effective March 31, 2020. These shares were issued on June 10, 2020 following the qualification of the Regulation A+.

The Company issued a convertible note in January 2020 in the amount of $100,000 to an accredited investor. The note bears interest at 8% per annum and was to mature March 31, 2020. The Company granted 1,250,000 warrants with an exercise price of $0.06 per share and a term of two years with this note and amended 1,312,500 previously issued warrants held by the investor to provide for a $.06 exercise price and an expiration date of March 31, 2022, the note was converted in June 2020.

**NOTE 6: PROMISSORY NOTES PAYABLE**

As of September 30, 2020 and December 31, 2019, the Company had the following promissory notes outstanding:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | September 30, 2020 | | | | | |  |  | December 31, 2019 | | | | | |  |
|  |  |  | Principal  (net) |  |  |  | Accrued  Interest |  |  |  | Principal  (net) |  |  |  | Accrued  Interest |  |
| February 2019, two promissory notes for $50,000 each (total of $100,000), maturing August 2019, extended to February 2020, at 8.00% interest (originally) and now 15% interest and extended to August 20, 2020 |  | $ | - |  |  | $ | - |  |  | $ | 100,000 |  |  |  | 5,410 |  |
| Debt discount |  |  | (- | ) |  |  | - |  |  |  | - |  |  |  | - |  |
| Total Promissory Notes Payable, Net |  | $ | - |  |  | $ | - |  |  | $ | 100,000 |  |  | $ | 5,410 |  |

The Company issued two separate promissory notes on February 20, 2019 at $50,000 each (total of $100,000) that were to mature on August 20, 2019 and accrued interest at 8.00% per annum. In connection with the promissory notes, the Company issued warrants to purchase 1,250,000 shares of common stock. The Company recorded the relative fair value of the warrants as a debt discount of $28,721 and amortized the discount over the life of the note (6 months). Amortization of debt discount for the year ended December 31, 2019 was $28,721 and is recorded as interest expense on the statement of operations for the year ended December 31, 2019.

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On August 20, 2019, the two noteholders agreed to extend these notes another six-months to February 20, 2020, then amended again for six-months and the notes now mature August 20, 2020. In consideration for the extension, the note holders received 750,000 warrants (375,000 each) and the interest rate on the notes increased from 8% to 15% per annum. The interest expense on these notes for the nine months ended September 30, 2020 and 2019 amounted to $8,032 and $5,640, and $0 is accrued for as of September 30, 2020.

The Company repaid $50,00 of these notes plus $13,442 in accrued interest, and settled the remaining $50,000 into 1,851,852 shares of common stock effective July 14, 2020.

**NOTE 7: STOCKHOLDERS’ DEFICIT**

**Common Stock**

The Company has 950,000,000 shares of common stock authorized, with a par value of $0.001, and as of September 30, 2020 and December 31, 2019, the Company has 234,700,228 and 184,845,821 shares issued and outstanding, respectively.

On March 28, 2019, the Company’s board of directors approved a reverse 1-for-8 stock split, and a decrease in the authorized shares from 2,000,000,000 to 950,000,000. The reverse stock split went effective by FINRA on June 28, 2019.

**Preferred Stock**

As of September 30, 2020 and December 31, 2019, the Company has 20,000,000 shares of Preferred stock authorized with a par value of $0.001. The Company’s Board of Directors is authorized to provide for the issuance of shares of preferred stock in one or more series, fix or alter the designations, preferences, rights, qualifications, limitations or restrictions of the shares of each series, including the dividend rights, dividend rates, conversion rights, voting rights, term of redemption including sinking fund provisions, redemption price or prices, liquidation preferences and the number of shares constituting any series or designations of such series without further vote or action by the shareholders. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of management without further action by the shareholders and may adversely affect the voting and other rights of the holders of common stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control to others.

On October 8, 2018 the Company created out of the shares of Preferred Stock, par value $0.001 per share, of the Company, as authorized in Article IV of the Company’s Certificate of Incorporation, a series of Preferred Stock of the Company, to be named “Series B Convertible Preferred Stock,” consisting of Five Million (5,000,000) shares.

On March 27, 2019 the Company created out of the shares of Preferred Stock, par value $0.001 per share, of the Company, as authorized in Article IV of the Company’s Certificate of Incorporation, a series of Preferred Stock of the Company, to be named “Series C Convertible Preferred Stock,” consisting of Five Million (5,000,000) shares.

*Series A Convertible Preferred Stock (“Series A Convertible Preferred”)*

In June 2015, the Series A Certificate of Designation was filed with the Delaware Secretary of State to designate 2.5 million shares of our preferred stock as Series A Convertible Preferred. Effective March 31, 2016, the Company amended the Certificate of Designations, Preferences and Rights of Series A Convertible Preferred of the Registrant, increasing the maximum number of shares of Series A Convertible Preferred from 2,500,000 shares to 5,000,000 shares. The following summarizes the current rights and preferences of the Series A Convertible Preferred:

Liquidation Preference. The Series A Convertible Preferred has a liquidation preference of $5.00 per share.

Dividends. Shares of Series A Convertible Preferred do not have any separate dividend rights.

Conversion. Subject to certain limitations set forth in the Series A Certificate of Designation, each share of Series A Convertible Preferred is convertible, at the option of the holder, into that number of shares of common stock (the “*Series A Conversion Shares*”) equal to the liquidation preference thereof, divided by Conversion Price (as such term is defined in the Series A Certificate of Designation), currently $4.00.

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In the event the Company completes an equity or equity-based public offering, registered with the SEC, resulting in gross proceeds to the Company totaling at least $5.0 million, all issued and outstanding shares of Series A Convertible Preferred at that time will automatically convert into Series A Conversion Shares.

Redemption. Subject to certain conditions set forth in the Series A Certificate of Designation, in the event of a Change of Control (defined in the Series A Certificate of Designation as the time at which as a third party not affiliated with the Company or any holders of the Series A Convertible Preferred shall have acquired, in one or a series of related transactions, equity securities of the Company representing more than fifty percent 50% of the outstanding voting securities of the Company), the Company, at its option, will have the right to redeem all or a portion of the outstanding Series A Convertible Preferred in cash at a price per share of Series A Convertible Preferred equal to 100% of the Liquidation Preference.

Voting Rights. Holders of Series A Convertible Preferred are entitled to vote on all matters, together with the holders of common stock, and have the equivalent of five (5) votes for every Series A Conversion Share issuable upon conversion of such holder’s outstanding shares of Series A Convertible Preferred. However, the Series A Conversion Shares, when issued, will have all the same voting rights as other issued and outstanding common stock of the Company, and none of the rights of the Series A Convertible Preferred.

Liquidation. Upon any liquidation, dissolution, or winding-up of the Company, whether voluntary or involuntary (a “*Liquidation*”), the holders of Series A Convertible Preferred shall be entitled to receive out of the assets, whether capital or surplus, of the Company an amount equal to the liquidation preference of the Series A Convertible Preferred before any distribution or payment shall be made to the holders of any junior securities, and if the assets of the Company is insufficient to pay in full such amounts, then the entire assets to be distributed to the holders of the Series A Convertible Preferred shall be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Certain Price and Share Adjustments.

a) *Stock Dividends and Stock Splits*. If the Company (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of common stock on shares of common stock or any other common stock equivalents; (ii) subdivides outstanding shares of common stock into a larger number of shares; (iii) combines (including by way of a reverse stock split) outstanding shares of common stock into a smaller number of shares; or (iv) issues, in the event of a reclassification of shares of the common stock, any shares of capital stock of the Company, then the conversion price shall be adjusted accordingly.

b) *Merger or Reorganization*. If the Company is involved in any reorganization, recapitalization, reclassification, consolidation or merger in which the Common Stock is converted into or exchanged for securities, cash or other property than each share of Series A Preferred shall be convertible into the kind and amount of securities, cash or other property that a holder of the number of shares of common stock issuable upon conversion of one share of Series A Convertible Preferred prior to any such merger or reorganization would have been entitled to receive pursuant to such transaction.

