

United States
Securities and Exchange Commission
Washington, D.C. 20549

FORM 10-K

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

For the year ended: December 31, 2021

or

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

For the period ended:

QSAM Biosciences, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-55148
(Commission
File Number)

20-1602779
(I.R.S. Employer
Identification No.)

9442 Capital of Texas Hwy N, Plaza 1, Suite 500
Austin, TX 78759
(Address of Principal Executive Offices)

(512) 343-4558
(Registrant's Telephone Number, including area code)

(Former name or former address, if changed since last report.)

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock, par value \$0.0001

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 Exchange 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 Exchange Act 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company or emerging growth company:

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging Growth Company	<input type="checkbox"/>		

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates computed by reference to the average bid and asked price of such common stock on OTCQB of \$0.35, as of the last business day of the Registrant's most recently completed second fiscal quarter, was approximately \$5.6 million.

As of February 21, 2022, there were issued and outstanding 66,484,085 shares of the registrant's common stock.

Documents incorporated by reference: None.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This document contains certain forward-looking statements that are subject to various risks and uncertainties. Forward-looking statements are generally identifiable by use of forward-looking terminology such as “may,” “will,” “should,” “potential,” “intend,” “expect,” “outlook,” “seek,” “anticipate,” “estimate,” “approximately,” “believe,” “could,” “project,” “predict,” or other similar words or expressions. Forward-looking statements are based on certain assumptions, discuss future expectations, describe future plans and strategies, contain financial and operating projections or state other forward-looking information. Our ability to predict results or the actual effect of future events, actions, plans or strategies is inherently uncertain. Although we believe that the expectations reflected in our forward-looking statements are based on reasonable assumptions, our actual results and performance could differ materially from those set forth or anticipated in our forward-looking statements. Factors that could have a material adverse effect on our forward- looking statements and upon our business, results of operations, financial condition, funds derived from operations, cash available for dividends, cash flows, liquidity and prospects include, but are not limited to, the factors referenced in this document, including those set forth below:

- our lack of an operating history;
- the net losses that we expect to incur as we develop our business;
- obtaining FDA or other regulatory approvals or clearances for our technology;
- implementing and achieving successful outcomes for clinical trials of our products;
- convincing physicians, hospitals and patients of the benefits of our technology and to convert from current technology;
- the ability of users of our products (when and as developed) to obtain third-party reimbursement;
- any failure to comply with rigorous FDA and other government regulations; and
- securing, maintaining and defending patent or other intellectual property protections for our technology.

When considering forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this document. Readers are cautioned not to place undue reliance on any of these forward-looking statements, which reflect our views as of the date of this document. The matters summarized below and elsewhere in this document could cause our actual results and performance to differ materially from those set forth or anticipated in forward-looking statements. Accordingly, we cannot guarantee future results or performance. Furthermore, except as required by law, we are under no duty to, and we do not intend to, update any of our forward-looking statements after the date of this document, whether as a result of new information, future events or otherwise.

MARKET DATA

Certain market and industry data included in this document is derived from information provided by third-party market research firms, or third-party financial or analytics firms that we believe to be reliable. Market estimates are calculated by using independent industry publications, government publications and third-party forecasts in conjunction with our assumptions about our markets. We have not independently verified such third-party information. The market data used in this document involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. While we are not aware of any misstatements regarding any market, industry or similar data presented herein, such data involves risks and uncertainties and are subject to change based on various factors, including those discussed below and set forth in the “Risk Factors” section of this document. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. Certain data are also based on our good faith estimates, which are derived from management’s knowledge of the industry and independent sources. Industry publications, surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but there can be no assurance as to the accuracy or completeness of included information. We have not independently verified any of the data from third-party sources nor have we ascertained the underlying economic assumptions relied upon therein. Statements as to our market position are based on market data currently available to us. While we are not aware of any misstatements regarding the industry data presented herein, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading “Risk Factors” in this document. Similarly, we believe our internal research is reliable, even though such research has not been verified by any independent sources.

PART I

ITEM 1. BUSINESS

In this Annual Report, references to the “Company,” “we,” “our,” “us” and words of similar import refer to QSAM Biosciences, Inc., the Registrant, a Delaware corporation. References to “QSAM” or the “Subsidiary” refer to QSAM Therapeutics Inc., a Texas corporation, our wholly-owned subsidiary and operating company.

Overview

We are developing next-generation nuclear medicines for the treatment of cancer and related diseases. Our initial technology is Samarium-153 DOTMP, a/k/a CycloSam[®] (“CycloSam[®]” or the “New Technology”), a clinical-stage bone targeting radiopharmaceutical. CycloSam[®] features a patented, low specific activity form of Samarium-153, a beta-emitting radioisotope with a short 46-hour half-life, and the chelating agent DOTMP, which selectively targets sites of high bone mineral turnover and reduces off-site migration of the tumor-killing radiation. We believe improvements in formulation and manufacturing from a prior FDA-approved drug utilizing the same radioisotope (Quadramet[®]) has resulted in our drug candidate demonstrating significantly less impurities, lower costs and more frequent availability. Samarium-153 and DOTMP form a highly stable complex, which we believe, when used either as a monotherapy or in combination with other more widely used treatments such as external beam radiation, may demonstrate meaningful disease modifying results in primary and metastatic bone cancer. Ultimately, we may seek to further develop and commercialize CycloSam[®] for one or more market indications or license the technology to a larger pharmaceutical partner.

In August 2021, the Food & Drug Administration (FDA) cleared our Investigational New Drug (IND) application to commence Phase 1 clinical trials for CycloSam[®] as a treatment for cancer that has metastasized to the bone from the lung, breast, prostate and other areas. We initiated this trial at our first site (Houston, TX) in November 2021 and we seek to commence dosing patients in this open-label, dose escalating study in the first quarter of 2022. Also in August 2021, the FDA granted Orphan Drug Designation for the use of CycloSam[®] to treat a primary bone cancer called osteosarcoma, a devastating disease that mostly affects children and young adults. Although patients with osteosarcoma or Ewing’s sarcoma are eligible to participate in our initial Phase 1 trials, we anticipate filing an amended protocol to our current commercial IND application in 2022 to commence clinical trials specifically for these primary, pediatric bone cancers. In May 2020, CycloSam[®] was also utilized in a Single Patient Investigational New Drug for Emergency Use at the Cleveland Clinic. We believe the study we conducted at the Cleveland Clinic showed promising safety results in connection with a bone marrow ablation procedure, including patient tolerability at high dosages. To date, CycloSam[®] has completed animal studies in both small and large animals, including treating bone cancer in patient dogs at a university veterinary clinic.

Current Development Stage of CycloSam[®] for Target Indications. Our initial IND to commence Phase 1 clinical trials for CycloSam[®] as a treatment for cancer that has metastasized to the bone from the lung, breast, prostate and other areas has been cleared by the FDA, and we seek to commence dosing patients in the first quarter of 2022. Patients with primary bone cancer, such as osteosarcoma or Ewing’s sarcoma, are eligible to participate in our initial Phase 1 trials; however, we anticipate filing an amended protocol to our current commercial IND application in 2022 to commence an additional clinical trial specifically for these primary, pediatric bone cancers. Our initial Phase 1 trial is an open label, dose escalating study of approximately 20 patients. Enrollment commenced in February 2022 and the Phase 1 trials are expected to continue over the following 12 to 24 months.

What is CycloSam[®]. CycloSam[®] is a targeted, bone seeking radiopharmaceutical that combines the beta-emitting radioisotope Samarium-153 (¹⁵³Sm) with a chelating agent, DOTMP (1, 4, 7, 10-tetraazacyclododecane-1, 4, 7, 10-tetramethylenephosphonic acid). Samarium-153 is acquired from a nuclear reactor from a third party and the chelating agent is supplied in the form of kits. Chelating agents are organic compounds capable of linking together metal ions to form complex ring-like structures. This combination forms a stable complex which delivers a radioactive dose to sites of rapid bone mineral turnover such as bone cancers and tumors. CycloSam[®] has a physical half-life of 46 hours (radiation decreases by half in 46 hours) and emits both medium-energy beta particles that produce the therapeutic effect, and gamma photons that make it possible to take images of the skeleton and locate and characterize the size and nature of tumors. The use of radioisotopes to both diagnose and treat disease is called “theranostics” and is a rapidly growing area of medical discovery.

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How CycloSam[®] Works – Mechanism of Action & Administration. CycloSam[®] utilizes a chelating agent called DOTMP that seeks out bone locations of high mineral turnover, typical in cancer cells and tumor growth. The DOTMP part of the molecule is taken up by calcium turnover locations in bones and carries the radioactive “payload” along with it. The radioisotope Samarium-153 emits radiation as it decomposes in the form of beta particles. Approximately 50% of the radioactivity concentrates in bone mineral with a very high lesion-to-normal bone ratio. We believe this provides a radiation dose to the adjacent tumor cells. The absorbed radiation dose produces the presumed therapeutic effect to the tumor, killing the cancer cells or slowing their growth by damaging their DNA. Our pre-clinical studies and single patient IND performed at the Cleveland Clinic has demonstrated that the remaining half of the administered activity is rapidly excreted through the kidneys.

Generally, radiation therapy does not immediately kill cancer cells and more than one treatment is expected to eradicate a tumor, dramatically reduce its size, or slow its growth. CycloSam[®] has a short half-life of 46 hours and is rapidly eliminated from the body. This avoids an undesirable radioactive buildup in healthy tissues and organs when used in multiple treatments, which we believe, is an important feature of CycloSam[®] over predecessor drugs. CycloSam[®] has also not demonstrated saturation of the bone sites in animal studies, which supports a multi-dosage treatment regimen. Additionally, we believe that high dosages may be administered for ablating the marrow in patients that may require procedures such as stem cell transplants.

The final drug product of CycloSam[®] is prepared from DOTMP kits and ¹⁵³SmCl in 0.1 N HCl at a nuclear pharmacy local to the patient administration site. The final drug product is then delivered to the physician for use as an intravenous (IV) injection within 72 hours.

How is CycloSam[®] Made – Method of Manufacturing. CycloSam[®] uses a patented, low-specific-activity Samarium-153 which is produced in the lower flux region (beryllium reflector) of the nuclear reactor and can be accessed with a pneumatic tube on a daily basis. Once prescribed by radiation oncologists and nuclear medicine physicians, we order the radioisotopes from Missouri University Research Reactor (MURR) to be sent overnight to an onsite or nearby (to the patient) nuclear pharmacy to be compounded with a DOTMP “cold kit” and delivered to the treating physician for administration. While CycloSam[®] is still in clinical development, we believe that we have already established an efficient and cost-effective manufacturing process and supply chain, allowing the clinician to treat the patient within approximately three days from order.

The DOTMP “cold kit” is patent pending, and developed by IsoTherapeutics LLC, the inventors of CycloSam[®]. Although we believe the IsoTherapeutics cGMP manufacturing facility has the capacity to manufacture sufficient supply for our initial rollout, we are concurrently securing secondary manufacturing partners for the kits. MURR has been our source of Samarium-153 used in both our animal studies and the Single Patient IND for Emergency Use at the Cleveland Clinic, and MURR has verbally committed to supply us Samarium-153 in the future. Although we expect MURR to be our primary supplier of Samarium-153 in the U.S. subject to definitive agreements, and we believe they have the capability to produce our requirements of Samarium-153 on a commercial scale for U.S. distribution, we plan to qualify additional suppliers in 2022 as part of our supply chain and general business risk diversification strategy.

