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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

Form 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: March 31, 2021

OR

TRANSITION REPORT 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

(State or other jurisdiction of
incorporation or organization)

80-0138937

(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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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

Smaller reporting company

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

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 May __, 2021, there were 320,292,714 shares of the registrant's common stock outstanding, 2,171,006 shares of the registrant's Series A Convertible Preferred Stock outstanding, 436,653 of the registrant's Series B Convertible Preferred Stock outstanding and 385,302 of the registrant's Series C Convertible Preferred Stock outstanding.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

VIVOS INC
CONDENSED BALANCE SHEETS
MARCH 31, 2021 (UNAUDITED) AND DECEMBER 31, 2020

	<u>MARCH 31,</u> <u>2021</u> <u>(UNAUDITED)</u>	<u>DECEMBER 31,</u> <u>2020</u>
<u>ASSETS</u>		
Current Assets:		
Cash	\$ 2,511,845	\$ 903,704
Prepaid expenses	7,200	33,835
Total Current Assets	<u>2,519,045</u>	<u>937,539</u>
TOTAL ASSETS	<u>\$ 2,519,045</u>	<u>\$ 937,539</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</u>		
LIABILITIES		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 206,345	\$ 361,880
Related party accounts payable	32,110	32,110
Accrued interest payable	106,690	100,954
Payroll liabilities payable	47,291	66,143
Convertible notes payable, related party, net	-	-
Convertible notes payable, net	57,861	107,418
Promissory notes payable, net of discount	-	-
Related party promissory note	237,000	237,000
Total Current Liabilities	<u>687,297</u>	<u>905,505</u>
Total Liabilities	<u>687,297</u>	<u>905,505</u>
Commitments and contingencies	-	-
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, par value, \$0.001, 20,000,000 shares authorized, Series A Convertible Preferred, 5,000,000 shares authorized, 2,171,006 and 2,171,006 shares issued and outstanding, respectively	2,171	2,171
Additional paid in capital - Series A Convertible preferred stock	8,857,358	8,857,358
Series B Convertible Preferred, 5,000,000 shares authorized, 436,653 and 436,653 shares issued and outstanding, respectively	436	436
Additional paid in capital - Series B Convertible preferred stock	385,235	385,235
Series C Convertible Preferred, 5,000,000 shares authorized, 385,302 and 385,302 shares issued and outstanding, respectively	385	385
Additional paid in capital - Series C Convertible preferred stock	500,507	500,507
Common stock, par value, \$0.001, 950,000,000 shares authorized, 320,292,714 and 292,278,591 issued and outstanding, respectively	320,292	292,279
Additional paid in capital - common stock	66,611,654	64,551,764
Subscription receivable	-	-
Accumulated deficit	(74,846,290)	(74,558,101)
Total Stockholders' Equity (Deficit)	<u>1,831,748</u>	<u>32,034</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	<u>\$ 2,519,045</u>	<u>\$ 937,539</u>

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

VIVOS INC
CONDENSED STATEMENTS OF OPERATIONS (UNAUDITED)
FOR THE THREE MONTHS ENDED MARCH 31, 2021 AND 2020

	<u>2021</u>	<u>2020</u>
Revenues, net	\$ -	\$ -
Cost of Goods Sold	-	-
Gross profit	-	-
OPERATING EXPENSES		
Professional fees	78,214	53,992
Stock based compensation	-	-
Payroll expenses	49,341	30,000
Research and development	71,700	1,028
General and administrative expenses	35,835	35,353
Total Operating Expenses	<u>235,090</u>	<u>120,373</u>
OPERATING LOSS	<u>(235,090)</u>	<u>(120,373)</u>
NON-OPERATING INCOME (EXPENSE)		
Interest expense	(6,549)	(239,858)
Forgiveness of debt	129,745	-
Loss on debt extinguishment	(176,295)	-
Total Non-Operating Income (Expenses)	<u>(53,099)</u>	<u>(239,858)</u>
NET LOSS BEFORE PROVISION FOR INCOME TAXES	<u>(288,189)</u>	<u>(360,231)</u>
Provision for income taxes	-	-
NET LOSS	<u>\$ (288,189)</u>	<u>\$ (360,231)</u>
Net loss per share - basic and diluted	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>
Weighted average common shares outstanding - basic	<u>300,540,380</u>	<u>189,097,921</u>

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

VIVOS INC
CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (UNAUDITED)
FOR THE THREE MONTHS ENDED MARCH 31, 2021 AND 2020

	Series A Preferred		Additional Paid-In Capital - Series A	Series B Preferred		Additional Paid-In Capital - Series B	Series C Preferred		Additional Paid-In Capital - Series C	Common Stock		Additional Paid-In Capital -	(Subscription Receivable)/	Accumulated	Total
	Shares	Amount	Preferred	Shares	Amount	Preferred	Shares	Amount	Preferred	Shares	Amount	Common	Issued	Deficit	
Balance - December 31, 2019	2,552,642	\$ 2,553	\$8,870,626	1,113,245	\$ 1,113	\$ 665,195	821,292	\$ 821	\$ 674,457	184,845,821	\$184,846	\$61,721,809	\$ -	\$(73,601,109)	\$(1,479,689)
Stock issued for:															
Cash	-	-	-	-	-	-	-	-	-	-	-	-	6,870	-	6,870
Note conversions	-	-	-	-	-	-	-	-	-	-	-	-	526,113	-	526,113
Redemption of preferred stock in convertible note agreement	-	-	-	(100,000)	(100)	(49,900)	-	-	-	-	-	-	-	-	(50,000)
Conversion of preferred stock into common stock	-	-	-	-	-	-	(435,990)	(436)	(173,950)	5,449,875	5,449	168,937	-	-	-
Warrants issued with notes payable (discount)	-	-	-	-	-	-	-	-	-	-	-	28,482	-	-	28,482
Options and warrants issued for services	-	-	-	-	-	-	-	-	-	-	-	77,883	-	-	77,883
Share adjustment	-	-	-	-	-	-	-	-	-	(62)	-	-	-	-	-
Net loss for the period	-	-	-	-	-	-	-	-	-	-	-	-	-	(360,231)	(360,231)
Balance - March 31, 2020	<u>2,552,642</u>	<u>\$ 2,553</u>	<u>\$8,870,626</u>	<u>1,013,245</u>	<u>\$ 1,013</u>	<u>\$ 615,295</u>	<u>385,302</u>	<u>\$ 385</u>	<u>\$ 500,507</u>	<u>190,295,634</u>	<u>\$190,295</u>	<u>\$61,997,111</u>	<u>\$ 532,983</u>	<u>\$(73,961,340)</u>	<u>\$(1,250,572)</u>
Balance - December 31, 2020	2,171,007	\$ 2,171	\$8,857,358	436,653	\$ 436	\$ 385,235	385,302	\$ 385	\$ 500,507	292,278,591	\$292,279	\$64,551,764	\$ -	\$(74,558,101)	\$ 32,034
Stock issued for:															
Cash	-	-	-	-	-	-	-	-	-	22,500,000	22,500	1,777,500	-	-	1,800,000
Note conversions/settlements	-	-	-	-	-	-	-	-	-	1,259,250	1,259	225,406	-	-	226,665
Accounts payable	-	-	-	-	-	-	-	-	-	384,445	384	49,616	-	-	50,000
Warrant exercises	-	-	-	-	-	-	-	-	-	3,870,428	3,870	(3,870)	-	-	-
Warrants purchased for cash	-	-	-	-	-	-	-	-	-	-	-	11,238	-	-	11,238
Net loss for the year	-	-	-	-	-	-	-	-	-	-	-	-	-	(288,189)	(288,189)
Balance - March 31, 2021	<u>2,171,007</u>	<u>\$ 2,171</u>	<u>\$8,857,358</u>	<u>436,653</u>	<u>\$ 436</u>	<u>\$ 385,235</u>	<u>385,302</u>	<u>\$ 385</u>	<u>\$ 500,507</u>	<u>320,292,714</u>	<u>\$320,292</u>	<u>\$66,611,654</u>	<u>\$ -</u>	<u>\$(74,269,912)</u>	<u>\$ 1,831,748</u>

