**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-K**

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

**For the fiscal year ended December 31, 2019**

or

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

**For the transition period from \_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_**

**Commission file number: 0-53497**

**VIVOS INC**

(Exact name of registrant as specified in its charter)

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

**719 Jadwin Avenue ● Richland, Washington 99352**

(Address of principal executive offices) (Zip Code)

**(509) 736-4000**

Registrant’s telephone number, including area code

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $0.001 Par Value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [  ] No [X]

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 [X]

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

Indicate by check mark whether the registrant has submitted electronically 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 [X] No [  ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [  ]

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

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| **Large Accelerated Filer** | [  ] | **Accelerated Filer** | [  ] |
| **Non-Accelerated Filer** | [X] | **Smaller Reporting Company** | [X] |
|  |  | **Emerging growth company** | [  ] |

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

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

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| **Title of Each Class** |  | **Trading Symbol** |  | **Name of Each Exchange on which registered** |
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The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant’s most recently completed second fiscal quarter was approximately $3,483,131. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the outstanding common stock of the registrant have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. Without acknowledging that any individual director of registrant is an affiliate, all directors have been included as affiliates with respect to shares owned by them.

As of April 24, 2020, there were 214,421,364 shares of the registrant’s common stock outstanding, 2,552,642 shares of the registrant’s Series A Convertible Preferred Stock outstanding, 1,013,245 of the registrant’s Series B Convertible Preferred Stock outstanding and 385,302 of the registrant’s Series C Convertible Preferred Stock outstanding.

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**VIVOS INC**

**Report on Form 10-K**

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**PART I**

***FORWARD LOOKING STATEMENTS***

Except for statements of historical fact, certain information described in this Annual Report on Form 10-K (“*Annual 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 Annual 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 Annual Report, as well as other cautionary language in this Annual 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.

**ITEM 1. BUSINESS.**

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

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

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

**Overview**

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

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

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

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

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

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

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

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

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

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

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

**Vista Veterinary Hospital**

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

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

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

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

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

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

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

**Regulatory History**

*Human Therapy*

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

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

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

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

**Financing and Strategy**

Research and development of the Company’s brachytherapy product line has been funded with proceeds from the sale of equity and debt securities as well as a series of grants. The Company requires funding of approximately $2.3 million annually to maintain current operating activities. Over the next 12 to 24 months, the Company believes it will cost approximately $5.0 million to $10.0 million to: (1) fund the FDA approval process and initial deployment of the brachytherapy products, and (2) initiate regulatory approval processes outside of the United States. The continued deployment of the brachytherapy products and a worldwide regulatory approval effort will require additional resources and personnel. The principal variables in the timing and amount of spending for the brachytherapy products in the next 12 to 24 months will be the FDA’s classification of the Company’s brachytherapy products as Class II or Class III devices (or otherwise) and any requirements for additional studies which may possibly include clinical studies. Thereafter, the principal variables in the amount of the Company’s spending and its financing requirements would be the timing of any approvals and the nature of the Company’s arrangements with third parties for manufacturing, sales, distribution and licensing of those products and the products’ success in the U.S. and elsewhere. The Company intends to fund its activities through strategic transactions such as licensing and partnership agreements or additional capital raises.

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

The following recent financing events have supported the Company’s execution of its development strategy:

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|  | ● | In November 2019, the Company had its Regulation A+ approved by the Securities and Exchange Commission for an offering up to 150 million shares of common stock. |
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|  | ● | During the Company’s second and third fiscal quarters, the Company secured approximately $300,000 in convertible promissory notes. |
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|  | ● | The Company recognized its first few sales of IsoPet®. |

The Company obtained Regulation A+ approval. The intent is to obtain up to $3,000,000 in tranches of $250,000 over time. The Company intends to use these proceeds as follows:

For the animal therapy market:

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

For the human market:

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

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Based on the Company’s financial history since inception, its auditor 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 execution of its business strategy and may not be able to continue operations. Although management believes that it will be able to secure necessary working capital to fund its development programs and execute its business strategy, no assurances can be given. The Company has raised $125,280 in proceeds under this Regulation A+ in March 2020, which was in escrow until April 2020 at which time it was deposited into the Company’s accounts. The common shares for these proceeds were issued in April 2020. In addition, the Company converted their outstanding convertible notes payable of $415,000, $23,427 in accrued interest and $87,686 in an exchange premium stipulated in the note agreements into shares of common stock effective March 31, 2020. These shares were issued in April 2020, however effective as of March 31, 2020.

**Product Features**

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

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|  | ● | 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; |
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|  | ● | 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; |
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|  | ● | 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; |
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|  | ● | The short half-life also means that any medical waste can be stored for thirty days then disposed as normal hospital waste; |
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|  | ● | 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 |
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|  | ● | 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.

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*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:

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|  | 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; |
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|  | 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; |
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|  | 3. | Submit an Investigational Device Exemption (“*IDE*”) to obtain permission to conduct human clinical studies; and |
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|  | 4. | File a de novo or Pre-Market Approval application. |

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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.

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| ● | Skin cancer | ● | Non-dendritic brain |
| ● | Involved lymph nodes | ● | Pediatric cancers – several types |
| ● | Bladder | ● | Rectal |
| ● | Liver | ● | Gynecological |
| ● | Localized prostate | ● | Spinal |
| ● | Pancreas | ● | Recurrent esophageal |
| ● | Head and neck (including sino-nasal and oropharyngeal) | ● | Breast cancer resection cavity |
| ● | Ocular melanoma | ● | 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 RadioGelTM 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 RadioGelTM should be classified as a device for animal therapy of feline sarcomas and canine soft tissue sarcomas.

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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 RadioGelTM 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 RadioGelTM 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.

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***Raw Materials***

The Company currently subcontracts the manufacturing of RadioGelTM at IsoTherapeutics. PerkinElmer Inc., 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.

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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.

***Employees***

As of December 31, 2019, 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.

***Available Information***

The Company prepares and files annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and certain other information with the United States Securities and Exchange Commission (the “*SEC*”). The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at http://www.sec.gov. Moreover, the Company maintains a website at http://www.RadioGel.com that contains important information about the Company, including biographies of key management personnel, as well as information about the Company’s business. This information is publicly available and is updated regularly. The content on any website referred to in this Annual Report is not incorporated by reference into this Annual Report, unless (and only to the extent) expressly so stated herein.

**ITEM 1A. RISK FACTORS.**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding whether to invest in our securities. The occurrence of any of the events or developments described below could harm our business, financial condition, operating results, and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.*

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**RISKS ASSOCIATED WITH THE COMPANY’S BUSINESS**

***Our independent registered public accounting firms’ reports on its financial statements questions the Company’s ability to continue as a going concern.***

The Company’s independent registered public accounting firms’ reports on the Company’s financial statements for the years ended December 31, 2019 and 2018 express substantial doubt about the Company’s ability to continue as a going concern. The reports include an explanatory paragraph stating that the Company has suffered recurring losses, used significant cash in support of its operating activities and, based on its current operating levels, require additional capital or significant restructuring to sustain its operation for the foreseeable future. There is no assurance that the Company will be able to obtain sufficient additional capital to continue its operations and to alleviate doubt about its ability to continue as a going concern. If the Company obtains additional financing, such funds may not be available on favorable terms and likely would entail considerable dilution to existing shareholders. Any debt financing, if available, may involve restrictive covenants that restrict its ability to conduct its business. It is extremely remote that the Company could obtain any financing on any basis that did not result in considerable dilution for shareholders. Inclusion of a “going concern qualification” in the report of its independent accountants or in any future report may have a negative impact on its ability to obtain debt or equity financing and may adversely impact its stock price.

***A combination of our current financial condition and the FDA’s determinations to date regarding our brachytherapy products raise material concerns about ability to continue as a going concern.***

The Company will not be able to continue as a going concern unless the Company obtains financing. Depending upon the amount of financing, if any, the Company is able to obtain, the Company may not receive adequate funds to continue the approval process for RadioGel™ or other brachytherapy products with the FDA.

***The Company has generated operating losses since inception, which are expected to continue, and has increasing cash requirements, which it may be unable to satisfy*.**

The Company has generated material operating losses since inception. The Company has had recurring net losses since inception which has resulted in an accumulated deficit of $73,601,109 and $71,991,012 as of December 31, 2019 and 2018, respectively including net losses of $1,610,097 and $7,702,845 for the years ended December 31, 2019 and 2018. Of these losses $(18,744) and $418,755 represent net gains (losses) attributable to the recorded derivative liabilities and extinguishment of debt for the years ended December 31, 2019 and 2018, respectively. Historically, the Company has relied upon investor funds to maintain its operations and develop its business. The Company needs to raise additional capital within the next quarter from investors for working capital as well as business expansion, and there is no assurance that additional investor funds will be available on terms acceptable to the Company, or at all. If the Company is unable to unable to obtain additional financing to meet its working capital requirements, the Company likely would cease operations.

The Company requires funding of at least $2.3 million per year to maintain current operating activities. Over the next 24 months, the Company believes it will cost approximately $5.0 million to $10.0 million to fund: (1) the FDA approval process and initial deployment of the brachytherapy products and (2) initiate regulatory approval processes outside of the United States. The continued deployment of the brachytherapy products and a worldwide regulatory approval effort will require additional resources and personnel.

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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.

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

***The Company has a limited operating history, which may make it difficult to evaluate its business and prospects.***

The Company has a limited operating history upon which one can base an evaluation of its business and prospects. As a company in the development stage, there are substantial risks, uncertainties, expenses and difficulties to which its business is subject. To address these risks and uncertainties, the Company must do the following:

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|  | ● | successfully develop and execute the business strategy; |
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|  | ● | respond to competitive developments; and |
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|  | ● | attract, integrate, retain and motivate qualified personnel. |

There is no assurance that the Company will achieve or maintain profitable operations or that the Company will obtain or maintain adequate working capital to meet its obligations as they become due. The Company cannot be certain that its business strategy will be successfully developed and implemented or that the Company will successfully address the risks that face its business. In the event that the Company does not successfully address these risks, its business, prospects, financial condition, and results of operations could be materially and adversely affected.

***The Company’s products are regulated and require appropriate clearances and approvals to be marketed in the U.S. and globally.***

There is no assurance the FDA or other global regulatory authorities will grant the Company permission to market the Company’s brachytherapy Y-90 RadioGel™ device.

The Company has been working with the FDA to obtain clearance for its brachytherapy Y-90 RadioGelTM device, but no assurances have been received. On December 23, 2014, the Company announced that it submitted a *de novo* to the FDA for marketing clearance for its patented Y-90 RadioGelTM device pursuant to Section 513(f)(2) of the U.S. Food, Drug and Cosmetic Act (the “*Act*”). In June 2015, the FDA notified the Company the *de novo* was not granted. In February 2014, the FDA found the same device under Section 510(k) of the Act not substantially equivalent and concluded that the device is classified by statute as a Class III medical device, unless the device is reclassified. The Company is seeking reclassification of the product to Class II. If the Company is successful in seeking reconsideration of the Company’s *de novo* application, as a regulatory matter, the device could be on an easier and faster path to market in the United States. However, there would still be the requirements to complete the in vitro and in vivo testing, and then some human clinical trials. That testing date is submitted in a de novo pre-market application and if accepted we could then go to market. As a practical matter, the Company would still need to secure funding and commercial arrangements before marketing could commence. If the *de novo* is declined and if the Company obtains funding to permit it to continue operations, the Company will explore steps toward seeking approval for the device as a Class III medical device. Generally, the time period and cost of seeking approval as a Class III medical device is materially greater than the time period and cost of seeking approval as a Class II medical device. If the Company seeks approval as a Class III device, human clinical trials will be necessary. Generally, human trials for Class III products are larger, of longer duration and costlier than those for Class II devices.

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If human clinical trials are necessary, there will be additional cost and time to reach marketing clearance or approval. Unless the Company obtains sufficient funding, it will be unable to do the foregoing activities. There can be no assurance that the product will be approved as either a Class II or Class III device by the FDA even if additional data is provided. In August 2017, the Company met again with the FDA in a pre-submission meeting to once again go through the requirements for pre-clinical testing and to answer the previous FDA questions submitted years before. There can be no assurance that the Company will receive FDA approval, or if it does, the timing thereof.

***If the Company is successful in increasing the size of its organization, the Company may experience difficulties in managing growth.***

The Company is a small organization with a minimal number of employees. If the Company is successful, it may experience a period of significant expansion in headcount, facilities, infrastructure and overhead and further expansion may be required to address potential growth and market opportunities. Any such future growth will impose significant added responsibilities on members of management, including the need to improve the Company’s operational and financial systems and to identify, recruit, maintain and integrate additional managers. The Company’s future financial performance and its ability to compete effectively will depend, in part, on the ability to manage any future growth effectively.

***The Company’s business is dependent upon the continued services of the Company’s Chief Executive Officer, Michael Korenko. Should the Company lose the services of Dr. Korenko, the Company’s operations will be negatively impacted.***

The Company’s business is dependent upon the expertise of its Chief Executive Officer, Michael Korenko. Dr. Korenko is essential to the Company’s operations. Accordingly, an investor must rely on Dr. Korenko’s management decisions that will continue to control the Company’s business affairs. The Company does not maintain key man insurance on Dr. Korenko’s life. The loss of the services of Dr. Korenko would have a material adverse effect upon the Company’s business. To mitigate this risk, David Swanberg has been groomed as a replacement candidate. He has extensive experience as a co-founder of IsoRay and has been actively working with Dr. Korenko as a consultant for the last two years.

***The Company is heavily dependent on consultants for many of the services necessary to continue operations. The loss of any of these consultants could have a material adverse effect on the Company’s business, results of operations and financial condition.***

The Company’s success is heavily dependent on the continued active participation of certain consultants and collaborating scientists. Certain key employees and consultants have no written employment contracts. Loss of the services of any one or more of its consultants could have a material adverse effect upon the Company’s business, results of operations and financial condition.

***If the Company is unable to hire and retain additional qualified personnel, the business and financial condition may suffer.***

The Company’s success and achievement of its growth plans depend on its ability to recruit, hire, train and retain highly qualified technical, scientific, regulatory and managerial employees, consultants and advisors. Competition for qualified personnel among pharmaceutical and biotechnology companies is intense, and an inability to attract and motivate additional highly skilled personnel required for the expansion of the Company’s activities, or the loss of any such persons, could have a material adverse effect on its business, results of operations and financial condition.

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***The Company’s revenues have historically been derived from sales made to a small number of customers. The Company has discontinued prior operations related to its core business. To succeed, we will need to recommence our operations and achieve sales to a materially larger number of customers.***

During 2014, the Company ceased all previous manufacturing and sales activities. Our revenues for the year ended December 31, 2017 consisted of only consulting revenue, and our revenues for the year ended December 31, 2018 consisted of only $17,583 of grant revenue. The Company’s consulting revenues for the year ended December 31, 2017 were made to one customer, and those sales constituted 100% of total revenues for that years. At such time as the Company recommences active operations, no assurances can be given that the Company will be successful in commercializing its products or expanding the number of customers purchasing its products and services. The Company had $9,500 in operating revenues, net of discounts for the year ended December 31, 2019, and no operating revenues for the year ended December 31, 2018 as they have commenced sales of IsoPet®.

***Many of the Company’s competitors have greater resources and experience than the Company has.***

Many of the Company’s competitors have greater financial resources, longer history, broader experience, greater name recognition, and more substantial operations than the Company has, and they represent substantial long-term competition for us. The Company’s competitors may be able to devote more financial and human resources than the Company can to research, new product development, regulatory approvals, and marketing and sales. The Company’s competitors may develop or market products that are viewed by customers as more effective or more economical than the Company’s products. There is no assurance that the Company will be able to compete effectively against current and future competitors, and such competitive pressures may adversely affect the Company’s business and results of operations.

***The Company’s future revenues depend upon acceptance of its current and future products in the markets in which they compete.***

The Company’s future revenues depend upon receipt of financing, regulatory approval and the successful production, marketing, and sales of the various isotopes the Company might market in the future. The rate and level of market acceptance of each of these products, if any, may vary depending on the perception by physicians and other members of the healthcare community of its safety and efficacy as compared to that of any competing products; the clinical outcomes of any patients treated; the effectiveness of its sales and marketing efforts in the United States, Europe, Far East, Middle East, and Russia; any unfavorable publicity concerning its products or similar products; the price of the Company’s products relative to other products or competing treatments; any decrease in current reimbursement rates from the Centers for Medicare and Medicaid Services or third-party payers; regulatory developments related to the manufacture or continued use of its products; availability of sufficient supplies to either purchase or manufacture its products; its ability to produce sufficient quantities of its products; and the ability of physicians to properly utilize its products and avoid excessive levels of radiation to patients. Any material adverse developments with respect to the commercialization of any such products may adversely affect revenues and may cause the Company to continue to incur losses in the future.

***The Company currently relies on a single supplier for Y-90 particles, and that supplier is the only supplier in the United States. An inability to procure Y-90 particles will harm the Company’s business.***

There is only one supplier of Y-90 particles in the United States, requiring us to rely entirely on this supplier to provide the Y-90 particles needed to produce RadioGelTM. If we are unable to obtain a sufficient supply of Y-90 particles, we will not be able to proceed with our development of RadioGelTM and our business may be materially harmed.

The Company currently subcontracts the manufacturing of RadioGelTM to IsoTherapeutics. PerkinElmer Inc. is the sole supplier of the Y-90 particles used by IsoTherapeutics and is the only supplier of Y-90 particles in the United States. In the event PerkinElmer is unable to satisfy our supply requirements or stope producing Y-90 particles, we will be unable to continue with development of RadioGel™ and our business would be materially harmed.

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***The Company will rely heavily on a limited number of suppliers for the foreseeable future.***

Some of the products the Company might market, and components thereof are currently available only from a limited number of suppliers, several of which are international suppliers. Failure to obtain deliveries from these sources could have a material adverse effect on the Company’s ability to operate.

***The Company may incur material losses and costs as a result of product liability claims that may be brought against it.***

The Company faces an inherent business risk of exposure to product liability claims in the event that products supplied by the Company fail to perform as expected or such products result, or is alleged to result, in bodily injury. Any such claims may also result in adverse publicity, which could damage the Company’s reputation by raising questions about the safety and efficacy of its products and could interfere with its efforts to market its products. A successful product liability claim against the Company in excess of its available insurance coverage or established reserves may have a material adverse effect on its business. Although the Company currently maintains liability insurance in amounts it believes are commercially reasonable, any product liability the Company may incur may exceed its insurance coverage.

***The Company is subject to the risk that certain third parties may mishandle the Company’s products.***

If the Company markets products, the Company likely will rely on third parties, such as commercial air courier companies, to deliver the products, and on other third parties to package the products in certain specialized packaging forms requested by customers. The Company thus would be subject to the risk that these third parties may mishandle its product, which could result in material adverse effects, particularly given the radioactive nature of some of the products.