What are CycloSam[®]’s anticipated competitive advantages. We believe CycloSam[®] has competitive advantages over current radiopharmaceutical offerings in the marketplace. Such potential competitive advantages include:

- CycloSam®’s radioisotope, Samarium-153, emits beta particles that travel farther than alpha particles with what we believe is sufficient energy to slow the growth or decrease the size of target cancer cells. We believe beta particles penetrate bone matter deeper than the alpha emitting radiopharmaceuticals currently in the marketplace and may be more effective in treating tumors that form in or metastasize to bones.
- CycloSam®’s delivery agent, DOTMP, compared to other chelating agents such as EDTMP used in Quadramet®, has shown in animal and other pre-clinical testing to have a high bone binding affinity allowing for the maximum delivery of the radioactive “payload” adjacent to the tumor without saturation of the bone, as observed from our pre-clinical trials.
- Our method of manufacturing Samarium-153 compared to Quadramet®, has shown in our pharmacopeial limits studies to produce a 30-fold reduction in levels of the long-lived radioactive impurity Europium-154. We believe this may mitigate toxicity issues with the patient.
- Our initial studies show CycloSam® has fewer toxicities and a short 46 hour half-life that may allow for more frequent and repeated dosing of our radiopharmaceutical. We believe this may have a greater ability to slow or reverse tumor growth.
- We believe we have in place an efficient and cost-effective manufacturing process and established distribution system that may in the future allow for 24/7 availability and enable the clinician to order and have the treatment delivered to the patient within approximately 72 hours.

The competitive advantages we believe to be important to CycloSam® are based on pre-clinical animal and other studies including our single patient IND at the Cleveland Clinic. We cannot be sure that our technology will perform similarly in clinical trials with multiple human patients. Failure to achieve these competitive advantages could negatively affect our ability to achieve FDA approval as a new drug, or our ability to market CycloSam® as a treatment for bone cancer.

Intellectual Property

Pursuant to the License Agreement, our IP estate includes 14 total patents issued and pending across three distinct patent families that we believe provide protection for the use of CycloSam® as a radiopharmaceutical in the U.S. and internationally. Under the License Agreement, the Company holds two issued patents in the US, two issued patents in Japan, one issued patent in Canada, one allowed patent in Europe, and seven pending patents in international jurisdictions. Notably, the CycloSam® kit that will be commercialized is protected by the extensive patent estate that broadly protects DOTMP kit formulations for radioisotopes, potentially allowing for efficient distribution of the product and widespread use. Additionally, the patents cover the use of low-specific activity Samarium-153 allowing for daily supply of the highly toxicity-reduced isotope, and methods relating to repeat dosing regimens for therapeutic radiopharmaceutical agents, which suggest increased efficacy based on prior research. Taken together, management believes that the patent family provides for a significant barrier to entry for a competitor as it is expected to prevent a generic product from being developed; however, we cannot guarantee that a competitor will not or cannot challenge our patents or otherwise circumvent our patents, or that we would have the resources to defend any patent infringement.

A list of our patents and status of prosecution is included in the following table:

	Country/ Region	Status	App No	Filing Date	Pub No	Pub Date	Patent No	Issue Date	Expiration Date
“High purity therapeutic bone agents”									
ITG-16 CA	Canada	Granted	2,926,652	6-Apr-2016	CA 2926652	Apr-2015	2,926,652	Jul-2021	Oct-2034
ITG-16 EP	Europe	Allowed*	14852866.4	5-May-2016	EP3054996	Aug-2016			
ITG-16 JP	Japan	Granted	2016-521278	7-Apr-2016	2016-532652	Oct-2016	6787781	Nov-2020	Oct-2034
ITG-16 JP 1	Japan	Pending	2019-061398	27-Mar-2019					
ITG-16 US	United States	Granted	15/027,280	5-Apr-2016	US2016/0250359	Sep-2016	10,172,965	Jan-2019	Nov-2034
ITG-16 US 1	United States	Granted	16/194,324	17-Nov-2018	US2019/0083661	Mar-2019	110,596,277	Mar-2020	Nov-2034
“DOTMP kit formulations for radioisotopes”									
ITG-17 CA	Canada	Pending	2987242	23-Nov-2017					
ITG-17 EP	Europe	Granted	16800631	20-Nov-2017	EP3302496	Apr-2018	3302496	Jan-2021	May-2036
ITG-17 JP	Japan	Granted	2017-561326	24-Nov-2017	2018-515585	Jun-2018			May-2036
ITG-17 US 1	United States	Pending			US2020/0261607				
			16/866,001	04-May-2020	A1	Aug-2020			
“Method of use for therapeutic bone agents”									
ITG-18 CA	Canada	Pending	05782981	7-Aug-2019					
ITG-18 EP	Europe	Pending	18751017.7	22-Aug-2019					
ITG-18 JP	Japan	Pending	2019-563340	7-Aug-2019	2020-506239	Feb-2020			
ITG-18 US	United States	Pending			US 2021-0138095 A1				
			16/484,706	8-Aug-2019		May-2021			

Pursuant to the License Agreement, the Company also has the right to use the registered trademark “CycloSam®” for the marketing and sale of the drug candidate.

Competition

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, a strong emphasis on intellectual property and intense competition. We face substantial potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions.

In addition to the current methods of care for cancer patients, the field of radiopharmaceuticals is deeply studied and many parties are pursuing commercial and academic clinical trials. Early results from these trials have fueled continued interest in radiopharmaceuticals, which are pursued by several biotechnology companies as well as by large pharmaceutical companies.

We consider our direct competitors to be companies developing targeted alpha radiopharmaceuticals for the treatment of cancer. There are several companies developing targeted alpha-based radiopharmaceuticals for the treatment of cancer, including Bayer AG, or Bayer, Novartis AG, or Novartis, Actinium Pharmaceuticals, Inc., RadioMedix, Inc, Orano Med, Telix Pharmaceuticals Limited, and Fusion Pharmaceuticals Inc., as well as several early-stage companies who recently entered the field such as RayzeBio, Inc. These companies are targeting a wide range of solid and hematologic malignancies using various alpha emitting isotopes, including Radium-223, Actinium-225 and Thorium-227. The first and only approved alpha particle-based therapy is Bayer’s Xofigo, a salt of radium that is not currently attached to a targeting molecule, but naturally localizes to regions where cancer cells are infiltrating bone. Xofigo was approved in the United States by the FDA in 2013 for the treatment of bone metastases associated with prostate cancer.

There are several companies with approved or late clinical stage beta-based radiopharmaceuticals, including Progenics Pharmaceuticals, Inc., Novartis, Bayer and Q BioMed Inc., which we also consider competitors. Another competitive company, POINT Biopharma Global Inc., has two indications using beta-emitting particles in Phase 3 trials. The beta emitting isotopes used by these companies include Iodine-131, Lutetium-177, Strontium-89 and Yttrium-90. There are other beta particle-based radiopharmaceuticals in various stages of clinical development by companies including Novartis AG, Ipsen S.A., Y-mAbs Therapeutics, Inc. and Clovis Oncology, Inc.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies and materials complementary to, or necessary for, our programs.

We could see a reduction or elimination in our commercial opportunity if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive or with a more favorable label than our product candidates. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of imaging diagnostics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Radiopharmaceutical Market

The radiopharmaceutical market is projected to reach \$13.8 Billion by 2028 from \$7.6 Billion in 2021, according to a published study by The Insight Partners: “Radiopharmaceuticals Market to 2028 – Global Analysis and Forecast.” Overall, the market is expected to grow at a CAGR of 9.0% during 2021–2028. North America dominates the global radiopharmaceuticals market, which is attributed to the prevalence of chronic disorders and the presence of supportive government plans for the development of research regarding radiopharmaceuticals. Based on type, the radiopharmaceuticals market is bifurcated into diagnostic nuclear medicine and therapeutic nuclear medicine. The diagnostic nuclear medicine segment is holding a larger share of the market and is anticipated to register a higher CAGR during 2021–2028. By application, the market is segmented into oncology, cardiology, neurology, and others, with the oncology segment holding the largest market share in 2021.

Overall, we believe that the recent technological developments in radiopharmaceuticals, including promising new alpha-emitting candidates, will continue to provide supportive tailwinds to this sector. As a result, management believes that it is well positioned to capitalize on these future opportunities.

History of CycloSam® development and past studies and trials

The Company has an exclusive worldwide patent and technology License Agreement for CycloSam®. The New Technology was developed at IsoTherapeutics Group, LLC (“IsoTherapeutics”) by its founders Jim Simone, PhD and R. Keith Frank, PhD (the “Inventors”). The Inventors also developed one of the first commercial radiopharmaceuticals on the market, Quadramet®, approved by the FDA in 1997 for pain palliation. Drs. Simone and Frank each have over 30 years of experience in radiopharmaceuticals publishing more than 100 papers and authoring over 60 patents in the field. The Inventors spent much of their careers at Dow Chemical Company prior to divestiture of its radiopharmaceutical business. According to the Inventors, CycloSam® was developed to address the shortcomings of other radiopharmaceuticals, including Quadramet, such as toxicity, saturation effects, long-lived impurities, and supply-chain complexities.

Prior generation Quadramet vs Improvements in CycloSam®. CycloSam® is a second-generation bone-seeking radiopharmaceutical based on Quadramet. Although Quadramet was clinically proven to be effective for pain palliation associated with metastatic bone cancer, the toxicity of the drug made repeat doses undesirable. Therefore, Quadramet’s use has been limited to pain control, not tumor reduction, elimination or disease modification. The loose binding affinity of Quadramet’s chelating agent, EDTMP, means the ratio of chelant to Samarium-153 is extremely high (~300:1). This resulting problem of bone saturation prohibits usage of Quadramet in high doses required for treatment of bone cancer or bone marrow ablation. Additionally, high levels of impurities from the Samarium-153 production, namely Europium-154, made repeated dosing of Quadramet undesirable. Lastly, Quadramet faced supply-chain and distribution limitations because the Samarium-153 it uses could only be accessed from the reactor once per week. We believe that because of these challenges, Quadramet demonstrated limited market success, and to our knowledge, was recently discontinued by its manufacturer and distributor. We believe CycloSam® overcomes these inherent limitations of Quadramet in terms of toxicity, usage, and availability.

The Vienna Protocol – Precedent of Efficacy. In August 2011, Dr. Helmut Sinzinger published a study in the Quarterly Journal of Nuclear Medicine and Molecular Imaging, which demonstrated that despite the described limitations of Samarium-153 EDTMP (Quadramet®), it could still be used to effectively treat bone metastasis.

The Vienna Protocol, as it was labeled, was based on a 550 patient study developed by Dr. Sinzinger to deliver therapeutic doses of Quadramet® on a periodic low dose basis balancing hematological toxicity and europium buildup with clinical results. The specific regimen used very low doses of the predecessor drug (30 mCi) on an outpatient basis. The treatment was administered at three month intervals during the first year, followed by another five treatments at six month intervals, then five therapies at nine month intervals, and then annually indefinitely. The dosing schedule was driven by hematological concerns and constant monitoring was required.

