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xbrli:shares xbrli:pure

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-K**

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

**For the fiscal year ended December 31, 2021**

or

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

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

**Commission file number: 0-53497**

**VIVOS INC**

(Exact name of registrant as specified in its charter)

|  |  |  |
| --- | --- | --- |
| **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 ☒

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

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

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

Indicate by check mark 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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Large Accelerated Filer** | ☐ | **Accelerated Filer** |  | ☐ |
| **Non-Accelerated Filer** | ☒ | **Smaller Reporting Company** |  | ☒ |
|  |  | **Emerging growth company** |  | ☐ |

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

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

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

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 $36,693,047. 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 March 4, 2022, there were 343,530,678 shares of the registrant’s common stock outstanding, 2,071,007 shares of the registrant’s Series A Convertible Preferred Stock outstanding, 200,363 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. is a radiation oncology medical device company engaged in the development of its yttrium-90 (“Y-90”) based brachytherapy device, RadioGel™, for the treatment of non-resectable tumors. A prominent team of radiochemists, scientists and engineers, collaborating with strategic partners, including national laboratories, universities and private corporations, lead the Company’s development efforts. The Company’s overall vision is to globally empower physicians, medical researchers and patients by providing them with new isotope technologies that offer safe and effective treatments for cancer.

In 2013 the FDA issued the determination that RadioGel™ is a device for human therapy for non-resectable cancers in humans. This should result in a faster path than a drug for final approval.

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

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

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

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

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

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

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

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

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

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

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

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**Intellectual Property**

Our original license with Battelle National Laboratory is reaching its end of life in 2022. During the past several years, in anticipation of this we have expanded our proprietary knowledge and our trademark and patent protection.

We have expanded our trademark protection from RadioGel to now include IsoPet. We obtained the International Certificate of Registration for ISOPET, which is the first step to file in several countries**.**

The Company received the Patent Cooperation Treaty (“PCT”) International Search Report on our patent application (No.1811.191). Seven of our claims were immediately ruled as having novelty, inventive step and industrial applicability. This gives us the basis to extend for many years the patent protection for our proprietary Yttrium-90 phosphate particles utilized in Isopet® and Radiogel™. Vivos, Inc. filed its particle patent in several countries and in parallel is pursuing amendments to increase the number of claims.

In addition to the United States of America, our new patent team filed in Canada, the European Union, Japan, Australia, Brazil, China, India, South Korea, and the Russian Eurasian (Russia, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Tajikistan, and Turkmenistan).

We have just filed a new provisional patent to protect our current and planned developments. It includes a summary of our improved hydrogel formulation and production process, the use of other particles incorporating other isotopes beyond Y-90, and the anti-circumvention techniques we discovered that would make it more difficult for competitors to engineer around our proprietary hydrogel with other hydrogels from our defensive effort we call our “knock-off red team exercise”.

Following the provisional patent, we will file for utility patents on our polymer/hydrogel improvements. These include reducing the polymer production time and increasing the output by a factor of three. We have also further reduced the level of trace contaminants to be well below the FDA guidelines.

We currently are developing a micro-injection system for small tumor therapy. This will provide more precise controls for treating cancerous thyroid lymph nodes. It will also be valuable if the company pursues other future indications for use that will require precise micro-injections, e.g. ocular melanoma, spinal tumors and brain cancers.

**Vista Veterinary Hospital**

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

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

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

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

There have been 84 expressions of interest in IsoPet® therapy from across the United States, but only about 10% of these were treated and they were very advanced cases. The reasons are instructive. Most of the cases were for so advanced that the pet parents found out about IsoPet® on the Internet as a last hope. Several others were internal cancers that could not be reached, for example deep in the throat. Several cases were treatable, but the pets weighed more than 20 pounds and the pet parents were not willing to fly them in the “Safe Cargo” holds. Those patients would have been treated by regional clinics once we implement that strategy. Several cases were mast cell cancers. The Company is confident that those tumors could have been treated, but once killed they release mast cells in a process called granulation. This could cause a shock to the animal’s system. The Company will focus one of our clinical studies on the optimum approach for those therapies.

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

Since IsoPet® has shown to be effective in killing cancer at the site of injection the current focus is in optimizing the techniques to help the pet resorb the necrotic tissue rapidly. In addition, IsoPet® was used to treat a mast cell tumor. When these cancers are destroyed, they release their mast cell. The animal was treated with a steroid to counter this effect and to date is doing well.

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.

The Company worked closely with FX Masse to develop nine certification training modules for use in potential regional clinics. These modules are necessary to satisfy the radioactive material handling licenses. This approach is very cost effective.

Johns Hopkins University VCTN, Veterinary Clinical Trials Network, is now an Isopet® regional clinic. Additionally, Johns Hopkins will also perform new Isopet® animal studies on various specific cancers. They have the required radioactive material license and have completed their training certification for Isopet®. This important relationship will also help meet our objective of obtaining high quality data on a range of cancers that can be published in leading journals. These publications are the optimal way to increase awareness of Isopet® and to gain broader acceptance from the veterinarian/oncology community.

We currently are working with the NY Surgical Center on Long Island to become a new IsoPet Regional Center. They have completed their certification training and have submitted their Radioactive Material Handling License application to the NY regulators. Aside from the normal solid tumor therapy they are interested in treating the margins for resected tumors and to use their surgical techniques to treat tumors deep within the body, such as bladder cancers.

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

Based on advice from the FDA the Company has scheduled a Pre-Submission meeting on November 30, 2021 to discuss a draft of an Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies. Using this process results in more rapid feedback to prepare the final IDE.

The FDA was very supportive and had suggested this Q-Submission path for rapid turnaround and dialog. The Mayo Clinic physicians did an excellent job presenting the need for Radiogel™ to treat recurrent thyroid cancer and to answer a range of questions from the new FDA review team. The FDA provided many helpful suggestions on a range of subjects from labeling to dosimetry to the Mayo protocol for clinical testing, and the need for some additional specific testing. They suggested having another Q-Sub Review and conference call dedicated to the details of the dosimetry calculations.

In parallel the Company working with the Mayo Clinic’s principal investigators to improve the clinical trial protocol for their Institutional Review Board.

The MAB selected eighteen applications for RadioGel™, each of which meet the criteria described above. This large number confirms the wide applicability of the device and defines the path for future business growth. The Company’s application establishes a single Indication for Use - treatment of cancerous tissue or solid tumors pathologically associated with locoregional papillary thyroid carcinoma and recurrent papillary thyroid carcinoma. We anticipate that this initial application will facilitate each subsequent application for additional Indications for Use, and the testing for many of the subsequent applications could be conducted in parallel, depending on available resources.

**Financing and Strategy**

The Company’s stock offering under Regulation A+ was qualified by the Securities and Exchange Commission (“SEC”) on June 3, 2020. A second Regulation A+ was qualified by the SEC on September 15, 2021 to raise capital for 50,000,000 shares at a price of $0.10 for a maximum of $5,000,000.

The Company’s initial Regulation A+ raised approximately $4,000,000 from the sale of shares under Regulation A+, and intends to use the proceeds generated as follows:

For the animal therapy market:

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

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

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 from proceeds to be raised from the recent qualified Regulation A+.

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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. The Company has started to in recent weeks to continue their marketing to the animal therapy market and attempt to increase the exposure to their product and generate revenue accordingly.

As of December 31, 2021, the Company has $1,606,123 cash on hand. There are currently commitments to vendors for products and services purchased. To continue the development of the Company’s products, the current level of cash may not be enough to cover the fixed and variable obligations of the Company.

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

**Product Features**

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

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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. |

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**Steps from Production to Therapy**

*Device Production*

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

*Production of the Hydrogel*

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

*Production of the Yttrium-90 Phosphate Particles*

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

*Shipment*

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

*At the User*

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

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

**Principal Markets**

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

*Medical Sector*

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

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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. |

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 |

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*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.

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.

***Competitors***

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

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

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

***Raw Materials***

The Company currently subcontracts the manufacturing of RadioGelTM at IsoTherapeutics. Prior to 2021, Eckert and Ziegler was the only supplier of Y-90 in the United States, and was 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.

During 2021, utilized Akina, Inc. as an alternate supplier of its hydrogel polymer component.