*Series B Convertible Preferred Stock (“Series B Convertible Preferred”)*

In October 2018, the Series B Certificate of Designation was filed with the Delaware Secretary of State to designate 5.0 million shares of our preferred stock as Series B Convertible Preferred. The following summarizes the current rights and preferences of the Series B Convertible Preferred:

Liquidation Preference. The Series B Convertible Preferred has a liquidation preference of $1.00 per share.

Dividends. Shares of Series B Convertible Preferred do not have any separate dividend rights.

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Conversion. Subject to certain limitations set forth in the Series B Certificate of Designation, each share of Series B Convertible Preferred is convertible, at the option of the holder, into that number of shares of common stock (the “*Series B Conversion Shares*”) equal to the liquidation preference thereof, divided by Conversion Price (as such term is defined in the Series B Certificate of Designation), currently $0.08.

Redemption. Subject to certain conditions set forth in the Series B Certificate of Designation, in the event of a Change of Control (defined in the Series B Certificate of Designation as the time at which as a third party not affiliated with the Company or any holders of the Series B Convertible Preferred shall have acquired, in one or a series of related transactions, equity securities of the Company representing more than fifty percent 50% of the outstanding voting securities of the Company), the Company, at its option, will have the right to redeem all or a portion of the outstanding Series B Convertible Preferred in cash at a price per share of Series B Convertible Preferred equal to 100% of the Liquidation Preference.

Voting Rights. Holders of Series B Convertible Preferred are entitled to vote on all matters, together with the holders of common stock, and have the equivalent of two (2) votes for every Series B Conversion Share issuable upon conversion of such holder’s outstanding shares of Series B Convertible Preferred. However, the Series B Conversion Shares, when issued, will have all the same voting rights as other issued and outstanding common stock of the Company, and none of the rights of the Series A Convertible Preferred.

Liquidation. Upon any liquidation, dissolution, or winding-up of the Company, whether voluntary or involuntary (a “*Liquidation*”), the holders of Series B Convertible Preferred shall be entitled to receive out of the assets, whether capital or surplus, of the Company an amount equal to the liquidation preference of the Series B Convertible Preferred before any distribution or payment shall be made to the holders of any junior securities, and if the assets of the Company is insufficient to pay in full such amounts, then the entire assets to be distributed to the holders of the Series B Convertible Preferred shall be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Certain Price and Share Adjustments.

a) *Stock Dividends and Stock Splits*. If the Company (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of common stock on shares of common stock or any other common stock equivalents; (ii) subdivides outstanding shares of common stock into a larger number of shares; (iii) combines (including by way of a reverse stock split) outstanding shares of common stock into a smaller number of shares; or (iv) issues, in the event of a reclassification of shares of the common stock, any shares of capital stock of the Company, then the conversion price shall be adjusted accordingly.

b) *Merger or Reorganization*. If the Company is involved in any reorganization, recapitalization, reclassification, consolidation or merger in which the Common Stock is converted into or exchanged for securities, cash or other property than each share of Series B Convertible Preferred shall be convertible into the kind and amount of securities, cash or other property that a holder of the number of shares of common stock issuable upon conversion of one share of Series B Convertible Preferred prior to any such merger or reorganization would have been entitled to receive pursuant to such transaction.

*Series C Convertible Preferred Stock (“Series C Convertible Preferred”)*

In March 2019, the Series C Certificate of Designation was filed with the Delaware Secretary of State to designate 5.0 million shares of our preferred stock as Series C Convertible Preferred. The following summarizes the current rights and preferences of the Series C Convertible Preferred:

Liquidation Preference. The Series C Convertible Preferred has a liquidation preference of $1.00 per share.

Dividends. Shares of Series C Convertible Preferred do not have any separate dividend rights.

Conversion. Subject to certain limitations set forth in the Series C Certificate of Designation, each share of Series C Convertible Preferred is convertible, at the option of the holder, into that number of shares of common stock (the “*Series C Conversion Shares*”) equal to the liquidation preference thereof, divided by Conversion Price (as such term is defined in the Series C Certificate of Designation), currently $0.08.

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The Series C Convertible Preferred will only be convertible at any time after the date that the Company shall have amended its Certificate of Incorporation to increase the number of shares of common stock authorized for issuance thereunder or effect a reverse stock split of the outstanding shares of common stock by a sufficient amount to permit the conversion of all Series C Convertible Preferred into shares of common stock (“*Authorized Share Approval*”) (such date, the “*Initial Convertibility Date*”), each share of Series C Convertible Preferred shall be convertible into validly issued, fully paid and non-assessable shares of Common Stock on the terms and conditions set forth in the Series C Certificate of Designation under the definition “*Conversion Rights*”.

Redemption. Subject to certain conditions set forth in the Series C Certificate of Designation, in the event of a Change of Control (defined in the Series C Certificate of Designation as the time at which as a third party not affiliated with the Company or any holders of the Series C Convertible Preferred shall have acquired, in one or a series of related transactions, equity securities of the Company representing more than fifty percent 50% of the outstanding voting securities of the Company), the Company, at its option, will have the right to redeem all or a portion of the outstanding Series B Convertible Preferred in cash at a price per share of Series C Convertible Preferred equal to 100% of the Liquidation Preference.

Voting Rights. Holders of Series C Convertible Preferred are entitled to vote on all matters, together with the holders of common stock, and have the equivalent of thirty-two (32) votes for every Series C Conversion Share issuable upon conversion of such holder’s outstanding shares of Series C Convertible Preferred. However, the Series C Conversion Shares, when issued, will have all the same voting rights as other issued and outstanding common stock of the Company, and none of the rights of the Series C Convertible Preferred.

Liquidation. Upon any liquidation, dissolution, or winding-up of the Company, whether voluntary or involuntary (a “*Liquidation*”), the holders of Series C Convertible Preferred shall be entitled to receive out of the assets, whether capital or surplus, of the Company an amount equal to the liquidation preference of the Series C Convertible Preferred before any distribution or payment shall be made to the holders of any junior securities, and if the assets of the Company is insufficient to pay in full such amounts, then the entire assets to be distributed to the holders of the Series C Convertible Preferred shall be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Certain Price and Share Adjustments.

a) *Stock Dividends and Stock Splits*. If the Company (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of common stock on shares of common stock or any other common stock equivalents; (ii) subdivides outstanding shares of common stock into a larger number of shares; (iii) combines (including by way of a reverse stock split) outstanding shares of common stock into a smaller number of shares; or (iv) issues, in the event of a reclassification of shares of the common stock, any shares of capital stock of the Company, then the conversion price shall be adjusted accordingly.

b) *Merger or Reorganization*. If the Company is involved in any reorganization, recapitalization, reclassification, consolidation or merger in which the Common Stock is converted into or exchanged for securities, cash or other property than each share of Series C Convertible Preferred shall be convertible into the kind and amount of securities, cash or other property that a holder of the number of shares of common stock issuable upon conversion of one share of Series C Convertible Preferred prior to any such merger or reorganization would have been entitled to receive pursuant to such transaction.