During Dr. Sinzinger’s trials, a wide range of positive clinical responses were seen including arrested tumor growth and even regression of the cancer in the bone. Some patients were treated for over five years exhibiting significant clinical response. While effective, this regimen required significant time on the part of both the physician and patient both of which were considered overly burdensome. Although this study was well published and the efficacy results were promising, wide clinical adoption did not occur due to the overall effort that was required to deliver a true therapeutic dose while avoiding the toxicity issues. Quadramet was never approved by the FDA for the treatment of bone cancer, but rather, just for pain management associated with the disease.

Improvements of CycloSam® over Predecessor Drug

CycloSam® is a new, advanced generation Samarium-153 drug with a dramatically different clinical profile than Quadramet®. By producing the Samarium-153 in a different part of the nuclear reactor, the decay by-product Europium has shown in studies to be nearly non-existent, thus eliminating long-term buildup concerns [Source: IsoTherapeutics Group. (2021). Preparation and Stability of CycloSam® Sm-153-DOTMP. (Report No. QSM-1)]. Secondly, the superior binding affinity of the new chelating agent, DOTMP, means more energy can be delivered to the target, thus minimizing off-target concerns. Further, the method of harvesting the patented low specific activity Samarium-153 means it can be accessed on a daily basis, compared to weekly for Quadramet®, at a reduced cost. We believe that all of these clinical and manufacturing improvements were achieved without any reduction in either the tumor killing power of Samarium-153 or its ability to travel deep into the bone tumor.

Potential Market Indications for CycloSam®.

CycloSam’s therapeutic profile and presumed advantages over other radiopharmaceuticals, including Quadramet, translate to several potential key market indications

as detailed in the following table:

Market	Estimated New Cases Diagnosed Annually (US)
Bone Metastases (Breast, Prostate, Lung)	400,000
Other Primary Bone Cancers	2,400
Primary Bone Cancer – Osteosarcoma	1,000
Bone Marrow Ablation	15,000
Primary Bone Cancer – Ewing’s Sarcoma	200

Source: American Cancer Society estimates of new cases reported each year in the United States. Data as of July 2020.

Bone metastases arise in about 5% of all types of cancer, 29% of patients with multiple myeloma (15,000), 16% of lung (37,000), 6% of prostate (48,000) and 7% of breast cancers (70,000). Roughly 70% of patients with bone metastases will experience bone pain, and many are at risk for skeletal-related events including fracture and spinal cord compression. The total annual cost for treatment of metastatic bone disease is approximately \$12.7 billion or 17% of the total of \$74 billion that was spent on direct medical costs of these cancers [Source: Schulman KL, Kohles J. Economic burden of metastatic bone disease in the U.S. *Cancer*. 2007 Jun 1;109(11):2334-42. doi: 10.1002/cncr.22678. PMID: 17450591]. In addition to metastatic bone cancers, according to the National Institute of Health SEER, there are approximately 14,000 people living with osteosarcoma in the US at any one time [Source: Damron TA, Ward WG, Stewart A. Osteosarcoma, chondrosarcoma, and Ewing’s sarcoma: National Cancer Data Base Report. *Clin Orthop Relat Res*. 2007 Jun;459:40-7. doi: 10.1097/BLO.0b013e318059b8c9. PMID: 17414166, and National Cancer Institute: Surveillance, E., and End Results Program Cancer Stat Facts: Bone and Joint Cancer, <<https://seer.cancer.gov/statfacts/html/bones.html>> (2020)] and their cost of care is estimated to exceed \$100,000 per patient [Source: American Cancer Society. *Key Statistics About Bone Cancer*].

Metastatic bone cancer is currently incurable, and therefore palliation and arrest or deceleration of the progress of disease are important near-term goals. Quadramet® (Samarium-153-EDTP) and Metastron™ (89Sr chloride) were approved by the FDA for pain palliation resulting from osteoblastic bone metastases, but their widespread acceptance and use is hampered by concern about the perceived risk of myelosuppression when administered concurrently with chemotherapy. Xofigo, an alpha particle emitter, was approved in May 2013 and initially was expected to capture significant market share rapidly; however, the product has only recently proven market success after many additional clinical trials.

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Osteosarcoma is the most common childhood and adolescent/young adult (ages 15-39) primary high-grade bone malignancy [Source: Taran SJ, Taran R, Malipatil NB. Pediatric Osteosarcoma: An Updated Review. *Indian J Med Paediatr Oncol*. 2017;38(1):33-43. doi:10.4103/0971-5851.203513]. Patients can often have metastatic cancer at diagnosis, and metastasis to the lungs is often fatal for these patients. For patients who develop or present with metastatic cancer in this diagnosis, the 5-year survival rate is 66% [Source: Osteosarcoma - Childhood and Adolescence - Statistics.” *Cancer.Net*, 30 Sept. 2021, <https://www.cancer.net/cancer-types/osteosarcoma-childhood-and-adolescence/statistics>]. Osteosarcoma standard-of-care usually involves chemotherapy which has substantial negative side effects, or drastic surgeries such as limb salvage or amputation. Osteosarcoma is relatively resistant to External Beam Radiation Therapy (EBRT), and currently approved radiopharmaceutical therapeutics fall short due to myelotoxicity and long-lived radioactive impurities. There is a tremendous unmet need for a better treatment that is more efficacious against pediatric osteosarcoma and better tolerated by patients.

Preclinical and Clinical Studies

Preclinical Studies. Preclinical toxicology studies of CycloSam® in rats and dogs have shown that a single intravenous dose of non-radioactive Samarium-153 DOTMP elicited no significant systemic toxicity. Skeletal uptake has also been studied in rats over a wide range of doses to determine whether CycloSam® displays a similar saturation effect which has been observed in studies of Samarium-153 EDTMP (aka Quadramet). In the rat saturation study, no statistically significant difference was found in uptake as a function of increased dosage of CycloSam®.

In addition to rat and dog toxicological studies, a proof-of-concept study was conducted in ten dogs with spontaneously occurring bone cancer treated with 1-2 mCi/kg of CycloSam®. Treatment was well tolerated with seven dogs treated at a dose of 1 mCi/kg and one dog treated with 2 mCi/kg who did not experience a dose limiting toxicity. One dog treated with 2 mCi/kg and one dog treated with 2.3 mCi/kg experienced grade 4 asymptomatic thrombocytopenia and neutropenia; which refers to a manageable depressed level of platelets and neutrophils in the blood. Results from these preclinical studies suggested CycloSam® has potential as a therapeutic agent in the treatment of primary bone cancer and metastatic bone disease.

Safety/Tox Studies. Non-radioactive CycloSam® has been through a full-scale 14-day, acute toxicological study in both rats and dogs. This study was designed to determine the toxicokinetics of the product at four different dose levels that are higher than expected to be used in the current clinical trials. The studies showed no systemic toxicity in either of the species with a single intravenous administration of CycloSam® (non-radioactive). Some mild to moderate allergic-like responses were seen in dogs at the highest dose, which is much higher than would be expected for clinical use.

Non-clinical testing. Rat and rabbit pharmacology and targeted bone pharmacology studies have been undertaken and published in both patents and in the literature for Samarium-153-DOTMP and their preclinical results demonstrated significant skeletal uptake fractions. We believe these studies suggest CycloSam® has promise as a bone seeking radiopharmaceutical.

Clinical Pharmacology. The majority of non-clinical pharmacology studies with CycloSam® have been done in rats. When administered through the tail vein, much of the Samarium-153-DOTMP binds to the bone; the half-life is 46.3 hours, but the portion of the drug not bound to bone or calcified tissue is completely eliminated through the kidneys within 6 hours of administration. Two additional studies in dogs with osteosarcoma have also elicited promising results, and confirm bone uptake, preliminary safety, and preliminary clinical benefit against bone tumor. Preclinical results demonstrated significant skeletal uptake fractions.

Clinical Studies. CycloSam® was recently studied for the first time in humans under a Single Patient Investigational New Drug (IND) for Emergency Use at the Cleveland Clinic. The patient, a 25 year-old male who suffered from myelodysplastic syndrome (MDS) and high-risk osteosarcoma, received a single low dose of 1 mCi/kg of CycloSam® on March 24, 2020 for dosimetry. This was followed seven days later on March 31, 2020 by a single high dose of 32 mCi/kg (1919 mCi) of CycloSam®. No injection site effects were noted at the time of injection. At 48 hours post-injection of the second dose there was no renal toxicity observed. The estimated dose delivered to the skeleton was 40 Gy with bone lesion uptake of 60 Gy. The abbreviation Gy stands for “gray”, which is a measurement of radiation reaching the target. In this instance, a 45 Gy is considered required to deliver the radiation to the target, and therefore, 60 Gy was considered very good. The patient received an allogeneic stem cell transfusion two weeks following high dose injection of Samarium-153 DOTMP; however, the stem cell transplant failed to fully engraft. The patient, who was terminally ill prior to the treatment, passed away on August 18, 2020, a month after bone marrow ablation and after additional procedures not using a radiopharmaceutical were performed, from complications of an infection unrelated to the infusion of CycloSam® according to the investigator.

The investigator concluded that high-dose CycloSam[®] can be given safely with no apparent renal toxicity and no unexpected adverse events attributable to Samarium-153 DOTMP. Skeletal targeting with sparing of other tissues was observed after the high dose. This was only a single patient human clinical trial, and the patient did not survive long enough for full observation, so additional safety and efficacy clinical trial data will have to be developed.

License Agreement, Collaborations and Partnerships

Collaborations, partnerships and similar agreements, including license agreements, are a key component of the Company's corporate strategy. As a clinical stage biotechnology company without revenue, partnerships are an essential part of our future development.

License Agreement. The Company, through its wholly-owned subsidiary QSAM Therapeutics, entered into an exclusive worldwide patent and technology License Agreement with IGL Pharma, Inc. ("IGL") on April 20, 2020 with respect to the innovative work of Jim Simone, PhD and R. Keith Frank, PhD, at IsoTherapeutics on Samarium-153 DOTMP. IGL is an affiliated company with IsoTherapeutics, and the President of IGL, Richard Piazza, also serves as our Executive Chairman. We amended the License Agreement on November 24, 2021.

Our License Agreement, as amended, with IGL is for 20 years or until the expiration of the multiple patents covered under the license and requires multiple milestone-based payments including: up to \$410,000 as CycloSam[®] advances through Phase 3 of clinical trials, and \$2 million upon commercialization. IGL has also received 500,000 shares of the Company as additional compensation. Upon commercialization, IGL will receive an on-going royalty equal to 4.5% of Net Sales, as defined in the License Agreement, and 5% of any consideration we receive pursuant to a sublicense, sale of the asset, or sale of QSAM Therapeutics. We will also pay for ongoing patent filing and maintenance fees, and we have certain requirements to defend the patents against infringement claims. The parties have agreed to mutual indemnification.

Either party may terminate the License Agreement 30 days after notice in the event of an uncured breach, or immediately in the case of bankruptcy or insolvency of the other party. QSAM Therapeutics may terminate for any reason upon 30 days' notice. In the case IGL terminates due to an uncured breach, IGL will repay to us 25% of our direct clinical costs to assume ownership of data and other information gained in that process.

In connection with the License Agreement, QSAM Therapeutics signed a two-year Consulting and Confidentiality Agreement (the "Consulting Agreement") with IGL, which provides IGL with payments of \$8,500 per month continuing through April 2022. The Consulting Agreement is to provide us with additional consulting and advisory services from the technology's founders to assist in the clinical development of CycloSam[®]. Our Executive Chairman serves as President of IGL, receives a \$500 per month fee, and holds options to acquire less than 1% equity stake in IGL.