***The Company is subject to uncertainties regarding reimbursement for use of its products.***

Hospitals and freestanding clinics may be less likely to purchase the Company’s products if they cannot be assured of receiving favorable reimbursement for treatments using its products from third-party payers, such as Medicare and private health insurance plans. Third-party payers are increasingly challenging the pricing of certain medical services or devices, and there is no assurance that they will reimburse the Company’s customers at levels sufficient for it to maintain favorable sales and price levels for the Company’s products. There is no uniform policy on reimbursement among third-party payers, and there is no assurance that the Company’s products will continue to qualify for reimbursement from all third-party payers or that reimbursement rates will not be reduced. A reduction in or elimination of third-party reimbursement for treatments using the Company’s products would likely have a material adverse effect on the Company’s revenues.

***The Company’s future growth is largely dependent upon its ability to develop new technologies that achieve market acceptance with appropriate margins.***

The Company’s business operates in global markets that are characterized by rapidly changing technologies and evolving industry standards. Accordingly, future growth rates depend upon a number of factors, including the Company’s ability to (i) identify emerging technological trends in the Company’s target end-markets, (ii) develop and maintain competitive products, (iii) enhance the Company’s products by adding innovative features that differentiate the Company’s products from those of its competitors, and (iv) develop, manufacture and bring products to market quickly and cost-effectively. The Company’s ability to develop new products based on technological innovation can affect the Company’s competitive position and requires the investment of significant resources. These development efforts divert resources from other potential investments in the Company’s business, and they may not lead to the development of new technologies or products on a timely basis or that meet the needs of the Company’s customers as fully as competitive offerings. In addition, the markets for the Company’s products may not develop or grow as it currently anticipates. The failure of the Company’s technologies or products to gain market acceptance due to more attractive offerings by the Company’s competitors could significantly reduce the Company’s revenues and adversely affect the Company’s competitive standing and prospects.

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***The Company may rely on third parties to represent it locally in the marketing and sales of its products in international markets and its revenue may depend on the efforts and results of those third parties.***

The Company’s future success may depend, in part, on its ability to enter into and maintain collaborative relationships with one or more third parties, the collaborator’s strategic interest in the Company’s products and the Company’s products under development, and the collaborator’s ability to successfully market and sell any such products.

The Company intends to pursue collaborative arrangements regarding the marketing and sales of its products; however, it may not be able to establish or maintain such collaborative arrangements, or if it is able to do so, the Company’s collaborators may not be effective in marketing and selling its products. To the extent that the Company decides not to, or is unable to, enter into collaborative arrangements with respect to the sales and marketing of its products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. To the extent that the Company depends on third parties for marketing and distribution, any revenues received by the Company will depend upon the efforts and results of such third parties, which may or may not be successful.

***The Company may pursue strategic acquisitions that may have an adverse impact on its business.***

Executing the Company’s business strategy may involve pursuing and consummating strategic transactions to acquire complementary businesses or technologies. In pursuing these strategic transactions, even if the Company does not consummate them, or in consummating such transactions and integrating the acquired business or technology, the Company may expend significant financial and management resources and incur other significant costs and expenses. There is no assurance that any strategic transactions will result in additional revenues or other strategic benefits for the Company’s business. The Company may issue the Company’s stock as consideration for acquisitions, joint ventures or other strategic transactions, and the use of stock as purchase consideration could dilute the interests of its current stockholders. In addition, the Company may obtain debt financing in connection with an acquisition. Any such debt financing may involve restrictive covenants relating to capital-raising activities and other financial and operational matters, which may make it more difficult for the Company to obtain additional capital and pursue business opportunities, including potential acquisitions. In addition, such debt financing may impair the Company’s ability to obtain future additional financing for working capital, capital expenditures, acquisitions, general corporate or other purposes, and a substantial portion of cash flows, if any, from the Company’s operations may be dedicated to interest payments and debt repayment, thereby reducing the funds available to the Company for other purposes.

***The Company will need to hire additional qualified accounting personnel in order to remediate a material weakness in its internal control over financial accounting, and the Company will need to expend any additional resources and efforts that may be necessary to establish and to maintain the effectiveness of its internal control over financial reporting and its disclosure controls and procedures.***

As a public company, the Company is subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and the Sarbanes-Oxley Act of 2002. The Company’s management is required to evaluate and disclose its assessment of the effectiveness of the Company’s internal control over financial reporting as of each year-end, including disclosing any “material weakness” in the Company’s internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. As a result of its assessment, management has determined that there is a material weakness due to the lack of segregation of duties and, due to this material weakness, management concluded that, as of December 31, 2019 and 2018, the Company’s internal control over financial reporting was ineffective. This material weakness has the potential of adversely impacting the Company’s financial reporting process and the Company’s financial reports. Because of this material weakness, management also concluded that the Company’s disclosure controls and procedures were ineffective as of December 31, 2019 and 2018. The Company needs to hire additional qualified accounting personnel in order to resolve this material weakness. The Company also will need to expend any additional resources and efforts that may be necessary to establish and to maintain the effectiveness of the Company’s internal control over financial reporting and disclosure controls and procedures.

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***The Company may be unable to make timely license and patent payments***

Patent costs associated with existing and new technologies are significant; however, the licensing contract with Battelle Pacific Northwest Laboratory (“*Battelle*”) was re-negotiated to significantly reduce these costs. Existing patent and license fees must be paid for the Company to maintain rights to its technologies. The Company would forfeit its exclusive rights to licensed technologies in the event it fails to pay patent and rights fees in a timely fashion. No assurance can be given that the Company will be able to continue to pay license fees in the event it is unable to secure adequate working capital. Battelle has advised the Company that if we did not make a payment they would not attempt to relicense but would allow the patents to lapse. The Company has decided to pursue additional patents outside the Battelle contract based on exclusive proprietary manufacturing techniques developed by the Company.

***The Company’s patented or other technologies may infringe on other patents, which may expose it to costly litigation.***

It is possible that the Company’s patented or other technologies may infringe on patents or other rights owned by others. The Company may have to alter its products or processes, pay licensing fees, defend infringement actions or challenge the validity of the patents in court, or cease activities altogether because of patent rights of third parties, thereby causing additional unexpected costs and delays to the Company. Patent litigation is costly and time consuming, and the Company may not have sufficient resources to pursue such litigation. If the Company does not obtain a license under such patents, if it is found liable for infringement, or if it is not able to have such patents declared invalid, the Company may be liable for significant money damages, may encounter significant delays in bringing products to market or may be precluded from participating in the manufacture, use or sale of products or methods of treatment requiring such licenses.

***Protecting the Company’s intellectual property is critical to its innovation efforts.***

The Company owns or has a license to use several U.S. and foreign patents and patent applications, trademarks and copyrights. The Company’s intellectual property rights may be challenged, invalidated or infringed upon by third parties, or it may be unable to maintain, renew or enter into new licenses of third party proprietary intellectual property on commercially reasonable terms. In some non-U.S. countries, laws affecting intellectual property are uncertain in their application, which can adversely affect the scope or enforceability of the Company’s patents and other intellectual property rights. Any of these events or factors could diminish or cause the Company to lose the competitive advantages associated with the Company’s intellectual property, subject the Company to judgments, penalties and significant litigation costs, or temporarily or permanently disrupt its sales and marketing of the affected products or services.

***The Company may not be able to protect its trade secrets and other unpatented proprietary technology, which could give competitors an advantage.***

The Company relies upon trade secrets and other unpatented proprietary technology. The Company may not be able to adequately protect its rights with regard to such unpatented proprietary technology, or competitors may independently develop substantially equivalent technology. The Company seeks to protect trade secrets and proprietary knowledge, in part through confidentiality agreements with its employees, consultants, advisors and collaborators. Nevertheless, these agreements may not effectively prevent disclosure of the Company’s confidential information and may not provide the Company with an adequate remedy in the event of unauthorized disclosure of such information, and as result the Company’s competitors could gain a competitive advantage.

***General economic conditions in markets in which the Company does business can impact the demand for the Company’s goods and services. Decreased demand for the Company’s products and services could have a negative impact on its financial performance and cash flow.***

Demand for the Company’s products and services, in part, depends on the general economic conditions affecting the countries and industries in which the Company does business. A downturn in economic conditions in a country or industry that the Company serves may adversely affect the demand for the Company’s products and services, in turn negatively impacting the Company’s operations and financial results. Further, changes in demand for the Company’s products and services can magnify the impact of economic cycles on the Company’s businesses. Unanticipated contract terminations by customers can negatively impact operations, financial results and cash flow. The Company’s earnings, cash flow and financial position are exposed to financial market risks worldwide, including interest rate and currency exchange rate fluctuations and exchange rate controls. Fluctuations in domestic and world financial markets could adversely affect interest rates and impact the Company’s ability to obtain credit or attract investors.

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***The Company is subject to extensive government regulation in jurisdictions around the world in which it does business. Regulations address, among other things, environmental compliance, import/export restrictions, healthcare services, taxes and financial reporting, and those regulations can significantly increase the cost of doing business, which in turn can negatively impact operations, financial results and cash flow.***

If the Company is successful in developing manufacturing capability, the Company will be subject to extensive government regulation and intervention both in the U.S. and in all foreign jurisdictions in which it conducts business. Compliance with applicable laws and regulations will result in higher capital expenditures and operating costs, and changes to current regulations with which the Company complies can necessitate further capital expenditures and increases in operating costs to enable continued compliance. Additionally, from time to time, the Company may be involved in proceedings under certain of these laws and regulations. Foreign operations are subject to political instabilities, restrictions on funds transfers, import/export restrictions, and currency fluctuation.

***Volatility in raw material and energy costs, interruption in ordinary sources of supply, and an inability to recover from unanticipated increases in energy and raw material costs could result in lost sales or could increase significantly the cost of doing business.***

Market and economic conditions affecting the costs of raw materials, utilities, energy costs, and infrastructure required to provide for the delivery of the Company’s products and services are beyond the Company’s control. Any disruption or halt in supplies, or rapid escalations in costs, could adversely affect the Company’s ability to manufacture products or to competitively price the Company’s products in the marketplace. To date, the ultimate impact of energy costs increases has been mitigated through price increases or offset through improved process efficiencies; however, continuing escalation of energy costs could have a negative impact upon the Company’s business and financial performance.

**RISKS RELATED TO THE COMPANY’S COMMON STOCK**

***The Company’s common stock is currently quoted on the OTCQB Marketplace. Failure to develop or maintain a more active trading market may negatively affect the value of the Company’s common stock, may deter some potential investors from purchasing the Company’s common stock or other equity securities, and may make it difficult or impossible for stockholders to sell their shares of common stock.***

The Company’s average daily volume of shares traded for the years ended December 31, 2019 and 2018 was 681,623 and 1.795.854, respectively. Failure to develop or maintain an active trading market may negatively affect the value of the Company’s common stock, may make some potential investors unwilling to purchase the Company’s common stock or equity securities that are convertible into or exercisable for the Company’s common stock, and may make it difficult or impossible for the Company’s stockholders to sell their shares of common stock and recover any part of their investment.

***The Company’s outstanding securities, the stock or other securities that it may become obligated to issue under existing agreements, and certain provisions of those securities, may cause immediate and substantial dilution to existing stockholders and may make it more difficult to raise additional equity capital.***

The Company had 214,421,364 shares of common stock outstanding on April 24, 2020. The Company also had outstanding on that date dilutive securities consisting of preferred stock, restricted stock units, options, warrants, and convertible notes (collectively, “*Common Stock Equivalents*”) that if they had been exercised and converted in full on April 24, 2020, would have resulted in the issuance of up to 94,681,140 additional shares of common stock. The issuance of shares upon the exercise of the Common Stock Equivalents may result in substantial dilution to each stockholder by reducing that stockholder’s percentage ownership of the Company’s total outstanding shares of common stock. The issuance of some or all those warrants and any exercise of those warrants will have the effect of further diluting the percentage ownership of the Company’s other stockholders.

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***Future sales of the Company’s securities, including sales following exercise or conversion of derivative securities, or the perception that such sales may occur, may depress the price of common stock and could encourage short sales.***

The sale or availability for sale of substantial amounts of the Company’s shares in the public market, including shares issuable upon exercise of the Common Stock Equivalents, or the perception that such sales may occur, may adversely affect the market price of the Company’s common stock. Any decline in the price of the Company’s common stock may encourage short sales, which could place further downward pressure on the price of the Company’s common stock.

***The Company’s stock price is likely to be volatile.***

For the year ended December 31, 2019, the reported low closing price for the Company’s common stock was $0.0112 per share, and the reported high closing price was $0.0893 per share. For the year ended December 31, 2018, the reported low closing price for the Company’s common stock was $0.0208 per share, and the reported high closing price was $0.80 per share. There is generally significant volatility in the market prices, as well as limited liquidity, of securities of early stage companies, particularly early stage medical product companies. Contributing to this volatility are various events that can affect the Company’s stock price in a positive or negative manner. These events include, but are not limited to: governmental approvals, refusals to approve, regulations or other actions; market acceptance and sales growth of the Company’s products; litigation involving the Company or the Company’s industry; developments or disputes concerning the Company’s patents or other proprietary rights; changes in the structure of healthcare payment systems; departure of key personnel; future sales of its securities; fluctuations in its financial results or those of companies that are perceived to be similar to us; investors’ general perception of us; and general economic, industry and market conditions. If any of these events occur, it could cause the Company’s stock price to fall, and any of these events may cause the Company’s stock price to be volatile.

***The Company’s common stock is subject to the “Penny Stock” rules of the SEC and the trading market in its securities is limited, which makes transactions in its common stock cumbersome and may reduce the value of an investment in the Company’s stock.***

The SEC has adopted Rule 3a51-1, which establishes the definition of a “penny stock,” for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, Rule 15g-9 requires that a broker or dealer approve a person’s account for transactions in penny stocks and that the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person’s account for transactions in penny stocks, the broker or dealer must obtain financial information and investment experience and objectives of the person and must make a reasonable determination that the transactions in penny stocks are suitable for that person and that the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which sets forth the basis on which the broker or dealer made the suitability determination, and that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the “penny stock” rules. This may make it more difficult for investors to dispose of the Company’s common stock and may cause a decline in the market value of its stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

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***As a result of the Company issuing preferred stock, the rights of holders of the Company’s common stock and the value of the Company’s common stock may be adversely affected.***

The Company’s Board of Directors is authorized to issue classes or series of preferred stock, without any action on the part of the stockholders. The Company’s Board of Directors also has the power, without stockholder approval, to set the terms of any such classes or series of preferred stock, including voting rights, dividend rights and preferences over the common stock with respect to dividends or upon the liquidation, dissolution or winding-up of its business, and other terms. The Company has issued preferred stock that has a preference over the common stock with respect to the payment of dividends or upon liquidation, dissolution or winding-up, and with respect to voting rights. In accordance with that and with the issuance of preferred stock, our common stockholders voting rights have been diluted and it is possible that the rights of holders of the common stock or the value of the common stock have been adversely affected.

***The Company does not expect to pay any dividends on common stock for the foreseeable future.***

The Company has not paid any cash dividends on its common stock to date and does not anticipate it will pay cash dividends on its common stock in the foreseeable future. Accordingly, stockholders must be prepared to rely on sales of their common stock after price appreciation to earn an investment return, which may never occur. Any determination to pay dividends in the future will be made at the discretion of the Company’s board of directors and will depend on the Company’s results of operations, financial conditions, contractual restrictions, restrictions imposed by applicable law, and other factors that the Company’s board deems relevant.

***Pandemics including COVID-19 may adversely affect our business.***

The recent unprecedented events related to COVID-19, the disease caused by the novel coronavirus (SARS-CoV-2), have had significant health, economic, and market impacts and may have short-term and long-term adverse effects on our business that we cannot predict as the global pandemic continues to evolve. The extent and effectiveness of responses by governments and other organizations also cannot be predicted.

Our ability to access the capital markets is unknown during the COVID-19 pandemic. Any such limitation on available financing would adversely affect our business.

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

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

**ITEM 2. PROPERTIES.**

The Company is headquartered in Richland, Washington. Our Chief Executive Officer currently works from his home office in virtual communication with key personnel. Cadwell Laboratories, which is controlled by Carl Cadwell, a director of the Company, provides office space to management on an as-needed basis until such time as the Company leases permanent office space.

**ITEM 3. LEGAL PROCEEDINGS.**

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

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

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

**ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

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**PART II**

**ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

***Market Information***

The Company’s common stock is traded on the OTCQB Marketplace under the symbol “RDGL.” The following table sets forth, in U.S. dollars, the high and low closing prices for each of the calendar quarters indicated, as reported by the OTCQB Marketplace, for the past two fiscal years. Such OTCQB Marketplace quotations reflect inter-dealer prices, without markup, markdown or commissions and, particularly because our common stock is traded infrequently, may not necessarily represent actual transactions or a liquid trading market.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **High** | |  |  | **Low** | |  |
| **2019** |  |  |  |  |  |  |  |  |
| Quarter ended December 31 |  | $ | 0.057 |  |  | $ | 0.0275 |  |
| Quarter ended September 30 |  | $ | 0.0893 |  |  | $ | 0.0112 |  |
| Quarter ended June 30 |  | $ | 0.0392 |  |  | $ | 0.02 |  |
| Quarter ended March 31 |  | $ | 0.068 |  |  | $ | 0.0192 |  |
|  |  |  |  |  |  |  |  |  |
| **2018** |  |  |  |  |  |  |  |  |
| Quarter ended December 31 |  | $ | 0.31 |  |  | $ | 0.04 |  |
| Quarter ended September 30 |  | $ | 0.19 |  |  | $ | 0.02 |  |
| Quarter ended June 30 |  | $ | 0.26 |  |  | $ | 0.02 |  |
| Quarter ended March 31 |  | $ | 0.80 |  |  | $ | 0.21 |  |

***Holders***

As of April 24, 2020, we had 214,421,364 shares of common stock, par value $0.001 per share, issued and outstanding, which were held by approximately 228 shareholders of record. Our transfer agent is Pacific Stock Transfer, 6725 Via Austi Pkwy, Suite 300, Las Vegas, NV 89119.