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

VIVOS INC
CONDENSED STATEMENTS OF CASH FLOWS (UNAUDITED)
FOR THE THREE MONTHS ENDED MARCH 31, 2021 AND 2020

	2021	2020
CASH FLOW FROM OPERATING ACTIVITIES		
Net loss	\$ (288,189)	\$ (360,231)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of convertible debt discount	-	53,527
Amortization of BCF discount	-	6,187
Loss on conversion of debt	176,295	-
Forgiveness of debt	(129,745)	-
Warrants issued for interest expense	-	77,883
Exchange premium in conversion of notes	-	77,683
Changes in assets and liabilities		
Prepaid expenses and other assets	26,635	16,394
Accounts payable and accrued expenses	24,210	(5,341)
Accounts payable and accrued expenses from related party	-	-
Payroll liabilities	(18,852)	30,000
Accrued interest	6,549	16,651
Total adjustments	<u>85,092</u>	<u>272,984</u>
Net cash used in operating activities	<u>(203,097)</u>	<u>(87,247)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Redemption of preferred stock	-	(50,000)
Proceeds from sale of common stock and warrants	1,811,238	6,870
Proceeds from convertible debt	-	100,000
Proceeds from promissory notes - related party, net of repayments	-	15,000
Net cash provided by financing activities	<u>1,811,238</u>	<u>71,870</u>
NET INCREASE (DECREASE) IN CASH	1,608,141	(15,377)
CASH - BEGINNING OF PERIOD	<u>903,704</u>	<u>20,381</u>
CASH - END OF PERIOD	<u>\$ 2,511,845</u>	<u>\$ 5,004</u>
CASH PAID DURING THE PERIOD FOR:		
Interest expense	<u>\$ -</u>	<u>\$ 7,500</u>
Income taxes	<u>\$ -</u>	<u>\$ -</u>
SUPPLEMENTAL INFORMATION - NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Conversion of preferred stock into common stock	<u>\$ -</u>	<u>\$ 174,386</u>
Recognition of debt discount at inception of notes payable	<u>\$ -</u>	<u>\$ 28,482</u>
Conversion of notes payable and accrued interest into common stock	<u>\$ 50,370</u>	<u>\$ 526,113</u>
Common stock issued in cashless exercise of warrants	<u>\$ 3,870</u>	<u>\$ -</u>

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

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, 2021, are not necessarily indicative of the results that may be expected for any future period or the fiscal year ending December 31, 2021 and should be read in conjunction with the Company’s Annual Report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission on March 24, 2021.

Business Overview

The Company was incorporated under the laws of Delaware on December 23, 1994 as Savage Mountain Sports Corporation (“*SMSC*”). On September 6, 2006, the Company changed its name to Advanced Medical Isotope Corporation, and on December 28, 2017, the Company began operating as Vivos Inc. The Company has authorized capital of 950,000,000 shares of common stock, \$0.001 par value per share, and 20,000,000 shares of preferred stock, \$0.001 par value per share.

Our principal place of business is located at 719 Jadwin Avenue, Richland, WA 99352. Our telephone number is (509) 736-4000. Our corporate website address is <http://www.radiogel.com>. Our common stock is currently quoted on the OTC Pink Marketplace under the symbol “RDGL.”

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 RadioGel™ 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, RadioGel™ 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 RadioGel™ are used synonymously throughout this document. The only distinction between IsoPet® and RadioGel™ is the FDA’s recommendation that we use “IsoPet®” for veterinarian usage, and reserve “RadioGel™” 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.

IsoPet Solutions

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

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

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

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

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

Commencing in July 2019, the Company recognized its first commercial sale of IsoPet®. A veterinarian from 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. This sale met the revenue recognition requirements under ASC 606 as the performance obligation was satisfied. The Company completed sales for an additional four animals that received the IsoPet® during 2019.

Our plan is to incorporate the data assembled from our work with IsoPet® in animal therapy to support the Company's efforts in the development of our RadioGel™ device candidate, including obtaining approval from the FDA to market and sell RadioGel™ as a Class II medical device. RadioGel™ is an injectable particle-gel for brachytherapy radiation treatment of cancerous tumors in people and animals. RadioGel™ is comprised of a hydrogel, or a substance that is liquid at room temperature and then gels when reaching body temperature after injection into a tumor. In the gel are small, less than two microns, 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.

Recently, the Company modified its Indication for Use from skin cancer to cancerous tissue or solid tumors pathologically associated with locoregional papillary thyroid carcinoma and recurrent papillary thyroid carcinoma having discernable tumors associated with metastatic lymph nodes or extranodal disease in patients who are not surgical candidates or who have declined surgery, or patients who require post-surgical remnant ablation (for example, after prior incomplete radioiodine therapy). Papillary thyroid carcinoma belongs to the general class of head and neck tumors for which tumors are accessible by intraoperative direct needle injection. The Company's Medical Advisory Board felt that demonstrating efficacy in clinical trials was much easier with this new indication.

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 (March 2022). Other intellectual property protection includes proprietary production processes and trademark protection in 17 countries. The Company plans to continue efforts to develop new refinements on the production process, and the product and application hardware, as a basis for future patents.

The Company received the Patent Cooperation Treaty ("PCT") International Search Report on our patent application (No.1811.191). Seven of our claims were immediately ruled as having novelty, inventive step and industrial applicability. This gives us the basis to extend for many years the patent protection for our proprietary Yttrium-90 phosphate particles utilized in Isopet® and Radiogel™. As part of the normal review process, we have also submitted the technical justification for seven additional claims. We are in the process of filing patent claims in Canada, UK (Great Britain, Scotland, Wales and Ireland), Japan, Germany, Italy, France, Australia, Brazil, China, India, North Countries (Sweden, Norway, Finland, and Denmark).

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 million annually to maintain current operating activities.

The Company completed its reverse stock split which was approved by FINRA and went effective on June 28, 2019.

The Company's stock offering under Regulation A+ was qualified by the Securities and Exchange Commission ("SEC") on June 3, 2020.

The Company over the past twelve months has raised approximately \$4,000,000 from the sale of shares under Regulation A+, and intends to use the proceeds generated as follows:

For the animal therapy market:

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

For the human market:

- Enhance the pedigree of the Quality Management System.
- Complete the previously defined pre-clinical testing and additional testing on an animal model closely aligned with our revised indication for use. Report the results to the FDA in a pre-submission meeting.
- Use the feedback from that meeting to write the IDE (Investigational Device Exemption), which is required to initiate clinical trials.

Research and development of the Company's brachytherapy product line has been funded with proceeds from the sale of equity and debt securities. The Company may require additional funding of approximately \$2 million annually to maintain current operating activities. Over the next 12 to 24 months, the Company believes it will cost approximately \$9 million to: (1) fund the FDA approval process to conduct human clinical trials, (2) conduct Phase I, pilot, clinical trials, (3) activate several regional clinics to administer IsoPet® across the county, (4) create an independent production center within the current production site to create a template for future international manufacturing, and (5) initiate regulatory approval processes outside of the United States.

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

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

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

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

The Company has been impacted from the effects of COVID-19. The Company's headquarters are in Northeast Washington however their focus of the animal therapy market has been the Northwestern sector of the United States, the initial epicenter of the COVID-19 outbreak in the United States. The Company is hopeful that by the end of the third quarter of 2021, they will be allowed to continue their marketing to the animal therapy market and attempt to increase the exposure to their product and generate revenue accordingly.

As of March 31, 2021, the Company has \$2,511,845 cash on hand. There are currently commitments to vendors for products and services purchased. To continue the development of the Company's products, the current level of cash may not be enough to cover the fixed and variable obligations of the Company.

There is no guarantee that the Company will be able to raise additional funds or to do so at an advantageous price.

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

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.

The Company occasionally maintains cash balances in excess of the FDIC insured limit. The Company does not consider this risk to be material.

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 March 31, 2021 and December 31, 2020, the balances reported for cash, prepaid expenses, accounts receivable, accounts payable, and accrued expenses, approximate the fair value because of their short maturities.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Accounting Standards Codification (“ASC”) Topic 820 established a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). These tiers include:

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

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

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

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

Derivative Liabilities and Beneficial Conversion Feature

The Company evaluates its convertible debt, options, warrants or other contracts, if any, to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for in accordance with ASC Topic 815, Accounting for Derivative Instruments and Hedging Activities (“ASC 815”) as well as related interpretations of this standard and Accounting Standards Update 2017-11, which was adopted by the Company effective January 1, 2018. In accordance with this standard, derivative instruments are recognized as either assets or liabilities in the balance sheet and are measured at fair values with gains or losses recognized in earnings.