Contracted Research Organization. In January 2020, our licensor, IGL Pharma, entered into a Master Services Agreement (MSA) with a full-service Contract Research Organization (CRO) with over a 30 year history of service to pharmaceutical and biotechnology clients. The MSA was amended in February 2021 to add QSAM as a party and includes a fixed monthly retainer for regulatory and clinical trial consulting services as well as specific work orders for clinical trial execution services. The CRO has a full-time staff of project managers, statisticians, physicians, nurses and other regulatory and operational personnel to support our FDA interactions, filings and preclinical and clinical trial activities. Specifically, the CRO provides clinical trial management services, clinical study monitoring services, medical coding services, electronic data capture services, data management services, medical monitoring services, safety reporting and medical writing services.

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Legacy Business and Separation Agreement

Until November 2020, our primary business was acquiring and managing companies in the soil health sector (the "Legacy Business"), through an affiliated company, Earth Property Holdings LLC ("EPH"). In January 2020, our board of directors authorized a strategic plan comprised of: (1) securing new technologies and business opportunities in the broader biosciences sector, and (2) significantly reducing debt and liabilities of the Company, both of which have been accomplished. The first action under this plan included appointing Douglas R. Baum to our board of directors. Mr. Baum has over 28 years of experience in the bioscience and biotech industries, including development, commercialization and marketing of multiple drugs and medical devices. After his appointment to our board, Mr. Baum secured for the Company an Exclusive Dealing Option Agreement to provide us a 90-day period to negotiate with IGL Pharma Inc. ("IGL") for a license to CycloSam[®]. IGL is an affiliated entity of IsoTherapeutics Group LLC, whose founders created Quadramet[®] (Samarium-153-EDTMP) while working at Dow Chemical Company, one of the first effective commercial radiopharmaceuticals.

On April 20, 2020, we exercised our option and executed a Patent and Technology License Agreement and Trademark Assignment with IGL, through a newly created, wholly-owned subsidiary called QSAM Therapeutics Inc. ("QSAM Therapeutics"). The License Agreement, which was amended on November 24, 2021, provides us with exclusive, worldwide and sub-licensable rights to all of IGL's patents, product data and knowhow with respect to CycloSam[®]. The License Agreement also transfers to us the rights to the product name CycloSam[®] for the technology and provides us a first right of refusal to license other IsoTherapeutics' technologies in the future. See "**License Agreement**" above.

Our board of directors determined in the fourth quarter of 2020 that the opportunities presented through the development of the New Technology presented shareholders with the best path forward in terms of long term value creation. As a result, on November 6, 2020, we entered into an Omnibus Separation Agreement (the "Separation Agreement") with EPH. Under the terms of the Separation Agreement, all remaining assets for the Legacy Business were transferred to EPH in return for the release and termination of \$993,985 in debt and other liabilities owed to EPH. An additional \$114,700 in promissory notes plus accrued interest owed to an affiliate of EPH were converted into Company common stock. Under the Separation Agreement, the Management Agreement between the Company and EPH was terminated, and former employees of the Company engaged in the Legacy Business were released from non-compete agreements. We have presented revenue and expenses related to the Management Agreement, as well as other expenses, assets and liabilities related to the Legacy Business, as "discontinued operations" in our consolidated financial statements. Our sole business focus at this time is the development of radiopharmaceuticals for the treatment of cancer and other diseases.

Government Regulation and Product Approval

Clinical trials, the drug approval process, and the marketing of drugs are intensively regulated in the United States and in all major foreign countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("**FDA**"), and related regulations. Drugs are also subject to other federal, state, and local statutes and regulations. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the imposition by the FDA Institutional Review Board ("**IRB**") of a clinical hold on trials, the FDA's refusal to approve pending applications or supplements, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of biopharmaceutical products. These agencies and other federal, state, and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval, advertising, and promotion of product we develop in the future.

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The FDCA and/or FDA's policies may change, and additional government regulations may be enacted that could prevent or delay regulatory approval of any candidate drug product or approval of new disease indications or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Marketing Approval

The process required by the FDA before new drugs may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests;
- chemistry, manufacturing, and control testing (CMC), validation and documentation of all synthesis, preparation and production processes for all kit ingredients and finished products;
- submission of an Investigational New Drug (IND) application, which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses;
- pre-approval inspection of manufacturing facilities and clinical trial sites; and
- FDA approval of a New Drug Application (NDA) which must occur before a drug can be marketed or sold.

The testing and approval process requires substantial time and financial resources, and we cannot be certain that any approvals will be granted on a timely basis if at all.

We will need to successfully complete additional clinical trials in order to be in a position to submit an NDA to the FDA. Future trials may not begin or be completed on schedule, if at all. Trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory approval to commence a study;
- reaching agreement with third-party clinical trial sites and vendors and their subsequent performance in conducting accurate and reliable studies on a timely basis;
- obtaining institutional review board approval to conduct a study at a prospective site;
- recruiting subjects to participate in a study; and
- supply of the drug.

We must reach an agreement with the FDA on the proposed protocols for our future clinical trials, post-market safety monitoring, and on a Pediatric Development Plan in the United States. All new drugs now require the presentation to the FDA after Phase II clinical trials have ended of a Pediatric Development Plan outlining the strategy and steps to be taken by us to study CycloSam® in children as appropriate. A separate submission to the FDA must be made for each successive clinical trial to be conducted during product development. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. Informed consent must also be obtained from each study subject. Regulatory authorities, an IRB, a data safety monitoring board, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk. Such risks may include unexpected or serious adverse events, or increased severity or occurrence rate of known potential adverse events.

FDA Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including requirements for record-keeping and reporting of adverse experiences with the drug and/or additional post-market clinical trials. Drug manufacturers are required to register their facilities with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain quality processes, manufacturing controls, and documentation requirements upon us and our third-party manufacturers in order to ensure that the product is safe, has the identity and strength, and meets the quality and purity characteristics that it purports to have. Under the federal Prescription Drug Marketing Act, the sampling and distribution and tracking of drugs is regulated. It is designed to discourage the sale of counterfeit, adulterated, misbranded, subpotent, and expired prescription drugs. Certain states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, fail to approve any NDA or other application, require us to recall a drug from distribution, shut down manufacturing operations or withdraw approval of the NDA for that drug. Noncompliance with cGMP or other requirements can result in issuance of warning letters, civil and criminal penalties, seizures, and injunctive action.

Labeling, Marketing and Promotion

The FDA closely regulates the labeling, marketing, and promotion of drugs. While doctors are free to prescribe any drug approved by the FDA for any use, a company can only make claims relating to the safety and efficacy of a drug that are consistent with FDA approval and may only actively market a drug only for the particular use and treatment approved by the FDA. In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions, and potential civil and criminal penalties. Government regulators recently have increased their scrutiny of the promotion and marketing of drugs.

Pediatric Research Equity Act

The Pediatric Research Equity Act ("PREA") amended the FDCA to authorize the FDA to require certain research into drugs used in pediatric patients. The intent of the PREA is to compel sponsors whose drugs have pediatric applicability to study those drugs in pediatric populations, rather than ignoring pediatric indications for adult indications that could be more economically desirable. The Secretary of Health and Human Services may defer or waive these requirements under specified circumstances. The FDA may decide that an NDA will be approved only following completion of additional pediatric studies.

Anti-Kickback and False Claims Laws

In the United States, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other state and local government agencies. For example, sales, marketing, and scientific/educational grant programs must comply with the Anti-Kickback Statute, the False Claims Act, as amended, the privacy regulations promulgated

under HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

In the United States, we are subject to complex laws and regulations pertaining to healthcare “fraud and abuse,” including, but not limited to, the Anti-Kickback Statute, the federal False Claims Act, and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to or approval by the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion-dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. In addition, the federal civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers’ and manufacturers’ compliance with applicable fraud and abuse laws. The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), also created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti-Kickback Statute a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, a similar federal requirement Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (the “Affordable Care Act”) commonly referred to as the “Physician Payments Sunshine Act” requires manufacturers to track and report to the federal government certain payments and “transfers of value” made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, made in the previous calendar year. There are a number of states that have various types of reporting requirements as well. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

Patient Protection and Affordable Health Care Act

Historically in the United States, policy makers have attempted several healthcare reforms regarding the healthcare system that could expand access to healthcare, improve quality of healthcare, contain healthcare costs, prevent or delay approval of product candidates, restrict or regulate post-approval activities, and affect the profitable sale of drugs.

In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. Since its enactment, there have been judicial and political challenges to certain aspects of the ACA. Most recently on June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court’s decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA.

Congress and the Biden administration have generally indicated that they will continue to seek new legislative and/or administrative measures to control drug costs and improve access. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

The CycloSam[®] radioactive product is regulated by the federal Nuclear Regulatory Commission (NRC), and also by similar state regulatory agencies. The handling, packaging, shipping, transportation, and disposal of radioactive materials is highly regulated, and those regulations can change, and the Company would have to comply with all requirements, which could be costly. Additionally, if overnight delivery failures occur, the radioactive compounds cannot be used, and that can result in substantial increased costs and liabilities. The disposal of radioactive materials is also regulated by the Environmental Protection Agency (EPA), and also by similar state regulatory agencies and the Company would have to comply with all of those requirements, which could also be costly.

Radioactive waste from the medical sector is an environmental concern from a global perspective. However, most studies have concluded that radioactive material from the medical sector does not present a significant long term waste management problem when compared to wastes generated from nuclear fuel cycle operations. This is primarily due to the characteristics of biomedical waste, such as its short half-life and low radiotoxicity. For instance, Samarium-153 has a half-life of approximately 46 hours. Biomedical waste also typically contains low energy emitters, such as beta and gamma isotopes, and is generally of low total and specific activity. Further considerations are the volumes of this waste and any other hazardous properties associated with the waste such as biological and chemical risks.

Regardless of the relatively low risks in the preparation, use and disposal of medical isotopes, entities that handle such materials should implement an effective

program for biomedical radioactive waste management based on the principles of waste prevention and minimization, while providing for the protection of personnel and the environment, consistent with the requirements of applicable regulatory authorities. This assessment should include an analysis of the total radionuclide inventory and pattern of use, waste types and amounts generated and the potential routes for disposal.

We seek to assure that the nuclear reactor facilities that produce its Samarium-153, as well as the nuclear pharmacies that prepare doses for treatment, have proper and effective waste management procedures in place applicable to the risks presented by the actual material. Further, doctors and trial sites who handle radioactive materials must be educated on the dangers of handling hazardous substances and the proper methods of disposing radioactive or formally radioactive waste, similar to the handling of other medical and bio wastes.

Facilities

The Company currently conducts its business from offices in Austin, Texas and Palm Beach, Florida. The Company's office space in Austin is leased month-to-month at a rate of \$216 per month. The Company has no formal agreement for its Florida space which is leased by Greenblock Capital, a company for which our General Counsel is affiliated.

Legal Proceedings

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputation harm, and other factors.

Smaller Reporting Company

We are subject to the reporting requirements of Section 13 of the Exchange Act, and subject to the disclosure requirements of Regulation S-K of the SEC, as a "smaller reporting company." That designation will relieve us of some of the informational requirements of Regulation S-K.