***Common and Preferred Stock Issuances - 2020***

The Company in January 2020 paid $50,000 to redeem 100,000 shares of Series B Convertible Preferred Stock. The redemption price was agreed to by the investor.

In January 2020, the Company converted 435,990 shares of Series C Convertible Preferred stock into 5,449,875 shares of common stock.

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In March through June 2020, the Company entered into agreements to issue 18,440,000 shares of common stock conditioned upon the qualification of the offer and sale of such shares under Regulation A+ for $497,880. Additionally, the Company agreed to issue 9,220,000 warrants with a term of two years and an exercise price of $.045 for a purchase price of $8,143. These shares were issued in June 2020 and July 2020 following the qualification of the Regulation A+.

In March through June 2020, certain holders of convertible promissory notes entered into agreements to exchange certain notes totaling $651,044, including $525,000 in principal amount, $27,536 in accrued interest and an exchange premium as provided for in the note agreements of $98,508 into 21,770,668 shares of common stock effective upon the qualification of the offer and sale of such shares under Regulation A+. In connection with the holder’s agreement to enter into the exchange, the Company intends to issue 2,200,000 warrants with a two-year term and an exercise price of $0.045 per share and amend 4,400,000 previously issued warrants to provide for a $.045 exercise price and an expiration date of March 31, 2022. These shares were issued on June 10, 2020 following the qualification of the Regulation A+.

During the three months ended September 30, 2020, the Company issued 1,851,852 shares of common stock to settle $50,000 in promissory notes.

***Common and Preferred Stock Issuances - 2019***

In January 2019, the Company received $100,000 in gross proceeds resulting from the issuance to accredited investors of 1,250,000 shares of common stock, 100,000 shares of Series B Convertible Preferred and warrants to purchase 1,250,000 shares of common stock.

The Company issued 13,015,225 shares of common stock in consideration for the conversion of 1,041,218 shares of Series B Convertible Preferred.

The Company issued 821,292 shares of Series C Convertible Preferred in exchange for 821,292 shares of Series B Convertible Preferred.

The Company issued 562,500 shares of common stock in a settlement of accounts payable valued at $22,500.

The Company issued 312,500 shares of common stock for services rendered in connection with the raising of debt instruments valued at $12,500.

**NOTE 8: COMMON STOCK OPTIONS, WARRANTS AND RESTRICTED STOCK UNITS**

**Common Stock Options**

The Company recognizes in the financial statements compensation related to all stock-based awards, including stock options and warrants, based on their estimated grant-date fair value. The Company has estimated expected forfeitures and is recognizing compensation expense only for those awards expected to vest. All compensation is recognized by the time the award vests.

The following schedule summarizes the changes in the Company’s stock options:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | |  |  |  | |  |  | Weighted | |  |  |  | |  |  | Weighted | |  |
|  |  | Options Outstanding | | | | | |  |  | Average | |  |  |  | |  |  | Average | |  |
|  |  | Number | |  |  | Exercise | |  |  | Remaining | |  |  | Aggregate | |  |  | Exercise | |  |
|  |  | Of | |  |  | Price | |  |  | Contractual | |  |  | Intrinsic | |  |  | Price | |  |
|  |  | Shares | |  |  | Per Share | |  |  | Life | |  |  | Value | |  |  | Per Share | |  |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| Balance at December 31, 2019 |  |  | 34,524,580 |  |  | $ | 0.024-120.00 |  |  |  | 6.49 years |  |  | $ | 277,973 |  |  | $ | 0.08 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Options granted |  |  | - |  |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ | - |  |
| Options exercised |  |  | - |  |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ | - |  |
| Options expired |  |  | (- | ) |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance at September 30, 2020 |  |  | 34,524,580 |  |  | $ | 0.024-120.00 |  |  |  | 5.73 years |  |  | $ | 64,148 |  |  | $ | 0.08 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Exercisable at September 30, 2020 |  |  | 34,428,955 |  |  | $ | 0.024-120.00 |  |  |  | 5.73 years |  |  | $ | 63,861 |  |  | $ | 0.08 |  |

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In June 2019, the Company issued 382,500 stock options to consultants that vest through June 30, 2020. The grant date of these options was June 17, 2019, the date of board approval. On June 21, 2019, 46,250 stock options expired that were issued June 21, 2016. There was $6,529 expensed in 2019 and $2,176 remaining to be expensed through June 30, 2020 for these options.

The Company has granted 21,000,000 stock options under the Company’s 2015 Omnibus Securities and Incentive Plan to Dr. Korenko. The granting of the stock options occurs 10 days after the approval of the Company’s recent 1 for 8 reverse stock split that occurred on June 28, 2018. The vesting of the options are as follows: (i) 50% vested in equal amounts at the end of each of the two successive calendar quarters (25% for each of the quarters September 30, 2019, and December 31, 2019); (ii) 25% upon the Company filing a patent (completed on July 1, 2019); and (iii) 25% upon the first commercial sale of IsoPet®. The first commercial sale occurred in July 2019. The value of these options in the aggregate is $585,144.

In September 2019, the Company granted 1,000,000 stock options in a settlement agreement for past due legal fees. The options have a ten-year life and vest immediately. These options were valued at $33,829 which offset accounts payable. The Company recognized a gain of $34,106 on this transaction which is included in the net (gain) loss on debt extinguishment in the statement of operations for the year ended December 31, 2019.

In September 2019, the Company granted 500,000 stock options to a consultant for services rendered. The options have a ten-year life and vest immediately. These options were valued at $16,915.

In December 2019, the Company granted 370,309 stock options to consultants for accounts payable. The options have a ten-year life and vest immediately. These options were valued at $14,812.

During the nine months ended September 30, 2020 and 2019, the Company recognized $2,176 and $460,125, respectively, worth of stock based compensation related to the vesting of it stock options.

**Common Stock Warrants**

The following schedule summarizes the changes in the Company’s stock warrants:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Warrants Outstanding | | | | | |  |  | Weighted Average | |  |  |  | |  |  | Weighted Average | |  |
|  |  | Number  Of Shares | |  |  | Exercise  Price Per Share | |  |  | Remaining Contractual Life | |  |  | Aggregate Intrinsic Value | |  |  | Exercise  Price Per Share | |  |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| Balance at December 31, 2019 |  |  | 31,286,847 |  |  | $ | 0.04-80.00 |  |  |  | 0.97 years |  |  | $ | - |  |  | $ | 0.10 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Warrants granted |  |  | 12,670,000 |  |  | $ | 0.045-0.06 |  |  |  | - |  |  |  |  |  |  | $ | - |  |
| Warrants exercised |  |  | - |  |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ |  |  |
| Warrants expired/cancelled |  |  | - |  |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance at September 30, 2020 |  |  | 43,956,847 |  |  | $ | 0.04-80.00 |  |  |  | 0.34 years |  |  | $ | - |  |  | $ | 0.10 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Exercisable at September 30, 2020 |  |  | 43,956,847 |  |  | $ | 0.04-80.00 |  |  |  | 0.34 years |  |  | $ | - |  |  | $ | 0.10 |  |

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For the year ended December 31, 2019, the Company granted 1,250,000 warrants in the issuance of common and preferred shares issued for cash to accredited investors, 5,650,000 warrants in the issuance of promissory notes (recorded as a debt discount valued at $151,048), 750,000 warrants for the extension of promissory notes, recorded as interest expense valued at $25,656, 500,000 warrants for settlement of accounts payable valued at $18,500 (see Note 9) and 84,375 warrants issued for consulting services valued at $3,792.