Embedded derivatives that are not clearly and closely related to the host contract are bifurcated and are recognized at fair value with changes in fair value recognized as either a gain or loss in earnings.

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

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

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

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

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

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

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

Fixed Assets

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

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

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

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

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

License Fees

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

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

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

Calendar Year	Minimum Royalties per Calendar Year
2021	\$ 10,000
2022	4,000
Total	\$ 14,000

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 2021 fee was paid in December 2020.

Patents and Intellectual Property

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

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

There have been no such capitalized costs in the three months ended March 31, 2021 or years ended December 31, 2020 and 2019, respectively. However, a patent was filed on July 1, 2019 (No. 1811.191) filed by Michael Korenko and David Swanberg and assigned to the Company based on the Company's proprietary particle manufacturing process. The timing of this filing was important given the Company's plans to make IsoPet® commercially available, which it did on or about July 9, 2019. This additional patent protection will strengthen the Company's competitive position. It is the Company's intention to further extend this patent protection to several key countries within one year, as permitted under international patent laws and treaties.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (“FASB”) 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.

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

Loss Per Share

The Company accounts for its loss per common share by replacing primary and fully diluted earnings per share with basic and diluted earnings per share. Basic loss per share is computed by dividing loss available to common stockholders (the numerator) by the weighted-average number of common shares outstanding (the denominator) for the period, and does not include the impact of any potentially dilutive common stock equivalents since the impact would be anti-dilutive. The computation of diluted earnings per share is similar to basic earnings per share, except that the denominator is increased to include the number of additional common shares that would have been outstanding if potentially dilutive common shares had been issued. For the given periods of loss, of the periods ended in the three months ended March 31, 2021 and 2020, 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 March 31, 2021 and December 31, 2020, which include the following:

	March 31, 2021	December 31, 2020
Convertible debt	2,492	1,252,456
Preferred stock	12,988,195	12,988,195
Common stock options	28,885,461	28,885,461
Common stock warrants	37,162,500	32,064,375
Total potential dilutive securities	79,038,648	75,190,487

Research and Development Costs

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

The Company incurred \$71,700 and \$1,028 research and development costs for the three months ended March 31, 2021 and 2020, respectively, all of which were recorded in the Company’s operating expenses noted on the statements of operations for the periods then ended.

Advertising and Marketing Costs

Advertising and marketing costs are expensed as incurred except for the cost of tradeshows which are deferred until the tradeshow occurs. During the three months ended March 31, 2021 and 2020, the Company incurred no advertising and marketing costs.

Contingencies

In the ordinary course of business, the Company is involved in legal proceedings involving contractual and employment relationships, product liability claims, patent rights, and a variety of other matters. The Company records contingent liabilities resulting from asserted and unasserted claims against it, when it is probable that a liability has been incurred and the amount of the loss is reasonably estimable. The Company discloses contingent liabilities when there is a reasonable possibility that the ultimate loss will exceed the recorded liability. Estimated probable losses require analysis of multiple factors, in some cases including judgments about the potential actions of third-party claimants and courts. Therefore, actual losses in any future period are inherently uncertain. The Company has entered into various agreements that require them to pay certain fees to consultants and/or employees that have been fully accrued for as of March 31, 2021 and December 31, 2020.

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 three months ended March 31, 2021 and 2020. The Company did not have any deferred tax liability or asset on its balance sheet on March 31, 2021 and December 31, 2020.

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 three months ended March 31, 2021 and 2020, the Company did not recognize any interest or penalty expense related to income taxes. The Company believes that it is not reasonably possible for the amounts of unrecognized tax benefits to significantly increase or decrease within the next twelve months.

Stock-Based Compensation

The Company recognizes compensation costs under FASB ASC Topic 718, Compensation – Stock Compensation and ASU 2018-07. 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. The Company has determined that no amounts had to be revalued upon adoption of this amendment.

Recent Accounting Pronouncements

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

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

NOTE 2: RELATED PARTY TRANSACTIONS

Related Party Convertible Notes Payable

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

Interest expense for the three months ended March 31, 2021 and 2020 on the related party convertible notes payable amounted to \$0 and \$298, respectively.

Related Party Notes Payable

As of March 31, 2021 and December 31, 2020, the Company had the following related party notes outstanding:

	March 31, 2021	December 31, 2020
January 2019 \$60,000 Note, 8% interest, due January 2020	\$ 60,000	\$ 60,000
March 2019 \$48,000 Note, 8% interest, due March 2020	48,000	48,000
April 2019 \$29,000 Note, 8% interest, due April 2020	29,000	29,000
July 2019 \$50,000 Note 8% interest, due July 2020	50,000	50,000
November 2019 \$50,000 Note 8% interest, due November 2020	50,000	50,000
Total Related Party Notes Payable, Net	\$ 237,000	\$ 237,000

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

On March 27, 2019 the Company entered into a note payable with a trust related to one of our directors in the amount of \$48,000. The note is for a one-year period maturing March 27, 2020 and bears interest at an annual rate of 8%. The Company is in default of this note. On April 29, 2019 the Company entered into a note payable with a trust related to one of our directors in the amount of \$29,000. The Company is in default of this note. On July 5, 2019 the Company entered into a note payable with a trust related to one of our directors in the amount of \$50,000. The note is for a one-year period maturing July 5, 2020 and bears interest at an annual rate of 8%. The Company is in default of this note. On November 25, 2019 the Company entered into a note payable with a trust related to one of our directors in the amount of \$50,000. The note is for a one-year period maturing November 25, 2020 and bears interest at an annual rate of 8%. The Company is in default of this note. Interest expense for these notes for the three months ended March 31, 2021 and 2020 was \$4,662 and \$4,715, respectively and accrued interest at March 31, 2021 is \$34,829.

The Company borrowed \$15,000 in March 2020 from its CEO and repaid this amount in April 2020.

Related Party Payables

The Company periodically receives advances for operating funds from related parties or has related parties make payments on the Company's behalf. As a result of these activities the Company had related party payables of \$32,110 and \$32,110 as of March 31, 2021 and December 31, 2020, respectively.

Preferred and Common Shares Issued to Officers and Directors

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

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

The Company's Chief Executive Officer exercised 2,500,000 stock options for \$60,000 in December 2020.

NOTE 3: CONVERTIBLE NOTES PAYABLE

As of March 31, 2021 and December 31, 2020, the Company had the following convertible notes outstanding:

	2021	2020
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	\$ 45,000
November 2020 \$50,000 Note convertible into common shares at \$0.04, 6% interest, due May 30, 2021	-	50,000
Penalties on notes in default	12,861	12,418
Total Convertible Notes Payable, Net	\$ 57,861	\$ 107,418
Less: BCF Discount	-	-
Less: Debt Discount	-	-
	<u>\$ 57,861</u>	<u>\$ 107,418</u>

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

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

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

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

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

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

The Company entered into a \$50,000 convertible promissory note on November 30, 2020, that matures May 30, 2021. The convertible promissory notes bear interest at a rate of 6%. The convertible promissory note is convertible into shares of common stock at a price of \$0.04 per share. Upon the closing of an equity financing pursuant to an effective registration statement with gross proceeds to the Company totaling at least \$350,000 exclusive of any exchanges ("Qualified Financing"), the outstanding principal amount of this convertible promissory notes together with all accrued and unpaid interest shall be exchanged into such securities as are issued in the Qualified Financing at a rate of 1.20. Upon an exchange, the Payee shall be granted all rights afforded to an investor in the Qualified Financing. The Company along with the noteholder agreed to exchange 1,867,500 warrants into 933,750 common shares. These shares were issued in December 2020. The convertible note was converted into shares of common stock in January 2021.

Interest expense for the three months ended March 31, 2021 and 2020 on the convertible notes payable amounted to \$1,444 and \$14,961, respectively.

NOTE 4: PROMISSORY NOTES PAYABLE

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

On August 20, 2019, the two noteholders agreed to extend these notes another six-months to February 20, 2020, then amended again for six-months and the notes were to mature August 20, 2020. In consideration for the extension, the note holders received 750,000 warrants (375,000 each) and the interest rate on the notes increased from 8% to 15% per annum.

The interest expense on these notes for the three months ended March 31, 2021 and 2020 amounted to \$0 and \$3,726.