***Securities Authorized for Issuance Under Equity Compensation Plans***

The following table sets forth information as of December 31, 2019 with respect to the Company’s equity compensation plans previously approved by stockholders and equity compensation plans not previously approved by stockholders.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Equity Compensation Plan Information** | | | | | | | | | |  |
| **Plan Category** |  | **Number of securities to be issued upon exercise of outstanding**  **options, warrants**  **and rights** | |  |  | **Weighted-average**  **exercise price of**  **outstanding options,**  **warrants and rights** | |  |  | **Number of securities remaining available for future issuance under**  **equity compensation**  **plans (excluding**  **securities reflected in**  **column (a))** | |  |
|  |  |  | **(a)** |  |  |  | **(b)** |  |  |  | **(c)** |  |
| Equity compensation plans approved by stockholders |  |  | - |  |  | $ | - |  |  |  | 32,836,047 |  |
| Equity compensation plans not approved by stockholders |  |  | 34,370,493 |  |  | $ | 0.13 |  |  |  | - |  |
| Total |  |  | 34,370,493 | (1) |  | $ | 0.13 | (1) |  |  | - |  |

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| (1) | In addition to the 2015 Plan (defined below), the Company has individual compensation arrangements under which equity securities are authorized for issuance in exchange for consideration in the form of goods or services of certain individuals. |

**2015 Omnibus Securities and Incentive Plan**

In October 2015, our Board of Directors and stockholders approved the adoption of the 2015 Omnibus Securities and Incentive Plan (the “*2015 Plan*”). The 2015 Plan authorizes an aggregate number of shares of common stock for issuance to all employees of the Company or any subsidiary of the Company, any non-employee director, consultants and independent contractors of the Company or any subsidiary, and any joint venture partners (including, without limitation, officers, directors and partners thereof) of the Company or any subsidiary. The aggregate number of shares that may be issued under the Plan shall not exceed twenty percent (20%) of the issued and outstanding shares of common stock on an as converted primary basis on a rolling basis. For calculation purposes, the As Converted Primary Shares (as defined in the 2015 Plan) shall include all shares of common stock and all shares of common stock issuable upon the conversion of outstanding preferred stock and other convertible securities, but shall not include any shares of common stock issuable upon the exercise of options, warrants and other convertible securities issued pursuant to the 2015 Plan. As of December 31, 2019, the Converted Primary Shares calculation results in 32,836,047 aggregate shares that may be issued under the 2015 Plan. The 2015 Plan is administered by the Company’s Compensation Committee, who may issue awards in the form of stock options and/or restricted stock awards. Effective December 31, 2019, an aggregate total of 1,162,500 restricted stock units (“*RSUs*”) under the 2015 Plan were authorized, but as of April 24, 2020, 385,000 had been issued.

***Recent Sales of Unregistered Securities***

Below is a description of all unregistered securities issued by the Company during and subsequent to the quarter ended December 31, 2019, through the date of this report. Each of the issuances identified below were issued in transactions exempt from registration under the Securities Act of 1933, as amended, in reliance on Section 3(a)(9) and/or 4(2) thereof.

**Issuances During the Quarter Ended December 31, 2019**

During the months of October 2019, the Company issued 5.375.000 shares of common stock in consideration for the conversion of 430,000 shares of Series B Convertible Preferred issued to accredited investors.

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During the month of October 2019, the Company issued 385,000 shares of common stock in conversion of fully vested restricted stock units.

During the month of December 2019, the Company issued 500,000 shares of common stock in settlement of an outstanding payable to the Company’s former Chief Executive Officer.

**Issuances Subsequent to December 31, 2019**

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.

All of the notes (convertible and non-convertible) that had a maturity date of January 15, 2020 were in default, resulting in a default interest rate of 12.5% from this date through the date they were converted effective March 31, 2020.

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. In addition, certain holders of convertible promissory notes entered into agreements to exchange certain notes totaling $526,113, including $415,000 in principal amount, $23,427 in accrued interest and an exchange premium as provided for in the note agreements of $87,686 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 2,075,000 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.

**ITEM 6. SELECTED FINANCIAL DATA.**

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

**ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

*The following discussion and analysis is intended as a review of significant factors affecting the Company’s financial condition and results of operations for the periods indicated. The discussion should be read in conjunction with the Company’s financial statements and the notes presented herein. In addition to historical information, the following Management’s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve risks and uncertainties. The Company’s actual results could differ significantly from those anticipated in these forward-looking statements as a result of the risk factors set forth above in Item 1A and other factors discussed in this Annual Report.*

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***Results of Operations***

***Comparison for the Year Ended December 31, 2019 and December 31, 2018***

The following table sets forth information from the Company’s statements of operations for the years ended December 31, 2019 and 2018.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Year Ended  December 31, 2019 | |  |  | Year Ended  December 31, 2018 | |  |
| Revenues, net |  | $ | 9,500 |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |
| Cost of goods sold |  |  | 6,028 |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |
| Gross profit |  |  | 3,472 |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |
| Operating expense |  |  | 1,333,451 |  |  |  | 2,489,637 |  |
|  |  |  |  |  |  |  |  |  |
| Operating loss |  |  | (1,329,979 | ) |  |  | (2,489,637 | ) |
|  |  |  |  |  |  |  |  |  |
| Non-operating expense |  |  | (280,118 | ) |  |  | (5,213,208 | ) |
|  |  |  |  |  |  |  |  |  |
| Net loss |  | $ | (1,610,097 | ) |  | $ | (7,702,845 | ) |

***Revenue and Cost of Goods Sold***

We had no revenue for the year ended December 31, 2018, compared to $9,500 in revenue for the year ended December 31, 2019, a period over period increase of $9,500. These revenues are reflected net of discounts. The increase was a result of the Company’s recognition of their sales for IsoPet®.

We had no cost of goods sold for the year ended December 31, 2018, compared to $6,028 in cost of goods sold for the year ended December 31, 2019, a period over period increase of $6,028. The increase was a result of the Company’s recognition of their sales and related costs of goods sold for IsoPet®.

Management does not anticipate that the Company will generate sufficient revenue to sustain operations until such time as the Company secures multiple revenue-generating arrangements with respect to RadioGel™ and/or any of our other brachytherapy technologies.

***Operating Expenses***

Operating expenses for the years ended December 31, 2019 and 2018 consisted of the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Year ended  December 31, 2019 | |  |  | Year ended  December 31, 2018 | |  |
| Sales and marketing expense |  | $ | - |  |  | $ | 11,500 |  |
| Professional fees |  |  | 462,952 |  |  |  | 682,217 |  |
| Reserved stock units granted |  |  | - |  |  |  | 113,189 |  |
| Stock options and warrants granted |  |  | 608,588 |  |  |  | 1,164,885 |  |
| Payroll expense |  |  | 120,000 |  |  |  | 315,000 |  |
| Research and development |  |  | 67,584 |  |  |  | 104,208 |  |
| General and administrative expense |  |  | 74,327 |  |  |  | 98,638 |  |
|  |  | $ | 1,333,451 |  |  | $ | 2,489,637 |  |

Operating expenses for the years ended December 31, 2019 and 2018 were $1,333,451 and $2,489,637, respectively. The decrease in operating expense from 2018 to 2019 is attributable to decreased sales and marketing expense ($11,500 for the year ended December 31, 2018 versus $0 for the year ended December 31, 2019) due to slow down in operations as a result of cash flow issues the Company incurred, decreased stock options and warrants granted ($1,164,885 for the year ended December 31, 2018 versus $608,588 for the year ended December 31, 2019) as a result of granting of options with respect to revised employment agreements and increase in warrant grants as a result of the Path Forward agreements in 2018, decreased research and development ($104,208 for the year ended December 31, 2018 versus $67,584 for the year ended December 31, 2019) as a result of slow-down in operations as a result of cash flow issues, decreased general and administrative expense ($98,638 for the year ended December 31, 2018 versus $74,327 for the year ended December 31, 2019), decreased payroll expense ($315,000 for the year ended December 31, 2018 versus $120,000 for the year ended December 31, 2019) as a result of lack of cash flow to pay the employees and decreased professional fees ($682,217 for the year ended December 31, 2018 versus $462,952 for the year ended December 31, 2019), which resulted from reduced consulting expenses as the Company was restructuring debt in the last six months of the year for 2018.

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

Non-Operating income (expense) for the years ended December 31, 2019 and 2018 consisted of the following:

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Year ended  December 31, 2019 | |  |  | Year ended  December 31, 2018 | |  |
| Interest expense |  | $ | (261,374 | ) |  | $ | (5,649,546 | ) |
| Net gain (loss) on settlement of debt |  |  | (18,744 | ) |  |  | 605,601 |  |
| Recognized income from grants |  |  | - |  |  |  | 17,583 |  |
| Gain (loss) on derivative liability |  |  | - |  |  |  | (186,846 | ) |
| Forgiveness of debt |  |  | - |  |  |  | - |  |
|  |  | $ | (280,118 | ) |  | $ | (5,213,208 | ) |

Non-operating income (expense) for the year ended December 31, 2019 varied from the year ended December 31, 2018 primarily due to the difference in the gain (loss) on derivative liability of $595,334 (a $186,846 loss on derivative liability in 2018 versus a $0 loss on derivative liability in 2019), and the difference in the gain (loss) on settlement of debt of $658,451 (a $605,601 gain on settlement of debt in 2018 versus a $18,744 loss on settlement of debt in 2019). Additionally, there was a decrease in interest expense of $5,388,172, attributable to the notes payable activity from 2018 to 2019. Overall, the decrease in non-operating expenses, net was the result of additional interest expense as a result of the convertible debentures the Company entered into in 2018.

***Net Loss***

The Company’s net loss for the years ended December 31, 2019 and 2018 was $1,610,097 and $7,702,845, respectively, as a result of the items described above.

***Liquidity and Capital Resources***

At December 31, 2019, the Company had negative working capital of $1,479,689, as compared to negative working capital of $942,174 at December 31, 2018. During the year ended December 31, 2019, the Company experienced negative cash flow from operations of $837,113 and realized $852,000 of cash flows from financing activities. As of December 31, 2019, the Company did not have any commitments for capital expenditures.

Cash used in operating activities increased from $700,454 for the year ended December 31, 2018 to $837,113 for the year ended December 31, 2019. Cash used in operating activities was primarily a result of the Company’s non-cash items, such as loss from operations, loss on preferred and common stock and stock options and warrants issued for services and other expenses, and settlement of debt, and the loss realized from derivative liabilities. Cash provided from financing activities increased from $697,631 for the year ended December 31, 2018 to $852,000 for the year ended December 31, 2019. The increase in cash provided from financing activities was primarily a result of increase in proceeds from convertible debt and related parties offset by proceeds received from the sale of common and preferred stock.

The Company has generated material operating losses since inception. The Company had a net loss of $1,610,097 for the year ended December 31, 2019, and a net loss of $7,702,845 for the year ended December 31, 2018. 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. The Company recently completed its Regulation A+ with the Securities and Exchange Commission and went effective in November 2019.

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The Company currently requires funding of at least $2.3 million per year to maintain current operating activities. Over the next 24 months, the Company believes it will cost approximately $5.0 million to $10.0 million to: (1) fund the FDA approval process and initial deployment of RadioGel™ and other brachytherapy products and (2) initiate regulatory approval processes outside of the United States. The continued deployment of the Company’s brachytherapy products, including RadioGel™, 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.

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.

***Contractual Obligations (payments due by period as of December 31, 2019)***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Contractual Obligation** |  | **Total**  **Payments Due** | |  |  | **Less than**  **1 Year** | |  |  | **1-3 Years** | |  |  | **3-5 Years** | |  |  | **More than**  **5 Years** | |  |
| License Agreement with Battelle Memorial Institute |  | $ | 24,000 |  |  | $ | 10,000 |  |  | $ | 24,000 |  |  | $ | 4,000 |  |  | $ | - |  |

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%).

Our Chief Executive Officer currently works from his home office in virtual communication with key personnel. Cadwell Laboratories, which is controlled by Carl Cadwell, a director of the Company, provides office space to management on an as-needed basis until such time as the Company leases permanent office space.

***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.

***Accounting Policies***

**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.

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**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 asset.

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.

**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 ten-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.

**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.

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

**Income from Grants and Deferred Income**

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

**Net 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. 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. When the Company incurs a loss, the denominator is not increased by the potentially dilutive common shares as the effect would be anti-dilutive.

**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.

**Income Taxes**

The Company accounts for income taxes under FASB ASC Topic 740-10-25 (“*ASC 740-10-25*”). Under ASC 740-10-25, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

Under ASC 740-10-25, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

The Tax Cuts and Jobs Act (the “*Act*”) was enacted on December 22, 2017. The Act reduces the US federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced earnings. These amounts are provisional and subject to change. The most significant impact of the legislation for the Company was a $3,300,000 reduction of the value of net deferred tax assets (which represent future tax benefits) as a result of lowering the U.S. corporate income tax rate from 35% to 21%. The Act also includes a requirement to pay a one-time transition tax on the cumulative value of earnings and profits that were previously not repatriated for U.S. income tax purposes. The Company has no earnings and profits that were previously not repatriated for U.S. income tax purposes.

The Company does not anticipate any changes to its provision for income taxes for the tax bill that has gone into effect for fiscal years ending starting in 2018.

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The Company files income tax returns in the U.S. federal jurisdiction.

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 years ended December 31, 2019 and 2018, the Company did not recognize any interest or penalty expense related to income taxes. The Company believes that it is not reasonably possible for the amounts of unrecognized tax benefits to significantly increase or decrease within the next 12 months.

**Fair Value of Financial Instruments**

The Company adopted ASC Topic 820 (“*Fair Value Measurements*”) as of January 1, 2008 for financial instruments measured as fair value on a recurring basis. ASC Topic 820 defines fair value, established a framework for measuring fair value in accordance with accounting principles generally accepted in the United States and expands disclosures about fair value measurements.

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. 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:

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| --- | --- | --- |
|  | - | 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. |

**Stock-Based Compensation**

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

Equity instruments issued to other than employees are recorded on the basis of the fair value of the instruments, as required by FASB ASC Topic 505, Equity Based Payments to Non-Employees. In general, the measurement date is when either a (a) performance commitment, as defined, is reached or (b) the earlier of (i) the non-employee performance is complete or (ii) the instruments are vested. The measured value related to the instruments is recognized over a period based on the facts and circumstances of each particular grant as defined in the FASB Accounting Standards Codification.

**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 Accounting Standards Codification 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.

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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 the Black-Scholes 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.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

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

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

All financial information required by this Item is included on the pages immediately following the Index to Financial Statements appearing on page F-1 and is hereby incorporated by reference.

**ITEM 9.** **Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None

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**ITEM 9A. 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.

***Management’s Annual Report on Internal Control Over Financial Reporting***

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Exchange Act Rule 13a-15(f). Management conducted an evaluation of the effectiveness of the internal control over financial reporting as of December 31, 2019, using the criteria established in *Internal Control – Integrated Framework (2013 framework)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“*COSO*”). Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. As a result of management’s assessment, management has determined that there are material weaknesses due to the lack of segregation of duties and, due to the limited resources based on the size of the Company. Due to the material weaknesses management concluded that as of December 31, 2019, the Company’s internal control over financial reporting was ineffective. In order to address and resolve the weaknesses, the Company will endeavor to locate and appoint additional qualified personnel to the board of directors and pertinent officer positions as the Company’s financial means allow. To date, the Company’s limited financial resources have not allowed the Company to hire the additional personnel necessary to address the material weaknesses.

***Management’s Annual Report on Internal Control Over Financial Reporting***

This annual report does not include an attestation report of the Company’s registered public accounting firm regarding internal control over financial reporting. Management’s report was not subject to attestation by the Company’s registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management’s report in this annual report.

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

There have been no changes in the Company’s internal control over financial reporting that occurred during the Company’s last fiscal quarter (the Company’s fourth fiscal quarter in the case of an annual report) 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. |

**ITEM 9B. OTHER INFORMATION.**

None.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

The Company’s current directors and executive officers are as follows:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **NAME** |  | **AGE** |  | **POSITION** |
| Michael K. Korenko |  | 73 |  | President, Chief Executive Officer, and Director |
| Michael Pollack |  | 53 |  | Interim Chief Financial Officer |
| Carlton M. Cadwell |  | 75 |  | Chairman of the Board and Secretary |

**Term of Office**

All the Company’s directors hold office until the next annual meeting of the stockholders or until their successors is elected and qualified. The Company’s executive officers are appointed by the Company’s board of directors and hold office until their resignation, removal, death or retirement.

**Background and Business Experience**

The business experience during the past five years of each of the Company’s directors and executive officers is as follows:

***Dr. Michael K. Korenko*,** President and Chief Executive Officer of the Company since December 2016, and a member of the Board of Directors since August 2017, joined the Company as an Advisor to the Board of the Company during 2009 and served as member of the Board from May 2009 to March 2010. Dr. Korenko has also served on the Hanford Advisory Board since 2009. Dr. Korenko served as Business Development Manager for Curtiss-Wright from 2006 to 2009, as Chief Operating Officer for Curtiss-Wright from 2000 to 2005 and was Executive Vice President of Closure for Safe Sites of Colorado at Rocky Flats from 1994 to 2000. Dr. Korenko served as Vice President of Westinghouse from 1987 to 1994 and was responsible for the 300 and 400 areas, including the Fast Flux Testing Facility (“*FFTF*”) and all engineering, safety analysis, and projects for the Hanford site.

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Dr. Korenko is the author of 28 patents and has received many awards, including the National Energy Resources Organization Research and Development Award, the U.S. Steelworkers Award for Excellence in Promoting Safety, and the Westinghouse Total Quality Award for Performance Manager of the Year. Dr. Korenko has a Doctor of Science from MIT, was a NATO Postdoctoral Fellow at Oxford University, and was selected as a White House Fellow for the Department of Defense, reporting to Secretary Cap Weinberger.

Dr. Korenko brings to the Board over seven years’ experience working with and advising various small businesses, including companies involved in turnarounds. Dr. Korenko has also been involved as an advisor to the Company since 2009 in the development of medical isotopes.

***Carlton M. Cadwell****,* Chairman of the Board and Secretary since December 2016, joined the Company as a director in 2006. Dr. Cadwell brings over 30 years of experience in business management, strategic planning, and implementation. He co-founded Cadwell Laboratories, Inc. in 1979 and has served as its President since its inception. Cadwell Laboratories, Inc. is a major international provider of neurodiagnostic medical devices. After receiving his bachelor’s degree from the University of Oregon in 1966 and a doctoral degree from the University of Washington in 1970, he began his career serving in the United States Army as a dentist for three years. From 1973 to 1980, Dr. Cadwell practiced dentistry in private practice and since has started several businesses.

Mr. Cadwell brings to the Board over ten years of service on the Board and over forty-five years of experience as a successful entrepreneur, as well as medical expertise.

***Michael Pollack CPA,*** the Interim Chief Financial Officer, joined the Company as interim Chief Financial Officer in December 2018. Mr. Pollack has been a partner in a certified public accounting firm for the past fifteen years and specializes in accounting and auditing for small public companies. Mr. Pollack has approximately 30 years of experience in public accounting and consulting to over 100 publicly traded and 250 private companies. Mr. Pollack has also held CFO and Controller positions in an array of industries. Mr. Pollack graduated from the University of Maryland with a Bachelor of Arts in Economics. Mr. Pollack is a member of the American Institute of Certified Public Accountants, as well as licensed to practice in New Jersey, and New York.