The Company issued a convertible note in the amount of $100,000 to an accredited investor. The note bears interest at 8% per annum and matures March 31, 2020. The Company granted 1,250,000 warrants with an exercise price of $0.06 per share and a term of two years with this note and amended 1,312,500 previously issued warrants held by the investor to provide for a $.06 exercise price and an expiration date of March 31, 2022.

In March through June 2020, the Company entered into agreements to issue 18,440,000 shares of common stock conditioned upon the qualification of the offer and sale of such shares under Regulation A+ for $497,880. Additionally, the Company agreed to issue 9,220,000 warrants with a term of two years and an exercise price of $.045 for a purchase price of $8,143. These shares were issued in June 2020 and July 2020 following the qualification of the Regulation A+.

In March through June 2020, certain holders of convertible promissory notes entered into agreements to exchange certain notes totaling $651,044, including $525,000 in principal amount, $27,536 in accrued interest and an exchange premium as provided for in the note agreements of $98,508 into 21,770,668 shares of common stock effective upon the qualification of the offer and sale of such shares under Regulation A+. In connection with the holder’s agreement to enter into the exchange, the Company intends to issue 2,200,000 warrants with a two-year term and an exercise price of $0.045 per share and amend 4,400,000 previously issued warrants to provide for a $.045 exercise price and an expiration date of March 31, 2022. These shares were issued on June 10, 2020 following the qualification of the Regulation A+.

**Restricted Stock Units**

The following schedule summarizes the changes in the Company’s restricted stock units:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | |  |  | Weighted | |  |
|  |  | Number | |  |  | Average | |  |
|  |  | Of | |  |  | Grant Date | |  |
|  |  | Shares | |  |  | Fair Value | |  |
|  |  |  | |  |  |  | |  |
| Balance at December 31, 2019 |  |  | 262,500 |  |  | $ | 0.59 |  |
|  |  |  |  |  |  |  |  |  |
| RSU’s granted |  |  | - |  |  | $ | - |  |
| RSU’s vested |  |  | - |  |  | $ | - |  |
| RSU’s forfeited |  |  | - |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |
| Balance at September 30, 2020 |  |  | 262,500 |  |  | $ | 0.59 |  |

During the nine months ended September 30. 2020 and 2019, the Company recognized $0 and $0 worth of expense related to the vesting of its RSU’s. As of September 30, 2020, the Company had $155,400 worth of expense yet to be recognized for RSU’s not yet vested.

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**NOTE 9: LEGAL MATTERS**

The Company may, from time to time, be involved in various legal proceedings incidental to the conduct of our business. Historically, the outcome of all such legal proceedings has not, in the aggregate, had a material adverse effect on our business, financial condition, results of operations or liquidity. Other than as set forth below, there are no additional material pending or threatened legal proceedings at this time.

On January 28, 2019, James Katzaroff, (“*Plaintiff*”) the Company’s former Chief Executive Officer filed a lawsuit in the Superior Court in the State of Washington in and for the County of Benton against the Company and its current and former directors, alleging a default of the Separation Agreement and General Release (“*Release*”) that the Company entered into with Plaintiff on July 21, 2017 (the “*Complaint*”). The Company has made required payments under the Release.

On November 25, 2019, the Company and its current and former directors entered into a Settlement Agreement with the Plaintiff. Under the terms of the Settlement Agreement, the Company has agreed to issue 500,000 shares of common stock and 500,000 warrants to the Plaintiff, make an initial payment of $33,503 by December 4, 2019 and beginning on December 16, 2019, the Company will make payments of $10,000 per month for 10 months in full satisfaction of the Separation Agreement and General Release originally entered into on July 21, 2017. The Company has paid this liability in full as of September 11, 2020.

**NOTE 10: COMMITMENT**

On June 4, 2019, the Company entered into an Executive Employment Agreement (“Employment Agreement”) with Dr. Michael K. Korenko, the Company’s Chief Executive Officer. The employment term under the Employment Agreement commenced with an effective date of June 11, 2019 and expires on December 31, 2020, and December 31 of each successive year if the Employment Agreement is extended, unless terminated earlier as set forth in the Employment Agreement.

Under the terms of the Employment Agreement, the Company shall pay to Dr. Korenko a base compensation of $180,000. Of this amount, $120,000 is booked in monthly intervals and the remaining balance is only paid upon the Company achieving a cash balance that exceeds $1,000,000. The Company has elected to record the compensation as $120,000, and upon achieving the milestone of $1,000,000 in cash balances, will record the deferred compensation at that time.

**NOTE 11: SUBSEQUENT EVENTS**

Management has evaluated subsequent events, in accordance with FASB ASC Topic 855, “Subsequent Events”, through the date which the financial statements were available to be issued and there are no material subsequent events to report.

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

Except for statements of historical fact, certain information described in this Form 10-Q report contains “forward-looking statements” that involve substantial risks and uncertainties. You can identify these statements by forward-looking words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “should,” “will,” “would” or similar words. The statements that contain these or similar words should be read carefully because these statements discuss the Company’s future expectations, including its expectations of its future results of operations or financial position, or state other “forward-looking” information. Vivos Inc. believes that it is important to communicate its future expectations to its investors. However, there may be events in the future that the Company is not able to accurately predict or to control. Further, the Company urges you to be cautious of the forward-looking statements which are contained in this Form 10-Q report because they involve risks, uncertainties and other factors affecting its operations, market growth, service, products and licenses. The risk factors in the section captioned “Risk Factors” in Item 1A of the Company’s previously filed Form 10-K, as well as other cautionary language in this Form 10-Q report, describe such risks, uncertainties and events that may cause the Company’s actual results and achievements, whether expressed or implied, to differ materially from the expectations the Company describes in its forward-looking statements. The occurrence of any of the events described as risk factors could have a material adverse effect on the Company’s business, results of operations and financial position.

***General Statement of Business***

Vivos Inc. (the “*Company*” or “*we*”) was incorporated under the laws of Delaware on December 23, 1994 as Savage Mountain Sports Corporation (“*SMSC*”). On December 28, 2017, the Company changed its name from Advanced Medical Isotope Corp. to Vivos Inc.

On June 25, 2019, the Company amended their Certificate of Incorporation amending their authorized common shares to 950,000,000 from 2,000,000,000 shares. In addition, the 1 for 8 reverse stock-split was effective on June 28, 2019. The reverse stock-split reduced the number of common shares issued and outstanding from 1,421,687,688 to 177,710,961 shares. The par value for the common shares remained $0.001 per share, The Company did not amend their preferred stock which is 20,000,000 shares of preferred stock authorized, $0.001 par value per share.

Our principal place of business is located at 719 Jadwin Avenue, Richland, Washington 99352. Our telephone number is (509) 736-4000. Our corporate website address is http://www.radiogel.com. Our common stock is currently listed for quotation on the OTCQB Marketplace under the symbol “RDGL.”

**Overview**

The Company is a radiation oncology medical device company engaged in the development of its yttrium-90 based brachytherapy device, RadioGel™, for the treatment of non-resectable tumors. A prominent team of radiochemists, scientists and engineers, collaborating with strategic partners, including national laboratories, universities and private corporations, lead the Company’s development efforts. The Company’s overall vision is to globally empower physicians, medical researchers and patients by providing them with new isotope technologies that offer safe and effective treatments for cancer.