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

NOTE 5: 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 March 31, 2021 and December 31, 2020, the Company has 320,292,714 and 292,278,591 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 March 31, 2021 and December 31, 2020, the Company has 20,000,000 shares of Preferred stock authorized with a par value of \$0.001. The Company's Board of Directors is authorized to provide for the issuance of shares of preferred stock in one or more series, fix or alter the designations, preferences, rights, qualifications, limitations or restrictions of the shares of each series, including the dividend rights, dividend rates, conversion rights, voting rights, term of redemption including sinking fund provisions, redemption price or prices, liquidation preferences and the number of shares constituting any series or designations of such series without further vote or action by the shareholders. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of management without further action by the shareholders and may adversely affect the voting and other rights of the holders of common stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control to others.

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

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

Series A Convertible Preferred Stock ("Series A Convertible Preferred")

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

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

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

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

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

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

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

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

Certain Price and Share Adjustments.

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

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

Series B Convertible Preferred Stock ("Series B Convertible Preferred")

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

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

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

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

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

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

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

Certain Price and Share Adjustments.

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

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

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

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

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

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

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

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 C Convertible Preferred in cash at a price per share of Series C Convertible Preferred equal to 100% of the Liquidation Preference.

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

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

Certain Price and Share Adjustments.

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

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

Common and Preferred Stock Issuances - 2021

In January 2021, the Company issued 384,445 shares of common stock in a settlement of accounts payable valued at \$50,000.

In January 2021, the Company issued 1,259,250 shares of common stock in conversion of a note payable and accrued interest totaling \$50,370. The conversion resulted in a loss on conversion of \$176,295 that is reflected in the Condensed Statement of Operations for the three months ended March 31, 2021.

In March 2021, the Company issued 22,500,000 shares of common stock along with 11,237,500 warrants under the Regulation A+ for cash proceeds of \$1,800,000 for the common stock and the warrants were purchased for \$11,238.

Between January 8, 2021 and January 29, 2021, the Company issued 3,870,428 shares of common stock in the cashless exercise of 5,430,000 warrants.

Common and Preferred Stock Issuances - 2020

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

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

In March 2020, the Company entered into agreements to issue 4,640,000 shares of common stock conditioned upon the qualification of the offer and sale of such shares under Regulation A+ for \$125,280. Additionally, the Company agreed to issue 2,320,000 warrants with a term of two years and an exercise price of \$.045 for a purchase price of \$1,243. These shares were issued on June 10, 2020 following the qualification of the Regulation A+ and are reflected as shares to be issued as of March 31, 2020.

In March 2020, certain holders of convertible promissory notes entered into agreements to exchange certain notes totaling \$526,113, including \$425,000 in principal amount, \$23,430 in accrued interest and an exchange premium as provided for in the note agreements of \$77,683 into 19,485,668 shares of common stock effective upon the qualification of the offer and sale of such shares under Regulation A+. In connection with the holder's agreement to enter into the exchange, the Company intends to issue 2,200,000 warrants with a two-year term and an exercise price of \$0.045 per share and amend 4,400,000 previously issued warrants to provide for a \$.045 exercise price and an expiration date of March 31, 2022. These shares were issued on June 10, 2020 following the qualification of the Regulation A+ and are reflected as shares to be issued as of March 31, 2020.

NOTE 6: COMMON STOCK OPTIONS, WARRANTS AND RESTRICTED STOCK UNITS

Common Stock Options

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

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

	Options Outstanding		Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value	Weighted Average Exercise Price Per Share
	Number Of Shares	Exercise Price Per Share			
Balance at December 31, 2020	28,885,461	\$ 0.024-120.00	5.57 years	\$ 1,661,429	\$ 0.05
Options granted	-	\$ -	-	-	\$ -
Options exercised	-	\$ -	-	-	\$ -
Options expired	(-)	\$ -	-	-	\$ -
Balance at March 31, 2021	<u>28,885,461</u>	\$ 0.024-120.00	5.32 years	\$ 1,582,568	\$ 0.05
Exercisable at March 31, 2021	<u>28,789,836</u>	\$ 0.024-120.00	5.31 years	\$ 1,575,138	\$ 0.05

During the three months ended March 31, 2021 and 2020, the Company recognized \$0 and \$0, respectively, worth of stock based compensation related to the vesting of it stock options.

Common Stock Warrants

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

	Warrants Outstanding		Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value	Weighted Average Exercise Price Per Share
	Number Of Shares	Exercise Price Per Share			
Balance at December 31, 2020	32,064,375	\$ 0.04-80.00	1.65 years	\$ 1,614,567	\$ 0.06
Warrants granted	11,237,500	\$ 0.10	-		\$ -
Warrants exercised	(5,430,000)	\$ -	-		\$ -
Warrants expired/cancelled	(709,375)	\$ -	-		\$ -
Balance at March 31, 2021	<u>37,162,500</u>	\$ 0.04-80.00	1.69 years	\$ 1,182,301	\$ 0.07
Exercisable at March 31, 2021	<u>37,162,500</u>	\$ 0.04-80.00	1.69 years	\$ 1,182,301	\$ 0.07

Changes to these inputs could produce a significantly higher or lower fair value measurement. The fair value of each option/warrant is estimated using the Black-Scholes valuation model. The following assumptions were used for the periods as follows:

	Three Months Ended March 31, 2021	Year Ended December 31, 2020
Expected term	-	2 - 5 years
Expected volatility	-%	109 - 147%
Expected dividend yield	-	-
Risk-free interest rate	-%	0.20 - 0.58%

The Company issued a convertible note in the amount of \$100,000 to an accredited investor. The note bears interest at 8% per annum and matures March 31, 2020. The Company granted 1,250,000 warrants with an exercise price of \$0.06 per share and a term of two years with this note and amended 1,312,500 previously issued warrants held by the investor to provide for a \$.06 exercise price and an expiration date of March 31, 2022. This issuance resulted in a debt discount of \$28,482.

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

In March through June 2020, certain holders of convertible promissory notes entered into agreements to exchange certain notes totaling \$651,044, including \$525,000 in principal amount, \$27,536 in accrued interest and an exchange premium as provided for in the note agreements of \$98,508 into 21,770,668 shares of common stock effective upon the qualification of the offer and sale of such shares under Regulation A+. In connection with the holder's agreement to enter into the exchange, the Company issued 2,200,000 warrants with a two-year term and an exercise price of \$0.045 per share and amend 4,400,000 previously issued warrants to provide for a \$.045 exercise price and an expiration date of March 31, 2022. These shares were issued on June 10, 2020 following the qualification of the Regulation A+. The issuance of the warrants resulted in \$77,883 in additional warrant expense.

Between November 30, 2020 and December 2, 2020 the Company sold 19,200,000 warrants for \$19,200. These warrants have a two-year term and have an exercise price of \$0.06 per share.

On November 30, 2020, the Company exchanged 1,867,500 warrants into 933,750 shares of common stock, and between December 14, 2020 and December 28, 2020, there were cashless exercises of 6,860,000 warrants into 4,759,435 shares of common stock.

In the Company's quarter ended December 31, 2020, 22,364,972 warrants expired.

Between January 8, 2021 and January 29, 2021, the Company issued 3,870,428 shares of common stock in the cashless exercise of 5,430,000 warrants.

In March 2021 the Company sold 11,237,500 warrants for \$11,238. These warrants have a two-year term and have an exercise price of \$0.10 per share.

In the Company's quarter ended March 31, 2021, 709,375 warrants expired.

Restricted Stock Units

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

	Number Of Shares	Weighted Average Grant Date Fair Value
Balance at December 31, 2020	262,500	\$ 0.59
RSU's granted	-	\$ -
RSU's vested	-	\$ -
RSU's forfeited	-	\$ -
Balance at March 31, 2021	262,500	\$ 0.59

During the three months ended March 31, 2021 and 2020, the Company recognized \$0 and \$0 worth of expense related to the vesting of its RSU's. As of March 31, 2021, the Company had \$155,400 worth of expense yet to be recognized for RSU's not yet vested.

On May 3, 2021, the Company has granted 12,000,000 RSUs to a consultant that vest on the grant date.