***Identification of Significant Consultants***

***David J. Swanberg, M.S., P.E.*** Mr. Swanberg has over 30 years’ experience in radiochemical processing, medical isotope production, nuclear waste management, materials science, regulatory affairs, and project management. Mr. Swanberg has worked in diverse organizations ranging from small start-up businesses to corporations with multi-billion dollar annual revenues. From 2005 to 2008, he served as Executive Vice President of Operations and as a member of the Board of Directors for IsoRay Medical Inc. from 2005 to 2008 managing day-to-day operations, R&D, and New Product Development. Mr. Swanberg was a co-founder of IsoRay and led the initial Cs-131 brachytherapy seed product development, FDA 510(k) submission/clearance, and NRC Sealed Source review and registration. Mr. Swanberg led the radiation dosimetry evaluations to meet American Association of Physicists in Medicine guidelines and is a current member of the AAPM. Mr. Swanberg and participated in several capital financing rounds totaling over $30.0 million. Mr. Swanberg also served as Assistant General Manager of IsoRay LLC from 2000 to 2003, and in additionally in key management roles as IsoRay transitioned from IsoRay LLC to IsoRay Medical, Inc. Mr. Swanberg holds a BA in Chemistry from Bethel University (MN) and an MS in Chemical Engineering from Montana State University. Mr. Swanberg has numerous technical publications and holds several patents.

**Medical and Veterinarian Advisory Boards**

***Dr. Barry D. Pressman MD, FACR - Chairman Medical Advisory Board.*** Dr. Pressman is Professor and Chairman of the S. Mark Taper Foundation Imaging Centre and Department, and Chief of the Section of Neuroradiology and Head and Neck Radiology at Cedars-Sinai Medical Center, located in Los Angeles, California.

Dr. Pressman is a past President of The American College of Radiology, the Western Neuroradiological Society, as well as past President of the California Radiological Society. Currently he is a member of the American Society of Neuroradiology and the American Society of Pediatric Neuroradiology.

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Dr. Pressman earned his medical degree Cum Laude from Harvard Medical School after graduating Summa Cum Laude from Dartmouth College. After a surgical internship at Harvard’s Peter Bent Brigham Hospital in Boston, he completed a diagnostic radiology residency at Columbia-Presbyterian Medical Center in New York and a Neuroradiology fellowship at George Washington University Hospital. During this period, he wrote many original papers for Computer Tomography (CT).

***Dr. Albert S. DeNittis MD, MS, FCPP - Medical Advisory Board.*** Dr. Albert S. DeNittis is currently is the Chief of Radiation Oncology at Lankenau Medical Center and Clinical Professor at Lankenau Institute for Medical Research in Wynnewood, Pennsylvania and the Director of Radiation Oncology at Brodesseur Cancer Center in New Jersey. He is also the Principal Investigator and in charge of a grant awarded by the NIH for its National Cancer Oncology Research Program (NCORP) at Main Line Health. Dr. DeNittis’ practice experience includes image-guided radiosurgery, stereotactic body radiation therapy (SBRT), intensity modulated radiation therapy (IMRT), image guided radiation therapy (IGRT), high-dose rate (HDR) brachytherapy, cranial and extracranial stereotactic radiosurgery, respiratory gating, and Cyberknife.

Dr. DeNittis has served on numerous regional, national and government committees related to key issues in Dr. DeNittis earned a BA and a MS at Rutgers University and a MD from the Robert Wood Johnson Medical School at the University of Medicine and Dentistry of New Jersey. He completed postdoctoral training internships and residency at the Department of Radiation Oncology at the Hospital of the University of Pennsylvania. Dr. DeNittis is board certified by the American Board of Radiology and Licensed in New Jersey and Pennsylvania.

***Dr. Alice Villalobos, DVM, FNAP - Chair of the Veterinary Medicine Advisory Board.*** Dr. Alice Villalobos is a well-known pioneer in the field of cancer care for companion animals and a founding member of the Veterinary Cancer Society. A 1972 graduate of UC Davis, she completed Dr. Gordon Theilen’s first mock residency program in oncology and has served the profession by consulting, writing and lecturing in the rapidly growing field of veterinary oncology and end of life care.

Dr. Alice Villalobos is President Emeritus of the Society for Veterinary Medical Ethics, Past President of the American Association of Human Animal Bond Veterinarians and Chair of the Veterinary Academy for the National Academies of Practice. She operated Coast Pet Clinic/Animal Cancer Center for 25 years, which is now VCA Coast Animal Hospital. She is the author of numerous articles, papers, and including her classic veterinarian textbook, Canine and Feline Geriatric Oncology: Honoring the Human-Animal Bond. She has lectured worldwide on oncology, quality of life, the human-animal bond and end of life care and bioethics. She founded Pawspice, an end of life care program that embraces kinder, gentler palliative cancer medicine and integrative care for pets with cancer and terminal illness (www.Pawspice.com). Dr. Alice is Director of Animal Oncology Consultation Service in Woodland Hill, California and Pawspice at VCA Coast Animal Hospital in Hermosa Beach, California. Dr. Alice was elected 2016 Hermosa Beach Woman of the Year.

Dr. Villalobos’ role with the Company is to support the commercialization of the Company’s yttrium-90 brachytherapy products for use in companion animals.

***Dr. Richard Weller, DVM, DACVIM (Internal Medicine; Oncology) DipMS - Veterinary Medicine Advisory Board Member*.** Prior to his retirement in 2014, Dr. Weller was a Senior Program Manager in the Radiation Biology Group of the Biological Sciences Division at Pacific Northwest National Laboratory (PNNL), where he was involved in the development of RadioGel. A 1973 graduate of Washington State University. Dr. Weller has extensive experience in designing and executing clinical studies, treatment planning, mechanisms of carcinogenesis, radiation biology, targeted delivery systems for chemotherapeutic and radio-therapeutic agents, bio-markers of disease, and comparative oncology; as well as over 30 years of experience developing and using animal models, including the use of spontaneous tumors in companion animals, for bio-medical applications.

Dr. Weller is board-certified by the American College of Veterinary Internal Medicine in Internal Medicine (1980) and Oncology (1987), Past Chairperson of the Organizing Committee for the Specialty of Veterinary Medical Oncology, Past Chairperson of the Board of Regents of the American College of Veterinary Internal Medicine, Past President of the Board of Regents of the American College of Veterinary Internal Medicine, Past President of the Specialty of Oncology, and a Charter Member of the Veterinary Cancer Society which he served as Treasurer for 16 years. He is an Honorary Professor of the Institute of Veterinary Medicine in Kyiv, Ukraine. Dr. Weller has lectured and trained veterinarians worldwide and has authored or co-authored over 250 articles, technical reports, book chapters, and presentations in his fields of expertise.

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***Section 16(a) Beneficial Ownership Reporting Compliance***

Section 16(a) of the Securities Exchange Act of 1934 requires the Company’s executive officers, directors and persons who own more than 10% of the Company’s common stock to file with the SEC initial reports of beneficial ownership on Form 3, changes in beneficial ownership on Form 4, and an annual statement of beneficial ownership on Form 5. Such executive officers, directors and greater than 10% stockholders are required by SEC rules to furnish the Company with copies of all such forms that they have filed.

Based solely on its review of such forms filed with the SEC and received by the Company and representations from certain reporting persons, the Company believes that all reports required to be filed by each of each of its executive officers, directors and 10% stockholders were filed during the year ended December 31, 2019 and that such reports were timely.

***Code of Ethics***

The Company’s Board of Directors has not adopted a code of ethics that applies to the principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, because of the Company’s limited number of executive officers and employees that would be covered by such a code and the Company’s limited financial resources. The Company anticipates that it will adopt a code of ethics after it increases the number of executive officers and employees and obtain additional financial resources.

***Audit Committee and Audit Committee Financial Expert***

As of the date of this report, the Company has not established an audit committee, and therefore, the Company’s full board of directors performs the functions that customarily would be undertaken by an audit committee. The Company’s board of directors during 2019 was comprised of two directors, one of whom the Company had determined satisfied the general independence standards of the NASDAQ listing requirements.

The Company’s Board of Directors has determined that none of its current members qualifies as an “audit committee financial expert,” as defined by the rules of the SEC. In the future, the Company intends to establish board committees and to appoint such persons to those committees as are necessary to meet the corporate governance requirements imposed by a national securities exchange, although it is not required to comply with such requirements until the Company elects to seek listing on a national securities exchange.

**ITEM 11. EXECUTIVE COMPENSATION.**

***Summary Compensation Table***

The following table sets forth the compensation paid to the Company’s Chief Executive Officer and those executive officers that earned in excess of $100,000 during the year ended December 31, 2019 (collectively, the “*Named Executive Officers*”):

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name and Principal Position (1) |  | Year | |  |  | Salary ($) | |  |  | Bonus ($) | |  |  | Stock  Awards ($) | |  |  | Option  Awards ($)(2) | |  |  | Total ($) | |  |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| Dr. Michael K. Korenko |  |  | 2019 |  |  | $ | 120,000 | (4) |  | $ | - |  |  | $ | - |  |  | $ | 585,144 |  |  | $ | 705,144 |  |
| CEO, President and Director |  |  | 2018 |  |  | $ | 20,000 |  |  | $ | - |  |  | $ | 206,306 |  |  | $ | - |  |  | $ | 226,306 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| L. Bruce Jolliff (3) |  |  | 2019 |  |  | $ | - |  |  | $ | - |  |  | $ | - |  |  | $ | - |  |  | $ | - |  |
| Former CFO |  |  | 2018 |  |  | $ | 64,000 |  |  | $ | - |  |  | $ | 90,479 |  |  | $ | - |  |  | $ | 154,629 |  |

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|  | (1) | Michael Pollack began serving as the Company’s Interim Chief Financial Officer in December 2018 and was paid no compensation in 2018 or 2019. Accordingly, he has not been included in this table. |
|  |  |  |
|  | (2) | The amounts in this column represent the grant date fair value of stock option awards, computed in accordance with FASB ASC Topic 718. |
|  |  |  |
|  | (3) | Mr. Jolliff was terminated as Chief Financial Officer in November 2018. |
|  | (4) | Of the $120,000 due Mr. Korenko, $100,000 is accrued for as of December 31, 2019. |

***Narrative Disclosure to Summary Compensation Table***

*Dr. Michael K. Korenko.* On October 24, 2018, Mr. Korenko entered into an employment agreement with the Company (the “*Old Employment Agreement*”), which was scheduled to terminate on December 31, 2019. On June 4, 2019, Mr. Korenko and the Company entered into a new employment agreement, effective June 11, 2019, which shall terminate on December 31, 2020 and December 31 of subsequent years (the “*Termination Date*”) if the agreement is extended pursuant to its terms. Under the terms of his employment agreement, the Company may terminate Dr. Korenko’s employment either with or without cause prior to the Termination Date, but in the event of a termination without cause, Dr. Korenko shall be entitled to receive monthly payments of his base salary for a period of six months thereafter, all of Dr. Korenko’s outstanding options, if any, shall vest, and Dr. Korenko shall be entitled to receive all past due compensation within three weeks of the date of termination.

The Company shall pay to Dr. Korenko an annual base compensation of $180,000, which is payable in equal monthly intervals. Of the $180,000 in annual base salary, $60,000 of annual pay shall be deferred and accrued until the Company’s cash balance exceeds $1,000,000. Dr. Korenko’s employment agreement provides that he shall receive a stock option grant issued under the Company’s 2015 Omnibus Securities and Incentive Plan in an amount equal to 21 million options ten days after the Company’s 1-for-8 reverse split, which was consummated in late June 2019. The options shall have a seven year term, shall be exercisable at a price of $0.024 per share, and shall vest as follows: 50% shall vest in equal amounts at the end of each quarter for the two quarters after grant date, 25% shall vest upon the Company filing for a patent, and the remaining 25% shall vest upon the first commercial sale of IsoPet.

Pursuant to Dr. Korenko’s Old Employment Agreement, the Company agreed to issue to Dr. Korenko 3,500,000 shares of common stock and warrants to purchase 1,762,321 shares of common stock in satisfaction of his past due and accrued compensation. In addition, in consideration for Dr. Korenko’s past performance, the Company agreed to compensate Dr. Korenko with a cash bonus in the amount of $200,000, which will be deferred until the cash balance exceeds $2,000,000. The Company also granted Dr. Korenko a stock option grant of 8,120,152 options under the 2015 Omnibus Securities and Incentive Plan on October 24, 2018. The options vested immediately upon issuance, have a term of seven years, and are exercisable at a price of $0.112 per share.

*L. Bruce Jolliff*. On October 24, 2018, Mr. Jolliff entered into an employment agreement with the Company, which was scheduled to terminate on December 31, 2019 (the “*Termination Date*”) and September 30 of subsequent years if the agreement were extended. Under the terms of his employment agreement, the Company could terminate Mr. Jolliff’s employment either with or without cause prior to the Termination Date, but in the event of a termination without cause, Mr. Jolliff would be entitled to receive monthly payments of his base salary for a period of six months thereafter. The Company also granted Mr. Jolliff a stock option grant of 3,045,057 options under the 2015 Omnibus Securities and Incentive Plan on October 22, 2018. The options vested immediately upon issuance, have a term of seven years, and are exercisable at a price of $0.112 per share. The options were granted prior to the termination of Mr. Jolliff and have not been canceled. In November 2018, the Company terminated Mr. Jolliff for reasons other than cause, and paid Mr. Jolliff his monthly agreed upon, non-deferred salary of $10,000 per month for a period of six months through May 2019.

The Company paid bonuses to certain employees based on their performance, the Company’s need to retain such employees, and funds available. All bonus payments were approved by the Company’s Board of Directors.

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***Outstanding Equity Awards at Fiscal Year-End Table***

The following table sets forth all outstanding equity awards held by the Company’s Named Executive Officers as of the end of last fiscal year.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Option Awards | | | | | | | | | | | | |
| Name |  | Number of Securities Underlying Unexercised Options(#) Exercisable | |  |  | Number of Securities Underlying Unexercised Options (#) Unexercisable | |  |  | Option  Exercise  Price ($) | |  |  | Option  Exercise Date |
| L. Bruce Jolliff (1) (2) |  |  | 60,000 |  |  |  | - |  |  | $ | 4.00 |  |  | 6/21/21 |
| L. Bruce Jolliff (1)(2) |  |  | 3,045,057 |  |  |  | - |  |  | $ | 0.112 |  |  | 10/24/25 |
| Michael Korenko (3) |  |  | 8,120,152 |  |  |  | - |  |  | $ | 0.112 |  |  | 10/24/25 |
| Michael Korenko |  |  | 21,000,000 |  |  |  | - |  |  | $ | 0.024 |  |  | 7/7/26 |

|  |  |  |
| --- | --- | --- |
|  | (1) | As noted above, Mr. Jolliff was terminated as Chief Financial Officer in November 2018. |
|  | (2) | Issued pursuant to employment contract dated October 24, 2018 |
|  | (3) | Issued pursuant to employment contract dated October 24, 2018 |
|  | (3) | Issued pursuant to employment contract dated July 7, 2019 |

***Compensation of Directors***

During the year ended December 31, 2019, the Company’s non-employee directors were not paid any compensation.

The following table sets forth, for each of the Company’s non-employee directors who served during 2019, the aggregate number of stock awards and the aggregate number of stock option awards that were outstanding as of December 31, 2019:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **Outstanding** |  |  |  | **Outstanding** |  |
|  |  |  | **Stock** |  |  |  | **Stock** |  |
| **Name** |  |  | **Awards (#)** |  |  |  | **Options (#)** |  |
| Carlton M. Cadwell |  |  | - |  |  |  | - |  |

During June 2016, the Company granted to Mr. Cadwell options to purchase 12,500 shares of common stock at an exercise price of $8.00 per share, which options expired June 21, 2019. These options had a grant date fair value of $34,771, which amounts were calculated in accordance with ASC Topic 718.

Additionally, the Company granted warrants to purchase 6,425,503 shares of Company common stock to Carlton Cadwell in 2018 as a result of the Path Forward Agreements and conversion of his advances to the Company.

There are no employment contracts or compensatory plans or arrangements with respect to any director that would result in payments by the Company to such person because of his or her resignation as a director or any change in control of the Company.

***Compensation Committee Interlocks and Insider Participation***

None of our officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more officers serving as a member of our board of directors.

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**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

***Beneficial Ownership of the Company’s Common Stock***

The following table sets forth, as of April 24, 2020, the number of shares of common stock beneficially owned by the following persons: (i) all persons the Company knows to be beneficial owners of at least 5% of the Company’s common stock, (ii) the Company’s current directors, (iii) the Company’s current executive officers, and (iv) all current directors and executive officers as a group.

As of April 24, 2020, there were 214,421,364 shares of common stock outstanding and up to 94,681,140 shares issuable upon exercise of common stock equivalents, assuming exercise and conversion occurred as of that date, for a total of 309,102,504 shares.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name and Address of Beneficial Owner(1)** |  | **Amount and Nature**  **of Beneficial**  **Ownership(2)** | |  |  | **Percent of Class** | |  |
| Cadwell Family Irrevocable Trust |  |  | 26,912 |  |  |  | \* | % |
|  |  |  |  |  |  |  |  |  |
| Carlton M. Cadwell (3) |  |  | 20,601,446 |  |  |  | 6.7 | % |
|  |  |  |  |  |  |  |  |  |
| Michael K. Korenko (4) |  |  | 36,952,543 |  |  |  | 12 | % |
|  |  |  |  |  |  |  |  |  |
| **All Current Directors and Executive Officers as a group (3 individuals) (5)** |  |  | 57,580,901 |  |  |  | 18.75 | % |

\*Less than 1%

|  |  |
| --- | --- |
| (1) | The address of each of the beneficial owners above is c/o Vivos Inc, 719 Jadwin Avenue, Richland, WA 99336, except that the address of the Cadwell Family Irrevocable Trust (the “*Cadwell Trust*”) is 909 North Kellogg Street, Kennewick, WA 99336. |
|  |  |
| (2) | In determining beneficial ownership of the Company’s common stock as of a given date, the number of shares shown includes shares of common stock which may be acquired upon exercise of the common stock equivalents within 60 days of that date. In determining the percent of common stock owned by a person or entity on April 24, 2020, (a) the numerator is the number of shares of the class beneficially owned by such person or entity, including shares which may be acquired within 60 days on exercise of the common stock equivalents, and (b) the denominator is the sum of (i) the total shares of common stock outstanding on April 24, 2020, and (ii) the total number of shares that the beneficial owner may acquire upon conversion of the common stock equivalents. Subject to community property laws where applicable, the Company believes that each beneficial owner has sole power to vote and dispose of its shares, except that under the terms of the Cadwell Trust, Dr. Cadwell does not have or share voting or investment power over the shares beneficially owned by the Cadwell Trust. |
|  |  |
| (3) | Includes 1,136,137 shares issuable upon conversion of Series A Preferred; 4,816,275 shares issuable upon conversion of Series C Preferred; and 6,425,503 shares issuable upon the exercise of warrants that may be exercised within 60 days of April 24, 2020. |
|  |  |
| (4) | Includes 125,000 shares issuable upon conversion of Series A Preferred; 825,000 of vested Restricted Stock Units; 29,120,152 shares issuable upon the exercise of stock options exercisable within 60 days of April 24, 2020; and 2,212,321 shares issuable upon the exercise of warrants that may be exercised within 60 days of November 15, 2019. |
|  |  |
| (5) | Michael Pollack, the Company’s Interim Chief Financial Officer, does not hold any Company securities, and has therefore been omitted from this table. |

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***Beneficial Ownership of the Company’s Series A Convertible Preferred Stock***

As of April 24, 2020, there were 2,552,642 shares of Series A Preferred issued and outstanding, convertible into 3,190,803 shares of the Company’s common stock.