In January 2018, the Center for Veterinary Medicine Product Classification Group ruled that RadioGelTM should be classified as a device for animal therapy of feline sarcomas and canine soft tissue sarcomas. Additionally, after a legal review, the Company believes that the device classification obtained from the Food and Drug Administration (“*FDA*”) Center for Veterinary Medicine is not limited to canine and feline sarcomas, but rather may be extended to a much broader population of veterinary cancers, including all or most solid tumors in animals. We expect the result of such classification and label review will be that no additional regulatory approvals are necessary for the use of IsoPet® for the treatment of solid tumors in animals. The FDA does not have premarket authority over devices with a veterinary classification, and the manufacturers are responsible for assuring that the product is safe, effective, properly labeled, and otherwise in compliance with all applicable laws and regulations.

Based on the FDA’s recommendation, RadioGelTM will be marketed as “IsoPet®” for use by veterinarians to avoid any confusion between animal and human therapy. The Company already has trademark protection for the “IsoPet®” name. IsoPet® and RadioGelTM are used synonymously throughout this document. The only distinction between IsoPet® and RadioGelTM is the FDA’s recommendation that we use “IsoPet®” for veterinarian usage, and reserve “RadioGelTM” for human therapy. Based on these developments, the Company has shifted its primary focus to the development and marketing of Isopet® for animal therapy, through the Company’s IsoPet® Solutions division.

The Company’s IsoPet Solutions division was established in May 2016 to focus on the veterinary oncology market, namely engagement of university veterinarian hospital to develop the detailed therapy procedures to treat animal tumors and ultimately use of the technology in private clinics. The Company has worked with three different university veterinarian hospitals on IsoPet® testing and therapy. Washington State University treated five cats for feline sarcoma and served to develop the procedures which are incorporated in our label. They concluded that the product was safe and effective in killing cancer cells. Colorado State University demonstrated the CT and PET-CT imaging of IsoPet®. A contract was signed with University of Missouri to treat canine sarcomas and equine sarcoids starting in November 2017.

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The dogs were treated for canine soft tissue sarcoma. Response evaluation criteria in solid tumors (“*RECIST*”) is a set of published rules that define when tumors in cancer patients improve (respond), stay the same (stabilize), or worsen (progress) during treatment. The criteria were published by an international collaboration including the European Organisation for Research and Treatment of Cancer (EORTC), National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group.

The testing at the University of Missouri met its objective to demonstrate the safety of IsoPet®. Using its advanced CT and PET equipment it was able to demonstrate that the dose calculations were accurate and that the injections perfused into the cell interstices and did not stay concentrated in a bolus. This results in a more homogeneous dose distribution. There was insignificant spread of Y-90 outside the points of injection demonstrating the effectiveness of the particles and the gel to localize the radiation with no spreading to the blood or other organs nor to urine or fecal material. This confirms that IsoPet® is safe for same day therapy.

The effectiveness of IsoPet® for life extension was not the prime objective, but it resulted in valuable insights. Of the cases one is still cancer-free but the others eventually recurred since there was not a strong focus on treating the margins. The University of Missouri has agreed to become a regional center to administer IsoPet® therapy and will incorporate the improvements suggested by the testing program.

The Company anticipates that future profits, if any, will be derived from direct sales of RadioGel™ (under the name IsoPet®) and related services, and from licensing to private medical and veterinary clinics in the U.S. and internationally. The Company intends to report the results from the IsoPet® Solutions division as a separate operating segment in accordance with GAAP.

Commencing in July 2019, the Company recognized its first commercial sale of IsoPet®. A doctor brought his cat with a re-occurrent spindle cell sarcoma tumor on his face. The cat had previously received external beam therapy, but now the tumor was growing rapidly. He was given a high dose of 400Gy with heavy therapy at the margins. This sale met the revenue recognition requirements under ASC 606 as the performance obligation was satisfied. The Company completed sales for an additional four animals that received the IsoPet® during 2019.

Our plan is to incorporate the data assembled from our work with Isopet® in animal therapy to support the Company’s efforts in the development of our RadioGel™ device candidate, including obtaining approval from the *FDA* to market and sell RadioGel™ as a Class II medical device. RadioGel™ is an injectable particle-gel for brachytherapy radiation treatment of cancerous tumors in people and animals. RadioGel™ is comprised of a hydrogel, or a substance that is liquid at room temperature and then gels when reaching body temperature after injection into a tumor. In the gel are small, one micron, yttrium-90 phosphate particles (“*Y-90*”). Once injected, these inert particles are locked in place inside the tumor by the gel, delivering a very high local radiation dose. The radiation is beta, consisting of high-speed electrons. These electrons only travel a short distance so the device can deliver high radiation to the tumor with minimal dose to the surrounding tissue. Optimally, patients can go home immediately following treatment without the risk of radiation exposure to family members. Since Y-90 has a half-life of 2.7 days, the radioactivity drops to 5% of its original value after ten days.

The Company’s lead brachytherapy products, including RadioGel™, incorporate patented technology developed for Battelle Memorial Institute (“*Battelle*”) at Pacific Northwest National Laboratory, a leading research institute for government and commercial customers. Battelle has granted the Company an exclusive license to patents covering the manufacturing, processing and applications of RadioGel™ (the “*Battelle License*”). This exclusive license is to terminate upon the expiration of the last patent included in this agreement (January 2022). Other intellectual property protection includes proprietary production processes and trademark protection in 17 countries. The Company plans to continue efforts to develop new refinements on the production process, and the product and application hardware, as a basis for future patents.

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**Vista Veterinary Hospital**

Vista Veterinary Hospital (“*Vista*”) was selected as the pilot private clinic to initiate commercial sales of IsoPet®. It is good management practice to implement and learn from a pilot program before spreading to regional clinics across the country. Vista is located in the Tri-Cities Washington area which is convenient for interactions with key personnel of Vista Inc. The pilot is being used to

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|  | ● | Refine the Memorandum of Understanding to define all the germane interfaces, roles and liabilities between Vista Inc and the private clinics, including the pilot responsivity to document and share the key aspects of all therapies with the Company; |
|  | ● | Create and implement proprietary certification training packages; |
|  | ● | Amend the production center radioactive material license at IsoTherapeutics, the Company’s IsoPet® production center, to allow distribution for commercial applications; |
|  | ● | Work with the pilot program to obtain a radioactive material licensing in an NRC agreement state; |
|  | ● | Create equipment and supplies list; |
|  | ● | Create and post regulatory signage; |
|  | ● | Explore different IsoPet® pricing options; |
|  | ● | Evaluate different approaches to obtain patients; |
|  | ● | Optimize patient scheduling practices to reduce cost to the pet owners; and |
|  | ● | Develop communication material and a liability document for the pet owners. |

Vista Veterinary Hospital has done well on two audits by the Washington State Department of Health. The Company is working closely with the Washington State Department of Health to refine and improve the radioactive material license. The Company has added several detailed procedures, which will benefit future regional clinics. In addition, a second veterinarian has completed all the preliminary requirements to become certified. All that remains is to demonstrate proficiency in three therapies.

The testing at the universities and at Vista Veterinary Hospital have demonstrated that IsoPet® is effective on killing cancer tissue in close proximity to the injections. It is most effective in early cases before the cancer has begun to spread. Later stage cancers are more difficult to treat since the tendrils from the primary cancer site are not well defined and therefore can lead to recurrence.