On May 3, 2021, as part of an Employment Agreement with the CEO, the Company granted 30,000,000 RSUs to the CEO. Of the 30,000,000 RSUs, 15,000,000 of them vest as follows: 5,000,000 on the grant date, 5,000,000 on the first anniversary and 5,000,000 on the second anniversary. The remaining 15,000,000 RSUs vest as performance-based grants, with the Board of Directors determining the criteria of each 5,000,000 RUSs at the nine-month anniversary, eighteen-month anniversary and twenty-seven month anniversary intervals. The Board of Directors has 90 days from May 3, 2021 to determine the performance criteria.

NOTE 7: LEGAL MATTERS

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

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

On November 25, 2019, the Company and its current and former directors entered into a Settlement Agreement with the Plaintiff. Under the terms of the Settlement Agreement, the Company issued 500,000 shares of common stock and 500,000 warrants to the Plaintiff, made an initial payment of \$33,503 by December 4, 2019 and beginning on December 16, 2019, the Company made payments of \$10,000 per month for 10 months in full satisfaction of the Separation Agreement and General Release originally entered into on July 21, 2017.

NOTE 8: 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. The Company on December 31, 2020 extended this agreement through December 31, 2021 while renegotiating terms of a new Employment Agreement. On May 3, 2021, the Company and the Chief Executive Officer agreed the terms of a new Employment Agreement with an effective date of January 1, 2021 that has a term of three years and expires December 31, 2023.

Under the terms of the Employment Agreement, the Company shall pay to Dr. Korenko a base compensation of \$225,000. In addition, there is a discretionary bonus to be earned in the amount of \$7,500 per quarter upon the satisfaction of conditions to be determined by the Board of Directors of the Company.

NOTE 9: SUBSEQUENT EVENTS

On May 3, 2021, the Company and the Chief Executive Officer agreed the terms of a new Employment Agreement with an effective date of January 1, 2021 that has a term of three years and expires December 31, 2023.

On May 3, 2021, the Company has granted 12,000,000 RSUs to a consultant that vest on the grant date.

On May 3, 2021, as part of an Employment Agreement with the CEO, the Company granted 30,000,000 RSUs to the CEO. Of the 30,000,000 RSUs, 15,000,000 of them vest as follows: 5,000,000 on the grant date, 5,000,000 on the first anniversary and 5,000,000 on the second anniversary. The remaining 15,000,000 RSUs vest as performance-based grants, with the Board of Directors determining the criteria of each 5,000,000 RUSs at the nine-month anniversary, eighteen-month anniversary and twenty-seven month anniversary intervals. The Board of Directors has 90 days from May 3, 2021 to determine the performance criteria.

On May 5, 2021, the Company’s CEO surrendered 8,120,152 stock options.

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.

Vivos Inc. is a radiation oncology medical device company engaged in the development of its yttrium-90 ("Y-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 2013 the FDA issued the determination that RadioGel™ is a device for human therapy for non-resectable cancers in humans. This should result in a faster path than a drug for final approval.

In January 2018, the Center for Veterinary Medicine Product Classification Group ruled that RadioGel™ 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, RadioGel™ 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 RadioGel™ are used synonymously throughout this document. The only distinction between IsoPet® and RadioGel™ is the FDA's recommendation that we use "IsoPet®" for veterinarian usage, and reserve "RadioGel™" for human therapy. Based on these developments, the Company has shifted its primary focus to the development and marketing of IsoPet® for animal therapy, through the Company's IsoPet® Solutions division.

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

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

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

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

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

Commencing in July 2019, the Company recognized its first commercial sale of IsoPet®. A veterinarian from 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. This sale met the revenue recognition requirements under ASC 606 as the performance obligation was satisfied. The Company completed sales for an additional four animals that received the IsoPet® during 2019.

Our plan is to incorporate the data assembled from our work with Isopet® in animal therapy to support the Company’s efforts in the development of our RadioGel™ device candidate, including obtaining approval from the *FDA* to market and sell RadioGel™ as a Class II medical device. RadioGel™ is an injectable particle-gel for brachytherapy radiation treatment of cancerous tumors in people and animals. RadioGel™ is comprised of a hydrogel, or a substance that is liquid at room temperature and then gels when reaching body temperature after injection into a tumor. In the gel are small, less than two microns, Y-90 phosphate particles. 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.

Recently, the Company modified its Indication for Use from skin cancer to cancerous tissue or solid tumors pathologically associated with locoregional papillary thyroid carcinoma and recurrent papillary thyroid carcinoma having discernable tumors associated with metastatic lymph nodes or extranodal disease in patients who are not surgical candidates or who have declined surgery, or patients who require post-surgical remnant ablation (for example, after prior incomplete radioiodine therapy). Papillary thyroid carcinoma belongs to the general class of head and neck tumors for which tumors are accessible by intraoperative direct needle injection. The Company’s Medical Advisory Board felt that demonstrating efficacy in clinical trials was much easier with this new indication.

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 (May 2022). Other intellectual property protection includes proprietary production processes and trademark protection in 17 countries.

The Company plans to continue efforts to develop new refinements on the production process, and the product and application hardware, as a basis for future patents.

The Company received the Patent Cooperation Treaty (“PCT”) International Search Report on our patent application (No.1811.191). Seven of our claims were immediately ruled as having novelty, inventive step and industrial applicability. This gives us the basis to extend for many years the patent protection for our proprietary Yttrium-90 phosphate particles utilized in IsoPet® and Radiogel™. As part of the normal review process, we have also submitted the technical justification for seven additional claims. We are in the process of filing patent claims in Canada, UK (Great Britain, Scotland, Wales and Ireland), Japan, Germany, Italy, France, Australia, Brazil, China, India, North Countries (Sweden, Norway, Finland, and Denmark).

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 the Company. The pilot is being used to

- 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;
- Develop communication material and a liability document for the pet owners; and
- Further refine the therapy techniques for advanced cancers.

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

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

There have been 63 expressions of interest in IsoPet® therapy from across the United States, but only about 10% of these were treated and they were very advanced cases. The reasons are instructive. Most of the cases were for so advanced that the pet parents found out about IsoPet® on the Internet as a last hope. Several others were internal cancers that could not be reached, for example deep in the throat. Several cases were treatable, but the pets weighed more than 20 pounds and the pet parents were not willing to fly them in the “Safe Cargo” holds. Those patients would have been treated by regional clinics once we implement that strategy. Several cases were mast cell cancers. The Company is confident that those tumors could have been treated, but once killed they release mast cells in a process called granulation. This could cause a shock to the animal’s system. The Company will focus one of our clinical studies on the optimum approach for those therapies.

Vista Veterinary Hospital accepted advanced cancer cases and has gained experience to extend the animal's lives. The first cat was terminally ill and had previously had external beam, surgery and chemotherapy. The facial tumor was treated with 400 Gy and the biopsy confirmed that the cancer was killed. In about seven months the cancer returned in the throat and could not be treated so the cat had to be put down. Dr. Bauder, the veterinarian pet parent, was still elated about the life extension and is asking us to use him as a reference. The other cases were also very advanced with multiple tumors and they recurred since they had already spread before therapy. One animal, Yukon had a large tumor on his leg that was recommended for amputation. The tumor size decreased 50% after the first treatment, but then stopped decreasing. For the first time a second therapy was administered and the tumor has continued to decrease in size.

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

Regulatory History

Human Therapy

RadioGel[™] has a long regulatory history with the Food and Drug Administration ("FDA"). Initially, the Company submitted a pre-submission (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.

In November 2020 the Company submitted a request for a Breakthrough Device Designation. Ultimately, this was denied, but the FDA acknowledged, “The FDA does believe that RadioGel™ meets criterion #2a: Device represents breakthrough technology. Your device *does meet this criterion* because it is a novel application of a brachytherapy device outside of the liver.” More importantly the process resulted in a rapid review of our existing data and approach. It led to a redirection of our efforts on writing the IDE and saved the Company much time in the review of that future application.

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 cancerous tissue or solid tumors pathologically associated with locoregional papillary thyroid carcinoma and recurrent papillary thyroid carcinoma. 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.

Financing and Strategy

The Company’s stock offering under Regulation A+ was qualified by the Securities and Exchange Commission (“SEC”) on June 3, 2020.

The Company over the past twelve months has raised approximately \$4,000,000 from the sale of shares under Regulation A+, and intends to use the proceeds generated as follows:

For the animal therapy market:

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

For the human market:

- Enhance the pedigree of the Quality Management System.
- Complete the previously defined pre-clinical testing and additional testing on an animal model closely aligned with our revised indication for use. Report the results to the FDA in a pre-submission meeting.
- Use the feedback from that meeting to write the IDE (Investigational Device Exemption), which is required to initiate clinical trials.