Sarbanes/Oxley Act

Except for the limitations excluded by the JOBS Act discussed under the preceding heading "Emerging Growth Company," we are also subject to the Sarbanes-Oxley Act of 2002. The Sarbanes/Oxley Act created a strong and independent accounting oversight board to oversee the conduct of auditors of public companies and strengthens auditor independence. It also requires steps to enhance the direct responsibility of senior members of management for financial reporting and for the quality of financial disclosures made by public companies; establishes clear statutory rules to limit, and to expose to public view, possible conflicts of interest affecting securities analysts; creates guidelines for audit committee members' appointment, compensation and oversight of the work of public companies' auditors; management assessment of our internal controls; prohibits certain insider trading during pension fund blackout periods; requires companies and auditors to evaluate internal controls and procedures; and establishes a federal crime of securities fraud, among other provisions. Compliance with the requirements of the Sarbanes/Oxley Act will substantially increase our legal and accounting costs.

Exchange Act Reporting Requirements

Section 14(a) of the Exchange Act requires all companies with securities registered pursuant to Section 12(g) of the Exchange Act, like we are, to comply with the rules and regulations of the SEC regarding proxy solicitations, as outlined in Regulation 14A. Matters submitted to shareholders at a special or annual meeting thereof or pursuant to a written consent will require us to provide our shareholders with the information outlined in Schedules 14A (where proxies are solicited) or 14C (where consents in writing to the action have already been received or anticipated to be received) of Regulation 14, as applicable; and preliminary copies of this information must be submitted to the SEC at least 10 days prior to the date that definitive copies of this information are forwarded to our shareholders.

We are also required to file annual reports on Form 10-K and quarterly reports on Form 10-Q with the SEC on a regular basis, and will be required to timely disclose certain material events (e.g., changes in corporate control; acquisitions or dispositions of a significant amount of assets other than in the ordinary course of business; and bankruptcy) in a Current Report on Form 8-K.

Number of Total Employees and Number of Full Time Employees

As of the date of this Annual Report, we have four full-time employees. Our interim CFO is currently part-time, but has agreed to join the Company on a full time basis as Chief Financial Officer upon the closing of the Company's next fund raising.

In 2022 and subject to adequate funding, we seek to provide our employees with health care coverage and other benefits to help attract and maintain our workforce. We are not currently obligated to provide health insurance, however, we believe this is an important addition to our benefits package. All employees receive at least three weeks of paid time off per year. We have historically provided incentive stock options and other equity incentives to officers, directors and key employees to provide ownership and alignment of interests with our shareholders. We also use in certain instances performance-based vesting for stock options, whereby we set milestones to reflect important value creating initiatives of the Company. As a company, we seek diversity and inclusion in our workplace.

Available Information

We maintain an internet website at www.qsambio.com. We make available on or through our website, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practical after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. We do not intend the address of our website to be an active link or to otherwise incorporate the contents of our website into this Annual Report. You may also find all of the reports that we have filed electronically with the SEC at their Internet site www.sec.gov.

ITEM 1A. RISK FACTORS

General Risks Related to our Business and Technology

Drug development is a long and inherently uncertain process with a high risk of failure at every stage of development.

Drug development is a highly uncertain scientific and medical endeavor, and failure can unexpectedly occur at any stage of clinical development. Typically, there is a high rate of attrition for product candidates in preclinical and clinical trials due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. Pre-clinical studies and clinical trials are long, expensive and highly uncertain processes that can take many years. It will take us several years to complete our clinical trials and the time required for completing, testing and obtaining approvals is uncertain. The start or end of a clinical trial is often delayed or halted due to changing regulatory

requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes, or financial constraints. The FDA and other U.S. and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical trials, require additional clinical development or other testing, delay, condition or withhold registration and marketing approval and mandate product withdrawals, including recalls. Additionally, we may also amend, suspend or terminate clinical trials at any time if we believe that the participating patients are being exposed to unacceptable health risks. Results attained in our single early human clinical trial may not be indicative of results in later clinical trials. Our failure to demonstrate adequately the safety and efficacy of a product under development would delay or prevent marketing approval, which could adversely affect our operating results and credibility. The failure of one or more of our product candidates could have a material adverse effect on our business, financial condition and results of operations.

The future of our business and operations depends on the success of our development and commercialization programs.

Our business and operations entail a variety of serious risks and uncertainties and are inherently risky. The development programs on which we focus involve novel approaches to treating bone cancer and related diseases. Our product candidates are in clinical development, and in some respects, involve technologies with which we have limited prior experience. We are subject to the risks of failure inherent in the development and commercialization of product candidates based on new technologies. There is some precedent for the successful commercialization of products based on our technologies, but there are still a number of technological challenges that we must overcome to complete our clinical trials and development efforts. We may not be able to successfully develop our product candidates. We must successfully complete clinical trials and obtain regulatory approvals for potential commercial products. Once approved, if at all, commercial product sales are subject to general and industry-specific local and international economic, regulatory, technological and policy developments and trends. Delays, higher costs or other weaknesses in the manufacturing process or any of our contracted manufacturing organizations could hinder the development and commercialization of our product pipeline. The oncology space in which we operate presents numerous significant risks and uncertainties that may be expected to increase to the extent it becomes more competitive or less favored in the commercial healthcare marketplace.

We currently have no in-house sales, marketing or distribution capabilities and have limited experience in marketing products. We may in the future develop an in-house marketing and sales team, which would require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we decide against absorbing marketing and sales responsibilities in-house, we will need to collaborate with third-parties. However, there can be no assurance that such collaborations will be successful or even if they are, they will be profitable for the Company after expending capital resources in fees and expenses. There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product.

If we do not obtain regulatory approval for our product candidates on a timely basis, or at all, or if the terms of any approval impose significant restrictions or limitations on use, our business, results of operations and financial condition will be adversely affected. Setbacks in clinical development programs could have a material adverse effect on our business.

Regulatory approvals are necessary to market product candidates and require demonstration of a product's safety and efficacy through extensive pre-clinical and clinical trials. We may not obtain regulatory approval for product candidates on a timely basis, or at all, and the terms of any approval (which in some countries includes pricing and reimbursement approval) may impose significant restrictions, limitations on use or other commercially unattractive conditions. The process of obtaining FDA and foreign regulatory approvals often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. We have had only limited experience in filing and pursuing applications and other submissions necessary to gain marketing approvals. Products under development may never obtain marketing approval from the FDA or other regulatory authorities necessary for commercialization.

We or regulators may also amend, suspend or terminate clinical trials if we or they believe that the participating patients are being exposed to unacceptable health risks, and after reviewing trial results, we may abandon projects which we previously believed to be promising for commercial or other reasons unrelated to patient risks. During this process, we may find, for example, that results of pre-clinical studies are inconclusive or not indicative of results in human clinical trials, clinical investigators or contract research organizations do not comply with protocols or applicable regulatory requirements, or that product candidates do not have the desired efficacy or have undesirable side effects or other characteristics that preclude marketing approval or limit their potential commercial use if approved. In such circumstances, the entire development program for that product candidate could be adversely affected, resulting in delays in trials or regulatory filings for further marketing approval and a possible need to reconfigure our clinical trial programs to conduct additional trials or abandon the program involved. Conducting additional clinical trials or making significant revisions to a clinical development plan would lead to delays in regulatory filings. If clinical trials indicate, or regulatory bodies are concerned about, actual or possible serious problems with the safety or efficacy of a product candidate, we may stop or significantly slow development or commercialization of affected products. As a result of such concerns, the development programs for our product candidates may be significantly delayed or terminated altogether.

The results of our preclinical or initial single patient clinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs and biologics proceeding through clinical trials.

If the results of any of our clinical trials are not satisfactory or we encounter problems and/or delays enrolling patients, clinical trial supply issues, setbacks in developing drug formulations or in clinical trials, including raw material supply, manufacturing, stability or other difficulties, or issues complying with protocols or applicable regulatory requirements, the entire development program for our product candidates could be adversely affected in a material manner. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies or clinical trials nonetheless failed to obtain FDA approval or approval from foreign regulatory authorities.

Our business is highly dependent on our product candidate, CycloSam[®], and a failure to obtain regulatory approval or successfully commercialize our product could adversely affect our financial condition and results of operations.

In April 2020, the Company, through its wholly-owned subsidiary QSAM Therapeutics entered into an exclusive worldwide patent and technology license agreement and trademark assignment with respect to CycloSam[®] and obtained exclusive commercial rights to the patent portfolio developed by IGL Pharma Inc. ("IGL") (the "Original Agreement"). The agreement was mutually amended on November 24, 2021 (collectively with the Original Agreement referred to hereinafter as the "License Agreement"). The License Agreement is terminable in the event of a material breach by us that is not cured within a predefined period of time after notice of the breach is provided to us. If the License Agreement is terminated, the Company will not have further rights to CycloSam[®] and will be unable to continue its regulatory approval process or if already commercialized, benefit from the future sales of CycloSam[®]. Further, the Company may be liable for damages for the breach and may suffer additional losses, which could adversely impact our financial condition. As of the date of this prospectus, the Company's focus is to solely develop CycloSam[®] and it does not possess licenses to other product candidates. If we do not obtain regulatory approval for CycloSam[®] or fail to successfully commercialize CycloSam[®], we currently have no fall back options to continue our business operations unless we secure licenses of or develop alternative drug candidates. There is no assurance that either will occur.

We must design and conduct successful clinical trials for our product candidates to obtain regulatory approval. We rely on third parties to conduct our clinical

trials, which reduces our control over their timing, conduct and expense and may expose us to conflicts of interest. Clinical trial results may be unfavorable or inconclusive, and often take longer and cost more than expected.

We have limited internal resources for conducting clinical trials, and we rely on or obtain the assistance of others to design, conduct, supervise, or monitor some or all aspects of some of our clinical trials. In relying on these third parties, we have less control over the timing and other aspects of clinical trials than if we conducted them entirely on our own. Problems with the timeliness or quality of the work of a contract research organization or clinical data management organization may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials and contractual restrictions may make such a change difficult or impossible. These third parties may also have relationships with other entities, some of which may be our competitors. In all events, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. The FDA and other foreign regulatory authorities require us to comply with good clinical practices for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements.

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To obtain regulatory approval of our product candidates we must demonstrate through preclinical studies and clinical trials that they are safe and effective. Adverse or inconclusive clinical trial results concerning any of our product candidates that regulators find deficient in scope, design or one or more other material respects, could require additional trials, resulting in increased costs, significant delays in submissions of approval applications, approvals in narrower indications than originally sought, or denials of approval, none of which we can predict. As a result, any projections that we publicly announce of commencement and duration of clinical trials are not certain. Clinical trial delays may occur as a result of slower than anticipated enrollment. Delays can be caused by, among other things, deaths or other adverse medical events; regulatory or patent issues; interim or final results of ongoing clinical trials; failure to enroll clinical sites as expected; competition for enrollment from other clinical trials; scheduling conflicts with participating clinicians and institutions; disagreements, disputes or other matters arising from collaborations; our inability to obtain necessary funding; or manufacturing problems.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, or coronavirus, may materially and adversely affect our business and our financial results.

The COVID-19 pandemic, including the recent surges caused by the “delta variant” and “omicron variant”, has materially affected segments of the global economy and may affect our operations by causing a period of business disruption, supply chain issues, including the potential interruption of our clinical trial activities and delays or disruptions in the supply of our products and product candidates. In addition, there could be a potential effect of COVID-19 to the business at FDA or other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates.