The following table sets forth, as of April 24, 2020, the number of shares of Series A Preferred beneficially owned by the following persons: (i) all persons the Company known to be beneficial owners of at least 5% of the Company’s Series A Preferred, (ii) the Company’s current directors, (iii) the Company’s current executive officers, and (iv) all current directors and executive officers as a group.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name and Address of Beneficial Owner (1)** |  | **Amount and Nature**  **of Beneficial**  **Ownership (2)** | |  |  | **Percent of Class** | |  |
| Cadwell Family Irrevocable Trust |  |  | 148,309 |  |  |  | 5.8 | % |
|  |  |  |  |  |  |  |  |  |
| Carlton M. Cadwell |  |  | 908,910 |  |  |  | 35.6 | % |
|  |  |  |  |  |  |  |  |  |
| Michael K. Korenko |  |  | 100,000 |  |  |  | 3.9 | % |
|  |  |  |  |  |  |  |  |  |
| **All Current Directors and Executive Officers as a group (2 individuals)(3)** |  |  | 1,157,219 |  |  |  | 45.3 | % |
|  |  |  |  |  |  |  |  |  |
| **Major Shareholder(s):** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Jason Adelman(4) |  |  | 381,635 |  |  |  | 15.0 | % |
|  |  |  |  |  |  |  |  |  |
| L. Bruce Jolliff |  |  | 197,979 |  |  |  | 7.8 | % |
|  |  |  |  |  |  |  |  |  |
| Stoel Rives |  |  | 133,333 |  |  |  | 5.2 | % |

|  |  |
| --- | --- |
| (1) | The address of each of the beneficial owners above is c/o Vivos Inc, 719 Jadwin Avenue, Richland, WA 99336, except that the address of (i) the Cadwell Family Irrevocable Trust (the “*Cadwell Trust*” ) is 909 North Kellogg Street, Kennewick, WA 99336; (ii) Jason Adelman is 40 East 66th Street, New York, NY 10065; (iii) L. Bruce Jolliff is 206 N 41st St. Unit 1, Yakima, WA 98901; (iv) Stoel Rives is One Union Square, 600 University Street, Suite 3600, Seattle, WA 98101 and (v) MEF I, LLP is c/o Magna Management, 40 Wall Street, 58th Floor, New York, NY 10005. |
|  |  |
| (2) | Subject to community property laws where applicable, the Company believes that each beneficial owner has sole power to vote and dispose of its shares, except that Dr. Cadwell under the terms of the Cadwell Trust does not have or share voting or investment power over the Series A Convertible Preferred beneficially owned by the Cadwell Trust. |
|  |  |
| (3) | Michael Pollack, the Company’s Interim Chief Financial Officer, does not hold any Company securities, and has therefore been omitted from this table. |
|  |  |
| (4) | Includes 251,800 shares held by Cipher 06, LLC. |

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***Beneficial Ownership of the Company’s Series B Convertible Preferred Stock***

As of April 24, 2020, there were 1,013,245 shares of Series B Preferred issued and outstanding, convertible into 12,665,563 shares of the Company’s common stock.

The following table sets forth, as of April 24, 2020, the number of shares of Series B Preferred beneficially owned by the following persons: (i) all persons the Company known to be beneficial owners of at least 5% of the Company’s Series B Preferred, (ii) the Company’s current directors, (iii) the Company’s current executive officers, and (iv) all current directors and executive officers as a group.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name and Address of Beneficial Owner (1)** |  | **Amount and Nature**  **of Beneficial**  **Ownership (2)** | |  |  | **Percent of Class** | |  |
| Cadwell Family Irrevocable Trust |  |  | - |  |  |  | \* | % |
|  |  |  |  |  |  |  |  |  |
| Carlton M. Cadwell |  |  | - |  |  |  | \* | % |
|  |  |  |  |  |  |  |  |  |
| Michael K. Korenko |  |  | - |  |  |  | \* | % |
|  |  |  |  |  |  |  |  |  |
| **All Current Directors and Executive Officers as a group (2 individuals)** |  |  | - |  |  |  | \* | % |
|  |  |  |  |  |  |  |  |  |
| **Major Shareholder(s):** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Jason Adelman(3) |  |  | 1,012,882 |  |  |  | 99 | % |

\*Less than 1%

|  |  |
| --- | --- |
| (1) | None of the Company’s directors and executive officers hold any shares of the Company’s Series B Convertible Preferred, and they have therefore been omitted from this table. The address of each of the beneficial owners are as follows: (i) Jason Adelman is 40 East 66th St., New York, NY 10065; and (ii) Cipher 06, LLC, c/o Ellis Lake Capital, 444 Madison Avenue, 40th Floor, New York, NY 10022. |
|  |  |
| (2) | Subject to community property laws where applicable, the Company believes that each beneficial owner has sole power to vote and dispose of its shares. |
|  |  |
| (3) | Includes 200,000 shares of Series B Preferred held by JTA Resources LLC; and 576,592 shares of Series B Preferred held by Cipher 06 LLC, for which the holder has shared voting and investment power. |

**Beneficial Ownership of the Company’s Series C Convertible Preferred Stock**

As of April 24, 2020, there were 385,302 shares of Series C Preferred issued and outstanding, convertible into 4,816,275 shares of the Company’s common stock.

The following table sets forth, as of April 24, 2020, the number of shares of Series C Preferred beneficially owned by the following persons: (i) all persons the Company known to be beneficial owners of at least 5% of the Company’s Series C Preferred, (ii) the Company’s current directors, (iii) the Company’s current executive officers, and (iv) all current directors and executive officers as a group.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name and Address of Beneficial Owner (1)** |  | **Amount and**  **Nature**  **of Beneficial**  **Ownership (2)** | |  |  | **Percent of**  **Class** | |  |
| Carlton M. Cadwell |  |  | 385,302 |  |  |  | 100 | % |
|  |  |  |  |  |  |  |  |  |
| **All Current Directors and Executive Officers as a group (3 individuals) (3)** |  |  | 385,302 |  |  |  | 100 | % |

|  |  |  |
| --- | --- | --- |
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|  |  |
| --- | --- |
| (1) | The address of each of the beneficial owners above is c/o Vivos Inc, 719 Jadwin Avenue, Richland, WA 99336., |
|  |  |
| (2) | Subject to community property laws where applicable, the Company believes that each beneficial owner has sole power to vote and dispose of its shares, except that Dr. Cadwell under the terms of the Cadwell Trust does not have or share voting or investment power over the Series C Preferred beneficially owned by the Cadwell Trust. |
|  |  |
| (3) | Neither Michael Korenko, the Company’s Chief Executive Officer, nor Michael Pollack, the Company’s Interim Chief Financial Officer, hold any shares of the Company’s Series C Preferred, and they have therefore been omitted from this table. |

***Changes in Control***

The Company does not know of any arrangements, including any pledges of the Company’s securities that may result in a change in control of the Company.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.**

***Indebtedness from Related Parties***

Beginning in December 2008, the Company has obtained financing from Carlton M. Cadwell, a member of the Company’s Board of Directors and a beneficial owner of more than 10% of the Company’s common stock, in transactions which involved the Company’s issuance of convertible notes and common stock. On September 4, 2015, the Company exchanged $1,414,100 of convertible notes plus $810,538 of accrued interest into 148,311 shares of Series A Convertible Preferred and another $2,224,466 of convertible notes plus $889,838 of accrued interest into 207,620 shares of Series A Convertible Preferred. Additionally, the Company exchanged the remaining $906,572 of convertible notes plus $148,960 accrued interest into a $1,055,532 demand note, 8% interest rate, due on demand at any time after March 31, 2017. Such note was converted into 73,546 shares of Series A Convertible Preferred on May 19, 2016. At December 31, 2016, Mr. Cadwell had an aggregate total of $332,195 in promissory notes. In March 2017, the Company converted the $332,195 promissory note and $51,576 of accrued interest into a new promissory note totaling $383,771, due December 31, 2017. In December 2017, the note due date was extended to May 9, 2018. On October 19, 2018, the $383,771 promissory note and $58,880 of accrued interest was converted into 6,250,000 shares of Company common stock, 385,302 Series B Convertible Preferred shares, and 5,533,138 warrants that are exercisable into Company common stock at an exercise price of $0.08 per share.

During 2018, the Company executed various Path Forward Agreements with Mr. Cadwell and with the Chief Executive Officer of the Company, Michael Korenko, and converted related party debt and accrued interest into shares of common stock, Series B Convertible Preferred Stock and warrants.

On January 24, 2019, the Company entered into a note payable with a trust related to Mr. Cadwell in the amount of $60,000. The note is for a one-year period maturing January 24, 2020 and bears interest at an annual rate of 8.0%. This note is currently in default.

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On March 27, 2019 the Company entered into a note payable with a trust related to Mr. Cadwell 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 8.0%. This note is currently in default.

On April 29, 2019, the Company entered into a note payable with a trust related to Mr. Cadwell in the amount of $29,000. The note is for a one-year period maturing April 29, 2020 and bears interest at an annual rate of 8.0%.

On May 20, 2019 and May 23, 2019, Mr. Korenko advanced $20,000 collectively to the Company. Mr. Korenko is not charging interest on these amounts advanced and they are short-term advances, due on demand. Of this amount $5,000 was repaid and the balance of $15,000 was converted into a convertible note payable at an annual interest rate of 8% due January 15, 2020. This note was converted in April 2020.

On July 5, 2019, the Company entered into a note payable with a trust related to Mr. Cadwell 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 8.0%.

On November 25, 2019, the Company entered into a note payable with a trust related to Mr. Cadwell 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 8.0%.

In March 2020, Mr. Korenko advanced $15,000 to the Company which was repaid in April 2020.

***Independent Directors***

The Company’s common stock is traded on the OTCQB Marketplace, which does not impose any independence requirements on the Board of Directors or the board committees of the companies whose stock is traded on that market. The Company has decided to adopt the independence standards of the Nasdaq listing rules in determining whether the Company’s directors are independent. Generally, under those rules a director does not qualify as an independent director if the director or a member of the director’s immediate family has had in the past three years certain relationships or affiliations with the Company, the Company’s auditors, or other companies that do business with the Company. The Company’s Board of Directors has determined that Mr. Cadwell is qualified as an independent director under those Nasdaq rules, and accordingly, would have been qualified under those rules to serve on a compensation committee or a nominating committee, if the Company had established such committees of the Company’s Board of Directors. Dr. Korenko is not an independent director due to his employment by the Company as an executive officer.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.**

***Audit Fees***

The aggregate fees incurred by the Company’s principal accountant for the audit of the Company’s annual financial statements, review of financial statements included in the quarterly reports and other fees that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for the years ended December 31, 2019 and 2018 were $61,500 and $66,000, respectively, all of which was paid to Fruci & Associates II, PLLC.

***Audit Related Fees***

The aggregate fees billed for professional services that are reasonably related to the performance of the audit or review of the Company’s financial statements but are not reported “Audit Fees” for the years ended December 31, 2019 and 2018 in the amounts of $7,250 and $7,250, respectively. All services performed by the Company’s Registered Public Accounting Firm, Fruci & Associates II, PLLC have been pre-approved by the Company’s Board of Directors.

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***Tax Fees***

The aggregate fees billed for professional services rendered by principal accountant for tax compliance, tax advice and tax planning during the years ended December 31, 2019 and 2018 were $2,750 and $2,500, respectively, all of which was paid to Fruci & Associates II, PLLC.

***All Other Fees***

Other fees billed for products or services provided by the Company’s principal accountant during the years ended December 31, 2019 and 2018 There were no fees incurred to Fruci & Associates II, PLLC related to all other fees.

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.**

(a) Documents filed as part of this Report.

|  |  |
| --- | --- |
| ***1.*** | ***Financial Statements.*** The Vivos Inc. Balance Sheets as of December 31, 2019 and 2018, the Statements of Operations for the years ended December 31, 2019 and 2018, the Statements of Changes in Stockholders’ Deficit for the years ended December 31, 2019 and 2018, and the Statements of Cash Flows for the years ended December 31, 2019 and 2018, together with the notes thereto and the reports of Fruci & Associates II, PLLC as required by Item 8 are included in this 2019 Annual Report on Form 10-K as set forth in Item 8 above. |
|  |  |
| ***2.*** | ***Financial Statement Schedules***. All financial statement schedules have been omitted since they are either not required or not applicable, or because the information required is included in the financial statements or the notes thereto. |
|  |  |
| ***3.*** | ***Exhibits***. The following exhibits are either filed as a part hereof or are incorporated by reference. Exhibit numbers correspond to the numbering system in Item 601 of Regulation S-K. |

|  |  |  |
| --- | --- | --- |
| **Exhibit**  **Number** |  | **Description** |
| 3.1 |  | [Certificate of Incorporation of Savage Mountain Sports Corporation, dated January 11, 2000 (incorporated by reference to Exhibit 3.1 to the Company’s Registration Statement on Form 10-12G (File No. 000-53497) filed on November 12, 2008).](http://www.sec.gov/Archives/edgar/data/1449349/000119983508000697/exhibit_3-1.htm) |
| 3.2 |  | [By-Laws (incorporated by reference to Exhibit 3.2 to the Company’s Registration Statement on Form 10-12G (File No. 000-53497) filed on November 12, 2008).](http://www.sec.gov/Archives/edgar/data/1449349/000119983508000697/exhibit_3-2.htm) |
| 3.3 |  | [Certificate of Amendment of Certificate of Incorporation changing the name of the Company to Advanced Medical Isotope Corporation, dated May 23, 2006 (incorporated by reference to Exhibit 3.5 to the Company’s Registration Statement on Form 10-12G (File No. 000-53497) filed on November 12, 2008).](http://www.sec.gov/Archives/edgar/data/1449349/000119983508000697/exhibit_3-5.htm) |
| 3.4 |  | [Certificate of Amendment of Certificate of Incorporation increasing authorized capital dated September 26, 2006 (incorporated by reference to Exhibit 3.6 to the Company’s Registration Statement on Form 10-12G (File No. 000-53497) filed on November 12, 2008).](http://www.sec.gov/Archives/edgar/data/1449349/000119983508000697/exhibit_3-6.htm) |
| 3.5 |  | [Certificate of Amendment to the Certificate of Incorporation increasing authorized common stock and authorizing preferred stock, dated May 18, 2011 (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed on May 18, 2011).](http://www.sec.gov/Archives/edgar/data/1449349/000119983511000374/exhibit_3-1.htm) |
| 3.6 |  | [Certificate of Amendment to the Certificate of Incorporation authorizing a series of Preferred Stock to be named “Series A Convertible Preferred Stock”, consisting of 2,500,000 shares, which series shall have specific designations, powers, preferences and relative and other special rights, qualifications, limitations and restrictions as outlined in the Certificate of Designations, filed June 30, 2015 (incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed on July 7, 2015).](http://www.sec.gov/Archives/edgar/data/1449349/000119983515000279/exhibit_4-1.htm) |

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| 3.7 |  | [Certificate of Amendment to the Certificate of Incorporation increasing the authorized series of “Series A Convertible Preferred Stock” to 5,000,000 shares, filed March 31, 2016 (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on April 7, 2016).](http://www.sec.gov/Archives/edgar/data/1449349/000149315216008703/ex10-01.htm) |
| 3.8 |  | [Certificate of Amendment to the Certificate of Incorporation authorizing a series of Preferred Stock to be named “Series B Convertible Preferred Stock”, consisting of 5,000,000 shares, which series shall have specific designations, powers, preferences and relative and other special rights, qualifications, limitations and restrictions as outlined in the Certificate of Designations, filed October 10, 2018 (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed on October 17, 2018).](http://www.sec.gov/Archives/edgar/data/1449349/000165495418011250/ex3-1.htm) |
| 4.1 |  | [Form of Warrant (incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed on October 17, 2018).](http://www.sec.gov/Archives/edgar/data/1449349/000165495418011250/ex4-1.htm) |
| 10.1 |  | [Agreement and Plan of Reorganization, dated as of December 15, 1998, by and among HHH Entertainment, Inc. and Earth Sports Products, Inc. (incorporated by reference to Exhibit 10.1 to the Company’s Registration Statement on Form 10-12G (File No. 000-53497) filed on November 12, 2008).](http://www.sec.gov/Archives/edgar/data/1449349/000119983508000697/exhibit_10-1.htm) |
| 10.2 |  | [Agreement and Plan of Merger of HHH Entertainment, Inc. and Savage Mountain Sports Corporation, dated as of January 6, 2000 (incorporated by reference to Exhibit 10.2 to the Company’s Registration Statement on Form 10-12G (File No. 000-53497), filed on November 12, 2008).](http://www.sec.gov/Archives/edgar/data/1449349/000119983508000697/exhibit_10-2.htm) |
| 10.3 |  | [Agreement and Plan of Acquisition by and between Neu-Hope Technologies, Inc., UTEK Corporation and Advanced Medical Isotope Corporation, dated September 22, 2006 (incorporated by reference to Exhibit 10.4 to the Company’s Registration Statement on Form 10-12G (File No. 000-53497), filed on November 12, 2008).](http://www.sec.gov/Archives/edgar/data/1449349/000119983508000697/exhibit_10-4.htm) |
| 10.4 |  | [Agreement and Plan of Acquisition by and between Isonics Corporation and Advanced Medical Isotope Corporation dated June 13, 2007 (incorporated by reference to Exhibit 10.6 to the Company’s Registration Statement on Form 10-12G (File No. 000-53497), filed on November 12, 2008).](http://www.sec.gov/Archives/edgar/data/1449349/000119983508000697/exhibit_10-6.htm) |
| 10.5 |  | [Form of Non-Statutory Stock Option Agreement (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on March 15, 2012).](http://www.sec.gov/Archives/edgar/data/1449349/000119983512000114/exhibit_10-1.htm) |
| 10.6 |  | [Promissory Note dated December 16, 2008 between Advanced Medical Isotope Corporation and Carlton M. Cadwell (incorporated by reference to Exhibit 10.11 to the Company’s Annual Report on Form 10-K filed on March 3, 2012).](http://www.sec.gov/Archives/edgar/data/1449349/000119983512000130/exhibit_10-11.htm) |
| 10.7 |  | [2015 Omnibus Securities and Incentive Plan (incorporated by reference to Exhibit 10.12 to the Company’s Annual Report on Form 10-K, filed May 25, 2016).](http://www.sec.gov/Archives/edgar/data/1449349/000149315216010291/ex10-12.htm) |
| 10.8 |  | [Washington State University Sub-Award Agreement for the period December 15, 2017 through January 31, 2018.(incorporated by reference to Exhibit 10.13 to the Company’s Annual report on Form 10-K, filed April 2, 2018).](http://www.sec.gov/Archives/edgar/data/1449349/000149315218004456/ex10-13.htm) |
| 10.9 |  | [The Curators of the University of Missouri Sponsored Research Contract for the period November 1, 2017 through October 31, 2018. (incorporated by reference to Exhibit 10.14 to the Company’s Annual report on Form 10-K, filed April 2, 2018).](http://www.sec.gov/Archives/edgar/data/1449349/000149315218004456/ex10-14.htm) |
| 10.10 |  | [Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on October 17, 2018).](http://www.sec.gov/Archives/edgar/data/1449349/000165495418011250/ex10-1.htm) |
| 10.11 |  | [Employment Agreement by and between Vivos Inc. and Michael Korenko, dated June 4, 2019 (incorporated by reference to Exhibit 6.18 to the Company’s Offering Statement on Form 1-A filed on July 29, 2019).](http://www.sec.gov/Archives/edgar/data/1449349/000149315219011262/ex6-18.htm) |
| 31.1\* |  | [Certification of Chief Executive Officer pursuant to Sec. 302 of the Sarbanes-Oxley Act of 2002 (4)](ex31-1.htm) |
| 31.2\* |  | [Certification of Chief Financial Officer pursuant to Sec. 302 of the Sarbanes-Oxley Act of 2002 (4)](ex31-2.htm) |
| 32.1\* |  | [Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (4)](ex32-1.htm) |
| 101.INS\* |  | XBRL Instance Document |
| 101.SCH\* |  | XBRL Taxonomy Extension Schema |
| 101.CAL\* |  | XBRL Taxonomy Extension Calculation Linkbase |
| 101.DEF\* |  | XBRL Taxonomy Extension Definition Linkbase |
| 101.LAB\* |  | XBRL Taxonomy Extension Label Linkbase |
| 101.PRE\* |  | XBRL Taxonomy Extension Presentation Linkbase |

\* Filed herewith.