Research and development of the Company’s brachytherapy product line has been funded with proceeds from the sale of equity and debt securities. The Company may require additional funding of approximately \$2 million annually to maintain current operating activities. Over the next 12 to 24 months, the Company believes it will cost approximately \$9 million to: (1) fund the FDA approval process to conduct human clinical trials, (2) conduct Phase I, pilot, clinical trials, (3) activate several regional clinics to administer IsoPet® across the county, (4) create an independent production center within the current production site to create a template for future international manufacturing, and (5) initiate regulatory approval processes outside of the United States.

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

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

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

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

The Company has been impacted from the effects of COVID-19. The Company's headquarters are in Northeast Washington however the focus of the animal therapy market has been the Northwestern sector of the United States, the initial epicenter of the COVID-19 outbreak in the United States. The Company is hopeful that by the end of the third quarter of 2021, they will be allowed to continue their marketing to the animal therapy market and attempt to increase the exposure to their product and generate revenue accordingly.

As of March 31, 2021, the Company has \$2,511,845 cash on hand. There are currently commitments to vendors for products and services purchased. To continue the development of the Company's products, the current level of cash may not be enough to cover the fixed and variable obligations of the Company.

There is no guarantee that the Company will be able to raise additional funds or to do so at an advantageous price.

Product Features

The Company's RadioGel™ device has the following product features:

- Beta particles only travel a short distance so the device can deliver high radiation to the tumor with minimal dose to the nearby normal tissues. In medical terms Y-90 beta emitter has a high efficacy rate;
- Benefitting from the short penetration distance, the patient can go home immediately with no fear of exposure to family members, and there is a greatly reduced radiation risk to the doctor. A simple plastic tube around the syringe, gloves and safety glasses are all that is required. Other gamma emitting products require much more protection;
- A 2.7-day half-life means that only 5% of the radiation remains after ten days. This is in contrast to the industry-standard gamma irradiation product, which has a half-life of 17 days;
- The short half-life also means that any medical waste can be stored for thirty days then disposed as normal hospital waste;
- RadioGel™ can be administered with small diameter needles (27-gauge) so there is minimal damage to the normal tissue. This is in contrast to the injection of metal seeds, which does considerable damage; and
- After about 120 days the gel resorbs by a normal biological cycle, called the Krebs Cycle. The only remaining evidence of the treatment are phosphate particles so small in diameter that it requires a high-resolution microscope to find them. This is in contrast to permanent presence of metal seeds.

Steps from Production to Therapy

Device Production

During the next two years, the Company intends to outsource material aspects of manufacturing and distribution. As future product volume increases, the Company will reassess its make-buy decision on manufacturing and will analyze the cost/benefit of a centrally located facility.

Production of the Hydrogel

RadioGel™ is manufactured with a proprietary process under ventilated sterile hood by following strict Good Laboratory Practices (“GLP”) procedures. It is made in large batches that are frozen for up to three months. When the product is ready to ship, a small quantity of the gel is dissolved in a sterile saline solution. It is then passed through an ultra-fine filter to ensure sterility.

Production of the Yttrium-90 Phosphate Particles

The Y-90 particles are produced with simple ingredients via a proprietary process, again following strict GLP procedures. They are then mixed into a phosphate-buffered saline solution. They can be produced in large batches for several shipments. The number of particles per shipment is determined by the dose prescribed by the doctor.

Shipment

RadioGel™ is shipped in two containers, one with a solution of the gel and the other with a solution of the particles. Before shipment they are subjected to sterility testing, again by strict procedures. The vial with the Y-90 is put through a special radiation calibrator, which measures beta particles. The vials can be shipped via FedEx or UPS by following the proper protocols.

At the User

The user receives the two vials. The solution containing the RadioGel™ is mixed with the solution containing the Y-90 particles. This is then shaken to ensure homogeneity and withdrawn into a syringe. The quantities that are mixed are calculated from the information on the product label.

The specific injection technique depends on the Indication for Use. For small tumors, one centimeter in diameter or less, the cancer is treated with a single injection. For larger tumors, the cancer is treated with a series of small injections from the same syringe or multiple syringes.

Principal Markets

The Company is currently pursuing two synergistic business sectors, medical and veterinary, each of which are summarized below.

Medical Sector

RadioGel™ is currently fully developed, requiring only FDA approval before commercialization. The Company has been seeking FDA approval of RadioGel™ for almost five years. Recent progress has been delayed due to a lack of adequate funding. The principal issue preventing approval is that the Company attempted to obtain regulatory approval for a broad range of Indications for Use, including all non-resectable cancers, without sufficient supporting data.

Building on the FDA’s ruling of RadioGel™ as a device, the Company is currently developing test plans to address issues raised in the Company’s prior FDA submittal regarding RadioGel™. The Company intends to request FDA approval to submit RadioGel™ for *de novo* classification, which would reclassify the device from a Class III device to a Class II device and accelerate the regulatory approval path.

After analyzing the Company’s data and the last five years of communication from the FDA, the Company has taken the following steps:

1. Under new leadership, the Company is implementing all past recommendations from the FDA. The Company intends to narrow the Indications for Use, will provide test plans for FDA review to respond to answer all previous FDA questions, and will request a pre-submission meeting;
2. Prepare a pre-submission request document and FDA meeting request to obtain feedback on the test plans in order to initiate testing, to present the proposed content for the final application and to request permission to submit a *de novo*;
3. Submit an Investigational Device Exemption (“*IDE*”) to obtain permission to conduct human clinical studies; and
4. File a *de novo* or Pre-Market Approval application.

The critical path is the required testing – in vitro, animal testing, human clinical studies – all of which is resource dependent.

In previous submittals, the Company proposed applying a very broad range of cancer therapies, referred to as Indications for Use, to RadioGel™. The FDA has strongly advised the Company to reduce its Indications for Use. To comply with that request, the Company has expanded its MAB, consisting of Drs. Barry D. Pressman (Chairman), Albert DeNittis, and Howard Sandler.

The MAB evaluated the candidate cancer therapies based on three criteria: (i) the potential for FDA approval and successful therapy; (ii) notable advantages of RadioGel™ over current therapies; and (iii) the likelihood that RadioGel™ can be widely accepted by the medical community and profitably commercialized.

The MAB selected eighteen Indications for Use for RadioGel™, each of which meets the above-mentioned criteria. These eighteen Indications for Use are listed below. This large number confirms the wide applicability of the device and defines the path for future growth. The Company intends to apply to the FDA for a single Indication for Use, followed by subsequent applications for additional Indications for Use. The initial application should facilitate each subsequent application, and the testing for many of the subsequent applications could be conducted in parallel, depending on available resources.

- Skin cancer
- Involved lymph nodes
- Bladder
- Liver
- Localized prostate
- Pancreas
- Head and neck (including sino-nasal and oropharyngeal)
- Ocular melanoma
- Non-dendritic brain
- Pediatric cancers – several types
- Rectal
- Gynecological
- Spinal
- Recurrent esophageal
- Breast cancer resection cavity
- Anaplastic thyroid

After thorough review to prioritize indications, the MAB has selected basal cell and squamous cell carcinoma (skin cancers) as the first Indication for Use to be presented to the FDA. According to American Cancer Society, one out of every three new cancers diagnosed in the U.S. is a cancerous skin lesion of this type, representing 5.5 million tumors annually. The MAB believes RadioGel™ will be the preferred treatment in a reasonable number of cases in a very large market.

Veterinary Sector

There are approximately 150 million pet dogs and cats in the United States. Nearly one-half of dogs and one-third of cats are diagnosed with cancer at some point in their lifetime. The Veterinary Oncology & Hematology Center in Norwalk, Connecticut, reports that cancer is the number one natural cause of death in older cats and dogs, accounting for nearly 50 percent of pet deaths each year. The American Veterinary Medical Association reports that half of the dogs ten years or older will die because of cancer. The National Cancer Institute reports that about six million dogs are diagnosed with cancer each year, translating to more than 16,000 a day.

The Company's IsoPet[®] operating division focuses on the veterinary oncology market. Dr. Alice Villalobos, a founding member of the Veterinary Cancer Society and the Chair of our Veterinary Medicine Advisory Board, has been providing guidance to management regarding this market. The Veterinary Medicine Advisory Board gives us recommendations regarding the overall strategy for our animal business sector. Specially, they recommended the university veterinary hospitals for demonstration therapies, the specific cancers to be treated, and have provided business contact information to the private clinics.