The continued spread of COVID-19 globally could also adversely impact our clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. COVID-19, or another infectious disease, could also negatively affect our manufacturing operations, which could result in delays or disruptions in the supply of our product candidates.

We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted, which could have a material adverse effect on our business and our results of operation and financial condition.

Even if our product candidates obtain marketing approval, our ability to generate revenue will depend upon public perception of radiopharmaceuticals and will be diminished if our products are not accepted in the marketplace, or if we select pricing strategies for our products that are less competitive than those of our competitors, or fail to obtain acceptable prices or an adequate level of reimbursement for products from third-party payers or government agencies.

Adverse events in clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting negative publicity, as well as any other adverse events in the field of radiopharmaceuticals that may occur in the future, could result in a decrease in demand for our products or any product candidates that we may develop. If public perception is influenced by claims that radiopharmaceuticals or specific therapies within radiopharmaceuticals are unsafe, our products or product candidates may not be accepted by the general public or the medical community.

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The commercial success of our products will depend upon their acceptance by the medical community and third-party payers as clinically useful, cost effective and safe. Market acceptance of approved products is affected by a wide range of factors including the timing of regulatory approvals, product launches and the presence of generic, over-the-counter or other competitors; the pricing of the product and relative prices of competing products; product development efforts for new indications; the availability of reimbursement for the product; our ability to obtain sufficient commercial quantities of the product; success in arranging for necessary sublicense or distribution relationships; and general and industry-specific local and international economic pressures. If health care providers believe that patients can be managed adequately with alternative, currently available therapies, they may not prescribe our products, especially if the alternative therapies are viewed as more effective, as having a better safety or tolerability profile, as being more convenient to the patient or health care providers or as being less expensive. Third-party insurance coverage may not be available to patients for any products we develop. For pharmaceuticals administered in an institutional setting, the ability of the institution to be adequately reimbursed from government and health administration authorities, private health insurers and other third-party payers could also play a significant role in demand for our products. Significant uncertainty exists as to the reimbursement status of newly-approved pharmaceuticals. Government and other third-party payers increasingly are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for indications for which the FDA has not granted labeling approval. In most foreign markets, pricing and profitability of prescription pharmaceuticals are subject to government control. In the U.S., we expect that there will continue to be a number of federal and state proposals to implement similar government control and that the emphasis on managed care in the U.S. will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we can receive for any products in the future and adversely affect our ability to successfully commercialize our products. If any of our product candidates do not achieve market acceptance, we will likely lose our entire investment in that product candidate.

We are subject to extensive and ongoing regulation, which can be costly and time consuming, may interfere with marketing approval for our product candidates, and can subject us to unanticipated limitations, restrictions, delays and fines.

Our business, products and product candidates are subject to comprehensive regulation by the FDA and comparable authorities in other countries, and include the Sunshine Act under the Patient Protection and Affordable Care Act (“PPACA”). These agencies and other entities regulate the pre-clinical and clinical testing, safety, effectiveness, approval, manufacture, labeling, marketing, export, storage, recordkeeping, advertising, promotion and other aspects of our products and product candidates. We cannot guarantee that approvals of product candidates, processes or facilities will be granted on a timely basis, or at all. If we experience delays or failures in obtaining approvals, commercialization of our product candidates will be slowed or stopped. In addition to these uncertainties, there have been several attempts and public announcements by members of the U.S. Congress to repeal the PPACA and replace it with a curtailed system of tax credits and dissolve an expansion of the Medicaid program. For example, Tax Cuts and Jobs Act of 2017 was enacted in 2017, which, among other things, eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, and became effective January 1, 2019. There is considerable uncertainty regarding the future of the current PPACA framework, and any changes will likely take time to unfold. As such, we cannot predict what effect the PPACA or other healthcare reform initiatives that may be adopted in the future will have on our business.

Even if we obtain regulatory approval for a product candidate, the approval may include significant limitations on indicated uses for which the product could be marketed or other significant marketing restrictions.

If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be subject to forced removal of a product from the market, product seizure, civil and criminal penalties and other adverse consequences.

Our products may face regulatory, legal or commercial challenges even after approval.

Even if a product receives regulatory approval:

- It might not obtain labeling claims necessary to make the product commercially viable (in general, labeling claims define the medical conditions for which a drug product may be marketed, and are therefore very important to the commercial success of a product), or may be required to carry warnings that adversely affect its commercial success.
- Approval may be limited to uses of the product for treatment or prevention of diseases or conditions that are relatively less financially advantageous to us than approval of greater or different scope or subject to an FDA imposed Risk Evaluation and Mitigation Strategy (“REMS”) that imposes limits on the distribution or use of the product. While we may develop a product candidate with the intention of addressing a large, unmet medical need, the FDA or other foreign regulatory authorities may only approve the use of the drug for indications affecting a relatively small number of patients, thus greatly reducing the market size and our potential revenues.

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- Side effects identified after the product is on the market might hurt sales or result in mandatory safety labeling changes, additional pre-clinical testing or clinical trials, imposition of a REMS, product recalls or withdrawals from the market, reputational harm to us, and lawsuits (including class-action suits).
- Efficacy or safety concerns regarding a marketed product, or manufacturing or other problems, may lead to a recall, withdrawal of marketing approval, marketing restrictions, reformulation of the product, additional pre-clinical testing or clinical trials, changes in labeling, imposition of a REMS, warnings and contraindications, the need for additional marketing applications, declining sales or other adverse events. These potential consequences may occur whether or not the concerns originate from subsequent testing or other activities by us, governmental regulators, other entities or organizations or otherwise, and whether or not they are scientifically justified. If products lose previously received marketing and other approvals, our business, results of operations and financial condition would be materially adversely affected.
- In certain foreign jurisdictions, drug products cannot be marketed until pricing and reimbursement for the product is also approved. In the United States, reimbursement approval is not required, but if not available, that may severely limit the sales, and the Center for Medicare & Medicaid Services may require additional clinical studies, more than the FDA demands.
- We will be subject to ongoing FDA obligations and continuous regulatory review, and might be required to undertake post-marketing trials to verify the product’s efficacy or safety or other regulatory obligations.

We are increasingly dependent on information technology, and potential cyberattacks, security problems, or other disruption and expanding social media vehicles present new risks.

We rely on information technology networks and systems, including the internet, to process, transmit, and store electronic information, and to manage or support a variety of business processes, including financial transactions and records, billing, and operating data. We may purchase some of our information technology from vendors, on whom our systems will depend, and we rely on commercially available systems, software, tools, and monitoring to provide security for processing, transmission, and storage of confidential operator and other customer information. We depend upon the secure transmission of this information over public networks. Our networks and storage applications could be subject to unauthorized access by hackers or others through cyberattacks, which are rapidly evolving and becoming increasingly sophisticated, or by other means, or may be breached due to operator error, malfeasance or other system disruptions. In some cases, it will be difficult to anticipate or immediately detect such incidents and the damage they cause. Any significant breakdown, invasion, destruction, interruption, or leakage of information from our systems could harm our reputation and business.

In addition, the use of social media could cause us to suffer brand damage or information leakage. Negative posts or comments about us on any social networking website could damage our or our brands’ reputations. Employees or others might disclose non-public sensitive information relating to our business through external media channels, including through the use of social media. The continuing evolution of social media will present us with new challenges and risks.

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Risks Related to our Financial Position and Operating History

We have a limited operating history and are operating at a loss, and there is no guaranty that we will become profitable.

We recently began operations under our current business model and anticipate that we will operate at a loss for some time. Since we have limited operating history and no history of profitability, we have limited financial results upon which you may judge our potential. Further, our ability to become profitable depends upon our ability to generate revenue. We have recorded no revenue from continuing operations since inception. We do not expect to generate significant product revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates; or alternatively, out license or sell our drug candidates. Both of these scenarios are highly uncertain. In the future, we may experience under-capitalization, development delays, set-backs with our drug development programs, lack of funding options, setbacks and many of the problems, delays and expenses encountered by any early stage business, many of which are beyond our control. These include, but are not limited to:

- our lack of an operating history;
- the net losses that we expect to incur as we develop our business;
- obtaining FDA or other regulatory approvals or clearances for our technology;
- implementing and achieving successful outcomes for clinical trials of our products;
- convincing physicians, hospitals and patients of the benefits of our technology and to convert from current technology;
- the ability of users of our products (when and as developed) to obtain third-party reimbursement;
- any failure to comply with rigorous FDA and other government regulations; and
- securing, maintaining and defending patent or other intellectual property protections for our technology.

Because our history is limited and we are subject to intense competition, any investment in us would be inherently risky.

Because we are a company with limited operational history and no profitability, our business activity is early-staged and subject to numerous risks. The pharmaceutical

development business is highly competitive with many companies having access to the similar products and markets. Many of them have greater financial resources and longer operating histories than we have and can be expected to compete within the business in which we engage and intend to engage. There can be no assurance that we will have the necessary resources to become or remain competitive. We are subject to the risks which are common to all companies with a limited history of operations and profitability. Therefore, investors should consider an investment in us to be an extremely risky venture.

There is substantial doubt as to our ability to continue as a going concern.

The Report of our Independent Registered Public Accounting Firm issued in connection with our audited consolidated financial statements for the calendar years ended December 31, 2021 and 2020 expressed substantial doubt about our ability to continue as a going concern because of our recurring operating losses and our lack of liquidity and working capital. A going concern opinion means that there is substantial doubt that the Company can continue as an ongoing business for the next 12 months. While we expect to become a going concern upon the completion of the Company next planned offering, if we fail to successfully deploy our funds, fail to implement our business plan or commercialize our drug as planned, or fail to raise additional capital when required, there can be no assurance that we will not again lose our ability to continue as a going concern.

We will require additional financing.

Pharmaceutical development is inherently costly and requires significant capital. We expect our expenses to increase significantly as we enter into the next stage of our drug development including steps such as preclinical studies, clinical trials, research and development, and FDA marketing approvals. If we do obtain FDA approval, we expect to incur substantial costs in commercialization of the product. In addition, we will continue to incur costs to operate as a public company. Accordingly, we will need to obtain additional financing in connection with our continuing operations. There can be no assurance that additional funds will be available when and if needed, or on acceptable terms to the Company. If we are unable to obtain such financing, or if the terms thereof are too costly, we may be forced to curtail or cease operations until such time as alternative financing may be arranged, which could have a materially adverse impact on our planned operations and our shareholders' investment.

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Based upon our current operating plan, we believe that the net proceeds from an offering currently planned by the Company, together with our existing cash and cash equivalents, will enable us to fund our operations through at least 2022. In particular, we expect that the net proceeds from such planned offering and our existing cash and cash equivalents will allow us to complete the Phase 1 portion of our planned clinical trials for CycloSam[®] used in connection with metastatic bone cancer, and also may allow us to commence or prepare for commencement of clinical trials for additional indications, including primary bone cancer and osteosarcoma. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially additional collaborations, licenses and other similar arrangements. In addition, our ability to continue as a going concern is dependent on our ability to raise additional capital in order to implement our current business plan. If the market conditions are favorable or given our strategic considerations, even if we believe we have sufficient funds for our current or future operating plans, we may raise additional capital. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

Our success will be dependent on our management, and the continued service of key employees

Our success is dependent upon the decision making of our directors and executive officers. We believe that our success depends on the continued service of our key employees and our ability to hire additional key employees when and as needed. Although we currently intend to retain our existing management, we cannot assure you that such individuals will remain with us. Further, we cannot assure that we will be able to find and recruit new employees on terms acceptable to the Company. We have fixed term employment agreements with our three key employees – Messrs. Baum, Piazza and Nelson — but have not obtained key man life insurance on the lives of any of them. The unexpected loss of the services of one or more of our key executives, directors and advisors, or the inability to find new key employees within a reasonable period of time could have a material adverse effect on the economic condition and results of operations of the Company.