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

|  |  |  |
| --- | --- | --- |
|  | VIVOS INC. | |
|  |  |  |
| Date: April 28, 2020 | By: | */s/ Michael K. Korenko* |
|  | Name: | Michael K. Korenko |
|  | Title: | Chief Executive Officer |

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

|  |  |  |
| --- | --- | --- |
| Date: April 28, 2020 | By: | */s/ Michael K. Korenko* |
|  | Name: | Michael K. Korenko |
|  | Title: | Chief Executive Officer  (Principal Executive Officer) |
|  |  |  |
| Date: April 28, 2020 | By: | */s/ Michael Pollack* |
|  | Name: | Michael Pollack |
|  | Title: | Interim Chief Financial Officer  (Principal Financial and Accounting Officer) |
|  |  |  |
| Date: April 28, 2020 | By: | */s/ Carlton M. Cadwell* |
|  | Name: | Carlton M. Cadwell |
|  | Title: | Secretary and Chairman of the Board |

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**Vivos Inc.**

**Index to Financial Statements**

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of Vivos, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Vivos, Inc. (“the Company”) as of December 31, 2019 and 2018, and the related statements of operations, changes in stockholders’ deficit, and cash flows for each of the years in the two-year period ended December 31, 2019, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

**Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses, utilizes a significant amount of cash to fund its operations, and does not have sufficient cash to support current operations. These factors raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

|  |  |
| --- | --- |
|  |  |
| We have served as the Company’s auditor since 2016.    Spokane, Washington |  |
| April 28, 2020 |  |

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**VIVOS INC**

**BALANCE SHEETS**

**DECEMBER 31, 2019 AND DECEMBER 31, 2018**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **DECEMBER 31, 2019** | |  |  | **DECEMBER 31, 2018** | |  |
|  |  |  | |  |  |  | |  |
| **ASSETS** |  |  |  |  |  |  |  |  |
| Current Assets: |  |  |  |  |  |  |  |  |
| Cash |  | $ | 20,381 |  |  | $ | 5,494 |  |
| Prepaid expenses |  |  | 23,492 |  |  |  | 10,992 |  |
|  |  |  |  |  |  |  |  |  |
| Total Current Assets |  |  | 43,873 |  |  |  | 16,486 |  |
|  |  |  |  |  |  |  |  |  |
| **TOTAL ASSETS** |  | $ | 43,873 |  |  | $ | 16,486 |  |
|  |  |  |  |  |  |  |  |  |
| **LIABILITIES AND STOCKHOLDERS’ DEFICIT** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **LIABILITIES** |  |  |  |  |  |  |  |  |
| Current Liabilities: |  |  |  |  |  |  |  |  |
| Accounts payable and accrued expenses |  | $ | 511,817 |  |  | $ | 795,129 |  |
| Related party accounts payable |  |  | 32,110 |  |  |  | 38,610 |  |
| Accrued interest payable |  |  | 93,249 |  |  |  | 59,646 |  |
| Payroll liabilities payable |  |  | 100,000 |  |  |  | 11,451 |  |
| Convertible notes payable, related party, net |  |  | 14,500 |  |  |  | - |  |
| Convertible notes payable, net |  |  | 434,886 |  |  |  | 53,824 |  |
| Promissory notes payable, net of discount |  |  | 100,000 |  |  |  | - |  |
| Related party promissory note |  |  | 237,000 |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |
| Total Current Liabilities |  |  | 1,523,562 |  |  |  | 958,660 |  |
|  |  |  |  |  |  |  |  |  |
| **Total Liabilities** |  |  | 1,523,562 |  |  |  | 958,660 |  |
|  |  |  |  |  |  |  |  |  |
| Commitments and contingencies |  |  | - |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |
| **STOCKHOLDERS’ DEFICIT** |  |  |  |  |  |  |  |  |
| Preferred stock, par value, $0.001, 20,000,000 shares authorized,Series A Convertible Preferred, 5,000,000 shares authorized, 2,552,642 shares issued and outstanding, respectively |  |  | 2,553 |  |  |  | 2,553 |  |
| Additional paid in capital - Series A Convertible preferred stock |  |  | 8,870,626 |  |  |  | 8,870,626 |  |
| Series B Convertible Preferred, 5,000,000 shares authorized, 1,113,245 and   3,305,755 shares issued and outstanding, respectively |  |  | 1,113 |  |  |  | 3,306 |  |
| Additional paid in capital - Series B Convertible preferred stock |  |  | 665,195 |  |  |  | 1,876,768 |  |
| Series C Convertible Preferred, 5,000,000 shares authorized, 821,292 and   0 shares issued and outstanding, respectively |  |  | 821 |  |  |  | - |  |
| Additional paid in capital - Series C Convertible preferred stock |  |  | 674,457 |  |  |  | - |  |
| Common stock, par value, $0.001, 950,000,000 shares authorized,184,845,821 and 163,445,736 issued and outstanding, respectively |  |  | 184,846 |  |  |  | 163,446 |  |
| Additional paid in capital - common stock |  |  | 61,721,809 |  |  |  | 60,132,139 |  |
| Accumulated deficit |  |  | (73,601,109 | ) |  |  | (71,991,012 | ) |
|  |  |  |  |  |  |  |  |  |
| **Total Stockholders’ Deficit** |  |  | (1,479,689 | ) |  |  | (942,174 | ) |
|  |  |  |  |  |  |  |  |  |
| **TOTAL LIABILITIES AND STOCKHOLDERS’ DEFICIT** |  | $ | 43,873 |  |  | $ | 16,486 |  |

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

|  |  |  |
| --- | --- | --- |
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**VIVOS INC**

**STATEMENTS OF OPERATIONS**

**FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **2019** | |  |  | **2018** | |  |
|  |  |  | |  |  |  | |  |
| **Revenues, net** |  | $ | 9,500 |  |  | $ | - |  |
| **Cost of Goods Sold** |  |  | (6,028 | ) |  |  | - |  |
|  |  |  |  |  |  |  |  |  |
| **Gross profit** |  |  | 3,472 |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |
| **OPERATING EXPENSES** |  |  |  |  |  |  |  |  |
| Sales and marketing expenses |  |  | - |  |  |  | 11,500 |  |
| Professional fees |  |  | 462,952 |  |  |  | 682,217 |  |
| Reserved stock units granted |  |  | - |  |  |  | 113,189 |  |
| Stock based compensation |  |  | 608,588 |  |  |  | 1,164,885 |  |
| Payroll expenses |  |  | 120,000 |  |  |  | 315,000 |  |
| Research and development |  |  | 67,584 |  |  |  | 104,208 |  |
| General and administrative expenses |  |  | 74,327 |  |  |  | 98,638 |  |
|  |  |  |  |  |  |  |  |  |
| Total Operating Expenses |  |  | 1,333,451 |  |  |  | 2,489,637 |  |
|  |  |  |  |  |  |  |  |  |
| **OPERATING LOSS** |  |  | (1,329,979 | ) |  |  | (2,489,637 | ) |
|  |  |  |  |  |  |  |  |  |
| **NON-OPERATING INCOME (EXPENSE)** |  |  |  |  |  |  |  |  |
| Interest expense |  |  | (261,374 | ) |  |  | (5,649,546 | ) |
| Net gain (loss) on debt extinguishment |  |  | (18,744 | ) |  |  | 605,601 |  |
| Net loss on derivative liability |  |  | - |  |  |  | (186,846 | ) |
| Grant income |  |  | - |  |  |  | 17,583 |  |
|  |  |  |  |  |  |  |  |  |
| Total Non-Operating Income (Expenses) |  |  | (280,118 | ) |  |  | (5,213,208 | ) |
|  |  |  |  |  |  |  |  |  |
| **NET LOSS BEFORE PROVISION FOR INCOME TAXES** |  |  | (1,610,097 | ) |  |  | (7,702,845 | ) |
|  |  |  |  |  |  |  |  |  |
| Provision for income taxes |  |  | - |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |
| **NET LOSS** |  | $ | (1,610,097 | ) |  | $ | (7,702,845 | ) |
|  |  |  |  |  |  |  |  |  |
| **Net loss per share - basic and diluted** |  | $ | (0.01 | ) |  | $ | (0.14 | ) |
|  |  |  |  |  |  |  |  |  |
| **Weighted average common shares outstanding - basic** |  |  | 175,195,600 |  |  |  | 55,501,248 |  |

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

|  |  |  |
| --- | --- | --- |
|  | F-3 |  |

**VIVOS INC**

**STATEMENT OF CHANGES IN STOCKHOLDERS’ DEFICIT**

**FOR THE YEARS ENDED DECEMBER 31, 2019 AND DECEMBER 31, 2018**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | |  |  |  | |  |  | **Additional** | |  |  |  | |  |  |  | |  |  | **Additional** | |  |  |  | |  |  |  | |  |  | **Additional** | |  |  |  | | | | | |  |  |  | |  |  |  | |  |  |  | |  |
|  |  | **Series A Preferred** | | | | | |  |  | **Paid-In Capital -** | |  |  | **Series B Preferred** | | | | | |  |  | **Paid-In Capital -** | |  |  | **Series C Preferred** | | | | | |  |  | **Paid-In Capital -** | |  |  | **Common Stock** | | | | | |  |  | **Additional Paid-In** | |  |  |  | |  |  |  | |  |
|  |  | **Shares** | |  |  | **Amount** | |  |  | **Series A Preferred** | |  |  | **Shares** | |  |  | **Amount** | |  |  | **Series B Preferred** | |  |  | **Shares** | |  |  | **Amount** | |  |  | **Series C Preferred** | |  |  | **Shares** | |  |  | **Amount** | |  |  | **Capital - Common** | |  |  | **Accumulated Deficit** | |  |  | **Total** | |  |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| Balance - December 31, 2017 |  |  | 3,778,622 |  |  | $ | 3,779 |  |  | $ | 13,547,780 |  |  |  | - |  |  | $ | - |  |  | $ | - |  |  |  | - |  |  | $ | - |  |  | $ | - |  |  |  | 8,211,902 |  |  | $ | 8,212 |  |  | $ | 46,465,926 |  |  | $ | (64,288,167 | ) |  | $ | (4,262,470 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 1,250 |  |  |  | 1 |  |  |  | 448 |  |  |  | - |  |  |  | 449 |  |
| Conversion of preferred stock into common stock |  |  | (574,200 | ) |  |  | (575 | ) |  |  | (3,236,164 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 717,750 |  |  |  | 718 |  |  |  | 3,236,021 |  |  |  | - |  |  |  | - |  |
| Restricted units vested |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 77,500 |  |  |  | 78 |  |  |  | (78 | ) |  |  | - |  |  |  | - |  |
| Reserved shares for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 52,094 |  |  |  | - |  |  |  | 52,094 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 23,766 |  |  |  | - |  |  |  | 23,766 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (901,185 | ) |  |  | (901,185 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - March 31, 2018 |  |  | 3,204,422 |  |  |  | 3,204 |  |  |  | 10,311,616 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 9,008,402 |  |  |  | 9,009 |  |  |  | 49,778,177 |  |  |  | (65,189,352 | ) |  |  | (5,087,346 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Settlement of debt |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 5,143,258 |  |  |  | 5,143 |  |  |  | 371,038 |  |  |  | - |  |  |  | 376,181 |  |
| Conversion of preferred stock into common stock |  |  | (392,467 | ) |  |  | (393 | ) |  |  | (735,811 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 490,584 |  |  |  | 490 |  |  |  | 735,714 |  |  |  | - |  |  |  | - |  |
| Restricted units vested |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 77,500 |  |  |  | 78 |  |  |  | (78 | ) |  |  | - |  |  |  | - |  |
| Reserved shares for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 32,801 |  |  |  | - |  |  |  | 32,801 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 21,645 |  |  |  | - |  |  |  | 21,645 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (6,011,970 | ) |  |  | (6,011,970 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - June 30, 2018 |  |  | 2,811,955 |  |  |  | 2,811 |  |  |  | 9,575,805 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 14,719,744 |  |  |  | 14,720 |  |  |  | 50,939,297 |  |  |  | (71,201,322 | ) |  |  | (10,668,689 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Settlement of debt |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 74,558,393 |  |  |  | 74,558 |  |  |  | 2,789,922 |  |  |  | - |  |  |  | 2,864,480 |  |
| Conversion of preferred stock into common stock |  |  | (41,016 | ) |  |  | (41 | ) |  |  | (77,671 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 51,270 |  |  |  | 51 |  |  |  | 77,661 |  |  |  | - |  |  |  | - |  |
| Restricted units vested |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 77,500 |  |  |  | 78 |  |  |  | (78 | ) |  |  | - |  |  |  | - |  |
| Reserved shares for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 19,514 |  |  |  | - |  |  |  | 19,514 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (26,912,414 | ) |  |  | (26,912,414 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - September 30, 2018 |  |  | 2,770,939 |  |  |  | 2,770 |  |  |  | 9,498,134 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 89,406,907 |  |  |  | 89,407 |  |  |  | 53,826,316 |  |  |  | (98,113,736 | ) |  |  | (34,697,109 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cash |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 110,000 |  |  |  | 110 |  |  |  | 54,890 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 17,078,500 |  |  |  | 17,078 |  |  |  | 666,062 |  |  |  | - |  |  |  | 738,140 |  |
| Settlement of debt |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 2,995,755 |  |  |  | 2,996 |  |  |  | 1,542,078 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 48,827,137 |  |  |  | 48,827 |  |  |  | 2,346,420 |  |  |  | - |  |  |  | 3,940,321 |  |
| Accounts payable and accrued expenses |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 200,000 |  |  |  | 200 |  |  |  | 279,800 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 7,782,820 |  |  |  | 7,783 |  |  |  | 1,377,513 |  |  |  | - |  |  |  | 1,665,296 |  |
| Conversion of preferred stock into common stock |  |  | (218,297 | ) |  |  | (217 | ) |  |  | (627,508 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 272,872 |  |  |  | 273 |  |  |  | 627,452 |  |  |  | - |  |  |  | - |  |
| Restricted units vested |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 77,500 |  |  |  | 78 |  |  |  | (78 | ) |  |  | - |  |  |  | - |  |
| Reserved shares for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 8,779 |  |  |  | - |  |  |  | 8,779 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 1,279,675 |  |  |  | - |  |  |  | 1,279,675 |  |
| Net income for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 26,122,724 |  |  |  | 26,122,724 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - December 31, 2018 |  |  | 2,552,642 |  |  |  | 2,553 |  |  |  | 8,870,626 |  |  |  | 3,305,755 |  |  |  | 3,306 |  |  |  | 1,876,768 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 163,445,736 |  |  |  | 163,446 |  |  |  | 60,132,139 |  |  |  | (71,991,012 | ) |  |  | (942,174 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cash |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 100,000 |  |  |  | 100 |  |  |  | 49,900 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 1,250,000 |  |  |  | 1,250 |  |  |  | 48,750 |  |  |  | - |  |  |  | 100,000 |  |
| Conversion of preferred stock into common stock |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (524,218 | ) |  |  | (525 | ) |  |  | (209,163 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 6,552,725 |  |  |  | 6,553 |  |  |  | 203,135 |  |  |  | - |  |  |  | - |  |
| Conversion of Series B Preferred into Series C Preferred |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (821,292 | ) |  |  | (821 | ) |  |  | (674,457 | ) |  |  | 821,292 |  |  |  | 821 |  |  |  | 674,457 |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Warrants issued with notes payable (discount) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 28,721 |  |  |  | - |  |  |  | 28,721 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 3,792 |  |  |  | - |  |  |  | 3,792 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (236,382 | ) |  |  | (236,382 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - March 31, 2019 |  |  | 2,552,642 |  |  |  | 2,553 |  |  |  | 8,870,626 |  |  |  | 2,060,245 |  |  |  | 2,060 |  |  |  | 1,043,048 |  |  |  | 821,292 |  |  |  | 821 |  |  |  | 674,457 |  |  |  | 171,248,461 |  |  |  | 171,249 |  |  |  | 60,416,537 |  |  |  | (72,227,394 | ) |  |  | (1,046,043 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Conversion of preferred stock into common stock |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (517,000 | ) |  |  | (517 | ) |  |  | (206,283 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 6,462,500 |  |  |  | 6,462 |  |  |  | 200,338 |  |  |  | - |  |  |  | - |  |
| Adjustment for fractional shares in reverse split |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (140 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Warrants issued with notes payable (discount) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 12,592 |  |  |  | - |  |  |  | 12,592 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 2,176 |  |  |  | - |  |  |  | 2,176 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (200,305 | ) |  |  | (200,305 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - June 30, 2019 |  |  | 2,552,642 |  |  |  | 2,553 |  |  |  | 8,870,626 |  |  |  | 1,543,245 |  |  |  | 1,543 |  |  |  | 836,765 |  |  |  | 821,292 |  |  |  | 821 |  |  |  | 674,457 |  |  |  | 177,710,821 |  |  |  | 177,711 |  |  |  | 60,631,643 |  |  |  | (72,427,699 | ) |  |  | (1,231,580 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accounts payable |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 562,500 |  |  |  | 563 |  |  |  | 21,937 |  |  |  | - |  |  |  | 22,500 |  |
| Services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 312,500 |  |  |  | 312 |  |  |  | 12,188 |  |  |  | - |  |  |  | 12,500 |  |
| Warrants issued with notes payable (discount) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 95,437 |  |  |  | - |  |  |  | 95,437 |  |
| Warrants issued for extension of notes payable |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 25,656 |  |  |  | - |  |  |  | 25,656 |  |
| Options issued for settlement of accounts payable |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 33,829 |  |  |  | - |  |  |  | 33,829 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 457,949 |  |  |  | - |  |  |  | 457,949 |  |
| BCF recognized on convertible notes |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 59,957 |  |  |  | - |  |  |  | 59,957 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (669,372 | ) |  |  | (669,372 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - September 30, 2019 |  |  | 2,552,642 |  |  |  | 2,553 |  |  |  | 8,870,626 |  |  |  | 1,543,245 |  |  |  | 1,543 |  |  |  | 836,765 |  |  |  | 821,292 |  |  |  | 821 |  |  |  | 674,457 |  |  |  | 178,585,821 |  |  |  | 178,586 |  |  |  | 61,338,596 |  |  |  | (73,097,071 | ) |  |  | (1,193,124 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accounts payable |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 500,000 |  |  |  | 500 |  |  |  | 20,900 |  |  |  | - |  |  |  | 21,400 |  |
| Conversion of preferred stock into common stock |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (430,000 | ) |  |  | (430 | ) |  |  | (171,570 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 5,375,000 |  |  |  | 5,375 |  |  |  | 166,625 |  |  |  | - |  |  |  | - |  |
| Conversion of restricted stock units into common stock |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 385,000 |  |  |  | 385 |  |  |  | (385 | ) |  |  | - |  |  |  | - |  |
| Warrants issued with notes payable (discount) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 14,299 |  |  |  | - |  |  |  | 14,299 |  |
| Warrants issued in settlement of litgation |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 18,500 |  |  |  | - |  |  |  | 18,500 |  |
| Options issued for settlement of payables |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 14,812 |  |  |  | - |  |  |  | 14,812 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 148,462 |  |  |  | - |  |  |  | 148,462 |  |
| Net loss for the period |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (504,038 | ) |  |  | (504,038 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - December 31, 2019 |  |  | 2,552,642 |  |  | $ | 2,553 |  |  | $ | 8,870,626 |  |  |  | 1,113,245 |  |  | $ | 1,113 |  |  | $ | 665,195 |  |  |  | 821,292 |  |  | $ | 821 |  |  | $ | 674,457 |  |  |  | 184,845,821 |  |  | $ | 184,846 |  |  | $ | 61,721,809 |  |  | $ | (73,601,109 | ) |  | $ | (1,479,689 | ) |