Development of the product and application techniques and animal testing is allowed under FDA regulation. Commercial sales of RadioGel[™] for animals requires confirmation by the FDA Center for Veterinary Medicine ("CVM"). In January 2018, the Center for Veterinary Medicine Product Classification Group, the entity within the CVM that is responsible for determining the classification of a product, ruled that RadioGel[™] 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 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 all solid tumors in animals. We expect the result of such classification and label approval will be that no additional regulatory approvals are necessary for the use of RadioGel[™] 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.

The Company currently intends to utilize university veterinary hospitals for therapy development, given that veterinary hospitals offer superior and plentiful veterinarians and students, a large number of animal patients, radioactive material handling licenses, and are respected by private veterinary centers and hospitals.

Pursuant to the terms of the grant with Washington State University, it was responsible for conducting studies regarding in vivo dosimetry and toxicity of intralesional Y-90 phosphate nanoparticles for the treatment of spontaneous feline and canine sarcomas. The term of the grant was October 1, 2016 through January 31, 2018. The Company provided the university with the RadioGel[™] required to complete the studies, as well as technical support for dosimetry calculations. All payments provided to Washington State University in relation to the grant were made by Washington State Life Sciences Discovery Fund pursuant to a grant and were not paid by the Company. To compliment the grant, additional scope was added to explore the option of pre-mixing the vials prior to shipment and the Company was reimbursed \$17,583 as a separate contract to the grant.

Pursuant to the terms of the contract with the University of Missouri, it was responsible for conducting studies regarding in vivo dosimetry and toxicity of intralesional Y-90 phosphate nanoparticles for the treatment of soft tissue carcinoma and equine sarcoids. The term of the contract was initially from November 1, 2017 through October 31, 2018, but it has recently been working to extend this contract through testing completion on canine soft tissue sarcoma and equine sarcoids, plus additional tumors of interest defined by the University of Missouri principal investigators. This extension is dependent upon keeping current with paying for the expenses of the ongoing therapies.

Competitors

The Company competes in a market characterized by technological innovation, extensive research efforts, and significant competition.

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological changes. A number of companies are pursuing the development of pharmaceuticals and products that target the same diseases and conditions that our products target. We cannot predict with accuracy the timing or impact of the introduction of potentially competitive products or their possible effect on our sales. Certain potentially competitive products to our products may be in various stages of development. Also, there may be many ongoing studies with currently marketed products and other developmental products, which may yield new data that could adversely impact the use of our products in their current and potential future Indications for Use. The introduction of competitive products could significantly reduce our sales, which, in turn would adversely impact our financial and operating results.

There are a wide variety of cancer treatments approved and marketed in the U.S. and globally. General categories of treatment include surgery, chemotherapy, radiation therapy and immunotherapy. These products have a diverse set of success rates and side effects. The Company's products, including RadioGel™, fall into the brachytherapy treatment category. There are a number of brachytherapy devices currently marketed in the U.S. and globally. The traditional iodine-125 (I-125) and palladium-103 (Pd-103) technologies for brachytherapy are well entrenched with powerful market players controlling the market. The industry-standard I-125-based therapy was developed by Oncura, which is a unit of General Electric Company. Additionally, C.R. Bard, a major industry player competes in the I-125 brachytherapy marketplace. These market competitors are also involved in the distribution of Pd-103 based products. Cs-131 brachytherapy products are sold by IsoRay. Several Y-90 therapies have been FDA approved including SIR-Spheres by Sirtex, TheraSphere by Biocompatibles UK and Zevalin by Spectrum Pharmaceuticals.

Raw Materials

The Company currently subcontracts the manufacturing of RadioGel™ at IsoTherapeutics. Eckert and Ziegler the only supplier of Y-90 in the United States, is the sole supplier of the Y-90 used by IsoTherapeutics to manufacture the Company's RadioGel™. The Company obtains supplies, hardware, handling equipment and packaging from several different U.S. suppliers.

Customers

The Company anticipates that potential customers for our potential brachytherapy products likely would include those institutions and individuals that currently purchase brachytherapy products or other oncology treatment products.

Government Regulation

The Company's present and future intended activities in the development, manufacturing and sale of cancer therapy products, including RadioGel™, are subject to extensive laws, regulations, regulatory approvals and guidelines. Within the United States, the Company's therapeutic radiological devices must comply with the U.S. Federal Food, Drug and Cosmetic Act, which is enforced by FDA. The Company is also required to adhere to applicable FDA Quality System Regulations, also known as the Good Manufacturing Practices, which include extensive record keeping and periodic inspections of manufacturing facilities.

In the United States, the FDA regulates, among other things, new product clearances and approvals to establish the safety and efficacy of these products. We are also subject to other federal and state laws and regulations, including the Occupational Safety and Health Act and the Environmental Protection Act.

The Federal Food, Drug, and Cosmetic Act and other federal statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, distribution, use, reporting, advertising and promotion of such products. Noncompliance with applicable requirements can result in civil penalties, recall, injunction or seizure of products, refusal of the government to approve or clear product approval applications, disqualification from sponsoring or conducting clinical investigations, preventing us from entering into government supply contracts, withdrawal of previously approved applications, and criminal prosecution.

In the United States, medical devices are classified into three different categories over which the FDA applies increasing levels of regulation: Class I, Class II, and Class III. Most Class I devices are exempt from premarket notification 510(k); most Class II devices require premarket notification 510(k); and most Class III devices require premarket approval. RadioGel™ is currently classified as a Class III device.

Approval of new Class III medical devices is a lengthy procedure and can take a number of years and require the expenditure of significant resources. There is a shorter FDA review and clearance process for Class II medical devices, the premarket notification or 510(k) process, whereby a company can market certain Class II medical devices that can be shown to be substantially equivalent to other legally marketed devices.

The Company intends to apply for a *de novo* with an anticipated expenditure of \$10.0 million over the next four years. This expenditure estimate includes anticipated costs associated with in vitro and in vivo pre-clinical testing, our application for an Investigational Device Exemption, Phase I and Phase II clinical trials and our application for a *de novo*.

As a registered medical device manufacturer with the FDA, we are subject to inspection to ensure compliance with FDA's current Good Manufacturing Practices, or cGMP. These regulations require that we and any of our contract manufacturers design, manufacture and service products, and maintain documents in a prescribed manner with respect to manufacturing, testing, distribution, storage, design control, and service activities. Modifications or enhancements that could significantly affect the safety or effectiveness of a device or that constitute a major change to the intended use of the device require a new 510(k) premarket notification for any significant product modification.

The Medical Device Reporting regulation requires that we provide information to the FDA on deaths or serious injuries alleged to be associated with the use of our devices, as well as product malfunctions that are likely to cause or contribute to death or serious injury if the malfunction were to recur. Labeling and promotional activities are regulated by the FDA and, in some circumstances, by the Federal Trade Commission.

As a medical device manufacturer, we are also subject to laws and regulations administered by governmental entities at the federal, state and local levels. For example, our facility is licensed as a medical device manufacturing facility in the State of Washington and is subject to periodic state regulatory inspections. Our customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us.

In the United States, as a manufacturer of medical devices and devices utilizing radioactive byproduct material, we are subject to extensive regulation by not only federal governmental authorities, such as the FDA and FAA, but also by state and local governmental authorities, such as the Washington State Department of Health, to ensure such devices are safe and effective. In Washington State, the Department of Health, by agreement with the federal Nuclear Regulatory Commission ("NRC"), regulates the possession, use, and disposal of radioactive byproduct material as well as the manufacture of radioactive sealed sources to ensure compliance with state and federal laws and regulations. RadioGel™ constitutes both medical devices and radioactive sealed sources and are subject to these regulations.

Moreover, our use, management, and disposal of certain radioactive substances and wastes are subject to regulation by several federal and state agencies depending on the nature of the substance or waste material. We believe that we are in compliance with all federal and state regulations for this purpose.

Environmental Regulation

Our business does not require us to comply with any extraordinary environmental regulations. Our RadioGel™ product is manufactured in an independently owned and operated facility. Any environmental effects or contamination event that could result would be from the shipping company during shipment and misuse by the treatment facility upon arrival.