***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.

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

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

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

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

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

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

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

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

***Environmental Regulation***

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

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***Human Capital***

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

***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.*

**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, 2021 and 2020 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 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 $77,085,867 and $74,558,101 as of December 31, 2021 and 2020, respectively including net losses of $2,527,766 and $956,992 for the years ended December 31, 2021 and 2020. Historically, the Company has relied upon investor funds to maintain its operations and develop its business. The Company needs to raise additional capital 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 $5 million per year to maintain current operating activities. Over the next 24 months, the Company believes it will cost approximately $9 million to fund: (1) fund the FDA approval process to conduct human clinical trials, (2) conduct Phase I, pilot, clinical trials, (3) activate several regional clinics to administer IsoPet® across the county, (4) create an independent production center within the current production site to create a template for future international manufacturing, and (5) initiate regulatory approval processes outside of the United States.

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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 COVID-19 pandemic, 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 $14,887 and $7,000 in operating revenues, net of discounts for the years ended December 31, 2021 and 2020, respectively 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, 2021 and 2020, 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, 2021 and 2020. 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.

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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.

**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, 2021 and 2020 was 2,074,138 and 32,815, 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 343,530,678 shares of common stock outstanding on March 1, 2022. The Company also had outstanding on that date dilutive securities consisting of preferred stock, restricted stock units, options, and warrants (collectively, “*Common Stock Equivalents*”) that if they had been exercised and converted in full on March 1, 2022, would have resulted in the issuance of up to 69,287,379 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, 2021, the reported low closing price for the Company’s common stock was $0.068 per share, and the reported high closing price was $0.2592 per share. For the year ended December 31, 2020, the reported low closing price for the Company’s common stock was $0.0135 per share, and the reported high closing price was $0.245 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 unprecedented events related to COVID-19 and the variants, 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.

**GENERAL RISK FACTORS**

***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.

***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.

**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. Management believes that the Company’s sites are adequate to support the business and suitable for present purposes, and the properties and equipment have been well maintained.

**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. There are no material pending or threatened legal proceedings at this time.

**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** | |  |
| **2020** |  |  |  |  |  |  |  |  |
| Quarter ended December 31 |  | $ | 0.245 |  |  | $ | 0.0187 |  |
| Quarter ended September 30 |  | $ | 0.0387 |  |  | $ | 0.0226 |  |
| Quarter ended June 30 |  | $ | 0.0495 |  |  | $ | 0.0135 |  |
| Quarter ended March 31 |  | $ | 0.402 |  |  | $ | 0.02 |  |
|  |  |  |  |  |  |  |  |  |
| **2021** |  |  |  |  |  |  |  |  |
| Quarter ended December 31 |  | $ | 0.122 |  |  | $ | 0.07 |  |
| Quarter ended September 30 |  | $ | 0.13 |  |  | $ | 0.0882 |  |
| Quarter ended June 30 |  | $ | 0.1227 |  |  | $ | 0.077 |  |
| Quarter ended March 31 |  | $ | 0.1179 |  |  | $ | 0.0853 |  |

***Holders***

As of March 1, 2022, we had 343,530,678 shares of common stock, par value $0.001 per share, issued and outstanding, which were held by approximately 230 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, 2021 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 |  |  | 25,777,500 |  |  | $ | 0.09 |  |  |  | 32,836,047 |  |
| Equity compensation plans not approved by stockholders |  |  | 34,115,309 |  |  | $ | 0.07 |  |  |  | - |  |
| Total |  |  | 34,115,309 | (1) |  | $ | 0.07 | (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, 2021, 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, 2021, an aggregate total of 43,862,500 restricted stock units (“*RSUs*”) under the 2015 Plan were authorized, but as of March 1, 2022, 18,085,000 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, 2021, 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, 2021**

During the month of October 2021, the Company issued 2,005,693 shares of common stock in the cashless exercise of 3,500,000 warrants.

During November 2021, the Company issued 77,768 shares of common stock for services.

During December 2021, the Company issued 2,316,830 shares of common stock in conversion of related party notes payable and accrued interest.

During December 2021, the Company issued 401,373 shares of common stock in conversion of accounts payable to a related party.

During December 2021, the Company issued 2,953,625 shares in conversion of 236,290 shares of Series B Preferred Stock.

**Issuances Subsequent to December 31, 2021**

Through March 1, 2022, there have been no shares of common or preferred stock issued.

**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, 2021 and December 31, 2020***

The following table sets forth information from the Company’s statements of operations for the years ended December 31, 2021 and 2020.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Year Ended  December 31, 2021 | |  |  | Year Ended  December 31, 2020 | |  |
| Revenues, net |  | $ | 14,887 |  |  | $ | 7,000 |  |
| Cost of goods sold |  |  | 12,000 |  |  |  | 5,608 |  |
| Gross profit |  |  | 2,887 |  |  |  | 1,392 |  |
| Operating expense |  |  | 2,504,685 |  |  |  | 673,913 |  |
| Operating loss |  |  | (2,501,798 | ) |  |  | (672,521 | ) |
| Non-operating expense |  |  | (25,968 | ) |  |  | (284,471 | ) |
| Net loss |  | $ | (2,527,766 | ) |  | $ | (956,992 | ) |

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

We had $14,887 in revenues for the year ended December 31, 2021, compared to $7,000 in revenue for the year ended December 31, 2020, a period over period increase of $7,887. These revenues are reflected net of discounts relate to consulting income with respect to the IsoPet® therapies.

We had $12,000 in cost of goods sold for the year ended December 31, 2021, compared to $5,608 in cost of goods sold for the year ended December 31, 2020, a period over period increase of $6,392. The increase was a result of the Company’s recognition of their sales 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, 2021 and 2020 consisted of the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Year ended  December 31, 2021 | |  |  | Year ended  December 31, 2020 | |  |
| Professional fees |  | $ | 224,323 |  |  | $ | 243,942 |  |
| RSUs, stock options and warrants consideration |  |  | 1,614,000 |  |  |  | 2,176 |  |
| Payroll expense |  |  | 267,477 |  |  |  | 234,094 |  |
| Research and development |  |  | 286,848 |  |  |  | 84,668 |  |
| General and administrative expense |  |  | 112,037 |  |  |  | 109,033 |  |
|  |  | $ | 2,504,685 |  |  | $ | 673,913 |  |

Operating expenses for the years ended December 31, 2021 and 2020 was $2,504,685 and $673,913, respectively. The increase in operating expenses from 2020 to 2021 can be attributed to the decrease in professional fees ($243,942 for the year ended December 31, 2020 versus $224,323 for the year ended December 31, 2021) as the Company utilized more services due to amending their Regulation A+ and the fees incurred for the consultants engaged; the increase in general and administrative expense ($109,033 for the year ended December 31, 2020 versus $112,037 for the year ended December 31, 2021); the increase in research and development ($84,668 for the year ended December 31, 2020 versus $286,848 for the year ended December 31, 2021) as the Company ramped up the development of their products with the recent raising of capital, an increase in payroll expenses ($234,094 for the year ended December 31, 2020 versus $267,477 for the year ended December 31, 2021) related to the deferred compensation criteria in the CEOs employment contract taking effect, and an increase in stock-based compensation related to RSUs granted to consultants ($2,176 for the year ended December 31, 2020 versus $1,614,000 for the year ended December 31, 2021).

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

Non-Operating income (expense) for the years ended December 31, 2021 and 2020 consisted of the following:

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Year ended  December 31, 2021 | |  |  | Year ended  December 31, 2020 | |  |
|  |  |  | |  |  |  | |  |
| Interest expense |  | $ | (25,375 | ) |  | $ | (287,471 | ) |
| Loss on debt extinguishment |  |  | (137,038 | ) |  |  | - |  |
| Forgiveness of debt |  |  | 136,445 |  |  |  | - |  |
| Other income |  |  | - |  |  |  | 3,000 |  |
|  |  | $ | (25,968 | ) |  | $ | (284,471 | ) |

Non-operating income (expense) for the year ended December 31, 2021 varied from the year ended December 31, 2020 primarily due to a decrease in interest expense from $287,471 for the year ended December 31, 2020 to $25,375 for the year ended December 31, 2021 as a result of conversions of notes payable. The majority of the interest recorded by the Company consists of amortization of debt discount, BCF discount and the exchange premium resulting in additional shares to the noteholders on conversion. In addition, the Company converted a note in January 2021 which resulted in a loss on conversion and recognized a gain on forgiveness of debt on old payables as they satisfied the agreement with this vendor to pay a portion of the payable with the remaining amount forgiven.

***Net Loss***

The Company’s net loss for the years ended December 31, 2021 and 2020 was $2,527,766 and $956,992, respectively, as a result of the items described above.

***Liquidity and Capital Resources***

At December 31, 2021, the Company had working capital of $1,467,383, as compared to working capital of $32,034 at December 31, 2020. During the year ended December 31, 2021, the Company experienced negative cash flow from operations of $963,819 and realized $1,666,238 of cash flows from financing activities. As of December 31, 2021, the Company did not have any commitments for capital expenditures.