Risks Related to Working with Third Parties

We have been and expect to continue to be dependent on collaborators for the development, manufacturing and sales of certain products and product candidates, which expose us to the risk of reliance on these collaborators.

In conducting our operations, we currently depend, and expect to continue to depend, on numerous collaborators. In addition, certain clinical trials for our product candidates may be conducted by government-sponsored agencies, and consequently will be dependent on governmental participation and funding. These arrangements expose us to the same considerations we face when contracting with third parties for our own trials.

If any of our collaborators breach or terminate its agreement with us or otherwise fail to conduct successfully and in a timely manner the collaborative activities for which they are responsible, the preclinical or clinical development or commercialization of the affected product candidate or research program could be delayed or terminated. We generally do not control the amount and timing of resources that our collaborators devote to our programs or product candidates. We also do not know whether current or future collaboration partners, if any, might pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors, as a means for developing treatments for the diseases or conditions targeted by our collaborative arrangements. Our collaborators are also subject to similar development, regulatory, manufacturing, cyber-security and competitive risks as us, which may further impede their ability to successfully perform the collaborative activities for which they are responsible. Setbacks of these types to our collaborators could have a material adverse effect on our business, results of operations and financial condition.

We are dependent upon third parties for a variety of functions. These arrangements may not provide us with the benefits we expect.

We rely on third parties to perform a variety of functions. We are party to numerous agreements which place substantial responsibility on clinical research organizations, consultants and other service providers for the development of our product candidates. We also rely on medical and academic institutions to perform aspects of our clinical trials of product candidates. We may not be able to enter new arrangements without undue delays or expenditures, and these arrangements may not allow us to compete successfully. Moreover, if third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct clinical trials in accordance with regulatory requirements or applicable protocols, our product candidates may not be approved for marketing and commercialization or such approval may be delayed. If that occurs, we or our collaborators will not be able, or may be delayed in our efforts, to commercialize our product candidates.

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Our relationships with customers and third-party payers are or may become subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Health care providers, physicians and third-party payers play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payers and customers will or already do require us and them to comply with broadly applicable fraud and abuse and other health care laws and regulations, including both federal and state anti-kickback and false claims laws, that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products that obtain marketing approval. Efforts to ensure that business arrangements comply with applicable

health care laws and regulations involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If such operations are found to be in violation of any of these laws or other applicable governmental regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of related operations. If physicians or other providers or entities involved with our products are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may adversely affect us.

If we or our partners are unable to obtain sufficient quantities of the materials needed to make our products or product candidates, development of our products or product candidates or commercialization of our approved products could be slowed or stopped.

We have utilized Missouri University Research Reactor (“MURR”) to procure Samarium-153, a primary ingredient used in manufacturing of CycloSam®, for our recently conducted clinical studies. Samarium-153 is critical to manufacturing of CycloSam® and to our supply-chain process both during our clinical trials and if the product is commercialized. MURR has verbally committed to supply us Samarium-153 in the future and we are expecting to enter into definitive agreements with MURR in 2022. We also plan to qualify additional suppliers in 2022 as part of our supply chain and general business risk diversification strategy. However, if we fail to partner with MURR or secure other partners for supply of Samarium-153 or if our arrangements with a supplier do not satisfy our requirements in the future, it will directly and adversely impact the production of CycloSam®.

We or our partners may not be able to obtain the materials necessary to make a particular product or product candidate in adequate volume and quality. If any materials needed to make a product or product candidate is insufficient in quantity or quality, if a supplier fails to deliver in a timely fashion or at all or if these relationships terminate, we or our partners may not be able to fulfill manufacturing obligations for our products or product candidates, either on our own or through third-party suppliers. A delay or disruption of supplies of our products or product candidates would have a material adverse effect on our business as a whole. Our existing arrangements with suppliers may result in the supply of insufficient quantities of our product candidates needed to accomplish our clinical development programs or commercialization, and we may not have the right and in any event, do not currently have the capability to manufacture these products if our suppliers are unable or unwilling to do so. Some of these raw materials or their starting materials, components or ingredients may come from foreign countries, which can present significant supply chain issues. We currently arrange for supplies of critical raw materials used in production of our product candidates from single sources. We do not have long-term contracts with any of these suppliers. Any delay or disruption in the availability of materials would slow or stop product development and commercialization of the relevant product.

Manufacturing resources could limit or adversely affect our ability to commercialize products.

We or our partners may engage third parties, including nuclear reactor sites, to manufacture our product candidates. We or our partners may not be able to obtain adequate supplies from third-party manufacturers in a timely fashion for development or commercialization purposes, and commercial quantities of products may not be available from contract manufacturing organizations or CMOs at acceptable costs.

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In order to commercialize our product candidates successfully, we need to be able to manufacture or arrange for the manufacture of products in commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. Manufacture of our product candidates can be complex, difficult to accomplish even in small quantities, difficult to scale-up for large-scale production and subject to delays, inefficiencies and low yields of quality products. The manufacture of radiopharmaceuticals is relatively complex and requires significant capital expenditures. We continue to rely on CMOs for our product candidates. The cost of manufacturing our product candidates may make them prohibitively expensive. If adequate supplies of any of our product candidates or related materials are not available on a timely basis or at all, our clinical trials or commercialization of our product candidates could be seriously delayed, since these materials are time consuming to manufacture and cannot be readily obtained from third-party sources. We continue to be dependent on a limited number of highly specialized manufacturing and development partners, including single source manufacturers for certain of our product candidates. If we were to lose one or more of these key relationships, it could materially adversely affect our business. Establishing new manufacturing relationships, or creating our own manufacturing capability, would require significant time, capital and management effort, and the transfer of product-related technology and know-how from one manufacturer to another is an inherently complex and uncertain process.

Failure of any manufacturer of our various product candidates to comply with applicable regulatory requirements could subject us to penalties and have a material adverse effect on supplies of our product candidates.

Third-party manufacturers are required to comply with current goods manufacturing practice regulations or cGMP or similar regulatory requirements outside of the U.S. If manufacturers of our product candidates cannot successfully manufacture material that conforms to the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they may not be able to supply us with our product candidates. If these facilities are not approved for commercial manufacture, we may need to find alternative manufacturing facilities, which could result in delays of several years in obtaining approval for a product candidate. We do not control the manufacturing operations and are completely dependent on our third-party manufacturing partners or contractors for compliance with the applicable regulatory requirements for the manufacture of some of our product candidates. Manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMP and similar regulatory requirements. Failure of any manufacturer of any of our product candidates to comply with applicable cGMP or other regulatory requirements could result in sanctions being imposed on our collaborators or us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and have a material adverse impact on our business, financial condition and results of operations.

If the use of hazardous and biological materials by us or third parties, such as CROs or CMOs, in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities may involve the controlled use of potentially hazardous substances, including radioactive, chemical and biological materials, by us or third parties, such as contract research organizations or CROs and CMOs. Exposure to high levels of radiation can cause acute health effects such as skin burns and acute radiation syndrome (“radiation sickness”). It can also result in long-term health effects such as cancer and cardiovascular disease. We and such third parties are subject to federal, state, and local laws and regulations in the United States governing the use, manufacture, storage, handling, and disposal of medical and hazardous materials. Although we believe that our and such third-parties’ procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. In the event of any such contamination or injury, we may incur liability or local, city, state, or federal authorities may curtail the use of these materials and interrupt our business operations. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and manufacturing efforts, which could harm our business prospects, financial condition, or results of operations. We plan to maintain insurance coverage upon completion of this offering for injuries resulting from the hazardous materials we use; however, future claims may exceed the amount of our coverage. Also, we do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with such federal, state, provincial, local and foreign environmental regulations are not significant, and consist primarily of waste disposal expenses. However, they could become expensive, and current or future environmental laws or regulations may impair our research, development, production and commercialization efforts. Further, although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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Unexpected disruptions could seriously harm our future revenue and financial condition and increase our expenditures.

Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to events like earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates to meet our demands. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Risks Relating to Our Intellectual Property

The validity, enforceability and commercial value of our patents and other intellectual property rights are highly uncertain.

We license a number of issued patents and other patent applications that have not yet been issued. We must obtain, maintain and enforce patent and other rights to protect our intellectual property. The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves many complex legal and technical issues. There are many laws, regulations and judicial decisions that dictate and otherwise influence the manner in which patent applications are filed and prosecuted and in which patents are granted and enforced, all of which are subject to change from time to time. There is no clear policy involving the breadth of claims allowed, or the degree of protection afforded, under patents in this area. Accordingly, patent applications owned by or licensed to us may not result in patents being issued. Even if we own or license a relevant issued patent, we may not be able to preclude competitors from commercializing drugs that may compete directly with one or more of our products or product candidates, in which event such rights may not provide us with any meaningful competitive advantage. In the absence or upon successful challenge of patent protection, drugs may be subject to generic competition, which could adversely affect pricing and sales volumes of the affected products.

It is generally difficult to determine the relative strength or scope of a biotechnology or pharmaceutical patent position in absolute terms at any given time. The issuance of a patent is not conclusive as to its validity or enforceability, which can be challenged in litigation or via administrative proceedings. The License Agreement from which we derive or license intellectual property provide for various royalty, milestone, sublicensing and other payments, and include other provisions like patent prosecution and enforcement, insurance, indemnification and other obligations and rights, and is subject to certain reservations of rights. While we generally have the right to defend and enforce patents licensed to or by us, either in the first instance or if the licensor or licensee chooses not to do so, we must usually bear the cost of doing so.

Patents have a limited life and expire by law.

In addition to uncertainties as to scope, validity, enforceability and changes in law, patents by law have limited lives. Upon expiration of patent protection, our drug candidates and/or products may be subject to generic competition, which could adversely affect pricing and sales volumes of the affected products.

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We depend on intellectual property licensed from third parties and unpatented technology, trade secrets and confidential information. If we lose any of these rights, including by failing to achieve milestone requirements or to satisfy other conditions, our business, results of operations and financial condition could be harmed.

Our core product candidate is derived from intellectual property licensed from a third party. We could lose the right to patents and other intellectual property licensed to us if the related License Agreement is terminated due to a breach by us or otherwise. Our ability to commercialize products incorporating licensed intellectual property would be impaired if the related License Agreements were terminated. In addition, we are required to make substantial cash payments, achieve milestones and satisfy other conditions, including filing for and obtaining marketing approvals and introducing products, to maintain rights under our intellectual property license. Due to the nature of this agreement and the uncertainties of development, we may not be able to achieve milestones or satisfy conditions to which we have contractually committed, and as a result may be unable to maintain our rights under the license. If we do not comply with our License Agreement, the licensor may terminate it, which could result in our losing our rights to, and therefore being unable to commercialize, related products.

We also rely on unpatented technology, trade secrets and confidential information. Third parties may independently develop substantially equivalent information and techniques or otherwise gain access to our technology or disclose our technology, and we may be unable to effectively protect our rights in unpatented technology, trade secrets and confidential information. We require each of our employees, consultants and advisors to execute a confidentiality agreement at the commencement of an employment or consulting relationship with us. These agreements may, however, not provide effective protection in the event of unauthorized use or disclosure of confidential information. Any loss of trade secret protection or other unpatented technology rights could harm our business, results of operations and financial condition.

