**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: June 30, 2019

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 August 13, 2019, there were 177,710,821 shares of the registrant’s common stock outstanding, 2,552,642 shares of the registrant’s Series A Convertible Preferred Stock outstanding, 1,543,245 of the registrant’s Series B Convertible Preferred Stock outstanding and 821,292 of the registrant’s Series C Convertible Preferred Stock outstanding.

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**TABLE OF CONTENTS**

|  |  |  |
| --- | --- | --- |
|  |  | **Page** |
|  | [**PART I – FINANCIAL INFORMATION**](#a_001) |  |
|  |  |  |
| Item 1. | [Condensed Financial Statements](#a_002) | 1 |
|  |  |  |
|  | [Condensed Balance Sheets as of June 30, 2019 (unaudited) and December 31, 2018](#a_003) | 1 |
|  |  |  |
|  | [Condensed Statements of Operations for the Six and Three Months ended June 30, 2019 and 2018 (unaudited)](#a_004) | 2 |
|  |  |  |
|  | [Condensed Statement of Changes in Stockholders’ Deficit for the Six Months Ended June 30, 2019 (unaudited) and Year Ended December 31, 2018](#a_005) | 3 |
|  |  |  |
|  | [Condensed Statements of Cash Flow for the Six Months ended June 30, 2019 and 2018 (unaudited)](#a_006) | 4 |
|  |  |  |
|  | [Notes to Condensed Financial Statements (unaudited)](#a_007) | 5 |
|  |  |  |
| Item 2. | [Management’s Discussion and Analysis of Financial Condition and Results of Operations](#a_008) | 24 |
|  |  |  |
| Item 3. | [Quantitative and Qualitative Disclosures About Market Risk](#a_009) | 31 |
|  |  |  |
| Item 4. | [Controls and Procedures](#a_010) | 31 |
|  |  |  |
|  | [**PART II – OTHER INFORMATION**](#a_011) |  |
|  |  |  |
| Item 2. | [Unregistered Sales of Equity Securities and Use of Proceeds](#a_013) | 32 |
|  |  |  |
| Item 6. | [Exhibits](#a_014) | 32 |
|  |  |  |
| [**SIGNATURES**](#a_015) | | 33 |

|  |
| --- |
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**PART I – FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

**VIVOS INC**

**CONDENSED BALANCE SHEETS**

**JUNE 30, 2019 (UNAUDITED) AND DECEMBER 31, 2018**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **JUNE 30, 2019** | |  |  | **DECEMBER 31, 2018** | |  |
|  |  | **(UNAUDITED)** | |  |  |  | |  |
| **ASSETS** |  |  | |  |  |  | |  |
|  |  |  | |  |  |  | |  |
| Current Assets: |  |  |  |  |  |  |  |  |
| Cash |  | $ | 8,502 |  |  | $ | 5,494 |  |
| Prepaid expenses |  |  | 39,785 |  |  |  | 10,992 |  |
|  |  |  |  |  |  |  |  |  |
| Total Current Assets |  |  | 48,287 |  |  |  | 16,486 |  |
|  |  |  |  |  |  |  |  |  |
| **TOTAL ASSETS** |  | $ | 48,287 |  |  | $ | 16,486 |  |
|  |  |  |  |  |  |  |  |  |
| **LIABILITIES AND STOCKHOLDERS’ DEFICIT** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **LIABILITIES** |  |  |  |  |  |  |  |  |
| Current Liabilities: |  |  |  |  |  |  |  |  |
| Accounts payable and accrued expenses |  | $ | 779,299 |  |  | $ | 795,129 |  |
| Related party accounts payable |  |  | 40,585 |  |  |  | 38,610 |  |
| Accrued interest payable |  |  | 69,209 |  |  |  | 59,646 |  |
| Payroll liabilities payable |  |  | 50,000 |  |  |  | 11,451 |  |
| Advances - officer |  |  | 15,000 |  |  |  | - |  |
| Convertible notes payable, net |  |  | 96,731 |  |  |  | 53,824 |  |
| Promissory notes payable, net of discount |  |  | 92,043 |  |  |  | - |  |
| Related party promissory note |  |  | 137,000 |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |
| Total Current Liabilities |  |  | 1,279,867 |  |  |  | 958,660 |  |
|  |  |  |  |  |  |  |  |  |
| **Total Liabilities** |  |  | 1,279,867 |  |  |  | 958,660 |  |
|  |  |  |  |  |  |  |  |  |
| 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, 1,543,245 and 3,305,755 shares issued and outstanding, respectively |  |  | 1,544 |  |  |  | 3,306 |  |
| Additional paid in capital - Series B Convertible preferred stock |  |  | 836,765 |  |  |  | 1,876,768 |  |
| Series C Convertible Preferred, 5,000,000 shares authorized, 821,292 and 0 shares issued and outstanding, respectively |  |  | 821 |  |  |  | - |  |
| Additional paid in capital - Series C Convertible preferred stock |  |  | 674,457 |  |  |  | - |  |
| Common stock, par value, $0.001, 950,000,000 and 2,000,000,000 shares authorized, 177,710,821 and 163,445,736 issued and outstanding, respectively |  |  | 177,711 |  |  |  | 163,446 |  |
| Additional paid in capital - common stock |  |  | 60,631,642 |  |  |  | 60,132,139 |  |
| Accumulated deficit |  |  | (72,427,699 | ) |  |  | (71,991,012 | ) |
|  |  |  |  |  |  |  |  |  |
| **Total Stockholders’ Deficit** |  |  | (1,231,580 | ) |  |  | (942,174 | ) |
|  |  |  |  |  |  |  |  |  |
| **TOTAL LIABILITIES AND STOCKHOLDERS’ DEFICIT** |  | $ | 48,287 |  |  | $ | 16,486 |  |