There have been 36 expressions of interest in IsoPet® therapy from across the United States, but only four of these were treated and they were very advanced cases. The reasons are instructive. Most of the cases were for so advanced that the pet parents found out about IsoPet® on the Internet as a last hope. Several others were internal cancers that could not be reached, for example deep in the throat. Four cases were treatable, but the pets weighed more than 20 pounds and the pet parents were not willing to fly them in the “Safe Cargo” holds. Those patients would have been treated by regional clinics once we implement that strategy. Three cases were mast cell cancers. The Company is confident that those tumors could have been treated, but once killed they release mast cells in a process called granulation. This could cause a shock to the animal’s system. The Company will focus one of our clinical studies on the optimum approach for those therapies.

Vista Veterinary Hospital accepted four advanced cancer cases. The first cat was terminally ill and had previously had external beam, surgery and chemotherapy. The facial tumor was treated with 400 Gy and the biopsy confirmed that the cancer was killed. In about seven months the cancer returned in the throat and could not be treated so the cat had to be put down. Dr. Buader, the veterinarian pet parent, was still elated about the life extension and is asking us to use him as a reference. Two other cases were also very advanced with multiple tumors and they recurred since they had already spread before therapy.

The Company’s efforts are now to obtain more early stage cancer patients. The biggest obstacle is to convince the veterinarians of the pet parents to agree with IsoPet® therapy rather than using a more traditional method such as surgery. This is a slow process due to the conservative nature of the veterinarian professions. This is the prime motivation to continue with additional clinical trials and to publish the results.

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**Regulatory History**

*Human Therapy*

RadioGel™ has a long regulatory history with the Food and Drug Administration (“*FDA*”). Initially, the Company submitted a presubmission (Q130140) to obtain FDA feedback about the proposed product. The FDA requested that the Company file a request for designation with the Office of Combination Products (RFD130051), which led to the determination that RadioGel™ is a device for human therapy for non-resectable cancers, which must be reviewed and ultimately regulated by the Center for Devices and Radiological Health (“*CDRH*”). The Company then submitted a 510(k) notice for RadioGel™ (K133368), which was found Not Substantially Equivalent due to the lack of a suitable predicate, and RadioGel™ was assigned to the Class III product code NAW (microspheres). Class III products or devices are generally the highest risk devices and are therefore subject to the highest level of regulatory review, control and oversight. Class III products or devices must typically be approved by FDA before they are marketed. Class II devices represent lower risk products or devices than Class III and require fewer regulatory controls to provide reasonable assurance of the product’s or device’s safety and effectiveness. In contrast, Class I products and devices are deemed to be lower risk than Class I or II, and are therefore subject to the least regulatory controls.

A pre-submission meeting (Q140496) was held with the FDA on June 17, 2014, during which the FDA maintained that RadioGel™ should be considered a Class III device and therefore subject to pre-market approval. On December 29, 2014, the Company submitted a *de novo* petition for RadioGel™ (DEN140043). The *de novo* petition was denied by the FDA on June 1, 2015, with the FDA providing numerous comments and questions. On September 29, 2015, the Company submitted a follow-up pre-submission informational meeting request with the FDA (Q151569). This meeting took place on November 9, 2015, at which time the FDA indicated acceptance of the Company’s applied dosimetry methods and clarified the FDA’s outstanding questions regarding RadioGel™. Following the November 2015 pre-submission meeting, the Company prepared a new pre-submission package to obtain FDA feedback on the proposed testing methods, intended to address the concerns raised by the FDA staff and to address the suitability of RadioGel™ for *de novo* reclassification. This pre-submission package was presented to the FDA in a meeting on August 29, 2017. During the August 2017 meeting, the FDA clarified their position on the remaining pre-clinical testing needed for RadioGel™. Specifically, the FDA addressed proposed dosimetry calculating techniques, dosimetry distribution between injections, hydrogel viscoelastic properties, and the details of the Company’s proposed animal testing.

The Company believes that its submissions to the FDA to date have addressed all the FDA staff’s feedback over the past four years. Of particular importance, the Company has provided corresponding supporting data for proposed future testing of RadioGel™ to address any remaining questions raised by the FDA. We believe, although no assurances can be given, that the clinical testing modifications presented to the FDA in August 2017 will result in a *de novo* reclassification for RadioGel™ by the FDA. In addition, in previous FDA submittals, the Company proposed applying RadioGel™ for a very broad range of cancer therapies, referred to as Indication for Use. The FDA requested that the Company reduce its Indications for Use. To comply with that request, the Company expanded its Medical Advisory Board (“*MAB*”) and engaged doctors from respected hospitals who have evaluated the candidate cancer therapies based on three criteria: (1) potential for FDA approval and successful therapy; (2) notable advantage over current therapies; and (3) probability of wide-spread acceptance by the medical community.

The MAB selected eighteen applications for RadioGel™, each of which meet the criteria described above. This large number confirms the wide applicability of the device and defines the path for future business growth. The Company’s application establishes a single Indication for Use - treatment of basal cell and squamous cell skin cancers. We anticipate that this initial application will facilitate each subsequent application for additional Indications for Use, and the testing for many of the subsequent applications could be conducted in parallel, depending on available resources.

**Results of Operations**

***Comparison of the Nine Months Ended September 30, 2020 and 2019***

The following table sets forth information from our statements of operations for the nine months ended September 30, 2020 and 2019:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Nine Months Ended  September 30, 2020 | |  |  | Nine Months Ended  September 30, 2019 | |  |
| Revenues |  | $ | 7,000 |  |  | $ | 8,000 |  |
| Operating expenses |  |  | (384,267 | ) |  |  | (1,013,426 | ) |
| Operating loss |  |  | (377,267 | ) |  |  | (1,005,426 | ) |
| Non-operating income (expense): |  |  |  |  |  |  |  |  |
| Other income |  |  | 3,000 |  |  |  | 34,106 |  |
| Interest expense |  |  | (280,642 | ) |  |  | (134,739 | ) |
| Net loss |  | $ | (654,909 | ) |  | $ | (1,106,059 | ) |

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***Revenue***

Revenue was $7,000 and $8,000 for the nine months ended September 30, 2020 and 2019, respectively.

***Operating Expenses***

Operating expenses for the nine months ended September 30, 2020 and 2019, respectively consists of the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Nine months ended  September 30, 2020 | |  |  | Nine months ended  September 30, 2019 | |  |
| Professional fees |  | $ | 170,771 |  |  | $ | 356,248 |  |
| Stock based compensation |  |  | 2,176 |  |  |  | 463,917 |  |
| Payroll expenses |  |  | 94,029 |  |  |  | 90,000 |  |
| Research and development |  |  | 31,809 |  |  |  | 62,194 |  |
| General and administrative expenses |  |  | 85,482 |  |  |  | 41,067 |  |
| Total operating expenses |  | $ | 384,267 |  |  | $ | 1,013,426 |  |

Operating expenses for the nine months ended September 30, 2020 and 2019 was $384,267 and $1,013,426, respectively. The decrease in operating expenses from 2019 to 2020 can be attributed to the decrease in professional fees ($170,771 for the nine months ended September 30, 2020 versus $356,248 for the nine months ended September 30, 2020) as the Company utilized less services due to cash flow constraints; the decrease in stock based compensation ($2,176 for the nine months ended September 30, 2020 versus $463,917 for the nine months ended September 30, 2019) and the increase in general and administrative expense ($41,067 for the nine months ended September 30, 2019 versus $85,482 for the nine months ended September 30, 2020) as the Company continued to incur reasonable administrative costs to run the Company.