Cash used in operating activities increased from $875,807 for the year ended December 31, 2020 to $963,819 for the year ended December 31, 2021. Cash used in operating activities was primarily a result of the Company’s non-cash items, such as loss from operations, loss on conversion of debt and share based compensation offset by forgiveness of debt. Cash provided from financing activities decreased from $1,759,130 for the year ended December 31, 2020 to $1,666,238 for the year ended December 31, 2021. The cash provided from financing activities for 2020 was primarily a result of increase in proceeds from the Regulation A+ where the Company raised $1,662,780 from common stock and warrant issuances, $60,000 from the exercise of stock options, plus proceeds of $150,000 from convertible notes, which $50,000 was repaid. In 2021, the Company raised $1,811,238 from sales of common stock and warrants offset by repayments of convertible notes of $50,000 and related party notes of $100,000.

The Company has generated material operating losses since inception. The Company had a net loss of $2,527,766 for the year ended December 31, 2021, and a net loss of $956,992 for the year ended December 31, 2020. The Company expects to continue to experience net operating losses for the foreseeable future. Historically, the Company has relied upon investor funds to maintain its operations and develop the Company’s business. The Company anticipates raising additional capital within the next twelve months for working capital as well as business expansion, although the Company can provide no assurance that additional capital will be available on terms acceptable to the Company, if at all. If the Company is unable to obtain additional financing to meet its working capital requirements, it may have to curtail its business or cease all operations.

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The Company requires funding of at least $5 million per year to maintain current operating activities. Over the next 24 months, the Company believes it will cost approximately $9 million to fund: (1) fund the FDA approval process to conduct human clinical trials, (2) conduct Phase I, pilot, clinical trials, (3) activate several regional clinics to administer IsoPet® across the county, (4) create an independent production center within the current production site to create a template for future international manufacturing, and (5) initiate regulatory approval processes outside of the United States.

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

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

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

***Contractual Obligations (payments due by period as of December 31, 2021)***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |  | $ | 4,000 |  |  | $ | 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:

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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 asset.

**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.

The Company recognized revenue as they (i) identified the contracts with each 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.

**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.

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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, 2021 and 2020, the Company did not recognize any interest or penalty expense related to income taxes. The Company believes that it is not reasonably possible for the amounts of unrecognized tax benefits to significantly increase or decrease within the next 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 under FASB ASC Topic 718, Compensation – Stock Compensation and ASU 2018-07. Companies are required to measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Share based compensation arrangements include stock options, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. As such, compensation cost is measured on the date of grant at their fair value. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant.

**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, 2021, 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, 2021, 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:

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| (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 |  | 75 |  | President, Chief Executive Officer, and Director |
| Michael Pollack |  | 55 |  | Interim Chief Financial Officer |
| Carlton M. Cadwell |  | 77 |  | 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, 2021 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 2021 and 2020 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.

***Board of Directors; Attendance at Meetings***

The Board held two meetings and acted by unanimous written consent two times during the year ended December 31, 2020. Each director attended both Board meetings during the year ended December 31, 2020. In 2021, we conducted no board of director meetings. We have no formal policy with respect to the attendance of Board members at annual meetings of shareholders but encourage all incumbent directors and director nominees to attend each annual meeting of shareholders.

**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, 2021 (collectively, the “*Named Executive Officers*”):

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name and Principal Position (1) |  | Year | |  |  | Salary ($) | |  |  | Bonus ($) | |  |  | Stock  Awards ($) | |  |  | Option  Awards ($)(2) | |  |  | Total ($) | |  |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| Dr. Michael K. Korenko |  |  | 2021 |  |  | $ | 232,500 | (3) |  | $ | 30,000 |  |  | $ | - |  |  | $ | - |  |  | $ | 262,500 |  |
| CEO, President and Director |  |  | 2020 |  |  | $ | 120,086 | (3) |  | $ | 98,165 |  |  | $ | - |  |  | $ | - |  |  | $ | 218,251 |  |

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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 directly in 2020 or 2021. 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) | Of the $120,000 due Mr. Korenko for 2019, $69,914 is accrued for as of December 31, 2020, and as of December 31, 2021, the Company has no accrued compensation to Mr. Korenko. |

***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 employment agreement automatically renewed for another year through December 31, 2021.

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, which occurred in December 2020. 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. In December 2020, Mr. Korenko exercised 2,500,000 of these options for $60,000.

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.

On June 4, 2019, the Company entered into an Executive Employment Agreement (“Employment Agreement”) with Dr. Michael K. Korenko, the Company’s Chief Executive Officer. The employment term under the Employment Agreement commenced with an effective date of June 11, 2019 and expires on December 31, 2020, and December 31 of each successive year if the Employment Agreement is extended, unless terminated earlier as set forth in the Employment Agreement. The Company on December 31, 2020 extended this agreement through December 31, 2021 while renegotiating terms of a new Employment Agreement. On May 3, 2021, the Company and the Chief Executive Officer agreed the terms of a new Employment Agreement with an effective date of January 1, 2021 that has a term of three years and expires December 31, 2023.

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

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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 | |  |
| NONE |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

***Compensation of Directors***

During the year ended December 31, 2021, 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 2021, the aggregate number of stock awards and the aggregate number of stock option awards that were outstanding as of December 31, 2021:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **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. These warrants expired in October 2020.

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 March 1, 2022, 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 March 1, 2022, there were 343,530,678 shares of common stock outstanding and up to 69,287,379 shares issuable upon exercise of common stock equivalents, assuming exercise and conversion occurred as of that date, for a total of 412,818,057 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) |  |  | 15,406,979 |  |  |  | 3.73 | % |
|  |  |  |  |  |  |  |  |  |
| Michael K. Korenko (4) |  |  | 9.461,374 |  |  |  | 2.29 | % |
|  |  |  |  |  |  |  |  |  |
| Michael Pollack |  |  | 16,000 |  |  |  | \* |  |
|  |  |  |  |  |  |  |  |  |
| **All Current Directors and Executive Officers as a group (3 individuals)** |  |  | 24,895,265 |  |  |  | 6.02 | % |

\*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 March \_\_, 2022, (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 March \_\_, 2022, 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; and 4,816,275 shares issuable upon conversion of Series C Preferred, and 2,316,830 shares of common stock issued to AMIC Gift, LLC, an LLC controlled by Carlton and his wife. |
|  |  |
| (4) | Includes 75,000 shares issuable upon exercise of warrants. |

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

As of March 1, 2022, there were 2,071,007 shares of Series A Preferred issued and outstanding, convertible into 2,588,758 shares of the Company’s common stock.

The following table sets forth, as of March 1, 2022, 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 |  |  |  | 7.16 | % |
|  |  |  |  |  |  |  |  |  |
| Carlton M. Cadwell |  |  | 908,910 |  |  |  | 43.89 | % |
|  |  |  |  |  |  |  |  |  |
| Michael K. Korenko |  |  | - |  |  |  | - | % |
|  |  |  |  |  |  |  |  |  |
| **All Current Directors and Executive Officers as a group (2 individuals)(3)** |  |  | 1,057,219 |  |  |  | 51.05 | % |
|  |  |  |  |  |  |  |  |  |
| **Major Shareholder(s):** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| L. Bruce Jolliff |  |  | 197,979 |  |  |  | 9.56 | % |
|  |  |  |  |  |  |  |  |  |
| Stoel Rives |  |  | 133,333 |  |  |  | 6.44 | % |

|  |  |
| --- | --- |
| (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) L. Bruce Jolliff is 206 N 41st St. Unit 1, Yakima, WA 98901; and (iii) Stoel Rives is One Union Square, 600 University Street, Suite 3600, Seattle, WA 98101. |
|  |  |
| (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 Series A Convertible Preferred, and has therefore been omitted from this table. |

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

As of March 1, 2022, there were 200,363 shares of Series B Preferred issued and outstanding, convertible into 2,504.538 shares of the Company’s common stock.

The following table sets forth, as of March 1, 2022, 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** | |  |
| **All Current Directors and Executive Officers as a group (3 individuals)** |  |  | - |  |  |  | \* | % |
|  |  |  |  |  |  |  |  |  |
| **Major Shareholder(s):** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Jason Adelman(3) |  |  | 200,000 |  |  |  | 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 the beneficial owners is as follows: (i) Jason Adelman (JTA Resources LLC. is 40 East 66th St., New York, NY 10065. |
|  |  |
| (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) | Represents 200,000 shares of Series B Preferred held by JTA Resources LLC. |

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

As of March 1, 2022, 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 March 1, 2022, 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***

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 was converted into shares of common stock in December 2021.