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

|  |  |  |
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**VIVOS INC**

**STATEMENTS OF CASH FLOWS**

**FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **2019** | |  |  | **2018** | |  |
| **CASH FLOW FROM OPERTING ACTIVIITES** |  |  |  |  |  |  |  |  |
| Net loss |  | $ | (1,610,097 | ) |  | $ | (7,702,845 | ) |
| Adjustments to reconcile net loss to net cash used in operating activities |  |  |  |  |  |  |  |  |
| Amortization of convertible debt discount |  |  | 134,034 |  |  |  | 791,928 |  |
| Amortization of BCF discount |  |  | 55,740 |  |  |  | - |  |
| Common stock issued for services |  |  | 12,500 |  |  |  | 449 |  |
| Stock options and warrants for services |  |  | 612,379 |  |  |  | 1,325,085 |  |
| Warrants issued for interest expense |  |  | 25,656 |  |  |  | - |  |
| Reserved stock units issued for services |  |  | - |  |  |  | 113,189 |  |
| Derivatives recorded as loan fees |  |  | - |  |  |  | 4,636,517 |  |
| (Gain) on debt extinguishment |  |  | - |  |  |  | (605,601 | ) |
| Forgiveness of debt |  |  | (34,106 | ) |  |  | - |  |
| Loss on fair value of derivative liability |  |  | - |  |  |  | 186,846 |  |
| **Changes in assets and liabilities** |  |  |  |  |  |  |  |  |
| Prepaid expenses and other assets |  |  | (12,500 | ) |  |  | (3,612 | ) |
| Accounts payable and accrued expenses |  |  | (136,371 | ) |  |  | (1,338 | ) |
| Accounts payable and accrued expenses from related party |  |  | (6,500 | ) |  |  | (128,178 | ) |
| Payroll liabilities |  |  | 88,549 |  |  |  | 466,941 |  |
| Accrued interest |  |  | 33,603 |  |  |  | 220,165 |  |
| Total adjustments |  |  | 772,984 |  |  |  | 7,002,391 |  |
|  |  |  |  |  |  |  |  |  |
| **Net cash used in operating activities** |  |  | (837,113 | ) |  |  | (700,454 | ) |
|  |  |  |  |  |  |  |  |  |
| **CASH FLOWS FROM FINANCING ACTIVITES** |  |  |  |  |  |  |  |  |
| Proceeds from related party notes payable |  |  | 237,000 |  |  |  | - |  |
| Proceeds from sale of preferred stock |  |  | 50,000 |  |  |  | 55,000 |  |
| Proceeds from sale of common stock |  |  | 50,000 |  |  |  | 683,140 |  |
| Proceeds from convertible debt |  |  | 500,000 |  |  |  | 50,000 |  |
| Repayment of convertible notes |  |  | - |  |  |  | (200,000 | ) |
| Proceeds from promissory notes - related party, net of repayments |  |  | 15,000 |  |  |  | 109,491 |  |
| **Net cash provided by financing activities** |  |  | 852,000 |  |  |  | 697,631 |  |
|  |  |  |  |  |  |  |  |  |
| **NET INCREASE (DECREASE) IN CASH** |  |  | 14,887 |  |  |  | (2,823 | ) |
|  |  |  |  |  |  |  |  |  |
| **CASH - BEGINNING OF PERIOD** |  |  | 5,494 |  |  |  | 8,317 |  |
|  |  |  |  |  |  |  |  |  |
| **CASH - END OF PERIOD** |  | $ | 20,381 |  |  | $ | 5,494 |  |
|  |  |  |  |  |  |  |  |  |
| **CASH PAID DURING THE PERIOD FOR:** |  |  |  |  |  |  |  |  |
| Interest expense |  | $ | 4,000 |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |
| Income taxes |  | $ | - |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |
| **SUPPLEMENTAL INFORMATION - NON-CASH INVESTING AND FINANCING ACTIVITIES:** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Conversion of preferred stock into common stock |  | $ | 588,487 |  |  | $ | 4,678,380 |  |
| Conversion of convertible preferred B into convertible preferred C |  | $ | 675,278 |  |  | $ | - |  |
| Recognition of debt discount at inception of notes payable |  | $ | 151,048 |  |  | $ | - |  |
| Recognition of BCF discount at inception of notes payable |  | $ | 59,957 |  |  | $ | - |  |
| Common stock issued in settlement of accounts payable |  | $ | 43,900 |  |  | $ | - |  |
| Common and referred stock issued for accounts payable and accrued payroll |  | $ | - |  |  | $ | 1,665,296 |  |
| Stock options issued in settlement of accounts payable |  | $ | 48,643 |  |  | $ | - |  |
| Warrants issued for settlement of litigation |  | $ | 18,500 |  |  | $ | - |  |
| Vesting of restricted stock units |  | $ | - |  |  | $ | 2,480 |  |
| Reclassification of shareholder advances to convertible notes payable |  | $ | 15,000 |  |  | $ | 35,212 |  |
| Reclassification of accrued interest to related party notes payable and convertible notes payable |  | $ | - |  |  | $ | 1,343 |  |
| Conversion of notes payable and accrued interest into common stock |  | $ | - |  |  | $ | 7,290,473 |  |

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

|  |  |  |
| --- | --- | --- |
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**Vivos Inc.**

**Notes to Financial Statements**

**For the Years Ended December 31, 2019 and 2018**

**NOTE 1: ORGANIZATION & BASIS OF PRESENTATION**

**Business Overview**

Vivos Inc. (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.

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

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

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

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

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

**IsoPet Solutions**

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

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

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

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

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

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

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

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

**Going Concern**

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As shown in the accompanying financial statements, the Company has suffered recurring losses and used significant cash in support of its operating activities and the Company’s cash position is not sufficient to support the Company’s operations. Research and development of the Company’s brachytherapy product line has been funded with proceeds from the sale of equity and debt securities as well as a series of grants. The Company requires funding of approximately $2.3 million annually to maintain current operating activities.

The Company has completed its reverse stock split which was approved by FINRA and went effective on June 28, 2019 which will enable them to begin the process of raising capital through their Regulation A+ which was filed with the Securities and Exchange Commission (“SEC”) now that the Company has available authorized shares to issue and received approval form the SEC in November 2019.

The intent is to obtain up to $3,000,000 in tranches of $250,000 over time. The Company intends to use these proceeds as follows:

For the animal therapy market:

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

For the human market:

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

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The Company has raised $125,280 in proceeds under this Regulation A+ in March 2020, which was in escrow until April 2020 at which time it was deposited into the Company’s accounts. The common shares for these proceeds were issued in April 2020. In addition, the Company converted their outstanding convertible notes payable of $415,000, $23,427 in accrued interest and $87,686 in an exchange premium stipulated in the note agreements into shares of common stock effective March 31, 2020. These shares were issued in April 2020, however effective as of March 31, 2020.

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

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

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

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

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

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

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As of December 31, 2019, the Company has $20,381 cash on hand. There are currently commitments to vendors for products and services purchased that will necessitate liquidation of the Company if it is unable to raise additional capital. The current level of cash is not enough to cover the fixed and variable obligations of the Company. The Company was able to execute the following transactions to improve their balance sheet and decrease the liabilities incurred and increase their cash flow:

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|  | ● | In November 2019, the Company had its Regulation A+ approved by the Securities and Exchange Commission for an offering up to 150 million shares of common stock. |
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|  | ● | During the Company’s second and third fiscal quarters, the Company secured approximately $300,000 in convertible promissory notes. |
|  |  |  |
|  | ● | The Company recognized its first few sales of IsoPet®. |

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

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

**NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**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 audited financial statements so as to conform to current period classifications.

**Cash Equivalents**

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

**Inventory**

Inventory is reported at the lower of cost or market, determined using the first-in, first-out basis, or net realizable value. All inventories consisted of finished goods. The Company has no inventory for the years ended December 31, 2019 and 2018.

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**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 December 31, 2019 and 2018, the balances reported for cash, prepaid expenses, accounts receivable, accounts payable, and accrued expenses, approximate the fair value because of their short maturities.

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

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

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

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

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

**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.

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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:

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| 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%).

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

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

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

The 2020 fee was paid in January 2020.

**Patents and Intellectual Property**

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

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

There have been no such capitalized costs in the years ended December 31, 2019 and 2018, respectively. However, a patent was filed on July 1, 2019 (No. 1811.191) filed by Michael Korenko and David Swanberg and assigned to the Company based on the Company’s proprietary particle manufacturing process. The timing of this filing was important given the Company’s plans to make IsoPet® commercially available, which it did on or about July 9, 2019. This additional patent protection will strengthen the Company’s competitive position. It is the Company’s intention to further extend this patent protection to several key countries within one year, as permitted under international patent laws and treaties.

**Revenue Recognition**

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

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

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

All revenue generated during the year ended December 31, 2019 related to sales of product.

**Income from Grants and Deferred Income**

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

On December 22, 2017, the Company received notification that Washington State University awarded it $17,500 of grant funds from the sub-award project entitled “*Optimized Injectable Radiogels for High-dose Therapy of Non-Resectable Solid Tumors*”. The Company received the $17,500 of the grant award in the year ended December 31, 2018.

**Loss Per Share**

The Company accounts for its loss per common share by replacing primary and fully diluted earnings per share with basic and diluted earnings per share. Basic loss per share is computed by dividing loss available to common stockholders (the numerator) by the weighted-average number of common shares outstanding (the denominator) for the period, and does not include the impact of any potentially dilutive common stock equivalents since the impact would be anti-dilutive. The computation of diluted earnings per share is similar to basic earnings per share, except that the denominator is increased to include the number of additional common shares that would have been outstanding if potentially dilutive common shares had been issued. For the given periods of loss, of the years ended December 31, 2019 and 2018, the basic earnings per share equals the diluted earnings per share.

The following represent common stock equivalents that could be dilutive in the future as of December 31, 2019 and 2018, which include the following:

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | December 31, 2019 | |  |  | December 31, 2018 | |  |
| Convertible debt |  |  | 10,914,782 |  |  |  | 17,594 |  |
| Preferred stock |  |  | 27,372,515 |  |  |  | 44,512,740 |  |
| Common stock options |  |  | 34,524,580 |  |  |  | 11,318,021 |  |
| Common stock warrants |  |  | 31,286,847 |  |  |  | 23,052,472 |  |
| Total potential dilutive securities |  |  | 104,098,724 |  |  |  | 78,900,827 |  |

**Research and Development Costs**

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

The Company incurred $67,584 and $104,208 research and development costs for the years ended December 31, 2019, and 2018, respectively, all of which were recorded in the Company’s operating expenses noted on the statements of operations for the years then ended.

**Advertising and Marketing Costs**

Advertising and marketing costs are expensed as incurred except for the cost of tradeshows which are deferred until the tradeshow occurs. There were no tradeshow expenses incurred and not expensed for the years ended December 31, 2019, and 2018, respectively. During the years ended December 31, 2019 and 2018, the Company incurred $0 and $11,500, respectively, in advertising and marketing costs.

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**Shipping and Handling Costs**

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

**Contingencies**

In the ordinary course of business, the Company is involved in legal proceedings involving contractual and employment relationships, product liability claims, patent rights, and a variety of other matters. The Company records contingent liabilities resulting from asserted and unasserted claims against it, when it is probable that a liability has been incurred and the amount of the loss is reasonably estimable. The Company discloses contingent liabilities when there is a reasonable possibility that the ultimate loss will exceed the recorded liability. Estimated probable losses require analysis of multiple factors, in some cases including judgments about the potential actions of third-party claimants and courts. Therefore, actual losses in any future period are inherently uncertain. 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 December 31, 2019 and 2018.

**Income Taxes**

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

The Company files income tax returns in the U.S. federal jurisdiction. The Company did not have any tax expense for the years ended December 31, 2019 and 2018. The Company did not have any deferred tax liability or asset on its balance sheet on December 31, 2019 and 2018.

Interest costs and penalties related to income taxes, if any, will be classified as interest expense and general and administrative costs, respectively, in the Company’s financial statements. For the years ended December 31, 2019 and 2018, the Company did not recognize any interest or penalty expense related to income taxes. The Company believes that it is not reasonably possible for the amounts of unrecognized tax benefits to significantly increase or decrease within the next twelve months.

The Tax Cuts and Jobs Act (the “*Act*”) was enacted on December 22, 2017. The Act reduces the U.S. federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced earnings. These amounts are provisional and subject to change. The most significant impact of the legislation for the Company was a $3,300,000 reduction of the value of net deferred tax assets (which represent future tax benefits) as a result of lowering the U.S. corporate income tax rate from 35% to 21%. The Act also includes a requirement to pay a one-time transition tax on the cumulative value of earnings and profits that were previously not repatriated for U.S. income tax purposes. The Company has no earnings and profits that were previously not repatriated for U.S. income tax purposes.

**Stock-Based Compensation**

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

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

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

In July 2017, the FASB issued ASU 2017-11 “Earnings Per Share (Topic 260).” The amendments in the update change the classification of certain equity-linked financial instruments (or embedded features) with down round features. The amendments also clarify existing disclosure requirements for equity-classified instruments. For freestanding equity-classified financial instruments, the amendments require entities that present earnings per share (“EPS”) in accordance with Topic 260, Earnings Per Share, to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down round features would be subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt—Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). For public business entities, the amendments in Part I of this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The adoption did not have a material impact on the Company’s financial statements.

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

Other accounting standards that have been issued or proposed by FASB that do not require adoption until a future date are not expected to have a material impact on the consolidated financial statements upon adoption. The Company does not discuss recent pronouncements that are not anticipated to have an impact on or are unrelated to its financial condition, results of operations, cash flows or disclosures.

**NOTE 3: FIXED ASSETS**

Fixed assets consist of the following at December 31, 2019 and 2018:

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

There is no depreciation expense for the years ended December 31, 2019 and 2018.

In June 2019, the Company sold the one piece of equipment still held for $0. The basis of this piece of equipment was also $0, resulting in no gain or loss on the sale.

**NOTE 4: RELATED PARTY TRANSACTIONS**

**Related Party Convertible Notes Payable**

As of December 31, 2019 and 2018, the Company had the following related party convertible notes outstanding:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | December 31, 2019 | | | | | |  |  | December 31, 2018 | | | | | |  |
|  |  | Principal | |  |  | Accrued  Interest | |  |  | Principal | |  |  | Accrued  Interest | |  |
| September 2019 $15,000 Note, 8% interest, due January 2020 |  | $ | 15,000 |  |  | $ | 321 |  |  | $ | - |  |  | $ | - |  |
| Other related party notes |  |  | - |  |  |  | 1,054 |  |  |  | - |  |  |  | 1,054 |  |
| March 2017 $332,195 Note, 10% interest, due May 2017 |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Total Convertible Notes Payable, Net |  | $ | 15,000 |  |  | $ | 1,375 |  |  | $ | - |  |  | $ | 1,054 |  |
| Less: Debt Discount |  |  | (500 | ) |  |  | - |  |  |  | - |  |  |  | - |  |
|  |  | $ | 14,500 |  |  | $ | 1,375 |  |  | $ | - |  |  | $ | 1,054 |  |

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

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

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

Interest expense for the years ended December 31, 2019 and 2018 on the related party convertible notes payable amounted to $321 and $29,650, respectively.

**Related Party Notes Payable**

As of December 31, 2019 and December 31, 2018, the Company had the following related party notes outstanding:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | December 31, 2019 | | | | | |  |  | December 31, 2018 | | | | | |  |
|  |  | Principal | |  |  | Accrued  Interest | |  |  | Principal | |  |  | Accrued  Interest | |  |
| January 2019 $60,000 Note, 8% interest, due January 2020 |  | $ | 60,000 |  |  | $ | 4,472 |  |  | $ | - |  |  | $ | - |  |
| March 2019 $48,000 Note, 8% interest, due March 2020 |  |  | 48,000 |  |  |  | 2,927 |  |  |  | - |  |  |  | - |  |
| April 2019 $29,000 Note, 8% interest, due April 2020 |  |  | 29,000 |  |  |  | 1,559 |  |  |  | - |  |  |  | - |  |
| July 2019 $50,000 Note 8% interest, due July 2020 |  |  | 50,000 |  |  |  | 1,956 |  |  |  | - |  |  |  | - |  |
| November 2019 $50,000 Note 8% interest, due November 2020 |  |  | 50,000 |  |  |  | 393 |  |  |  | - |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Total Related Party Notes Payable, Net |  | $ | 237,000 |  |  | $ | 11,307 |  |  | $ | - |  |  | $ | - |  |

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

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. On July 5, 2019 the Company entered into a note payable with a trust related to one of our directors in the amount of $50,000. The note is for a one-year period maturing July 5, 2020 and bears interest at an annual rate of 8%. On November 25, 2019 the Company entered into a note payable with a trust related to one of our directors in the amount of $50,000. The note is for a one-year period maturing November 25, 2020 and bears interest at an annual rate of 8%. Interest expense for these notes for the year ended December 31, 2019 and accrued interest at December 31, 2019 is $11,307.