***Non-Operating Income (Expense)***

Non-operating income (expense) for the nine months ended September 30, 2020 and 2019 consists of the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Nine months ended  September 30, 2020 | |  |  | Nine months ended  September 30, 2019 | |  |
| Interest expense |  | $ | (280,642 | ) |  | $ | (134,739 | ) |
| Other income |  |  | 3,000 |  |  |  | 34,106 |  |
| Non-operating income (expense) |  | $ | (277,642 | ) |  | $ | (100,633 | ) |

Non-operating income (expense) for the nine months ended September 30, 2020 varied from the nine months ended September 30, 2019 primarily due to an increase in interest expense from as a result of the debt increase from 2019 to 2020 prior to conversion of this debt. The majority of the interest recorded by the Company consists of amortization of debt discount, BCF discount and the exchange premium resulting in additional shares to the noteholders on conversion.

***Net Loss***

Our net loss for the nine months ended September 30, 2020 and 2019 was $(654,909) and $(1,106,059), respectively.

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***Comparison of the Three Months Ended September 30, 2020 and 2019***

The following table sets forth information from our statements of operations for the three months ended September 30, 2020 and 2019:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Three Months Ended  September 30, 2020 | |  |  | Three Months Ended  September 30, 2019 | |  |
| Revenues |  | $ | 7,000 |  |  | $ | 8,000 |  |
| Operating expenses |  |  | (135,440 | ) |  |  | (615,207 | ) |
| Operating loss |  |  | (128,440 | ) |  |  | (607,207 | ) |
| Non-operating income (expense): |  |  |  |  |  |  |  |  |
| Other income |  |  | - |  |  |  | 34,106 |  |
| Interest expense |  |  | (7,151 | ) |  |  | (96,271 | ) |
| Net loss |  | $ | (135,591 | ) |  | $ | (669,372 | ) |

***Revenue***

Revenue was $7,000 and $8,000 for the three months ended September 30, 2020 and 2019, respectively.

***Operating Expenses***

Operating expenses for the three months ended September 30, 2020 and 2019, respectively consists of the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Three months ended  September 30, 2020 | |  |  | Three months ended  September 30, 2019 | |  |
| Professional fees |  | $ | 59,502 |  |  | $ | 87,075 |  |
| Stock based compensation |  |  | - |  |  |  | 457,949 |  |
| Payroll expenses |  |  | 34,029 |  |  |  | 30,000 |  |
| Research and development |  |  | 14,383 |  |  |  | 18,492 |  |
| General and administrative expenses |  |  | 27,526 |  |  |  | 21,691 |  |
| Total operating expenses |  | $ | 135,440 |  |  | $ | 615,207 |  |

Operating expenses for the three months ended September 30, 2020 and 2019 was $135,440 and $615,207, respectively. The decrease in operating expenses from 2019 to 2020 can be attributed to the decrease in professional fees ($59,502 for the three months ended September 30, 2020 versus $87,075 for the three months ended September 30, 2019) as the Company utilized less services due to cash flow constraints; the decrease in stock based compensation ($0 in the three months ended September 30, 2020 versus $457,949 for the three months ended September 30, 2020) and the increase in general and administrative expense ($21,691 for the three months ended September 30, 2019 versus $27,526 for the three months ended September 30, 2020) as the Company continued to incur reasonable administrative costs to run the Company.

***Non-Operating Income (Expense)***

Non-operating income (expense) for the three months ended September 30, 2020 and 2019 consists of the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Three months ended  September 30, 2020 | |  |  | Three months ended  September 30, 2019 | |  |
| Interest expense |  | $ | (7,151 | ) |  | $ | (96,271 | ) |
| Other income |  |  | - |  |  |  | 34,106 |  |
| Non-operating income (expense) |  | $ | (7,151 | ) |  | $ | (62,165 | ) |

Non-operating income (expense) for the three months ended September 30, 2020 varied from the three months ended September 30, 2019 primarily due to an increase in interest expense from as a result of the debt increase from 2019 to 2020 prior to conversion of this debt. The majority of the interest recorded by the Company consists of amortization of debt discount, BCF discount and the exchange premium resulting in additional shares to the noteholders on conversion.

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***Net Loss***

Our net loss for the three months ended September 30, 2020 and 2019 was $(135,591) and $(669,372), respectively.

**Liquidity and Capital Resources**

At September 30, 2020, the Company had a working capital deficit of $870,233 as compared to $1,479,689 at December 31, 2019. During the nine months ended September 30, 2020 the Company experienced negative cash flow from operations of $510,227 and it received $0 for investing activities while adding $504,780 of cash flows from financing activities. As of September 30, 2020, the Company had no commitments for capital expenditures.

Cash used in operating activities was primarily a result of the Company’s net loss, and the adjustments to reconcile the net loss to net cash which included the amortization of discounts as well as expense related to the warrants granted to note holders and the exchange premium recognized for the conversion of notes. Additionally there were increases in accrued payroll and accrued interest. The Company had no investing activities for the nine-month periods ended September 30, 2020 and 2019, respectively. In the nine months ended September 30, 2020 and 2019, the Company had cash provided by financing activities of $504,780 and $737,000, respectively. These activities were the result of proceeds received from notes payable (both related and unrelated parties) as well as from sales of common stock and preferred stock.

The Company has generated material operating losses since inception. The Company had a net loss of $654,909 for the nine months ended September 30, 2020, and a net loss of $1,106,059 for the nine months ended September 30, 2019. The Company expects to continue to experience net operating losses. Historically, the Company has relied upon investor funds to maintain its operations and develop the Company’s business.

The Company received $497,880 which were deposited into the Company’s accounts between April and June 2020. Following the clearance of the Regulation A+ offering by the SEC on June 3, 2020, the common shares for these proceeds were issued. In addition, the Company exchanged their outstanding convertible notes payable of $525,000, $27,536 in accrued interest and $98,508 in an exchange premium stipulated in the note agreements into shares of common stock through September 30, 2020, and repaid $50,000 in promissory notes payable.

Over the next 12 to 24 months, the Company believes it will cost approximately $5.0 million to $10.0 million to: (1) fund the FDA approval process and initial deployment of the brachytherapy products, and (2) initiate regulatory approval processes outside of the United States. The continued deployment of the brachytherapy products and a worldwide regulatory approval effort will require additional resources and personnel. The principal variables in the timing and amount of spending for the brachytherapy products in the next 12 to 24 months will be the FDA’s classification of the Company’s brachytherapy products as Class II or Class III devices (or otherwise) and any requirements for additional studies which may possibly include clinical studies. Thereafter, the principal variables in the amount of the Company’s spending and its financing requirements would be the timing of any approvals and the nature of the Company’s arrangements with third parties for manufacturing, sales, distribution and licensing of those products and the products’ success in the U.S. and elsewhere. The Company intends to fund its activities through strategic transactions such as licensing and partnership agreements or additional capital raises.

Following receipt of required regulatory approvals and financing, in the U.S., the Company intends to outsource material aspects of manufacturing, distribution, sales and marketing. Outside of the U.S., the Company intends to pursue licensing arrangements and/or partnerships to facilitate its global commercialization strategy.

In the longer-term, subject to the Company receiving adequate funding, regulatory approval for RadioGel™ and other brachytherapy products, and thereafter being able to successfully commercialize its brachytherapy products, the Company intends to consider resuming research efforts with respect to other products and technologies intended to help improve the diagnosis and treatment of cancer and other illnesses.

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Based on the Company’s financial history since inception, the Company’s independent registered public accounting firm has expressed substantial doubt as to the Company’s ability to continue as a going concern. The Company has limited revenue, nominal cash, and has accumulated deficits since inception. If the Company cannot obtain sufficient additional capital, the Company will be required to delay the implementation of its business strategy and may not be able to continue operations.