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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 was repaid in December 2021.

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%. This note was repaid in December 2021.

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%. Of this amount, $23,000 was paid in December 2021, and the balance was converted into shares of common stock in December 2021.

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%. This note was converted into shares of common stock in December 2021.

The Company borrowed $107,000 in the year ended December 31, 2020 from its CEO and repaid these amounts in full.

***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, 2021 and 2020 were $36,000 and $61,500, 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, 2021 and 2020 in the amounts of $2,250 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, 2021 and 2020 were $3,250 and $2,750, 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, 2021 and 2020 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, 2021 and 2020, the Statements of Operations for the years ended December 31, 2021 and 2020, the Statements of Changes in Stockholders’ Deficit for the years ended December 31, 2021 and 2020, and the Statements of Cash Flows for the years ended December 31, 2021 and 2020, together with the notes thereto and the reports of Fruci & Associates II, PLLC as required by Item 8 are included in this 2021 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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://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).](https://www.sec.gov/Archives/edgar/data/1449349/000149315219011262/ex6-18.htm) |
| 23 |  | [Consent of Independent Registered Public Accounting Firm](ex23.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\* |  | Inline XBRL Instance Document |
| 101.SCH\* |  | Inline XBRL Taxonomy Extension Schema |
| 101.CAL\* |  | Inline XBRL Taxonomy Extension Calculation Linkbase |
| 101.DEF\* |  | Inline XBRL Taxonomy Extension Definition Linkbase |
| 101.LAB\* |  | Inline XBRL Taxonomy Extension Label Linkbase |
| 101.PRE\* |  | Inline XBRL Taxonomy Extension Presentation Linkbase |
| 104 |  | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) |

\* 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: March 7, 2022 | 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: March 7, 2022 | By: | */s/ Michael K. Korenko* |
|  | Name: | Michael K. Korenko |
|  | Title: | Chief Executive Officer  (Principal Executive Officer) |
|  |  |  |
| Date: March 7, 2022 | By: | */s/ Michael Pollack* |
|  | Name: | Michael Pollack |
|  | Title: | Interim Chief Financial Officer  (Principal Financial and Accounting Officer) |
|  |  |  |
| Date: March 7, 2022 | 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, 2021 and 2020, and the related statements of operations, changes in stockholders’ equity, and cash flows for each of the years in the two-year period ended December 31, 2021, 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, 2021 and 2020 and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021, 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, has utilized significant cash in operations, and its cash position is not sufficient to support 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.

**Critical Audit Matters**

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

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***Recognition of common stock warrant transactions (Note 6 to the financial statements)***

*Description of the Critical Audit Matter*

The Company’s evaluation of common shares issued in exchange for stock warrants involved complexity and judgement in applying the relevant accounting standards when auditing management’s conclusions on the classification and recognition of warrants on issuance and on exercise.

*How the Critical Audit Matter Was Addressed in the Audit*

Our principal audit procedures to evaluate management’s calculation of common shares issued for exchange of stock warrants included the following:

|  |  |  |
| --- | --- | --- |
|  | ● | We evaluated the appropriateness and consistency of management’s methods and assumptions used in the identification, recognition, measurement, and disclosure of considerations of the underlying warrants, including the classification with respect to the terms and in considering applicable generally accepted accounting standards. |
|  |  |  |
|  | ● | We read the applicable agreements and compared the key terms to management’s analysis of the transaction. |
|  |  |  |
|  | ● | We read, evaluated, and tested the reasonableness of management’s calculation utilized in the determination of common shares issued in exchange for stock warrants. |
|  |  |  |
|  | ● | We evaluated whether management had appropriately considered new information that could significantly change the measurement or disclosure of common shares issued in exchange for stock warrants, and evaluated the disclosures related to the financial statement impacts of the transactions. |

We have served as the Company’s auditor since 2016.

Spokane, Washington

March 7, 2022

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**VIVOS INC**

**BALANCE SHEETS**

**DECEMBER 31, 2021 AND 2020**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **DECEMBER 31,** | |  |  | **DECEMBER 31,** | |  |
|  |  | **2021** | |  |  | **2020** | |  |
| **ASSETS** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Current Assets: |  |  |  |  |  |  |  |  |
| Cash |  | $ | 1,606,123 |  |  | $ | 903,704 |  |
| Prepaid expenses |  |  | 28,175 |  |  |  | 33,835 |  |
|  |  |  |  |  |  |  |  |  |
| Total Current Assets |  |  | 1,634,298 |  |  |  | 937,539 |  |
|  |  |  |  |  |  |  |  |  |
| **TOTAL ASSETS** |  | $ | 1,634,298 |  |  | $ | 937,539 |  |
|  |  |  |  |  |  |  |  |  |
| **LIABILITIES AND STOCKHOLDERS’ EQUITY** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **LIABILITIES** |  |  |  |  |  |  |  |  |
| Current Liabilities: |  |  |  |  |  |  |  |  |
| Accounts payable and accrued expenses |  | $ | 166,915 |  |  | $ | 361,880 |  |
| Related party accounts payable |  |  | - |  |  |  | 32,110 |  |
| Accrued interest payable |  |  | - |  |  |  | 100,954 |  |
| Payroll liabilities payable |  |  | - |  |  |  | 66,143 |  |
| Convertible notes payable, net |  |  | - |  |  |  | 107,418 |  |
| Related party promissory note |  |  | - |  |  |  | 237,000 |  |
|  |  |  |  |  |  |  |  |  |
| Total Current Liabilities |  |  | 166,915 |  |  |  | 905,505 |  |
|  |  |  |  |  |  |  |  |  |
| **Total Liabilities** |  |  | 166,915 |  |  |  | 905,505 |  |
|  |  |  |  |  |  |  |  |  |
| Commitments and contingencies |  |  | - |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |
| **STOCKHOLDERS’ EQUITY** |  |  |  |  |  |  |  |  |
| Preferred stock, par value, $0.001, 20,000,000 shares authorized, Series A Convertible Preferred, 5,000,000 shares authorized, 2,071,007 and 2,171,007 shares issued and outstanding, respectively |  |  | 2,071 |  |  |  | 2,171 |  |
| Additional paid in capital - Series A Convertible preferred stock |  |  | 8,842,458 |  |  |  | 8,857,358 |  |
| Series B Convertible Preferred, 5,000,000 shares authorized, 200,363 and 436,653 shares issued and outstanding, respectively |  |  | 200 |  |  |  | 436 |  |
| Additional paid in capital - Series B Convertible preferred stock |  |  | 290,956 |  |  |  | 385,235 |  |
| Series C Convertible Preferred, 5,000,000 shares authorized, 385,302 and 385,302 shares issued and outstanding, respectively |  |  | 385 |  |  |  | 385 |  |
| Additional paid in capital - Series C Convertible preferred stock |  |  | 500,507 |  |  |  | 500,507 |  |
| Preferred stock, value |  |  |  |  |  |  |  |  |
| Additional paid in capital |  |  |  |  |  |  |  |  |
| Common stock, par value, $0.001, 950,000,000 shares authorized, 343,530,678 and 292,278,591 issued and outstanding, respectively |  |  | 343,531 |  |  |  | 292,279 |  |
| Additional paid in capital - common stock |  |  | 68,573,142 |  |  |  | 64,551,764 |  |
| Accumulated deficit |  |  | (77,085,867 | ) |  |  | (74,558,101 | ) |
|  |  |  |  |  |  |  |  |  |
| **Total Stockholders’ Equity** |  |  | 1,467,383 |  |  |  | 32,034 |  |
|  |  |  |  |  |  |  |  |  |
| **TOTAL LIABILITIES AND STOCKHOLDERS’ EQUITY** |  | $ | 1,634,298 |  |  | $ | 937,539 |  |