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

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**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 $38,610 as of December 31, 2019 and 2018, respectively.

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

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

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

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+.

**NOTE 5: CONVERTIBLE NOTES PAYABLE**

As of December 31, 2019 and 2018, the Company had the following convertible notes outstanding:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | December 31, 2019 | | | | | |  |  | December 31, 2018 | | | | | |  |
|  |  | Principal | |  |  | Accrued  Interest | |  |  | Principal | |  |  | Accrued  Interest | |  |
| July and August 2012 $1,060,000 Notes convertible into common stock at $4.60 per share, 12% interest, due December 2013 and January 2014 |  | $ | 45,000 |  |  | $ | 39,998 |  |  | $ | 45,000 |  |  |  | 34,603 |  |
| May through October 2015 $605,000 Notes convertible into preferred stock at $1 per share, 8-10% interest, due September 30, 2015 |  |  | - |  |  |  | 17,341 |  |  |  | - |  |  |  | 17,341 |  |
| October through December 2015 $613,000 Notes convertible into preferred stock at $1 per share, 8% interest, due June 30, 2016, net of debt discount of $0 and $560,913, respectively |  |  | - |  |  |  | 5,953 |  |  |  | - |  |  |  | 5,953 |  |
| January through March 2016 $345,000 Notes convertible into preferred stock at $1 per share, 8% interest, due June 30, 2016 |  |  | - |  |  |  | 696 |  |  |  | - |  |  |  | 696 |  |
| May 2019 $60,000 Note convertible into common shares at $0.04 per share, 8% interest, due October 30, 2019 |  |  | 60,000 |  |  |  | 3,264 |  |  |  | - |  |  |  | - |  |
| July 2019 $50,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | 50,000 |  |  |  | 1,880 |  |  |  | - |  |  |  | - |  |
| September 2019 $50,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | 50,000 |  |  |  | 1,235 |  |  |  | - |  |  |  | - |  |
| September 2019 $38,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | 38,000 |  |  |  | 939 |  |  |  | - |  |  |  | - |  |
| September 2019 $25,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | 25,000 |  |  |  | 612 |  |  |  | - |  |  |  | - |  |
| September 2019 $50,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | 50,000 |  |  |  | 1,213 |  |  |  | - |  |  |  | - |  |
| September 2019 $50,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | 50,000 |  |  |  | 1,202 |  |  |  | - |  |  |  | - |  |
| September 2019 $37,000 Note convertible into common shares at $0.04 per share, 8% interest, due January 15, 2020 |  |  | 37,000 |  |  |  | 833 |  |  |  | - |  |  |  | - |  |
| December 2019 $50,000 Note convertible into common shares at $0.04 per share, 8% interest, due March 31, 2020 |  |  | 50,000 |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Penalties on notes in default |  |  | 10,618 |  |  |  | - |  |  |  | 8,824 |  |  |  | - |  |
| Total Convertible Notes Payable, Net |  | $ | 465,618 |  |  | $ | 75,166 |  |  | $ | 53,824 |  |  | $ | 58,593 |  |
| Less: BCF Discount |  |  | (6,187 | ) |  |  | - |  |  |  | - |  |  |  | - |  |
| Less: Debt Discount |  |  | (24,545 | ) |  |  | - |  |  |  | - |  |  |  | - |  |
|  |  | $ | 434,886 |  |  | $ | 75,166 |  |  | $ | 53,824 |  |  | $ | 58,593 |  |

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Interest expense for the years ended December 31, 2019 and 2018 on the convertible notes payable amounted to $16,563 and $187,741, respectively.

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

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

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

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

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

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| --- | --- | --- |
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The Company entered into $300,000 in convertible promissory notes in July and September 2019, that were to mature January 15, 2020. The convertible promissory notes bear interest at a rate of 8%, The convertible promissory notes are convertible into shares of common stock at a price of $0.04 per share. Upon the closing of an equity financing pursuant to an effective registration statement with gross proceeds to the Company totaling at least $250,000 exclusive of any exchanges (“Qualified Financing”), the outstanding principal amount of this convertible promissory notes together with all accrued and unpaid interest shall be exchanged into such securities as are issued in the Qualified Financing at a rate of 1.20. Upon an exchange, the Payee shall be granted all rights afforded to an investor in the Qualified Financing. The convertible promissory noteholders received 3,000,000 warrants at an exercise price ranging between $0.06 and $0.08 per share, that have a term of two years. The warrants were valued at $91,716 and represent a debt discount, which will be amortized over the life of the convertible promissory notes. In addition, the Company recognized a beneficial conversion feature discount to the notes of $59,957 that is being amortized over the life of the notes. For the year ended December 31, 2019, the Company recognized $53,770 in amortization of the BCF discount.

The Company is 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 this note effective March 31, 2020.

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, 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.

**NOTE 6: PROMISSORY NOTES PAYABLE**

As of December 31, 2019 and December 31, 2018, the Company had the following promissory notes outstanding:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | December 31, 2019 | | | | | |  |  | December 31, 2018 | | | | | |  |
|  |  | Principal  (net) | |  |  | Accrued Interest | |  |  | Principal  (net) | |  |  | Accrued Interest | |  |
| February 2019, two promissory notes for $50,000 each (total of $100,000), maturing August 2019, extended to February 2020, at 8.00% interest (originally) and now 15% interest |  | $ | 100,000 |  |  | $ | 5,410 |  |  | $ | - |  |  |  | - |  |
| Debt discount |  |  | (-) |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Total Promissory Notes Payable, Net |  | $ | 100,000 |  |  | $ | 5,410 |  |  | $ | - |  |  | $ | - |  |

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

|  |  |  |
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On August 20, 2019, the two noteholders agreed to extend these notes another six-months to February 20, 2020, then amended again for six-months and the notes now mature August 20, 2020. In consideration for the extension, the note holders received 750,000 warrants (375,000 each) and the interest rate on the notes increased from 8% to 15% per annum. The accrued interest at August 20, 2019 of $4,000 was paid to the note holders. The interest expense on these notes for the year ended December 31, 2019 amounted to $9,410, of which $5,410 is accrued for as of December 31, 2019.

**NOTE 7: INCOME TAXES**

The Tax Cuts and Jobs Act (the “*Act*”) was enacted on December 22, 2017. The Act reduces the US federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced earnings. The Company based on its assessment of the accounting for the tax effects of enactment of the Act; as described below, it has made a reasonable estimate of the effects on existing deferred tax balances. These amounts are provisional and subject to change. The most significant impact of the legislation for the Company was a $3,300,000 reduction of the value of the Company’s net deferred tax assets (which represent future tax benefits) as a result of lowering the U.S. corporate income tax rate from 35% to 21%. The Act also includes a requirement to pay a one-time transition tax on the cumulative value of earnings and profits that were previously not repatriated for U.S. income tax purposes. The Company has no earnings and profits that were previously not repatriated for U.S. income tax purposes.

Deferred taxes are provided on a liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry-forwards and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

Net deferred tax assets consist of the following components as of December 31, 2019 and 2018:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | December 31, 2019 | |  |  | December 31, 2018 | |  |
| Deferred tax assets: |  |  |  |  |  |  |  |  |
| Net operating loss carryover |  | $ | 5,890,000 |  |  | $ | 5,760,000 |  |
| Interest expense |  |  | 15,000 |  |  |  | - |  |
| Related party accrual |  |  | 23,400 |  |  |  | 2,300 |  |
| Capital Loss Carryover |  |  | 3,400 |  |  |  | 3,400 |  |
| Deferred tax liabilities |  |  |  |  |  |  |  |  |
| Depreciation |  |  | (2,100 | ) |  |  | (2,100 | ) |
| Valuation allowance |  |  | (5,929,700 | ) |  |  | (5,763,600 | ) |
| Net deferred tax asset |  | $ | - |  |  | $ | - |  |

The income tax provision differs from the amount of income tax determined by applying the U.S. Federal income tax rate to pretax income from continuing operations for the years ended December 31, 2019 and 2018 due to the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | December 31, 2019 | |  |  | December 31, 2018 | |  |
| Book income (loss) |  | $ | (338,100 | ) |  | $ | (1,617,600 | ) |
| Forgiveness of debt |  |  | (7,200 | ) |  |  | - |  |
| Depreciation |  |  | (1,100 | ) |  |  | (1,100 | ) |
| Interest expense |  |  | 15,000 |  |  |  | - |  |
| Related party accrual |  |  | 21,100 |  |  |  | (108,300 | ) |
| Meals and entertainment |  |  | - |  |  |  | 300 |  |
| Stock for services |  |  | 2,600 |  |  |  | 100 |  |
| Options expense |  |  | 134,000 |  |  |  | 302,000 |  |
| Non-cash interest expense |  |  | 39,900 |  |  |  | 1,046,900 |  |
| Other non-deductible expenses |  |  | - |  |  |  | 261,800 |  |
| Valuation allowance |  |  | 133,800 |  |  |  | 115,900 |  |
| Income tax expense |  | $ | - |  |  | $ | - |  |

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At December 31, 2019, the Company had net operating loss carryforwards of approximately $28,045,000.

Due to the change in ownership provisions of the Tax Reform Act of 1986, net operating loss carryforwards for Federal income tax reporting purposes are subject to annual limitations. Should a change in ownership occur, net operating loss carryforwards may be limited as to use in future years.

Topic 740 provides guidance on the accounting for uncertainty in income taxes recognized in a company’s financial statements. Topic 740 requires a company to determine whether it is more likely than not that a tax position will be sustained upon examination based upon the technical merits of the position. If the more-likely-than-not threshold is met, a company must measure the tax position to determine the amount to recognize in the financial statements. At the adoption date of January 1, 2007, the Company had no unrecognized tax benefit, which would affect the effective tax rate if recognized.

The Company includes interest and penalties arising from the underpayment of income taxes in the statements of operations in the provision for income taxes. As of December 31, 2019, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company files income tax returns in the U.S. federal jurisdiction. The Company is located in the state of Washington and Washington state does not require the filing of income taxes. With few exceptions, the Company is no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations by tax authorities for years before 2016.

**NOTE 8: 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 December 31, 2019 and December 31, 2018, the Company has 184,845,821 and 163,445,736 shares issued and outstanding, respectively.

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

**Preferred Stock**

As of December 31, 2019 and 2018, the Company has 20,000,000 shares of Preferred stock authorized with a par value of $0.001. The Company’s Board of Directors is authorized to provide for the issuance of shares of preferred stock in one or more series, fix or alter the designations, preferences, rights, qualifications, limitations or restrictions of the shares of each series, including the dividend rights, dividend rates, conversion rights, voting rights, term of redemption including sinking fund provisions, redemption price or prices, liquidation preferences and the number of shares constituting any series or designations of such series without further vote or action by the shareholders. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of management without further action by the shareholders and may adversely affect the voting and other rights of the holders of common stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control to others.

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

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

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*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.

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

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

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

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

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

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

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

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

Certain Price and Share Adjustments.

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

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

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

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

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

Certain Price and Share Adjustments.

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

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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 - 2019***

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

The Company issued 18,390,225 shares of common stock in consideration for the conversion of 1,471,218 shares of Series B Convertible Preferred.

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

The Company issued 1,062,500 shares of common stock in a settlement of accounts payable valued at $43,900. This includes 500,000 shares to the Company’s former CEO in settlement of that litigation (see Note 9).

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

The Company issued 385.000 shares of common stock in conversion of vested restricted stock units.

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

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

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

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

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

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

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

**Common Stock Options**

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

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | | | | | |  |  | Weighted | |  |  |  | |  |  | Weighted | |  |
|  |  | Options Outstanding | | | | | |  |  | Average | |  |  |  | |  |  | Average | |  |
|  |  | Number | |  |  | Exercise | |  |  | Remaining | |  |  | Aggregate | |  |  | Exercise | |  |
|  |  | Of | |  |  | Price | |  |  | Contractual | |  |  | Intrinsic | |  |  | Price | |  |
|  |  | Shares | |  |  | Per Share | |  |  | Life | |  |  | Value | |  |  | Per Share | |  |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| Balance at December 31, 2017 |  |  | 152,813 |  |  | $ | 4.00-120.00 |  |  |  | 3.91 years |  |  | $ | - |  |  | $ | 1.08 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Options granted |  |  | 11,165,208 |  |  | $ | 0.11 |  |  |  | - |  |  |  |  |  |  | $ | - |  |
| Options exercised |  |  | - |  |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ | - |  |
| Options expired |  |  | - |  |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance at December 31, 2018 |  |  | 11,318,021 |  |  | $ | 0.11-120.00 |  |  |  | - |  |  | $ | - |  |  | $ | 0.24 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Options granted |  |  | 23,252,809 |  |  | $ | 0.025 4-0.04 |  |  |  | - |  |  |  |  |  |  | $ | - |  |
| Options exercised |  |  | - |  |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ | - |  |
| Options expired |  |  | (46,250 | ) |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance at December 31, 2019 |  |  | 34,524,580 |  |  | $ | 0.024-120.00 |  |  |  | 6.49 years |  |  | $ | 277,973 |  |  | $ | 0.08 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Exercisable at December 31, 2019 |  |  | 34,428,955 |  |  | $ | 0.024-120.00 |  |  |  | 6.48 years |  |  | $ | 276,729 |  |  | $ | 0.08 |  |

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

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

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

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

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

During the years ending December 31, 2019 and 2018, the Company recognized $608,588 and $1,164,885, respectively, worth of stock based compensation related to the vesting of it stock options.

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**Common Stock Warrants**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | | | | | |  |  | Weighted | |  |  |  | |  |  | Weighted | |  |
|  |  | Warrants Outstanding | | | | | |  |  | Average | |  |  |  | |  |  | Average | |  |
|  |  | Number | |  |  | Exercise | |  |  | Remaining | |  |  | Aggregate | |  |  | Exercise | |  |
|  |  | Of | |  |  | Price | |  |  | Contractual | |  |  | Intrinsic | |  |  | Price | |  |
|  |  | Shares | |  |  | Per Share | |  |  | Life | |  |  | Value | |  |  | Per Share | |  |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| Balance at December 31, 2017 |  |  | 38,026 |  |  | $ | 0.14 |  |  |  | 1.19 years |  |  | $ | 749 |  |  | $ | 0.32 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Warrants granted |  |  | 23,043,663 |  |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ |  |  |
| Warrants exercised |  |  | - |  |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ |  |  |
| Warrants expired/cancelled |  |  | (29,217 | ) |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance at December 31, 2018 |  |  | 23,052,472 |  |  | $ | 0.08-80.00 |  |  |  | 1.77 years |  |  | $ | - |  |  | $ | 0.08 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Warrants granted |  |  | 8,234,375 |  |  | $ | 0.04-0.08 |  |  |  | - |  |  |  |  |  |  | $ |  |  |
| Warrants exercised |  |  | - |  |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ |  |  |
| Warrants expired/cancelled |  |  | , |  |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance at December 31, 2019 |  |  | 31,286,847 |  |  | $ | 0.04-80.00 |  |  |  | 0.97 years |  |  | $ | - |  |  | $ | 0.10 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Exercisable at December 31, 2019 |  |  | 31,286,847 |  |  | $ | 0.04-80.00 |  |  |  | 0.97 years |  |  | $ | - |  |  | $ | 0.10 |  |

For the year ended December 31, 2018, the Company granted 2,416,410 warrants to settle accrued payroll, 7,925,503 warrants to settle other payables, 2,725,000 warrants to settle accounts payable, 750,000 warrants issued for consulting services and 9,226,750 warrants in the issuance of shares issued for cash.

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

**Restricted Stock Units**

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

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | |  |  | Weighted | |  |
|  |  | Number | |  |  | Average | |  |
|  |  | Of | |  |  | Grant Date | |  |
|  |  | Shares | |  |  | Fair Value | |  |
|  |  |  | |  |  |  | |  |
| Balance at December 31, 2017 |  |  | 717,500 |  |  | $ | 0.59 |  |
|  |  |  |  |  |  |  |  |  |
| RSU’s granted |  |  | - |  |  | $ | - |  |
| RSU’s vested |  |  | (310,000 | ) |  | $ | - |  |
| RSU’s forfeited |  |  | (145,000 | ) |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |
| Balance at December 31, 2018 |  |  | 262,500 |  |  | $ | 0.59 |  |
|  |  |  |  |  |  |  |  |  |
| RSU’s granted |  |  | - |  |  | $ | - |  |
| RSU’s vested |  |  | - |  |  | $ | - |  |
| RSU’s forfeited |  |  | - |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |
| Balance at December 31, 2019 |  |  | 262,500 |  |  | $ | 0.59 |  |

|  |  |  |
| --- | --- | --- |
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During the years ended December 31, 2019 and 2018, the Company recognized $0 and $113,189 worth of expense related to the vesting of its RSU’s, respectively. As of December 31, 2019, the Company had $155,400 worth of expense yet to be recognized for RSU’s not yet vested.

**NOTE 9: LEGAL MATTERS**

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

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

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

**NOTE 10: COMMITMENT**

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

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

**NOTE 11: CONCENTRATIONS OF CREDIT AND OTHER RISKS**

**Accounts Receivable**

The Company had one customer that represented 100% of the Company’s total revenues for the year ended December 31, 2019. The customer that represented 100% of the Company’s total revenue for the year ended December 31, 2019 had no net accounts receivable balance at December 31, 2019.

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The loss of a significant customer representing the percentage of total revenue would have a temporary adverse effect on the Company’s revenue, which would continue until the Company located new customers to replace them.

The Company routinely assesses the financial strength of its customers and provides an allowance for doubtful accounts as necessary. As of December 31, 2019 and 2018, the Company had no allowance or bad debt expense recorded.

**Product Purchases**

Some of the products the Company might market and components thereof are currently available only from a limited number of suppliers including the source for the main component in the Company’s products, Y-90 which is only derived from one source, several of which are international suppliers. Failure to obtain deliveries from these sources could have a material adverse effect on the Company’s ability to operate.

**NOTE 12: SUBSEQUENT EVENTS**

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

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

All of the notes (convertible and non-convertible) that had a maturity date of January 15, 2020 were in default, resulting in a default interest rate of 12.5% from this date through the date they were converted effective March 31, 2020.

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

On February 15, 2020, the two notes for $50,000 each were extended to August 15, 2020.

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.

In March 2020, certain holders of convertible promissory notes entered into agreements to exchange certain notes totaling $526,113, including $415,000 in principal amount, $23,427 in accrued interest and an exchange premium as provided for in the note agreements of $87,686 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 2,075,000 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.

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