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

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**VIVOS INC**

**CONDENSED STATEMENTS OF OPERATIONS (UNAUDITED)**

**FOR THE SIX AND THREE MONTHS ENDED JUNE 30, 2019 AND 2018**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **SIX MONTHS ENDED** | | | | | |  |  | **THREE MONTHS ENDED** | | | | | |  |
|  |  | **JUNE 30, 2019** | |  |  | **JUNE 30, 2018** | |  |  | **JUNE 30, 2019** | |  |  | **JUNE 30, 2018** | |  |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| **Consulting revenues, net** |  | $ | - |  |  | $ | - |  |  | $ | - |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **OPERATING EXPENSES** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Sales and marketing expenses |  |  | - |  |  |  | 12,950 |  |  |  | - |  |  |  | 2,950 |  |
| Professional fees |  |  | 269,173 |  |  |  | 215,278 |  |  |  | 102,638 |  |  |  | 145,220 |  |
| Reserved stock units granted |  |  | - |  |  |  | 84,895 |  |  |  | - |  |  |  | 32,801 |  |
| Stock based compensation |  |  | 5,968 |  |  |  | 45,400 |  |  |  | 2,176 |  |  |  | 21,645 |  |
| Payroll expenses |  |  | 60,000 |  |  |  | 161,070 |  |  |  | 30,000 |  |  |  | 82,200 |  |
| Research and development |  |  | 43,702 |  |  |  | 74,580 |  |  |  | 20,016 |  |  |  | 41,766 |  |
| General and administrative expenses |  |  | 19,376 |  |  |  | 34,421 |  |  |  | 18,186 |  |  |  | 15,318 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Total Operating Expenses |  |  | 398,219 |  |  |  | 628,594 |  |  |  | 173,016 |  |  |  | 341,900 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **OPERATING LOSS** |  |  | (398,219 | ) |  |  | (628,594 | ) |  |  | (173,016 | ) |  |  | (341,900 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **NON-OPERATING INCOME (EXPENSE)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Interest expense |  |  | (38,468 | ) |  |  | (5,566,140 | ) |  |  | (27,289 | ) |  |  | (4,934,066 | ) |
| Net gain on debt extinguishment |  |  | - |  |  |  | 131,604 |  |  |  | - |  |  |  | 131,604 |  |
| Net loss on derivative liability |  |  | - |  |  |  | (867,608 | ) |  |  | - |  |  |  | (867,608 | ) |
| Grant income |  |  | - |  |  |  | 17,583 |  |  |  | - |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Total Non-Operating Income (Expenses) |  |  | (38,468 | ) |  |  | (6,284,561 | ) |  |  | (27,289 | ) |  |  | (5,670,070 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **NET LOSS BEFORE PROVISION FOR INCOME TAXES** |  |  | (436,687 | ) |  |  | (6,913,155 | ) |  |  | (200,305 | ) |  |  | (6,011,970 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Provision for income taxes |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **NET LOSS** |  | $ | (436,687 | ) |  | $ | (6,913,155 | ) |  | $ | (200,305 | ) |  | $ | (6,011,970 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Net loss per share - basic and diluted** |  | $ | (0.00 | ) |  | $ | (0.71 | ) |  | $ | (0.00 | ) |  | $ | (0.54 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Weighted average common shares outstanding - basic** |  |  | 169,693,285 |  |  |  | 9,762,923 |  |  |  | 173,196,401 |  |  |  | 11,038,538 |  |

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

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**VIVOS INC**

**CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS’ DEFICIT**

**FOR THE SIX MONTHS ENDED JUNE 30, 2019 (UNAUDITED) AND YEAR ENDED DECEMBER 31, 2018**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | |  |  |  | |  |  | **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 -** | |  |  | **Accumulated** | |  |  |  | |  |
|  |  | **Shares** | |  |  | **Amount** | |  |  | **Preferred** | |  |  | **Shares** | |  |  | **Amount** | |  |  | **Preferred** | |  |  | **Shares** | |  |  | **Amount** | |  |  | **Preferred** | |  |  | **Shares** | |  |  | **Amount** | |  |  | **Common** | |  |  | **Deficit** | |  |  | **Total** | |  |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| Balance - December 31, 2017 |  |  | 3,778,622 |  |  | $ | 3,779 |  |  | $ | 13,547,780 |  |  |  | - |  |  | $ | - |  |  | $ | - |  |  |  | - |  |  | $ | - |  |  | $ | - |  |  |  | 8,211,902 |  |  | $ | 8,212 |  |  | $ | 46,465,926 |  |  | $ | (64,288,167 | ) |  | $ | (4,262,470 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 1,250 |  |  |  | 1 |  |  |  | 448 |  |  |  | - |  |  |  | 449 |  |
| Conversion of preferred stock into common stock |  |  | (574,200 | ) |  |  | (575 | ) |  |  | (3,236,164 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 717,750 |  |  |  | 718 |  |  |  | 3,236,021 |  |  |  | - |  |  |  | - |  |
| Restricted units vested |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 77,500 |  |  |  | 78 |  |  |  | (78 | ) |  |  | - |  |  |  | - |  |
| Reserved shares for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 52,094 |  |  |  | - |  |  |  | 52,094 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 23,766 |  |  |  | - |  |  |  | 23,766 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (901,185 | ) |  |  | (901,185 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - March 31, 2018 |  |  | 3,204,422 |  |  |  | 3,204 |  |  |  | 10,311,616 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 9,008,402 |  |  |  | 9,009 |  |  |  | 49,778,177 |  |  |  | (65,189,352 | ) |  |  | (5,087,346 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Settlement of debt |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 5,143,258 |  |  |  | 5,143 |  |  |  | 371,038 |  |  |  | - |  |  |  | 376,181 |  |
| Conversion of preferred stock into common stock |  |  | (392,467 | ) |  |  | (393 | ) |  |  | (735,811 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 490,584 |  |  |  | 490 |  |  |  | 735,714 |  |  |  | - |  |  |  | - |  |
| Restricted units vested |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 77,500 |  |  |  | 78 |  |  |  | (78 | ) |  |  | - |  |  |  | - |  |
| Reserved shares for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 32,801 |  |  |  | - |  |  |  | 32,801 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 21,645 |  |  |  | - |  |  |  | 21,645 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (6,011,970 | ) |  |  | (6,011,970 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - June 30, 2018 |  |  | 2,811,955 |  |  |  | 2,811 |  |  |  | 9,575,805 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 14,719,744 |  |  |  | 14,720 |  |  |  | 50,939,297 |  |  |  | (71,201,322 | ) |  |  | (10,668,689 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Settlement of debt |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 74,558,393 |  |  |  | 74,558 |  |  |  | 2,789,922 |  |  |  | - |  |  |  | 2,864,480 |  |
| Conversion of preferred stock into common stock |  |  | (41,016 | ) |  |  | (41 | ) |  |  | (77,671 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 51,270 |  |  |  | 51 |  |  |  | 77,661 |  |  |  | - |  |  |  | - |  |
| Restricted units vested |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 77,500 |  |  |  | 78 |  |  |  | (78 | ) |  |  | - |  |  |  | - |  |
| Reserved shares for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 19,514 |  |  |  | - |  |  |  | 19,514 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (26,912,414 | ) |  |  | (26,912,414 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - September 30, 2018 |  |  | 2,770,939 |  |  |  | 2,770 |  |  |  | 9,498,134 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 89,406,907 |  |  |  | 89,407 |  |  |  | 53,826,316 |  |  |  | (98,113,736 | ) |  |  | (34,697,109 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cash |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 110,000 |  |  |  | 110 |  |  |  | 54,890 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 17,078,500 |  |  |  | 17,078 |  |  |  | 666,062 |  |  |  | - |  |  |  | 738,140 |  |
| Settlement of debt |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 2,995,755 |  |  |  | 2,996 |  |  |  | 1,542,078 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 48,827,137 |  |  |  | 48,827 |  |  |  | 2,346,420 |  |  |  | - |  |  |  | 3,940,321 |  |
| Accounts payable and accrued expenses |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 200,000 |  |  |  | 200 |  |  |  | 279,800 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 7,782,820 |  |  |  | 7,783 |  |  |  | 1,377,513 |  |  |  | - |  |  |  | 1,665,296 |  |
| Conversion of preferred stock into common stock |  |  | (218,297 | ) |  |  | (217 | ) |  |  | (627,508 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 272,872 |  |  |  | 273 |  |  |  | 627,452 |  |  |  | - |  |  |  | - |  |
| Restricted units vested |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 77,500 |  |  |  | 78 |  |  |  | (78 | ) |  |  | - |  |  |  | - |  |
| Reserved shares for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 8,779 |  |  |  | - |  |  |  | 8,779 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 1,279,675 |  |  |  | - |  |  |  | 1,279,675 |  |
| Net income for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 26,122,724 |  |  |  | 26,122,724 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 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 | ) |  |  | (524 | ) |  |  | (209,163 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 6,552,725 |  |  |  | 6,553 |  |  |  | 203,134 |  |  |  | - |  |  |  | - |  |
| 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 |  |  |  | 2,061 |  |  |  | 1,043,048 |  |  |  | 821,292 |  |  |  | 821 |  |  |  | 674,457 |  |  |  | 171,248,461 |  |  |  | 171,249 |  |  |  | 60,416,536 |  |  |  | (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 |  |  | $ | 1,544 |  |  | $ | 836,765 |  |  |  | 821,292 |  |  | $ | 821 |  |  | $ | 674,457 |  |  |  | 177,710,821 |  |  | $ | 177,711 |  |  | $ | 60,631,642 |  |  | $ | (72,427,699 | ) |  | $ | (1,231,580 | ) |