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, 2021 AND 2020**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **2021** | |  |  | **2020** | |  |
|  |  |  | |  |  |  | |  |
| **Revenues, net** |  | $ | 14,887 |  |  | $ | 7,000 |  |
| **Cost of Goods Sold** |  |  | (12,000 | ) |  |  | (5,608 | ) |
|  |  |  |  |  |  |  |  |  |
| **Gross profit** |  |  | 2,887 |  |  |  | 1,392 |  |
|  |  |  |  |  |  |  |  |  |
| **OPERATING EXPENSES** |  |  |  |  |  |  |  |  |
| Professional fees (including stock-based compensation of $1,614,000 and $2,176, respectively) |  |  | 1,838,323 |  |  |  | 246,118 |  |
| Payroll expenses |  |  | 267,477 |  |  |  | 234,094 |  |
| Research and development |  |  | 286,848 |  |  |  | 84,668 |  |
| General and administrative expenses |  |  | 112,037 |  |  |  | 109,033 |  |
|  |  |  |  |  |  |  |  |  |
| Total Operating Expenses |  |  | 2,504,685 |  |  |  | 673,913 |  |
|  |  |  |  |  |  |  |  |  |
| **OPERATING LOSS** |  |  | (2,501,798 | ) |  |  | (672,521 | ) |
|  |  |  |  |  |  |  |  |  |
| **NON-OPERATING INCOME (EXPENSE)** |  |  |  |  |  |  |  |  |
| Interest expense |  |  | (25,375 | ) |  |  | (287,471 | ) |
| Other income - SBA |  |  | - |  |  |  | 3,000 |  |
| Forgiveness of debt |  |  | 136,445 |  |  |  | - |  |
| Loss on debt extinguishment |  |  | (137,038 | ) |  |  | - |  |
|  |  |  |  |  |  |  |  |  |
| Total Non-Operating Income (Expenses) |  |  | (25,968 | ) |  |  | (284,471 | ) |
|  |  |  |  |  |  |  |  |  |
| **NET LOSS BEFORE PROVISION FOR INCOME TAXES** |  |  | (2,527,766 | ) |  |  | (956,992 | ) |
|  |  |  |  |  |  |  |  |  |
| Provision for income taxes |  |  | - |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |
| **NET LOSS** |  | $ | (2,527,766 | ) |  | $ | (956,992 | ) |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **Net loss per share - basic and diluted** |  | $ | (0.01 | ) |  | $ | (0.00 | ) |
|  |  |  |  |  |  |  |  |  |
| **Weighted average common shares outstanding - basic** |  |  | 325,851,906 |  |  |  | 222,804,039 |  |

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

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**VIVOS INC**

**STATEMENT OF CHANGES IN STOCKHOLDERS’ EQUITY**

**FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Shares** | |  |  | **Amount** | |  |  | **Series A Preferred** | |  |  | **Shares** | |  |  | **Amount** | |  |  | **Series B Preferred** | |  |  | **Shares** | |  |  | **Amount** | |  |  | **Series C Preferred** | |  |  | **Shares** | |  |  | **Amount** | |  |  | **Capital -**  **Common** | |  |  | **Accumulated**  **Deficit** | |  |  | **Total** | |  |
|  |  |  | |  |  |  | |  |  | **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, 2019 |  |  | 2,552,642 |  |  | $ | 2,553 |  |  | $ | 8,870,626 |  |  |  | 1,113,245 |  |  | $ | 1,113 |  |  | $ | 665,195 |  |  |  | 821,292 |  |  | $ | 821 |  |  | $ | 674,457 |  |  |  | 184,845,821 |  |  | $ | 184,846 |  |  | $ | 61,721,809 |  |  | $ | (73,601,109 | ) |  | $ | (1,479,689 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cash |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 60,617,778 |  |  |  | 60,618 |  |  |  | 1,576,062 |  |  |  | - |  |  |  | 1,636,680 |  |
| Note conversions/settlements |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 25,964,594 |  |  |  | 25,965 |  |  |  | 675,079 |  |  |  | - |  |  |  | 701,044 |  |
| Accounts payable |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accounts Payable, shares |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Services |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Services, shares |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock option exercises |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock option exercises, shares |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock option exercises, shares |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2,500,000 |  |
| RSUs |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| RSUs, shares |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Warrant exercises |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 8,193,185 |  |  |  | 8,193 |  |  |  | 51,807 |  |  |  | - |  |  |  | 60,000 |  |
| Redemption of preferred stock in convertible note agreement |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (100,000 | ) |  |  | (100 | ) |  |  | (49,900 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (50,000 | ) |
| Redemption of preferred stock for cash |  |  | (381,635 | ) |  |  | (382 | ) |  |  | (13,268 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (13,650 | ) |
| Conversion of preferred stock into common stock |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (576,592 | ) |  |  | (577 | ) |  |  | (230,060 | ) |  |  | (435,990 | ) |  |  | (436 | ) |  |  | (173,950 | ) |  |  | 12,657,275 |  |  |  | 12,657 |  |  |  | 392,366 |  |  |  | - |  |  |  | - |  |
| Warrants issued with notes payable (discount) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 28,482 |  |  |  | - |  |  |  | 28,482 |  |
| Warrants purchased for cash |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 26,100 |  |  |  | - |  |  |  | 26,100 |  |
| Options and warrants issued for services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 80,059 |  |  |  | - |  |  |  | 80,059 |  |
| Share adjustment |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (62 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |
| RSUs granted to consultants that have vested |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Net loss for the year |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (956,992 | ) |  |  | (956,992 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - December 31, 2020 |  |  | 2,171,007 |  |  |  | 2,171 |  |  |  | 8,857,358 |  |  |  | 436,653 |  |  |  | 436 |  |  |  | 385,235 |  |  |  | 385,302 |  |  |  | 385 |  |  |  | 500,507 |  |  |  | 292,278,591 |  |  |  | 292,279 |  |  |  | 64,551,764 |  |  |  | (74,558,101 | ) |  |  | 32,034 |  |
| Balance |  |  | 2,171,007 |  |  |  | 2,171 |  |  |  | 8,857,358 |  |  |  | 436,653 |  |  |  | 436 |  |  |  | 385,235 |  |  |  | 385,302 |  |  |  | 385 |  |  |  | 500,507 |  |  |  | 292,278,591 |  |  |  | 292,279 |  |  |  | 64,551,764 |  |  |  | (74,558,101 | ) |  |  | 32,034 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stock issued for: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cash |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 22,500,000 |  |  |  | 22,500 |  |  |  | 1,777,500 |  |  |  | - |  |  |  | 1,800,000 |  |
| Note conversions/settlements |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 3,576,080 |  |  |  | 3,576 |  |  |  | 408,435 |  |  |  | - |  |  |  | 412,011 |  |
| Accounts payable |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 1,305,298 |  |  |  | 1,305 |  |  |  | 120,805 |  |  |  | - |  |  |  | 122,110 |  |
| Services |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 77,768 |  |  |  | 78 |  |  |  | 3,678 |  |  |  | - |  |  |  | 3,756 |  |
| Stock option exercises |  |  | (100,000 | ) |  |  | (100 | ) |  |  | (14,900 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 2,125,000 |  |  |  | 2,125 |  |  |  | 12,875 |  |  |  | - |  |  |  | - |  |
| RSUs |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 12,000,000 |  |  |  | 12,000 |  |  |  | (12,000 | ) |  |  | - |  |  |  | - |  |
| Warrant exercises |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 6,714,316 |  |  |  | 6,714 |  |  |  | (6,714 | ) |  |  | - |  |  |  | - |  |
| Conversion of preferred shares to common shares |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (236,290 | ) |  |  | (236 | ) |  |  | (94,279 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 2,953,625 |  |  |  | 2,954 |  |  |  | 91,561 |  |  |  | - |  |  |  | - |  |
| Warrants purchased for cash |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 11,238 |  |  |  | - |  |  |  | 11,238 |  |
| RSUs granted to consultants that have vested |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 1,614,000 |  |  |  | - |  |  |  | 1,614,000 |  |
| Net loss for the year |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (2,527,766 | ) |  |  | (2,527,766 | ) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance - December 31, 2021 |  |  | 2,071,007 |  |  | $ | 2,071 |  |  | $ | 8,842,458 |  |  |  | 200,363 |  |  | $ | 200 |  |  | $ | 290,956 |  |  |  | 385,302 |  |  | $ | 385 |  |  | $ | 500,507 |  |  |  | 343,530,678 |  |  | $ | 343,531 |  |  | $ | 68,573,142 |  |  | $ | (77,085,867 | ) |  | $ | 1,467,383 |  |
| Balance |  |  | 2,071,007 |  |  | $ | 2,071 |  |  | $ | 8,842,458 |  |  |  | 200,363 |  |  | $ | 200 |  |  | $ | 290,956 |  |  |  | 385,302 |  |  | $ | 385 |  |  | $ | 500,507 |  |  |  | 343,530,678 |  |  | $ | 343,531 |  |  | $ | 68,573,142 |  |  | $ | (77,085,867 | ) |  | $ | 1,467,383 |  |