Human Capital

As of March 31, 2021, the Company had one full-time personnel. The Company utilizes several independent contractors to assist with its operations. The Company does not have a collective bargaining agreement with any of its personnel and believes its relations with its personnel are good.

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

The following table sets forth information from our statements of operations for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
Revenues	\$ -	\$ -
Operating expenses	(235,090)	(120,373)
Operating loss	(235,090)	(120,373)
Non-operating income (expense):		
Interest expense	(53,099)	(239,858)
Net loss	\$ (288,189)	\$ (360,231)

Revenue

Revenue was \$0 for the three months ended March 31, 2021 and 2020, respectively.

Operating Expenses

Operating expenses for the three months ended March 31, 2021 and 2020, respectively consists of the following:

	Three months ended March 31, 2021	Three months ended March 31, 2020
Professional fees	\$ 78,214	\$ 53,992
Payroll expenses	49,341	30,000
Research and development	71,700	1,028
General and administrative expenses	35,835	35,353
Total operating expenses	\$ 235,090	\$ 120,373

Operating expenses for the three months ended March 31, 2021 and 2020 was \$235,090 and \$120,373, respectively. The increase in operating expenses from 2020 to 2021 can be attributed to the increase in professional fees (\$53,992 for the three months ended March 31, 2020 versus \$78,214 for the three months ended March 31, 2021) as the Company utilized more services due to amending their Regulation A+ and the fees incurred for the consultants engaged; the increase in general and administrative expense (\$35,353 for the three months ended March 31, 2020 versus \$35,835 for the three months ended March 31, 2021); the increase in research and development (\$1,028 for the three months ended March 31, 2020 versus \$71,700 for the three months ended March 31, 2021) as the Company ramped up the development of their products with the recent raising of capital, and an increase in payroll expenses (\$30,000 for the three months ended March 31, 2020 versus \$49,341 for the three months ended March 31, 2021) related to the deferred compensation criteria in the CEOs employment contract taking effect.

Non-Operating Income (Expense)

Non-operating income (expense) for the three months ended March 31, 2021 and 2020 consists of the following:

	Three months ended March 31, 2021	Three months ended March 31, 2020
Interest expense	\$ (6,549)	\$ (239,858)
Forgiveness of debt	129,745	-
Loss on debt extinguishment	(176,295)	-
Non-operating income (expense)	<u>\$ (53,099)</u>	<u>\$ (239,858)</u>

Non-operating income (expense) for the three months ended March 31, 2021 varied from the three months ended March 31, 2020 primarily due to a decrease in interest expense from \$239,858 for the three months ended March 31, 2020 to \$6,549 for the three months ended March 31, 2021 as a result of conversions of notes payable. The majority of the interest recorded by the Company consists of amortization of debt discount, BCF discount and the exchange premium resulting in additional shares to the noteholders on conversion. In addition, the Company converted a note in January 2021 which resulted in a loss on conversion and recognized a gain on forgiveness of debt on old payables as they satisfied the agreement with this vendor to pay a portion of the payable with the remaining amount forgiven.

Net Loss

Our net loss for the three months ended March 31, 2021 and 2020 was \$(288,189) and \$(360,231), respectively.

Liquidity and Capital Resources

At March 31, 2021, the Company had working capital of \$1,831,748, as compared to working capital of \$32,034 at December 31, 2020. During the three months ended March 31, 2021, the Company experienced negative cash flow from operations of \$203,097 and realized \$1,811,238 of cash flows from financing activities. As of March 31, 2021, the Company did not have any commitments for capital expenditures.

Cash used in operating activities increased from \$87,247 for the three months ended March 31, 2020 to \$203,097 for the three months ended March 31, 2021. Cash used in operating activities was primarily a result of the Company's non-cash items, such as loss from operations, loss conversion of debt as well as forgiveness of debt as well as the changes in prepaid expenses and accounts payable. Cash provided from financing activities increased from \$71,870 for the three months ended March 31, 2020 to \$1,811,238 for the three months ended March 31, 2021. The increase in cash provided from financing activities was primarily a result of increase in proceeds from the Regulation A+ where the Company raised \$1,811,238 from common stock and warrant issuances in 2021 versus, the proceeds from convertible notes and related party notes of \$115,000, proceeds from the sale of common stock of \$6,870 and payment on the redemption of preferred stock of \$50,000 in 2020.

The Company has generated material operating losses since inception. The Company had a net loss of \$288,189 for the three months ended March 31, 2021, and a net loss of \$360,231 for the three months ended March 31, 2020. The Company expects to continue to experience net operating losses for the foreseeable future. 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 for working capital as well as business expansion, although the Company can provide no assurance that additional capital will be available on terms acceptable to the Company, if at all. If the Company is unable to obtain additional financing to meet its working capital requirements, it may have to curtail its business or cease all operations.

Over the next 12 to 24 months, the Company believes it will cost approximately \$2 million to fund: (1) fund the FDA approval process to conduct human clinical trials, (2) conduct Phase I, pilot, clinical trials, (3) activate several regional clinics to administer IsoPet[®] across the county, (4) create an independent production center within the current production site to create a template for future international manufacturing, and (5) initiate regulatory approval processes outside of the United States.

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.

Although the Company is seeking to raise additional capital and has engaged in numerous discussions with investment bankers and investors, to date, the Company has not received firm commitments for the required funding. Based upon its discussions, the Company anticipates that if the Company is able to obtain the funding required to retire outstanding debt, pay past due payables and maintain its current operating activities, that the terms associated with such funding will result in material dilution to existing shareholders.

Recent geopolitical events, including the inherent instability and volatility in global capital markets, as well as the lack of liquidity in the capital markets, could impact the Company's ability to obtain financing and its ability to execute its business plan.

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 March 31, 2021, 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, 2020, filed on March 24, 2021.

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.

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 March 31, 2021 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

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

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

On November 25, 2019, the Company and its current and former directors entered into a Settlement Agreement with the Plaintiff. Under the terms of the Settlement Agreement, the Company issued 500,000 shares of common stock and 500,000 warrants to the Plaintiff, made an initial payment of \$33,503 by December 4, 2019 and beginning on December 16, 2019, the Company made payments of \$10,000 per month for 10 months in full satisfaction of the Separation Agreement and General Release originally entered into on July 21, 2017.

Item 2. Unregistered Sales of Equity Securities

In January 2021, the Company issued 384,445 shares of common stock in a settlement of accounts payable valued at \$50,000.

In January 2021, the Company issued 1,259,250 shares of common stock in conversion of a note payable and accrued interest totaling \$50,370. The conversion resulted in a loss on conversion of \$176,295 that is reflected in the Condensed Statement of Operations for the three months ended March 31, 2021.

In March 2021, the Company issued 22,500,000 shares of common stock along with 11,237,500 warrants under the Regulation A+ for cash proceeds of \$1,800,000 for the common stock and the warrants were purchased for \$11,238.

Between January 8, 2021 and January 29, 2021, the Company issued 3,423,968 shares of common stock in the cashless exercise of 4,875,000 warrants.

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

Item 6. Exhibits.

Exhibit Number	Description
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes – Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes – Oxley Act of 2002
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350
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.

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.

Vivos Inc.

Date: May __, 2021

By: /s/ Michael Korenko

Name: Michael K. Korenko

Title: Chief Executive Officer

(Principal Executive Officer)

Date: May __, 2021

By: /s/ Michael Pollack

Name: Michael Pollack

Title: Interim Chief Financial Officer

(Interim Principal Financial and Accounting Officer)

EXHIBIT 31.1CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael K. Korenko, certify that:

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

Date: May __, 2021

/s/ Michael K. Korenko

Michael K. Korenko
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF INTERIM CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Pollack, certify that:

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

Date: May __, 2021

/s/ Michael Pollack

Michael Pollack
Interim Chief Financial Officer
(Interim Principal Financial Officer)

EXHIBIT 32.1

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

In connection with the accompanying quarterly report of Vivos Inc. (the "*Company*") on Form 10-Q for the quarter ended March 31, 2021 (the "*Report*"), the undersigned, Michael Korenko, Chief Executive Officer of the Company, and Michael Pollack, Interim Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May __, 2021

/s/ Michael K. Korenko

Name: Michael K. Korenko
Title: Chief Executive Officer

/s/ Michael Pollack

Name: Michael Pollack
Title: Interim Chief Financial Officer