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

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**VIVOS INC**

**CONDENSED STATEMENTS OF CASH FLOWS (UNAUDITED)**

**FOR THE SIX MONTHS ENDED JUNE 30, 2019 AND 2018**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **2019** | |  |  | **2018** | |  |
| **CASH FLOW FROM OPERTING ACTIVIITES** |  |  |  |  |  |  |  |  |
| Net loss |  | $ | (436,687 | ) |  | $ | (6,913,155 | ) |
| Adjustments to reconcile net loss to net cash used in operating activities |  |  |  |  |  |  |  |  |
| Amortization of convertible debt discount |  |  | 25,374 |  |  |  | 791,938 |  |
| Common stock issued for services |  |  | - |  |  |  | 449 |  |
| Stock options and warrants for services |  |  | 5,968 |  |  |  | 45,400 |  |
| Reserved stock units issued for services |  |  | - |  |  |  | 84,895 |  |
| Derivatives recorded as loan fees |  |  | - |  |  |  | 4,636,517 |  |
| (Gain) on debt extinguishment |  |  | - |  |  |  | (131,604 | ) |
| Loss of derivative liability |  |  | - |  |  |  | 867,608 |  |
| **Changes in assets and liabilities** |  |  |  |  |  |  |  |  |
| Prepaid expenses and other assets |  |  | (28,793 | ) |  |  | (781 | ) |
| Accounts payable and accrued expenses |  |  | (14,941 | ) |  |  | 266,795 |  |
| Accounts payable and accrued expenses from related party |  |  | 1,975 |  |  |  | (13,284 | ) |
| Payroll liabilities |  |  | 38,549 |  |  |  | 130,650 |  |
| Accrued interest |  |  | 9,563 |  |  |  | 137,696 |  |
| Total adjustments |  |  | 37,695 |  |  |  | 6,816,279 |  |
|  |  |  |  |  |  |  |  |  |
| **Net cash used in operating activities** |  |  | (398,992 | ) |  |  | (96,876 | ) |
|  |  |  |  |  |  |  |  |  |
| **CASH FLOWS FROM FINANCING ACTIVITES** |  |  |  |  |  |  |  |  |
| Proceeds from promissory notes |  |  | 150,000 |  |  |  | - |  |
| Proceeds from related party notes payable |  |  | 137,000 |  |  |  | - |  |
| Proceeds from sale of preferred stock |  |  | 50,000 |  |  |  | - |  |
| Proceeds from sale of common stock |  |  | 50,000 |  |  |  | - |  |
| Proceeds from related party and shareholder advances, net of repayments |  |  | 15,000 |  |  |  | 88,559 |  |
| **Net cash provided by financing activities** |  |  | 402,000 |  |  |  | 88,559 |  |
|  |  |  |  |  |  |  |  |  |
| **NET INCREASE (DECREASE) IN CASH** |  |  | 3,008 |  |  |  | (8,317 | ) |
|  |  |  |  |  |  |  |  |  |
| **CASH - BEGINNING OF PERIOD** |  |  | 5,494 |  |  |  | 8,317 |  |
|  |  |  |  |  |  |  |  |  |
| **CASH - END OF PERIOD** |  | $ | 8,502 |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |
| **CASH PAID DURING THE PERIOD FOR:** |  |  |  |  |  |  |  |  |
| Interest expense |  | $ | - |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |
| Income taxes |  | $ | - |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |
| **SUPPLEMENTAL INFORMATION - NON-CASH INVESTING AND FINANCING ACTIVITIES:** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Conversion of preferred stock into common stock |  | $ | 416,487 |  |  | $ | 3,972,942 |  |
| Conversion of convertible preferred B into convertible preferred C |  | $ | 675,278 |  |  | $ | - |  |
| Recognition of debt discount at inception of notes payable |  | $ | 41,313 |  |  | $ | - |  |
| Vesting of restricted stock units |  | $ | - |  |  | $ | 1,240 |  |
| Reclassification of shareholder advances to convertible notes payable |  | $ | - |  |  | $ | 32,279 |  |
| Conversion of notes payable and accrued interest into common stock |  | $ | - |  |  | $ | 376,181 |  |

The accompanying notes are an integral part of these condensed 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 three months ended March 31, 2019, are not necessarily indicative of the results that may be expected for any future period or the fiscal year ending December 31, 2019 and should be read in conjunction with the Company’s Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission on March 25, 2019.

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.

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*”) for a discussion regarding the Company’s application for FDA approval of RadioGel™.

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**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. To date, four dogs, listed below as Dog A, Dog B, Dog C, and Dog D, respectively, have been treated with IsoPet® at the University of Missouri.

Dog A was treated for canine soft tissue sarcoma in June 2018. 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 principal investigator from the University of Missouri rated the tumor as CR, Complete Response, after three months. This RECIST rating means that the tumor was completely eliminated by the IsoPet therapy. Dog B which was treated in July 2018 has displayed encouraging results. This patient had transient mild acute radiation side effects and had SD (stable disease) at the time of recheck. There was a small amount of growth, but not enough to be considered progression per the RECIST criteria. The CT on its last visit in February 2019 showed that the tumor site had a slightly larger but diffuse image. Based on this single observation, the diffuse image could mean that the hydrogel, in addition to trapping the particles, provides a secondary benefit of locking in the dead tumor tissue allowing for a slower rate of resorption of the necrotic tissue. This could be a positive outcome whereas killing a tumor and having it resorb within the tissue all at once might be a shock to the animal’s system. The latest examination confirmed the original tumor therapy was successful; however the tumor re-occurred, which is a characteristic of soft tissue sarcomas. This and the re-occurrence of the tumor in Dog B led to a recommendation for future therapy to treat a wide margin around the original tumor. This approach was used on the first commercial therapy at our pilot, Vista Veterinary Hospital. We will continue to monitor how this case proceeds.

Dog D was treated in January 2019. This very large, half-pound, tumor was initially scheduled for therapy in December 2018 but had to be rescheduled due to the hydrogel not meeting our rigid specifications. From this, we learned that frozen hydrogel has a limited shelf-life and this allowed us to make the appropriate adjustments to our product specifications. This patient had mild to moderate acute radiation side effects and has SD (stable disease) one-month post treatment. The February follow-up included a CT scan. The mass showed no new growth and measured almost the same as it did at the time of treatment. There is a small region at the bottom of the tumor where the mass seems to be draining. The tumor around the highest dose region appears dead with no blood supply, according to the CT. Dog D was outside of the scope of our criteria as an eligible patient prospect and we deem the patient as likely terminal, however, we treated it for humanitarian reasons and for discovery to determine residual effects of the treatment. Dog D was treated for canine soft tissue sarcoma in February 2019 Recent examinations indicate that the tumor was killed, but the dog was having trouble absorbing such a large mass. It has become infected and should be removed. In the future, the recommendation will be to surgically remove the large tumors after approximately two weeks, after all the beta radiation has been absorbed. These animal therapies generate data to assure the private veterinary clinics of the safety and efficacy of IsoPet®.