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, 2021 AND 2020**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **2021** | |  |  | **2020** | |  |
| **CASH FLOW FROM OPERTING ACTIVIITES** |  |  |  |  |  |  |  |  |
| Net loss |  | $ | (2,527,766 | ) |  | $ | (956,992 | ) |
| Adjustments to reconcile net loss to net cash used in operating activities |  |  |  |  |  |  |  |  |
| Amortization of convertible debt discount |  |  | - |  |  |  | 53,527 |  |
| Amortization of BCF discount |  |  | - |  |  |  | 6,187 |  |
| Common stock, stock options and warrants for services |  |  | 3,756 |  |  |  | 2,176 |  |
| RSUs issued for services |  |  | 1,614,000 |  |  |  | - |  |
| Loss on conversion of debt |  |  | 137,038 |  |  |  | - |  |
| Forgiveness of debt |  |  | (136,445 | ) |  |  | - |  |
| Warrants issued for interest expense |  |  | - |  |  |  | 77,883 |  |
| Exchange premium in conversion of notes |  |  | - |  |  |  | 98,508 |  |
| **Changes in assets and liabilities** |  |  |  |  |  |  |  |  |
| Accounts receivable |  |  |  |  |  |  |  |  |
| Prepaid expenses and other assets |  |  | 5,660 |  |  |  | (10,343 | ) |
| Accounts payable and accrued expenses |  |  | 31,480 |  |  |  | (149,937 | ) |
| Accounts payable and accrued expenses from related party |  |  | - |  |  |  | - |  |
| Payroll liabilities |  |  | (66,143 | ) |  |  | (33,857 | ) |
| Accrued interest |  |  | (25,399 | ) |  |  | 37,041 |  |
| Total adjustments |  |  | 1,563,947 |  |  |  | 81,185 |  |
|  |  |  |  |  |  |  |  |  |
| **Net cash used in operating activities** |  |  | (963,819 | ) |  |  | (875,807 | ) |
|  |  |  |  |  |  |  |  |  |
| **CASH FLOWS FROM FINANCING ACTIVITES** |  |  |  |  |  |  |  |  |
| Redemption of preferred stock |  |  | - |  |  |  | (63,650 | ) |
| Payments of convertible debt |  |  | (45,000 | ) |  |  | - |  |
| Payments of related party notes |  |  | (100,000 | ) |  |  | - |  |
| Proceeds from sale of common stock and warrants |  |  | - |  |  |  | 1,722,780 |  |
| Proceeds from convertible debt |  |  | - |  |  |  | 150,000 |  |
| Proceeds from common stock and warrants |  |  | 1,811,238 |  |  |  | - |  |
| Payment of notes payable |  |  | - |  |  |  | (50,000 | ) |
| **Net cash provided by financing activities** |  |  | 1,666,238 |  |  |  | 1,759,130 |  |
|  |  |  |  |  |  |  |  |  |
| **NET INCREASE IN CASH** |  |  | 702,419 |  |  |  | 883,323 |  |
|  |  |  |  |  |  |  |  |  |
| **CASH - BEGINNING OF YEAR** |  |  | 903,704 |  |  |  | 20,381 |  |
|  |  |  |  |  |  |  |  |  |
| **CASH - END OF YEAR** |  | $ | 1,606,123 |  |  | $ | 903,704 |  |
|  |  |  |  |  |  |  |  |  |
| **CASH PAID DURING THE PERIOD FOR:** |  |  |  |  |  |  |  |  |
| Interest expense |  | $ | 50,773 |  |  | $ | 13,442 |  |
|  |  |  |  |  |  |  |  |  |
| Income taxes |  | $ | - |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |
| **SUPPLEMENTAL INFORMATION - NON-CASH INVESTING AND FINANCING ACTIVITIES:** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Conversion of preferred stock into common stock |  | $ | 94,515 |  |  | $ | 405,023 |  |
| Recognition of debt discount at inception of notes payable |  | $ | - |  |  | $ | 28,482 |  |
| Conversion of notes payable and accrued interest into common stock |  | $ | 50,370 |  |  | $ | 701,044 |  |
| Conversion of notes payable - related parties and accrued interest into common stock |  | $ | 185,346 |  |  | $ | - |  |
| Common stock issued in cashless exercise of warrants |  | $ | 6,714 |  |  | $ | - |  |
| Common stock issued in settlement of accounts payable |  | $ | 90,000 |  |  | $ | - |  |
| Common stock issued in settlement of accounts payable - related parties |  | $ | 32,110 |  |  | $ | - |  |
| Stock options exercised for recission of common and preferred stock |  | $ | 60,000 |  |  | $ | - |  |
| RSUs vested into common stock |  | $ | 12,000 |  |  | $ | - |  |

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, 2021 and 2020**

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

**Business Overview**

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

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

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

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

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

**IsoPet Solutions**

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

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

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

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

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

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

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

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

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

**Intellectual Property**

Our original license with Battelle National Laboratory is reaching its end of life in 2022. During the past several years, in anticipation of this we have expanded our proprietary knowledge and our trademark and patent protection.

We have expanded our trademark protection from RadioGel to now include IsoPet. We obtained the International Certificate of Registration for ISOPET, which is the first step to file in several countries**.**

The Company received the Patent Cooperation Treaty (“PCT”) International Search Report on our patent application (No.1811.191). Seven of our claims were immediately ruled as having novelty, inventive step and industrial applicability. This gives us the basis to extend for many years the patent protection for our proprietary Yttrium-90 phosphate particles utilized in Isopet® and Radiogel™. Vivos Inc filed its particle patent in several counties and in parallel is pursuing amendments to increase the number of claims.

In addition to the USA the new patent team filed in Canada, the European Union, Japan, Australia, Brazil, China, India, South Korea, and the Russian Eurasian (Russia, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Tajikistan, and Turkmenistan).

We have just filed a new provisional patent to protect our current and planned developments. It includes a summary of our improved hydrogel formulation and production process, the use of other particles incorporating other isotopes beyond Y-90, and the anti-circumvention techniques we discovered that would make it more difficult for competitors to engineer around our proprietary hydrogel with other hydrogels from our defensive effort we call our “knock-off red team exercise”.

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Following the provisional patent, we will file for utility patents on our polymer/hydrogel improvements. These include reducing the polymer production time and increasing the output by a factor of three. We have also further reduced the level of trace contaminants to be well below the FDA guidelines.

We currently are developing a micro-injection system for small tumor therapy. This will provide more precise controls for treating cancerous thyroid lymph nodes. It will also be valuable if the company pursues other future indications for use that will require precise micro-injections, e.g. ocular melanoma, spinal tumors and brain cancers.

**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 $2.5 million annually to maintain current operating activities.

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

The Company’s stock offering under Regulation A+ was qualified by the Securities and Exchange Commission (“SEC”) on June 3, 2020. A second Regulation A+ was qualified by the SEC on September 15, 2021 to raise capital for 50,000,000 shares at a price of $0.10 for a maximum of $5,000,000.

The Company’s initial Regulation A+ raised approximately $4,000,000 from the sale of shares under Regulation A+, and intends to use the proceeds generated as follows:

For the animal therapy market:

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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 new regional clinics with their license and certification training. |

For the human market:

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

Research and development of the Company’s brachytherapy product line has been funded with proceeds from the sale of equity and debt securities. The Company may require additional funding of approximately $2.5 million annually to maintain current operating activities. Over the next 12 to 48 months, the Company believes it will cost approximately $9 million to: (1) fund the FDA approval process to conduct human clinical trials, (2) conduct Phase I, pilot, clinical trials, (3) activate several regional clinics to administer IsoPet® across the county, (4) create an independent production center within the current production site to create a template for future international manufacturing, and (5) initiate regulatory approval processes outside of the United States. The proceeds to be raised from the recent qualified Regulation A+ will be used to continue to fund this development.

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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 from proceeds to be raised from the recent qualified Regulation A+.

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. The Company has started to in recent weeks to continue their marketing to the animal therapy market and attempt to increase the exposure to their product and generate revenue accordingly.

As of December 31, 2021, the Company has $1,606,123 cash on hand. There are currently commitments to vendors for products and services purchased. To continue the development of the Company’s products, the current level of cash may not be enough to cover the fixed and variable obligations of the Company.

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

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

**Use of Estimates**

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

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**Financial Statement Reclassification**

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

**Cash Equivalents**

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

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

**Fair Value of Financial Instruments**

Fair value of financial instruments requires disclosure of the fair value information, whether or not recognized in the balance sheet, where it is practicable to estimate that value. As of December 31, 2021 and 2020, the balances reported for cash, prepaid expenses, accounts receivable, accounts payable, and accrued expenses, approximate the fair value because of their short maturities.