The Company has been impacted from the effects of COVID-19. The Company’s headquarters are in Northeast Washington however there focus of the animal therapy market has been the Northwestern sector of the United States, the initial epicenter of the COVID-19 outbreak in the United States. In addition to a slow down in the marketing of the services, the volatility of the stock market has contributed to a lack of funds that ordinarily may have been available to the Company. The Company is hopeful that by the end of the third quarter of 2020, they will be allowed to continue their marketing to the animal therapy market and attempt to increase the exposure to their product and generate revenue accordingly.

The financial statements do not include any adjustments relating to the recoverability and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company’s continuation as a going concern is dependent upon its ability to generate sufficient cash flow to meet its obligations on a timely basis and ultimately to attain profitability. The Company plans to seek additional funding to maintain its operations through debt and equity financing and to improve operating performance through a focus on strategic products and increased efficiencies in business processes and improvements to the cost structure. There is no assurance that the Company will be successful in its efforts to raise additional working capital or achieve profitable operations. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Accounting Policies and Estimates**

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results could differ from these estimates under different assumptions or conditions. During the period ended September 30, 2020, we believe there have been no significant changes to the items disclosed as significant accounting policies in management’s notes to the financial statements in our annual report on Form 10-K for the year ended December 31, 2019, filed on April 28, 2020.

**Off-Balance Sheet Arrangements**

The Company does not have any off-balance sheet arrangements that are reasonably likely to have a current or future effect on the Company’s financial condition, revenues, results of operations, liquidity or capital expenditures.

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

This item is not applicable to us because we are a smaller reporting company as defined by Rule 12b-2 under the Securities Exchange Act of 1934.

**Item 4. Controls and Procedures.**

**Disclosure Controls and Procedures**

Based on an evaluation as of the date of the end of the period covered by this report, the Company’s Chief Executive Officer and Interim Chief Financial Officer conducted an evaluation of the effectiveness of the design and operation of the Company’s disclosure controls and procedures, as required by Exchange Act Rule 13a-15. Based on that evaluation, the Company’s Chief Executive Officer and Interim Chief Financial Officer concluded that, because of the disclosed material weaknesses in the Company’s internal control over financial reporting, the Company’s disclosure controls and procedures were ineffective as of the end of the period covered by this report to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the SEC’s rules and forms.

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Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in the Company’s reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the Company’s reports filed under the Exchange Act is accumulated and communicated to management, including the Company’s Chief Executive Officer and the Company’s Interim Chief Financial Officer, to allow timely decisions regarding required disclosure.

**Changes in Internal Control Over Financial Reporting**

There have been no changes in the Company’s internal control over financial reporting that occurred during the period ended September 30, 2020 that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting.

The term “internal control over financial reporting” is defined as a process designed by, or under the supervision of, the registrant’s principal executive and principal financial officers, or persons performing similar functions, and effected by the registrant’s board of directors, management and other personnel, 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 and includes those policies and procedures that:

|  |  |  |
| --- | --- | --- |
|  | (a) | Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the registrant; |
|  |  |  |
|  | (b) | Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the registrant are being made only in accordance with authorizations of management and directors of the registrant; and |
|  |  |  |
|  | (c) | Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the registrant’s assets that could have a material effect on the financial statements. |

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**PART II**

**Item 1. Legal Proceedings**

The Company may, from time to time, be involved in various legal proceedings incidental to the conduct of our business. Historically, the outcome of all such legal proceedings has not, in the aggregate, had a material adverse effect on our business, financial condition, results of operations or liquidity. Other than as set forth below, there are no additional material pending or threatened legal proceedings at this time.

On January 28, 2019, James Katzaroff, (“*Plaintiff*”) the Company’s former Chief Executive Officer filed a lawsuit in the Superior Court in the State of Washington in and for the County of Benton against the Company and its current and former directors, alleging a default of the Separation Agreement and General Release (“*Release*”) that the Company entered into with Plaintiff on July 21, 2017 (the “*Complaint*”). The Company has made required payments under the Release.

On November 25, 2019, the Company and its current and former directors entered into a Settlement Agreement with the Plaintiff. Under the terms of the Settlement Agreement, the Company has agreed to issue 500,000 shares of common stock and 500,000 warrants to the Plaintiff, make an initial payment of $33,503 by December 4, 2019 and beginning on December 16, 2019, the Company will make payments of $10,000 per month for 10 months in full satisfaction of the Separation Agreement and General Release originally entered into on July 21, 2017. The Company has paid this liability in full as of September 11, 2020.

**Item 2. Unregistered Sales of Equity Securities**

The Company in January 2020 paid $50,000 to redeem 100,000 shares of Series B Convertible Preferred Stock. The redemption price was agreed to by the investor.

The Company issued a convertible note in the amount of $100,000 to an accredited investor. The note bears interest at 8% per annum and matures March 31, 2020. The Company granted 1,250,000 warrants with an exercise price of $0.06 per share and a term of two years with this note and amended 1,312,500 previously issued warrants held by the investor to provide for a $.06 exercise price and an expiration date of March 31, 2022.

In January 2020, the Company converted 435,990 shares of Series C Convertible Preferred stock into 5,449,875 shares of common stock.

The Company received $497,880 which were deposited into the Company’s accounts between April and June 2020. Following the clearance of the Regulation A+ offering by the SEC on June 3, 2020, the common shares for these proceeds were issued. In addition, the Company exchanged their outstanding convertible notes payable of $525,000, $27,536 in accrued interest and $98,508 in an exchange premium stipulated in the note agreements into shares of common stock through September 30, 2020.

The Company converted $50,000 of promissory notes payable into 1,851,852 shares effective July 14, 2020.

In connection with the above stock sales, we did not pay any underwriting discounts or commissions. None of the sales of securities described or referred to above was registered under the Securities Act of 1933, as amended (the “Securities Act”). For sales made pursuant to an exemption from registration contained in Section 4(a)(2) of the Securities Act, no general solicitation was used in connection with the sales.

**Item 6. Exhibits.**

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| **Exhibit** |  |  |
| **Number** |  | **Description** |
|  |  |  |
| 31.1\* |  | [Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes – Oxley Act of 2002](ex31-1.htm) |
|  |  |  |
| 31.2\* |  | [Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes – Oxley Act of 2002](ex31-2.htm) |
|  |  |  |
| 32.1\* |  | [Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350](ex32-1.htm) |
|  |  |  |
| 101.INS |  | XBRL Instance Document |
|  |  |  |
| 101.SCH |  | XBRL Taxonomy Extension Schema |
|  |  |  |
| 101.CAL |  | XBRL Taxonomy Extension Calculation Linkbase |
|  |  |  |
| 101.DEF |  | XBRL Taxonomy Extension Definition Linkbase |
|  |  |  |
| 101.LAB |  | XBRL Taxonomy Extension Label Linkbase |
|  |  |  |
| 101.PRE |  | XBRL Taxonomy Extension Presentation Linkbase |

\* Filed herewith.

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**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 hereunto duly authorized.

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|  | Vivos Inc. | |
|  |  |  |
| Date: November 2, 2020 | By: | */s/ Michael Korenko* |
|  | Name: | Michael K. Korenko |
|  | Title: | Chief Executive Officer |
|  |  | (Principal Executive Officer) |

|  |  |  |
| --- | --- | --- |
| Date: November 2, 2020 | By: | */s/ Michael Pollack* |
|  | Name: | Michael Pollack |
|  | Title: | Interim Chief Financial Officer |
|  |  | (Interim Principal Financial and Accounting Officer) |

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