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.

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On July 10, 2019, the Company recognized its first commercial sale of IsoPet®. Dr. Burgess Bauder from Sitka, Alaska 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.

**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.

**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 six-months ended June 30, 2019 and for the year ended December 31, 2018.

**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 June 30, 2019 and December 31, 2018, 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.

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**Derivative Liabilities**

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.

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.

**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.

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**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.

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%).

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Calendar Year** |  | **Minimum**  **Royalties per**  **Calendar Year** | |  |
| 2019 |  | $ | 10,000 |  |
| 2020 |  |  | 10,000 |  |
| 2021 |  |  | 25,000 |  |
| 2022 |  |  | 25,000 |  |
| Total |  | $ | 70,000 |  |

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 Company entered into a Letter Amendment #2 with Battelle Memorial Institute on December 20, 2018. as a result of this Amendment, the Company has agreed to revised terms regarding the license fee as indicated in the chart above. $10,000 of this fee due within 1 year relates to the 2018 license fee which was paid in January 2019. The Company also agreed to increase the royalty fee on net sales from 1% to 2%.

**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 six-months ended June 30, 2019 and 2018, 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.

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**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.

**Income from Grants and Deferred Income**

Government grants are recognized when all conditions of such grants are fulfilled or there is reasonable assurance that they will be fulfilled. The Company has chosen to recognize income from grants as it incurs costs associated with those grants, and until such time as it recognizes the grant as income those funds received will be classified as deferred income on the balance sheet.

On December 22, 2017, the Company received notification that Washington State University awarded it $17,500 of grant funds from the sub-award project entitled “*Optimized Injectable Radiogels for High-dose Therapy of Non-Resectable Solid Tumors*”. The Company received the $17,500 of the grant award in the six-months ended June 30, 2018.

**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 int eh six and three months ended June 30, 2019 and 2018, 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 June 30, 2019 and December 31, 2018, which include the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | June 30, 2019 | |  |  | December 31, 2018 | |  |
| Convertible debt |  |  | 1,892,594 |  |  |  | 17,594 |  |
| Preferred stock |  |  | 32,747,515 |  |  |  | 44,512,740 |  |
| Common stock options |  |  | 11,654,271 |  |  |  | 11,318,021 |  |
| Common stock warrants |  |  | 26,261,847 |  |  |  | 23,052,472 |  |
| Total potential dilutive securities |  |  | 72,556,227 |  |  |  | 78,900,827 |  |

**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.

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The Company incurred $43,702 and $74,580 research and development costs for the six-months ended June 30, 2019, and 2018, respectively, all of which were recorded in the Company’s operating expenses noted on the statements of operations for the three and six 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. There were no tradeshow expenses incurred and not expensed for the six-months ended June 30, 2019 and 2018, respectively. During the six-months ended June 30, 2019 and 2018, the Company incurred $0 and $12,950, respectively, in advertising and marketing costs.

**Shipping and Handling Costs**

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

**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. See Note 9 – Legal Matters for description of lawsuit filed against the Company on January 28, 2019. In addition, 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 June 30, 2019 and 2018.

**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 six-months ended June 30, 2019 and 2018. The Company did not have any deferred tax liability or asset on its balance sheet on June 30, 2019 and December 31, 2018.

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 six-months ended June 30, 2019 and 2018, 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.

The Tax Cuts and Jobs Act (the “*Act*”) was enacted on December 22, 2017. The Act reduces the U.S. federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced earnings.

These amounts are provisional and subject to change. The most significant impact of the legislation for the Company was a $3,300,000 reduction of the value of net deferred tax assets (which represent future tax benefits) as a result of lowering the U.S. corporate income tax rate from 35% to 21%. The Act also includes a requirement to pay a one-time transition tax on the cumulative value of earnings and profits that were previously not repatriated for U.S. income tax purposes. The Company has no earnings and profits that were previously not repatriated for U.S. income tax purposes.

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**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.

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.

**Recent Accounting Pronouncements**

In January 2017, the FASB issued ASU 2017-04, “Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment”, which eliminates Step 2 from the goodwill impairment test. When an indication of impairment was identified after performing the first step of the goodwill impairment test, Step 2 required that an entity determine the fair value at the impairment testing date of its assets and liabilities (including unrecognized assets and liabilities) using the same procedure that would be required in determining the fair value of assets acquired and liabilities assumed in a business combination. Under the amendments in ASU No. 2017-04, an entity would perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying value. An entity would recognize an impairment charge for the amount by which the carrying value exceeds the reporting unit’s fair value.

In addition, an entity must consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. A public business entity that is a SEC filer should adopt the amendments in ASU No. 2017-04 for its annual, or any interim, good will impairment tests in fiscal years beginning after December 15, 2019. The Company does not believe the guidance will have a material impact on its financial statements.

In August 2018, the FASB issued ASU 2018-13, “Changes to Disclosure Requirements for Fair Value Measurements,” which will improve the effectiveness of disclosure requirements for recurring and nonrecurring fair value measurements. The standard removes, modifies, and adds certain disclosure requirements, and is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company does not believe the guidance will have a material impact on its financial statements.

Other accounting standards that have been issued or proposed by FASB that do not require adoption until a future date are not expected to have a material impact on the consolidated financial statements upon adoption. 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.

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**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 $2.3 million annually to maintain current operating activities. 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 completed its reverse stock split which was approved by FINRA and went effective on June 28, 2019 which will enable them to begin the process of raising capital through their Regulation A+ which was filed with the Securities and Exchange Commission (“SEC”) on June 30, 2019 now that the Company has available authorized shares to issue.

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.

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**NOTE 3: FIXED ASSETS**

Fixed assets consist of the following at June 30, 2019 (unaudited) and December 31, 2018:

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | June 30, 2019 | |  |  | December 31, 2018 | |  |
| Production equipment |  | $ | - |  |  | $ | 15,182 |  |
| Less accumulated depreciation |  |  | (- | ) |  |  | (15,182 | ) |
|  |  | $ | - |  |  | $ | - |  |

There is no depreciation expense for the above fixed assets for the six months ended June 30, 2019 and 2018, 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 June 30, 2019 (unaudited) and December 31, 2018, the Company had the following related party convertible notes outstanding:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | June 30, 2019 | | | | |  |  |  | December 31, 2018 | | | | |  |
|  |  |  | Principal  (net) |  |  |  | Accrued  Interest |  |  |  | Principal  (net) |  |  |  | Accrued  Interest |  |
| March 2017 $332,195 Note, 10% interest, due May 2017 |  | $ | - |  |  | $ | - |  |  | $ | - |  |  | $ | - |  |
| Total Convertible Notes Payable, Net |  | $ | - |  |  | $ | - |  |  | $ | - |  |  | $ | - |  |

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. As of June 30, 2019 and December 31, 2018 the Related Party Note including accrued interest was fully paid off.

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.