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

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

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

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

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

**Derivative Liabilities and Beneficial Conversion Feature**

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

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

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

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

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

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

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

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

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

**Fixed Assets**

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

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

 SCHEDULE OF DEPRECIATION ESTIMATED USEFUL LIFE

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

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

**License Fees**

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

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

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

 SCHEDULE OF FUTURE MINIMUM ROYALTIES

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Minimum** | |  |
|  |  | **Royalties per** | |  |
| **Calendar Year** |  | **Calendar Year** | |  |
|  |  |  |  |  |
| 2022 |  | $ | 4,000 |  |
| Total |  | $ | 14,000 |  |

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

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

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**Revenue Recognition**

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

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

The Company recognized revenue as they (i) identified the contracts with each 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 recognized in the years ended December 31, 2021 and 2020 relate to consulting income with respect to the IsoPet® therapies.

**Loss Per Share**

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

The following represent common stock equivalents that could be dilutive in the future as of December 31, 2021 and 2020, which include the following:

 SCHEDULE OF DILUTIVE EARNINGS PER SHARE

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | December 31, 2021 | |  |  | December 31, 2020 | |  |
| Convertible debt |  |  | - |  |  |  | 2,492 |  |
| Preferred stock |  |  | 9,909,570 |  |  |  | 12,863,195 |  |
| Restricted stock units |  |  | 25,262,500 |  |  |  | 262,500 |  |
| Common stock options |  |  | 2,252,809 |  |  |  | 2,252,809 |  |
| Common stock warrants |  |  | 31,862,500 |  |  |  | 35,362,500 |  |
| Total potential dilutive securities |  |  | 69,287,379 |  |  |  | 50,743,496 |  |

**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 $286,848 and $84,668 research and development costs for the years ended December 31, 2021 and 2020, respectively, all of which were recorded in the Company’s operating expenses noted on the statements of operations for the periods then ended.

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**Advertising and Marketing Costs**

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

**Contingencies**

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

**Income Taxes**

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

The Company files income tax returns in the U.S. federal jurisdiction. The Company did not have any tax expense for the years ended December 31, 2021 and 2020. The Company did not have any deferred tax liability or asset on its balance sheet on December 31, 2021 and 2020.

Interest costs and penalties related to income taxes, if any, will be classified as interest expense and general and administrative costs, respectively, in the Company’s financial statements. For the years ended December 31, 2021 and 2020, the Company did not recognize any interest or penalty expense related to income taxes. The Company believes that it is not reasonably possible for the amounts of unrecognized tax benefits to significantly increase or decrease within the next twelve months.

**Stock-Based Compensation**

The Company recognizes compensation costs under FASB ASC Topic 718, Compensation – Stock Compensation and ASU 2018-07. Companies are required to measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Share based compensation arrangements include stock options, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. As such, compensation cost is measured on the date of grant at their fair value. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant.

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**Recent Accounting Pronouncements**

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

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

**NOTE 2: RELATED PARTY TRANSACTIONS**

**Related Party Convertible Notes Payable**

The Company from time to time receives non-interest bearing 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 was in default of this note. As a result of the default, the interest rate charged was changed to 12.5% through conversion of this note in April 2020.

Interest expense for the years ended December 31, 2021 and 2020 on the related party convertible notes payable amounted to $0 and $298, respectively.

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**Related Party Notes Payable**

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

 SCHEDULE OF RELATED PARTY TRANSACTION

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

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

On March 27, 2019 the Company entered into a note payable with a trust related to one of our directors in the amount of $48,000. The note is for a one-year period maturing March 27, 2020 and bears interest at an annual rate of 8%. On April 29, 2019 the Company entered into a note payable with a trust related to one of our directors in the amount of $29,000. 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 years ended December 31, 2021 and 2020 was $18,079 and $18,960, respectively. In December 2021, the Company repaid $100,000 of these notes and converted the remaining balance of $137,000 plus accrued interest of $48,346 into 2,316,830 shares of common stock valued at $185,346. No balances remain as of December 31, 2021.

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

**Related Party Payables**

The Company periodically receives advances for operating funds from related parties or has related parties make payments on the Company’s behalf. As a result of these activities the Company had related party payables of $0 and $32,110 as of December 31, 2021 and 2020, respectively. In December 2021, the Company converted the $32,110 into 401,373 shares of common stock.

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

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

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

The Company’s Chief Executive Officer exercised 2,500,000 stock options for $60,000 in December 2020. In addition, in June 2021, the Company’s Chief Executive Officer exercised 2,500,000 stock options for a value of $60,000 that was paid through the cancelation of 375,000 common shares and 100,000 Series A Convertible Preferred shares. The Chief Executive Officer in May 2021 rescinded 8,120,152 stock options and in June 2021 rescinded 16,000,000 stock options. In September 2021, the Chief Executive Officer exercised 150,000 warrants in a cashless exercise into 91,304 shares of common stock.

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**NOTE 3: CONVERTIBLE NOTES PAYABLE**

As of December 31, 2021 and 2020, the Company had the following convertible notes outstanding. All prior notes that have been converted into common stock or repaid prior to December 31, 2020 have been excluded from the chart:

 SCHEDULE OF CONVERTIBLE NOTES PAYABLE

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | 2021 | |  |  | 2020 | |  |
| July and August 2012 $1,060,000 Notes convertible into common stock at $4.60 per share, 12% interest, due December 2013 and January 2014 |  | $ | - |  |  | $ | 45,000 |  |
| November 2020 $50,000 Note convertible into common shares at $0.04, 6% interest, due May 30, 2021 |  |  | - |  |  |  | 50,000 |  |
| Penalties on notes in default |  |  | - |  |  |  | 12,418 |  |
| Principal |  | $ | - |  |  | $ | 107,418 |  |

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

All of the remaining convertible notes were repaid in November 2021 along with the accrued interest.

Interest expense for the years ended December 31, 2021 and 2020 on the convertible notes payable amounted to $7,296 and $21,394, respectively.

As of December 31, 2021, there remains no outstanding balances in the convertible notes payable.

**NOTE 4: PROMISSORY NOTES PAYABLE**

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

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

The interest expense on these notes for the years ended December 31, 2021 and 2020 amounted to $0 and $8,032.

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

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**NOTE 5: STOCKHOLDERS’ DEFICIT**

**Common Stock**

The Company has 950,000,000 shares of common stock authorized, with a par value of $0.001, and as of December 31, 2021 and December 31, 2020, the Company has 343,530,678 and 292,278,591 shares issued and outstanding, respectively.

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

**Preferred Stock**

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

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

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

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

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

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

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

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

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

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

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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.

In June 2021, 100,000 shares of Series A Convertible Preferred were canceled as partial payment for the exercise of stock options by the Chief Executive Officer.

*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.

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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.

In December 2021, 236,290 Series B Convertible Preferred shares were converted into 2,953,625 shares of common stock.

*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*”.

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

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

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

Certain Price and Share Adjustments.

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

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

***Common and Preferred Stock Issuances - 2021***

In January 2021, the Company issued 384,445 shares of common stock in a settlement of accounts payable valued at $50,000. In May 2021, the Company issued 519,480 shares of common stock in a settlement of accounts payable valued at $40,000.

In January 2021, the Company issued 1,259,250 shares of common stock in conversion of a note payable and accrued interest totaling $50,370. The conversion resulted in a loss on conversion of $176,295 that is reflected in the Condensed Statement of Operations for the nine months ended September 30, 2021.

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

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

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On June 28, 2021, the Company issued 2,500,000 shares of common stock for the exercise of 2,500,000 stock options to the Chief Executive Officer. In this transaction, the Company canceled 375,000 shares of common stock as partial payment for the exercise of the stock options.

In June 2021, the Company issued 12,000,000 shares of common stock for vested RSUs with a fair value of $1,080,000.

From July 9 through September 24, 2021, the Company issued 838,195 shares of common stock in the cashless exercise of 1,800,000 warrants.

In October 2021, the Company issued 2,005,693 shares of common stock in the cashless exercise of 3,500,000 warrants.

In November 2021, the Company issued 77,768 shares of common stock for services valued at $3,756.

In December 2021, the Company issued 401,373 shares of common stock in conversion of accounts payable to a related party in the amount of $32,110; issued 2,316,830 shares of common stock in conversion of related party note payables and accrued interest valued at $185,346; and issued 2,953,625 shares of common stock in conversion of 236,290 Series B Convertible Preferred stock.