Interest expense for the six-months ended June 30, 2019 and 2018 on the related party convertible notes payable amounted to $0 and $19,031, respectively.

**Related Party Notes Payable**

As of June 30, 2019 (unaudited) and December 31, 2018, the Company had the following related party notes outstanding:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | June 30, 2019 | | | | | |  |  | December 31, 2018 | | | | | |  |
|  |  | Principal  (net) | |  |  | Accrued  Interest | |  |  | Principal  (net) | |  |  | Accrued  Interest | |  |
| January 2019 $60,000 Note, 8% interest, due January 2020 |  | $ | 60,000 |  |  | $ | 2,059 |  |  | $ | - |  |  | $ | - |  |
| March 2019 $48,000 Note, 8% interest, due March 2020 |  |  | 48,000 |  |  |  | 997 |  |  |  | - |  |  |  | - |  |
| April 2019 $29,000 Note, 8% interest, due April 2020 |  |  | 29,000 |  |  |  | 602 |  |  |  | - |  |  |  | - |  |
| Total Notes Payable, Net |  | $ | 137,000 |  |  | $ | 3,658 |  |  | $ | - |  |  | $ | - |  |

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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 maturing January 24, 2020 and bears interest at an annual rate of 8.00%. 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%. 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 note is for a one-year period maturing April 29, 2020 and bears interest at an annual rate of 8%. Interest expense for these notes for the six-months ended June 30, 2019 and accrued interest at June 30, 2019 is $3,658.

**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 $40,585 and $38,610 as of June 30, 2019 (unaudited) and December 31, 2018, respectively.

**Related Party Advances**

The Company from time to time receives non-interest bearing advancers from its Chief Executive Officer that are due on demand. During the six months ended June 30, 2019, the Company received $20,000 in advances and repaid $5,000 of these and has $15,000 outstanding at June 30, 2019.

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

During 2018, the Company issued 4,832,820 shares of common stock and warrants to purchase shares of common stock totaling 2,416,410 in settlement of accrued compensation valued at $541,276. The warrants were valued at $238,973 and the Company reflected $586,936 as a loss on conversion of debt.

During 2018, the Company issued 450,000 shares of common stock in settlement of accounts payable and notes payable valued at $50,400. The Company granted 225,000 warrants in connection with this transaction and recognized a loss of $35,400 in accordance with this settlement.

**NOTE 5: CONVERTIBLE NOTES PAYABLE**

As of June 30, 2019 (unaudited) and December 31, 2018, the Company had the following convertible notes outstanding:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | June 30, 2019 | | | | | |  |  | December 31, 2018 | | | | | |  |
|  |  | Principal  (net) | |  |  | Accrued  Interest | |  |  | Principal  (net) | |  |  | 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 |  |  | $ | 37,273 |  |  | $ | 45,000 |  |  |  | 34,603 |  |
| 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 $0.032 per share, 8% interest, due October 30, 2019 (includes $10,000 in Original Issue Discount and $12,592 in Debt Discount at inception of note) |  |  | 60,000 |  |  |  | 393 |  |  |  | - |  |  |  | - |  |
| Penalties on notes in default |  |  | 9,713 |  |  |  | - |  |  |  | 8,824 |  |  |  | - |  |
| Total Convertible Notes Payable, Net |  | $ | 114,713 |  |  | $ | 61,656 |  |  | $ | 53,824 |  |  | $ | 58,593 |  |
| Less: Original Issue Discount |  |  | (7,960 | ) |  |  | - |  |  |  | - |  |  |  | - |  |
| Less: Debt Discount |  |  | (10,022 | ) |  |  | - |  |  |  | - |  |  |  | - |  |
|  |  |  | $96,731 |  |  |  | $61,656 |  |  |  | $53,824 |  |  |  | $58,593 |  |

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Interest expense for the six-months ended June 30, 2019 and 2018 on the convertible notes payable amounted to $3,064 and $115,790, 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 November 2017 Note totaling $166,666, $92,004 after debt discount, included an Investor’s Put Option whereby if the Company’s stock was not listed on the Nasdaq or NYSE by January 31, 2018, the lender had the right to require the Company to repurchase the Note at any time after January 31, 2018 in an amount equal to 130% of the sum of the Principal plus all accrued and unpaid interest. The Investor issued notice February 2, 2018 exercising it’s Put Option and requiring the Company repurchase the Note on April 19, 2018 in the aggregate amount of $228,332. The investor may elect to cancel the repurchase notice at any time prior to receiving the repurchase payment.

On October 10, 2018, the Company successfully completed the terms of the *Path Forward Agreements*, resulting in the automatic conversion of the outstanding balance due under certain outstanding convertible secured debentures and convertible promissory, amounting to an aggregate of $2,253,538, into an aggregate of 37,792,407 shares of Company common stock and 2,610,453 shares of Series B Convertible Preferred at a fixed conversion price of $0.032 per share. These shares were subject to a restriction on any sales below $0.16 through December 31, 2018 and will have volume limitations on any sales below $0.08 during the first six months of 2019.

The Company entered into a convertible note in the amount of $50,000 in July 2018 with an interest rate of 8%. This note was convertible upon a Company capital raise of at least $500,000. On October 30, 2018, the Company converted this note into 1,500,000 shares of common stock at a conversion rate of $0.112 (total of $60,000 which includes $10,000 of interest and other costs) and recognized a loss on extinguishment of $108,916 on this conversion.

The Company entered into a $50,000 convertible promissory note dated May 31, 2019, that matures 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 will be amortized over the life of the convertible promissory note.

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**NOTE 6: PROMISSORY NOTES PAYABLE**

As of June 30, 2019 (unaudited) and December 31, 2018, the Company had the following promissory notes outstanding:

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | June 30, 2019 | | | | | |  |  | December 31, 2018 | | | | | |  |
|  |  | Principal  (net) | |  |  | Accrued  Interest | |  |  | Principal  (net) | |  |  | Accrued  Interest | |  |
| February 2019, two promissory notes for $50,000 each (total of $100,000), maturing August 2019, at 8.00% interest |  | $ | 100,000 |  |  | $ | 2,842 |  |  | $ | - |  |  |  | - |  |
| Debt discount |  |  | (7,957 | ) |  |  | - |  |  |  | - |  |  |  | - |  |
| Total Promissory Notes Payable, Net |  | $ | 92,043 |  |  | $ | 2,842 |  |  | $ | - |  |  | $ | - |  |

The Company issued two separate promissory notes on February 20, 2019 at $50,000 each (total of $100,000) that mature on August 20, 2019 and accrue interest at 8.00% per annum. Interest expense for the six-months ended June 30, 2019 on the promissory notes and accrued at June 30, 2019 amounted to $2,842. 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 will amortize the discount over the life of the note (6 months). Amortization of debt discount for the six-months ended June 30, 2019 was $20,764 and is recorded as interest expense on the statement of operations for the six-months ended June 30, 2019.

**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 June 30, 2019 and December 31, 2018, the Company has 177,710,821 and 163,445,736 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 June 30, 2019 and December 31, 2018, 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:

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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.

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.

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*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.

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:

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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.

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.

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***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.

***Common and Preferred Stock Issuances - 2018***

During 2018, the Company issued 1,250 shares of common stock for services valued at $449.

During 2018, the Company issued 128,528,788 shares of common stock and 2,995,755 shares of Series B Convertible Preferred in conjunction with the settlement of $3,545,378 worth of convertible debt (both related and non-related) and $506,245 worth of accrued interest (both related and non-related). As part of these conversions, the Company recognized offsets of $4,823,363 for derivative liabilities and recognized a gain on extinguishment of debt of $1,694,005.

During 2018, the Company issued 1,532,476 shares of common stock valued at $4,678,380 in exchange for 1,225,981 shares of Series A Convertible Preferred.

During 2018, the Company issued 17,078,500 shares of common stock for cash in the amount of $683,140.

During 2018, the Company issued 110,000 shares of Series B Convertible Preferred for cash in the amount of $55,000.

During 2018, 7,782,820 shares of common stock and 200,000 shares of Series B Convertible Preferred were issued to officers and consultants for accrued compensation as well as to settle accounts payable and shareholder advances made during the year. The value of these shares were $1,665,285. The Company recognized a loss on extinguishment on these issuances of $1,256,972.

**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.

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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, 2018 |  |  | 11,318,021 |  |  | $ | 0.112-120.00 |  |  | 6.75 years |  | $ | - |  |  | $ | 0.24 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Options granted |  |  | 382,500 |  |  | $ | 0.024 |  |  | - |  |  |  |  |  | $ | - |  |
| Options exercised |  |  | - |  |  | $ | - |  |  | - |  |  |  |  |  | $ | - |  |
| Options expired |  |  | (46,250 | ) |  | $ | - |  |  | - |  |  |  |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance at June 30, 2019 |  |  | 11,654,271 |  |  | $ | 0.024-120.00 |  |  | 6.11 years |  | $ | - |  |  | $ | 0.19 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Exercisable at June 30, 2019 |  |  | 11,367,396 |  |  | $ | 0.024-120.00 |  |  | 6.14 years |  | $ | - |  |  | $ | 0.19 |  |

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.

The Company has granted 2,625,000 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 four successive calendar quarters (12.50% for each of the quarters September 30, 2019, December 31, 2019, March 31, 2020 and June 30, 2020); (ii) 25% upon the Company closing a financing of $1,000,000 or more; and (iii) 25% upon the first commercial sale of IsoPet®. The value of these options in the aggregate is $76,112.

During the six months ended June 30, 2019 and 2018, the Company recognized $2,176 and $45,400 worth of stock based compensation related to the vesting of its stock options.

**Common Stock Warrants**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | |  |  |  | |  |  | Weighted |  |  | |  |  | Weighted | |  |
|  |  | Warrants Outstanding | | | | | |  |  | Average |  |  | |  |  | Average | |  |
|  |  | Number | |  |  | Exercise | |  |  | Remaining |  | Aggregate | |  |  | Exercise | |  |
|  |  | Of | |  |  | Price | |  |  | Contractual |  | Intrinsic | |  |  | Price | |  |
|  |  | Shares | |  |  | Per Share | |  |  | Life |  | Value | |  |  | Per Share | |  |
|  |  |  | |  |  |  | |  |  |  |  |  | |  |  |  | |  |
| Balance at December 31, 2018 |  |  | 23,052,472 |  |  | $ | 0.08-80.00 |  |  | 1.77 years |  | $ | - |  |  | $ | 0.08 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Warrants granted |  |  | 3,209,375 |  |  | $ | 0.04-0.08 |  |  | - |  |  |  |  |  | $ | 0.06 |  |
| Warrants exercised |  |  | - |  |  | $ | - |  |  | - |  |  |  |  |  | $ |  |  |
| Warrants expired/cancelled |  |  | - |  |  | $ | - |  |  | - |  |  |  |  |  | $ |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance at June 30, 2019 |  |  | 26,261,847 |  |  | $ | 0.04-80.00 |  |  | 1.33 years |  | $ | - |  |  | $ | 0.10 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Exercisable at June 30, 2019 |  |  | 26,261,847 |  |  | $ | 0.04-80.00 |  |  | 1.33 years |  | $ | - |  |  | $ | 0.10 |  |

For the six months ended June 30, 2019, the Company granted 1,250,000 warrants in the issuance of common and preferred shares issued for cash to accredited investors, 1,875,000 warrants in the issuance of promissory notes (recorded as a debt discount valued at $41,313), and 84,375 warrants issued for consulting services valued at $3,792.

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**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, 2018 |  |  | 262,500 |  |  | $ | 0.59 |  |
|  |  |  |  |  |  |  |  |  |
| RSU’s granted |  |  | - |  |  | $ | - |  |
| RSU’s vested |  |  | - |  |  | $ | - |  |
| RSU’s forfeited |  |  | - |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |
| Balance at June 30, 2019 |  |  | 262,500 |  |  | $ | 0.59 |  |

During the six months ended June 30. 2019 and 2018, the Company recognized $0 and $84,895 worth of expense related to the vesting of its RSU’s. As of June 30, 2019, the Company had $155,400 worth of expense yet to be recognized for RSU’s not yet vested.

**NOTE 9: LEGAL MATTERS**

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. The Company believes the allegations in the Complaint are without merit and has engaged legal counsel to represent it and the current and former directors. The Company had offered to settle this with the Plaintiff, yet the settlement offering was declined. The Company intends to vigorously defend the Complaint, including bringing counterclaims for certain breaches of the Agreement by Plaintiff.

**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.

In addition to the cash compensation, the Company has granted 2,625,000 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 four successive calendar quarters (12.50% for each of the quarters September 30, 2019, December 31, 2019, March 31, 2020 and June 30, 2020); (ii) 25% upon the Company closing a financing of $1,000,000 or more; and (iii) 25% upon the first commercial sale of IsoPet®, with all vesting to accelerate and all unvested options to be vested upon a Change of Control, as defined in the Employment Agreement.

**NOTE 11: SUBSEQUENT EVENTS**

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 July 10, 2019, the Company recognized its first commercial sale of IsoPet®. As a result of this sale, 25% of the options issued to Dr. Korenko as noted in Note 10 have vested.

On July 12, 2019, the Company entered into a $50,000 Convertible Note Payable at 8% interest, with a maturity date of January 15, 2020. The Convertible Promissory note is convertible into shares of the Company’s common stock at $0.032 per share.

On July 29, 2019, the Company filed a Form 1-A, Regulation A Offering Statement with the SEC. The Company plans to raise capital upon the approval of the registration statement to assist in the funding of the Company’s products and for the FDA approval process.

The Company has evaluated subsequent events through the date of this filing pursuant to ASC Topic 855 and has determined that, except as disclosed herein, there are no additional subsequent events to disclose.

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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 OTC Pink 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.

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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. To date, four dogs, listed below as Dog A, Dog B, Dog C, and Dog D, respectively, have been treated with IsoPet® at the University of Missouri.

Dog A was treated for canine soft tissue sarcoma in June 2018. 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 principal investigator from the University of Missouri rated the tumor as CR, Complete Response, after three months. This RECIST rating means that the tumor was completely eliminated by the IsoPet therapy.