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

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

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

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

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

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

**Common Stock Options**

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

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

 SCHEDULE OF CHANGES IN STOCK OPTION

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | | | | | |  |  | Weighted | |  |  |  | |  |  | Weighted | |  |
|  |  | Options Outstanding | | | | | |  |  | Average | |  |  |  | |  |  | Average | |  |
|  |  | Number | |  |  | Exercise | |  |  | Remaining | |  |  | Aggregate | |  |  | Exercise | |  |
|  |  | Of | |  |  | Price | |  |  | Contractual | |  |  | Intrinsic | |  |  | Price | |  |
|  |  | Shares | |  |  | Per Share | |  |  | Life | |  |  | Value | |  |  | Per Share | |  |
| Balance at December 31, 2019 |  |  | 34,524,580 |  |  | $ | 0.024-120.00 |  |  |  | 6.49 years |  |  | $ | 277,973 |  |  | $ | 0.08 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Options granted |  |  | - |  |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ | - |  |
| Options exercised |  |  | (2,500,000 | ) |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ | - |  |
| Options expired |  |  | (3,139,119 | ) |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance at December 31, 2020 |  |  | 28,885,461 |  |  | $ | 0.024-120.00 |  |  |  | 5.57 years |  |  | $ | 1,661,429 |  |  | $ | 0.05 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Options granted |  |  | - |  |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ | - |  |
| Options exercised |  |  | (2,500,000 | ) |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ | - |  |
| Options expired/canceled |  |  | (24,132,652 | ) |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance at December 31, 2021 |  |  | 2,252,809 |  |  | $ | 0.024-0.04 |  |  |  | 7.70 years |  |  | $ | 83,992 |  |  | $ | 0.04 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Exercisable at December 31, 2021 |  |  | 2,252,809 |  |  | $ | 0.024-0.04 |  |  |  | 7.70 years |  |  | $ | 83,992 |  |  | $ | 0.04 |  |

During the year ended December 31, 2021, the Company’s CEO exercised 2,500,000 stock options, and rescinded 24,120,152, stock options. In addition, 12,500 options expired.

During the year ended December 31, 2021 and 2020, the Company recognized $0 and $2,176, respectively, worth of stock based compensation related to the vesting of it stock options.

**Common Stock Warrants**

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

 SCHEDULE OF CHANGES IN STOCK WARRANTS

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Warrants Outstanding | | | | | |  |  | Weighted | |  |  |  | |  |  | Weighted | |  |
|  |  | Number Of Shares | |  |  | Exercise Price Per Share | |  |  | Average Remaining Contractual Life | |  |  | Aggregate Intrinsic Value | |  |  | Average Exercise Price Per Share | |  |
| Balance at December 31, 2019 |  |  | 31,286,847 |  |  | $ | 0.08-80.00 |  |  |  | 0.97 years |  |  | $ | - |  |  | $ | 0.10 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Warrants granted |  |  | 31,870,000 |  |  | $ | 0.045 -0.06 |  |  |  | - |  |  |  |  |  |  | $ | - |  |
| Warrants exercised |  |  | (8,727,500 | ) |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ |  |  |
| Warrants expired/cancelled |  |  | (22,364,972 | ) |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance at December 31, 2020 |  |  | 32,064,375 |  |  | $ | 0.04-80.00 |  |  |  | 1.65 years |  |  | $ | 1,614,567 |  |  | $ | 0.06 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Warrants granted |  |  | 11,237,500 |  |  | $ | 0.10 |  |  |  | - |  |  |  |  |  |  | $ | - |  |
| Warrants exercised |  |  | (10,730,000 | ) |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ |  |  |
| Warrants expired/cancelled |  |  | (709,375 | ) |  | $ | - |  |  |  | - |  |  |  |  |  |  | $ |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Balance at December 31, 2021 |  |  | 31,862,500 |  |  | $ | 0.04-0.10 |  |  |  | 1.02 years |  |  | $ | 538,875 |  |  | $ | 0.07 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Exercisable at December 31, 2021 |  |  | 31,862,500 |  |  | $ | 0.04-0.10 |  |  |  | 1.02 years |  |  | $ | 538,875 |  |  | $ | 0.07 |  |

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

 SCHEDULE OF ASSUMPTIONS USED IN FAIR VALUE MEASUREMENT

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

The Company issued a convertible note in the amount of $100,000 to an accredited investor. The note bears interest at 8% per annum and matures June 30, 2020. The Company granted 1,250,000 warrants with an exercise price of $0.06 per share and a term of two years with this note and amended 1,312,500 previously issued warrants held by the investor to provide for a $.06 exercise price and an expiration date of March 31, 2022. This issuance resulted in a debt discount of $28,482.

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

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

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

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

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

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

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

From July 9 through September 24, 2021, the Company issued 838,195 shares of common stock in the cashless exercise of 1,800,000 warrants.

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In October 2021, the Company issued 2,005,693 shares of common stock in the cashless exercise of 3,500,000 warrants.

**Restricted Stock Units**

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

 SCHEDULE OF CHANGES IN RESTRICTED STOCK UNITS

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Number | |  |  | Weighted  Average | |  |
|  |  | Of | |  |  | Grant Date | |  |
|  |  | Shares | |  |  | Fair Value | |  |
|  |  |  | |  |  |  | |  |
| Balance at December 31, 2020 and 2019 |  |  | 262,500 |  |  | $ | 0.59 |  |
|  |  |  |  |  |  |  |  |  |
| RSU’s granted |  |  | 42,700,000 |  |  | $ | 0.08 |  |
| RSU’s vested |  |  | (17,700,000 | ) |  | $ | - |  |
| RSU’s forfeited |  |  | - |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |
| Balance at December 31, 2021 |  |  | 25,262,500 |  |  | $ | 0.08 |  |

During the year ended December 31, 2021 and 2020, the Company recognized $1,614,000 and $0 worth of expense related to the vesting of its RSU’s. As of December 31, 2021, the Company had $2,405,400 worth of expense yet to be recognized for RSU’s not yet vested.

On May 3, 2021, the Company has granted 12,000,000 RSUs to a consultant that vest on the grant date, and 700,000 RSUs to consultants that vest on the grant date. The Company has issued 12,000,000 common shares to the one consultant in June 2021.

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

**NOTE 7: COMMITMENT**

On June 4, 2019, the Company entered into an Executive Employment Agreement (“Employment Agreement”) with Dr. Michael K. Korenko, the Company’s Chief Executive Officer. The employment term under the Employment Agreement commenced with an effective date of June 11, 2019 and expires on December 31, 2020, and December 31 of each successive year if the Employment Agreement is extended, unless terminated earlier as set forth in the Employment Agreement. The Company on December 31, 2020 extended this agreement through December 31, 2021 while renegotiating terms of a new Employment Agreement. On May 3, 2021, the Company and the Chief Executive Officer agreed the terms of a new Employment Agreement with an effective date of January 1, 2021 that has a term of three years and expires December 31, 2023.

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

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**NOTE 8: INCOME TAXES**

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, 2021 and 2020:

 SCHEDULE OF NET DEFERRED TAX ASSETS

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | December 31, 2021 | |  |  | December 31, 2020 | |  |
| Deferred tax assets: |  |  |  |  |  |  |  |  |
| Net operating loss carryover |  | $ | 6,280,000 |  |  | $ | 6,080,000 |  |
| Interest expense |  |  | - |  |  |  | - |  |
| Related party accrual |  |  | - |  |  |  | 6,400 |  |
| Capital Loss Carryover |  |  | 3,400 |  |  |  | 3,400 |  |
| Deferred tax liabilities |  |  |  |  |  |  |  |  |
| Depreciation |  |  | (- | ) |  |  | (- | ) |
| Valuation allowance |  |  | (6,283,400 | ) |  |  | (6,089,800 | ) |
| 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, 2021 and 2020 due to the following:

 SCHEDULE OF FEDERAL INCOME TAX RATE

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | December 31, 2021 | |  |  | December 31, 2020 | |  |
| Book income (loss) |  | $ | (530,800 | ) |  | $ | (201,000 | ) |
| Forgiveness of debt |  |  | (28,700 | ) |  |  | (600 | ) |
| Depreciation |  |  | (1,100 | ) |  |  | (1,100 | ) |
| Interest expense |  |  | - |  |  |  | - |  |
| Related party accrual |  |  | (6,400 | ) |  |  | 4,000 |  |
| Stock for services |  |  | 339,700 |  |  |  | - |  |
| Options expense |  |  | - |  |  |  | 500 |  |
| Other non-deductible expenses |  |  | 25,700 |  |  |  | 5,900 |  |
| Valuation allowance |  |  | 201,600 |  |  |  | 192,300 |  |
| Income tax expense |  | $ | - |  |  | $ | - |  |

At December 31, 2021, the Company had net operating loss carryforwards of approximately $29,919,800.

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, 2021, 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 2017.

**NOTE 9: SUBSEQUENT EVENTS**

The Company in January 2022 settled $60,961 of accounts payable and recognized forgiveness of debt of $43,961 on these settlements.

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