Dog B, which was treated in July 2018, has displayed encouraging results. This patient had transient mild acute radiation side effects, and had SD (stable disease) at the time of recheck. There was a small amount of growth, but not enough to be considered progression per the RECIST criteria. The CT on its visit in February 2019 showed that the tumor site had a slightly larger but diffuse image. Based on this single observation, the diffuse image could mean that the hydrogel, in addition to trapping the particles, provides a secondary benefit of locking in the dead tumor tissue allowing for a slower rate of resorption of the necrotic tissue. This could be a positive outcome, whereas killing a tumor and having it resorb within the tissue all at once might be a shock to the animal’s system. The latest examination confirmed the original tumor therapy was successful; however, the tumor re-occurred, which is a characteristic of soft tissue sarcomas. This and the re-occurrence of the tumor in Dog B led to a recommendation for future therapy to treat a wide margin around the original tumor. This approach was used on the first commercial therapy at our pilot, Vista Veterinary Hospital. We will continue to monitor how this case proceeds

Dog D was treated in January 2019. This very large, half-pound, tumor was initially scheduled for therapy in December 2018 but had to be rescheduled due to the hydrogel not meeting our rigid specifications. From this, we learned that frozen hydrogel has a limited shelf life and this allowed us to make the appropriate adjustments to our product specifications. This patient had mild to moderate acute radiation side effects and has SD (stable disease) one-month post treatment. The February follow-up included a CT scan. The mass showed no new growth and measured almost the same as it did at the time of treatment. There is a small region at the bottom of the tumor where the mass seems to be draining. The tumor around the highest dose region appears dead with no blood supply, according to the CT. Dog D was outside of the scope of our criteria as an eligible patient prospect and we deem the patient as likely terminal, however, we treated it for humanitarian reasons and for discovery to determine residual effects of the treatment. Dog D was treated for canine soft tissue sarcoma in February 2019. Recent examinations indicate that the tumor was killed, but the dog was having trouble absorbing such a large mass. It has become infected and should be removed. In the future, the recommendation will be to surgically remove the large tumors after approximately two weeks, after all the beta radiation has been absorbed. These animal therapies generate data to assure the private veterinary clinics of the safety and efficacy of IsoPet®.

On July 10, 2019, the Company recognized its first commercial sale of IsoPet®. Dr. Burgess Bauder, a veterinarian from Sitka, Alaska, brought his cat with a re-occurrent spindle cell sarcoma tumor on his face for treatment. The cat had previously received external beam therapy, but the tumor was continuing to grow rapidly. The cat was given a high dose of 400Gy with heavy therapy at the margins. He currently is alive and well.

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. 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 received its Radioactive Material License and has completed the Vivos Ind certification training, however they are not cleared for commercial therapy as of yet.

**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.

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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.

In the event the FDA denies the Company’s application for *de novo* review, and therefore determines 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.

**Results of Operations**

***Comparison of the Three Months Ended June 30, 2019 and 2018***

The following table sets forth information from our statements of operations for the three months ended June 30, 2019 and 2018:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Three Months Ended June 30, 2019 | |  |  | Three Months Ended June 30, 2018 | |  |
| Revenues |  | $ | - |  |  | $ | - |  |
| Operating expenses |  |  | (173,016 | ) |  |  | (341,900 | ) |
| Operating loss |  |  | (173,016 | ) |  |  | (341,900 | ) |
| Non-operating income (expense): |  |  |  |  |  |  |  |  |
| Gain on debt extinguishment |  |  | - |  |  |  | 131,604 |  |
| Loss on derivative liability |  |  | - |  |  |  | (867,608 | ) |
| Interest expense |  |  | (27,289 | ) |  |  | (4,934,066 | ) |
| Net loss |  | $ | (200,305 | ) |  | $ | (6,011,970 | ) |

***Revenue***

Revenue was $0 for the three months ended June 30, 2019 and 2018, respectively.

***Operating Expenses***

Operating expenses for the three months ended June 30, 2019 and 2018, respectively consists of the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Three months ended  June 30, 2019 | |  |  | Three months ended  June 30, 2018 | |  |
| Professional fees |  | $ | 102,638 |  |  | $ | 145,220 |  |
| Reserved stock units granted |  |  | - |  |  |  | 32,801 |  |
| Stock based compensation |  |  | 2,176 |  |  |  | 21,645 |  |
| Payroll expenses |  |  | 30,000 |  |  |  | 82,200 |  |
| Research and development |  |  | 20,016 |  |  |  | 41,766 |  |
| General and administrative expenses |  |  | 18,186 |  |  |  | 15,318 |  |
| Sales and marketing expense |  |  | - |  |  |  | 2,950 |  |
| Total operating expenses |  | $ | 173,016 |  |  | $ | 341,900 |  |

Operating expenses for the three months ended June 30, 2019 and 2018 was $173,016 and $341,900, respectively. The decrease in operating expenses from 2018 to 2019 can be attributed to the decrease in payroll expense ($82,200 for the three months ended June 30, 2018 versus $30,000 for the three months ended June 30, 2019) as the Company used outsourced consultants in place of employees due to cash flow constraints; the decrease in professional fees ($145,220 for the three months ended June 30, 2018 versus $102,638 for the three months ended June 30, 2019) as the Company utilized legal and accounting services in 2018 as a result of the negotiations for the Path Forward Agreements; the decrease in reserved stock units granted ($32,801 for the three months ended June 30, 2018 versus $0 for the three months ended June 30, 2019); the decrease in stock based compensation ($21,645 for the three months ended June 30, 2018 versus $2,176 for the three months ended June 30, 2019) and decrease in research and development ($41,766 for the three months ended June 30, 2018 versus $20,016 for the three months ended June 30, 2019) in an effort to conserve cash and position themselves to complete certain corporate matters. These decreases in operating expenses were partially offset by an increase in general and administrative expenses ($15,318 for the three months ended June 30, 2018 versus $18,186 for the three months ended June 30, 2019) as the Company paid fees for certain regulatory costs in connection with the reverse stock split in June 2019 in addition to their normal recurring charges that were consistent with the prior period.

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

Non-operating income (expense) for the three months ended June 30, 2019 and 2018 consists of the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Three months ended  June 30, 2019 | |  |  | Three months ended  June 30, 2018 | |  |
| Interest expense |  | $ | (27,289 | ) |  | $ | (4,934,066 | ) |
| Gain on debt extinguishment |  |  | - |  |  |  | 131,604 |  |
| Loss on derivative liability |  |  | - |  |  |  | (867,608 | ) |
| Non-operating income (expense) |  | $ | (27,289 | ) |  | $ | (5,670,070 | ) |

Non-operating income (expense) for the three months ended June 30, 2019 varied from the three months ended June 30, 2018 primarily due to a decrease in interest expense from $4,934,066 for the three months ended June 30, 2018 to $27,289 for the three months ended June 30, 2019 as a result of conversions of notes payable in the fourth quarter of 2018; and decreases in fair value adjustments and extinguishment gains and losses from $736,004 for the three months ended June 30, 2018 to $0 in the three months ended June 30, 2019. The majority of the interest recorded by the Company consists of amortization of debt discount.

***Net Loss***

Our net loss for the three months ended June 30, 2019 and 2018 was $(200,305) and $(6,011,970), respectively.

**Results of Operations**

***Comparison of the Six Months Ended June 30, 2019 and 2018***

The following table sets forth information from our statements of operations for the six months ended June 30, 2019 and 2018:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Six Months Ended  June 30, 2019 | |  |  | Six Months Ended  June 30, 2018 | |  |
| Revenues |  | $ | - |  |  | $ | - |  |
| Operating expenses |  |  | (398,219 | ) |  |  | (628,594 | ) |
| Operating loss |  |  | (398,219 | ) |  |  | (628,594 | ) |
| Non-operating income (expense): |  |  |  |  |  |  |  |  |
| Grants received |  |  | - |  |  |  | 17,583 |  |
| Gain on debt extinguishment |  |  | - |  |  |  | 131,604 |  |
| Loss on derivative liability |  |  | - |  |  |  | (867,608 | ) |
| Interest expense |  |  | (38,468 | ) |  |  | (5,566,140 | ) |
| Net loss |  | $ | (436,687 | ) |  | $ | (6,913,155 | ) |

***Revenue***

Revenue was $0 for the six months ended June 30, 2019 and 2018, respectively.

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***Operating Expenses***

Operating expenses for the six months ended June 30, 2019 and 2018, respectively consists of the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Six months ended  June 30, 2019 | |  |  | Six months ended  June 30, 2018 | |  |
| Professional fees |  | $ | 269,173 |  |  | $ | 215,278 |  |
| Reserved stock units granted |  |  | - |  |  |  | 84,895 |  |
| Stock based compensation |  |  | 5,968 |  |  |  | 45,400 |  |
| Payroll expenses |  |  | 60,000 |  |  |  | 161,070 |  |
| Research and development |  |  | 43,702 |  |  |  | 74,580 |  |
| General and administrative expenses |  |  | 19,376 |  |  |  | 34,421 |  |
| Sales and marketing expense |  |  | - |  |  |  | 12,950 |  |
| Total operating expenses |  | $ | 398,219 |  |  | $ | 628,594 |  |

Operating expenses for the six months ended June 30, 2019 and 2018 was $398,219 and $628,594, respectively. The decrease in operating expenses from 2018 to 2019 can be attributed to the decrease in payroll expense ($161,070 for the six months ended June 30, 2018 versus $60,000 for the six months ended June 30, 2019) as the Company used outsourced consultants in place of employees due to cash flow constraints; the decrease in general and administrative expense ($34,421 for the six months ended June 30, 2018 versus $19,376 for the six months ended June 30, 2019) as the Company ramped down operations in cost cutting measures; the decrease in reserved stock units granted ($84,895 for the six months ended June 30, 2018 versus $0 for the six months ended June 30, 2019); the decrease in stock based compensation ($45,400 for the six months ended June 30, 2018 versus $5,968 for the six months ended June 30, 2019) and decrease in research and development ($74,580 for the six months ended June 30, 2018 versus $43,702 for the six months ended June 30, 2019) in an effort to conserve cash and position themselves to complete certain corporate matters. These decreases in operating expenses were partially offset by an increase in professional fees ($215,278 for the six months ended June 30, 2018 versus $269,173 for the six months ended June 30, 2019) as the Company went form salaried employees to consultants, and an increase in legal fees due to certain legal matters explained herein.

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

Non-operating income (expense) for the six months ended June 30, 2019 and 2018 consists of the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Six months ended  June 30, 2019 | |  |  | Six months ended  June 30, 2018 | |  |
| Interest expense |  | $ | (38,468 | ) |  | $ | (5,566,140 | ) |
| Gain on debt extinguishment |  |  | - |  |  |  | 131,604 |  |
| Loss on derivative liability |  |  | - |  |  |  | (867,608 | ) |
| Grants received |  |  | - |  |  |  | 17,583 |  |
| Non-operating income (expense) |  | $ | (38,468 | ) |  | $ | (6,284,561 | ) |

Non-operating income (expense) for the six months ended June 30, 2019 varied from the six months ended June 30, 2018 primarily due to a decrease in interest expense from $5,566,140 for the six months ended June 30, 2018 to $38,468 for the six months ended June 30, 2019 as a result of conversions of notes payable in the fourth quarter of 2018; and decreases in fair value adjustments and extinguishment gains and losses from $736,004 for the six months ended June 30, 2018 to $0 in the six months ended June 30, 2019. The majority of the interest recorded by the Company consists of amortization of debt discount. This was partially offset by a decrease in grant income from $17,583 for the six months ended June 30, 2018 to $0 for the six months ended June 30, 2019.

***Net Loss***

Our net loss for the six months ended June 30, 2019 and 2018 was $(436,687) and $(6,913,155), respectively.

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**Liquidity and Capital Resources**

At June 30, 2019, the Company had negative working capital of $1,231,580 as compared to $942,174 at December 31, 2018. During the six months ended June 30, 2019 the Company experienced negative cash flow from operations of $398,992 and it received $0 for investing activities while adding $402,000 of cash flows from financing activities. As of June 30, 2019, 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 decrease in accounts payable and accrued expenses of $14,941 for the six months ended June 30, 2019. For the six months ended June 30, 2018, the Company has used $96,876 in cash from operating activities which was the result of the net loss offset by adjustments for stock-based compensation and reserved stock units issued for services and an increase in accounts payable and accrued expenses. The Company had no investing activities for the six-month periods ended June 30, 2019 and 2018, respectively. In the six months ended June 30, 2019 and 2018, the Company had cash provided by financing activities of $402,000 and $88,559, 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 $436,687 for the six months ended June 30, 2019, and a net loss of $6,913,155 for the six months ended June 30, 2018. 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 anticipates raising additional capital within the next twelve months from investors for working capital as well as business expansion, although the Company can provide no assurance that additional investor funds will be available on terms acceptable to the Company. If the Company is unable to obtain additional financing to meet its working capital requirements, it may have to curtail its business. The Company has completed its reverse stock split which was approved by FINRA and went effective on June 28, 2019 which will enable them to begin the process of raising capital through their Regulation A+ which was filed with the SEC on June 30, 2019 now that the Company has available authorized shares to issue.

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 $2.3 million annually to maintain current operating activities. 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.

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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.

**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 June 30, 2019, we believe there have been no significant changes to the items disclosed as significant accounting policies in management’s notes to the consolidated financial statements in our annual report on Form 10-K for the year ended December 31, 2018, filed on March 25, 2019.

**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.

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.

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**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 June 30, 2019 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. |

**PART II**

**Item 1. Legal Proceedings**

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. The Company believes the allegations in the Complaint are without merit and has engaged legal counsel to represent it and the current and former directors. The Company had offered to settle this with the Plaintiff, yet the settlement offering was declined. The Company intends to vigorously defend the Complaint, including bringing counterclaims for certain breaches of the Agreement by Plaintiff.

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

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. In March 2019, the Company issued 821,292 shares of Series C Convertible Preferred I consideration for the conversion of 821,292 shares of Series B Convertible Preferred.

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”). We had or one of our affiliates had a prior business relationship with each of the purchasers, and no general solicitation was used in connection with the sales. In making the sales without registration under the Securities Act, we relied upon the exemption from registration contained in Section 4(a)(2) of the Securities Act.

**Item 6. Exhibits.**

|  |  |  |
| --- | --- | --- |
| **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: August 13, 2019 | By: | */s/ Michael Korenko* |
|  | Name: | Michael K. Korenko |
|  | Title: | Chief Executive Officer |
|  |  | (Principal Executive Officer) |

|  |  |  |
| --- | --- | --- |
| Date: August 13, 2019 | By: | */s/ Michael Pollack* |
|  | Name: | Michael Pollack |
|  | Title: | Interim Chief Financial Officer |
|  |  | (Interim Principal Financial and Accounting Officer) |

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