If we infringe third-party patent or other intellectual property rights, we may need to alter or terminate a product development program.

There may be patent or other intellectual property rights belonging to others that require us to alter our products, pay licensing fees or cease certain activities. If our products infringe patent or other intellectual property rights of others, the owners of those rights could bring legal actions against us claiming damages and seeking to enjoin manufacturing and marketing of the affected products. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected products. We may not prevail in any action brought against us, and any license required under any rights that we infringe may not be available on acceptable terms or at all.

Research, development and commercialization of a biopharmaceutical product often require choosing between alternative development and optimization routes at various stages in the development process. Preferred routes may depend on subsequent discoveries and test results and cannot be predicted with certainty at the outset. There are numerous third-party patents in our field, and we may need to obtain a license under a patent in order to pursue the preferred development route of one or more of our products or product candidates. The need to obtain a license would decrease the ultimate profitability of the applicable product. If we cannot negotiate a license, we might have to pursue a less desirable development route or terminate the program altogether.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to take legal action to enforce our patents or our licensors' patents against such infringing activity. Such enforcement proceedings can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is invalid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the compositions or activities in question. An adverse result could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense against these assertions, non-infringement, invalidity or unenforceability regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

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Post-grant proceedings provoked by third parties or brought by the United States Patent and Trademarks Office may be brought to determine the validity or priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer

us a license on commercially reasonable terms. Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as those within the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Risks Related to our common stock

Liquidity risks associated with our common stock.

There is a limited trading market for our shares of common stock and while the Company's common stock may be approved for listing on NASDAQ Capital Market, there can be no assurance that (1) an active trading market will be developed or sustained, (2) the liquidity of such market will increase, (3) our stockholders will be able sell their shares of common stock, or (4) the price that our stockholders may obtain for their common stock will be greater than the public offering price. If an active market for our common stock with meaningful trading volume does not develop or is not maintained, the market price of our common stock may decline materially and you may not be able to sell your shares. Our stock currently trades on OTCQB and our shares of common stock are thinly traded.

The price of our common stock may fluctuate significantly, which could lead to losses for stockholders.

The securities of public companies can experience extreme price and volume fluctuations, which can be unrelated or out of proportion to the operating performance of such companies. We expect our common stock price will be subject to similar volatility. Any negative change in the public's perception of the prospects of our Company or companies in our market could also depress our common stock price, regardless of our actual results. Factors affecting the trading price of our common stock may include:

- * Regulatory actions;
- * Variations in our operating results;

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- * Announcements of technological innovations, new products or product enhancements, strategic alliances or significant agreements by us or by our competitors;
- * Recruitment or departure of key personnel;
- * Litigation, legislation, regulation or technological developments that adversely affect our business;
- * Changes in the estimates of our operating results or changes in recommendations by any securities analysts that elect to follow our common stock; and
- * Market conditions in our industry, the industries of our customers and the economy as a whole.

The application of the "penny stock" rules could adversely affect the market price of our common stock and increase your transaction costs to sell those shares.

The open-market trading of our common stock is currently subject to the "penny stock" rules. The penny stock rules impose additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with assets in excess of \$1 million or annual income exceeding \$200,000 or \$300,000 together with their spouses). For transactions covered by these rules, the broker-dealer must make a special suitability determination for the purchase of securities and have received the purchaser's written consent to the transaction before the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the broker-dealer must deliver, before the transaction, a disclosure schedule prescribed by the Commission relating to the penny stock market. The broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information on the limited market in penny stocks. These additional burdens imposed on broker-dealers may restrict the ability or decrease the willingness of broker-dealers to sell our common stock, and may result in decreased liquidity of our common stock and increased transaction costs for sales and purchases of our common stock as compared to other securities. Therefore, as long as our shares of common stock are subject to the penny stock rules, the holders of such shares of common stock may find it more difficult to sell their securities.

We do not intend to pay dividends.

We have not paid any cash dividends on our common stock since inception and we do not anticipate paying any cash dividends in the foreseeable future. Earnings, if any, that we may realize will be retained in the business for further development and expansion.

Concentration of Stock Ownership and Control.

Our executive officers and directors currently control approximately 42% of the common stock of the Company, and Checkmate Capital and its affiliates, one of our former debt holders and lead investors in the Series B round, control approximately 14% of the common stock of the Company. The Company has employee options, incentive stock warrants, preferred stock and convertible notes that could result in further dilution. We may conduct funding rounds in the future, much of which may utilize our common stock. In this regard, management, prior investors and future investors may control a significantly large amount of equity, and as a result, these stockholders acting together will be able to influence many matters requiring stockholder approval including the election of directors and other significant corporate transactions. This concentration of ownership may have the effect of delaying, preventing or deterring a change in control, and could deprive our stockholders of an opportunity to receive a premium for their shares of common stock as part of a sale of our company and may affect the market price of our stock.

The Company has Preferred Stock with additional priority rights.

The Company has two classes of preferred stock, which provide voting, approval, liquidation, conversion, and other rights that are senior to the common stock of the Company. The Company may also issue up to an additional 4,998,071 shares of blank-check preferred stock in the future. As a result, the preferred stockholders can exert significant influence over the Company and can dilute the financial interests of the common stockholders.

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Series A preferred stockholders have rights to approve certain transactions, including additional debt, payment of dividends in certain scenarios, and other similar items, all voting together as a separate class. There are currently 480 Series A shares outstanding held by two institutional holders, convertible into approximately 4.2 million shares of common stock inclusive of accrued dividends. Series B preferred stock has liquidation preferences senior to the common stock; and all such shares and accrued

dividends are convertible into shares of common stock. This will lead to dilution of your shares. On December 6, 2021, all holders of Series E-1 preferred stock agreed to exchange their preferred shares for 28,839,428 million shares of common stock, and Series E-1 preferred stock was retired prior to this offering.

As long as shares of preferred stock are outstanding, whether now or in the future, common stockholders may have reduced control over certain affairs of the Company, lower priority at the time of liquidation, and continued dilution of their voting and economic rights in the shares of common stock of the Company.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2021, we had four full-time employees and one part-time employee. As our drug development and commercialization plans and strategies develop, we expect to need additional operational, sales, marketing, managerial, financial and other personnel, as well as additional resources to expand our operations.

We currently rely, and for the foreseeable future will continue to rely, in large part on certain third party organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical trial management and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to manage our outsourced activities effectively or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement our business plan to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a smaller reporting company as defined in the Exchange Act, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than \$250 million measured on the last business day of our second fiscal quarter, or our annual revenue is more than \$100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than \$700 million measured on the last business day of our second fiscal quarter. Smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We may choose to take advantage of the available exemptions for smaller reporting companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our shares price may be more volatile.

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If we fail to comply with the rules and regulations under the Sarbanes-Oxley Act, our operating results, our ability to operate our business and investors' views of us may be harmed.

Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, our efforts to comply with the rules and regulations under the Sarbanes-Oxley or new or changed laws, regulations, and standards may differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice. Regulatory authorities may investigate transactions disclosed in our "Management's Discussion and Analysis of Financial Condition and Results of Operations," and if legal proceedings are initiated against us, it may harm our business.

We have identified certain material weaknesses in our internal control over financial reporting and if our remediation of such material weaknesses is not effective, or if we fail to develop and maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired.

In the course of preparing our financial statements, we have historically identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses related to limited accounting personnel and resources resulting into lack of segregation of duties, lack of experience in accounting for equity transactions, and lack of internal controls. We have concluded that these material weaknesses in our internal control over financial reporting occurred because during 2020 and much of 2021, we did not have a chief financial officer and our principal accounting officer did not had the necessary business processes, systems, personnel and related internal controls necessary to satisfy the accounting and financial reporting requirements of a public company.

On December 1, 2021, we recruited an interim chief financial officer who has significant experience in public company accounting, and we believe that his expertise and oversight over preparation of financial statements and an understanding of SEC's rules and regulations will allow for better segregation of duties in our financial reporting processes and improve our procedure for disclosure controls. This interim CFO has agreed to join the Company on a full-time basis upon the completion of the next round of funding.

We believe we have taken necessary actions to substantially address each of the material weaknesses discussed above and as disclosed in prior financial reports, and our auditor found no material weaknesses in internal controls in connection with the preparation of this annual report. We plan to take additional steps to continue to improve our accounting function; and we must be able to confirm that such remedial measures have been operating effectively for a sufficient period of time. Further, we cannot assure you that any such actions we have or will take will prevent or avoid potential future material weaknesses. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods.

Our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting until after we become an "accelerated" or "large accelerated" filer as those terms are defined in the Exchange Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our internal control over financial reporting is documented, designed or operating. Any failure to implement and maintain effective internal control over financial reporting also could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will eventually be required to include in our periodic reports that are filed with the SEC. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock.

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Our financial statements may be materially affected if our estimates prove to be inaccurate as a result of our limited experience in making critical accounting estimates.

Financial statements prepared in accordance with GAAP require the use of estimates, judgments, and assumptions that affect the reported amounts. Actual results may differ materially from these estimates under different assumptions or conditions. These estimates, judgments, and assumptions are inherently uncertain, and, if they prove to be wrong, then we face the risk that charges to income will be required. In addition, because we have limited to no operating history and limited experience in making these estimates, judgments, and assumptions, the risk of future charges to income may be greater than if we had more experience in these areas. Any such charges could significantly harm our business, financial condition, results of operations, and the price of our securities. See “*Note 3 – Summary of Significant Accounting Policies*” under notes to our consolidated financial statements. For a discussion of the accounting estimates, judgments, and assumptions that we believe are the most critical to an understanding of our business, financial condition, and results of operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None. Not required for smaller reporting companies.

ITEM 2. PROPERTIES

The Company currently conducts its business from offices in Austin, Texas and Palm Beach, Florida. The Company’s office space in Austin is leased month-to-month at a rate of \$216 per month. The Company has no formal agreement for its Florida office space which is leased by Greenblock Capital, a company for which our General Counsel is affiliated.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any pending legal proceeding and, to the knowledge of our management, no federal, state or local governmental agency is presently contemplating any proceeding against us. No director, executive officer, affiliate of ours, or owner of record or beneficially of more than five percent of our common stock is a party adverse to the Company or has a material interest adverse to us in any proceeding.

ITEM 4. MINE SAFETY DISCLOSURES

None; not applicable.

PART II

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

Market Information

There is a limited “established trading market” for our shares of common stock. No assurance can be given that a robust market for our common stock will develop or be maintained. If a robust public market ever develops in the future, the sale of shares of our common stock that are deemed to be “restricted securities” pursuant to Rule 144 of the SEC by members of management or others may have a substantial adverse impact on any such market.

Set forth below are the high and low closing bid prices for our common stock for each quarter of the years 2020 and 2021. These bid prices were obtained from OTC Markets Group, Inc. All prices listed herein reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not represent actual transactions.

Period	High		Low	
January 1, 2020 through March 31, 2020	\$	0.58	\$	0.16
April 1, 2020 through June 30, 2020	\$	0.50	\$	0.24
July 1, 2020 through September 30, 2020	\$	0.55	\$	0.20
October 1, 2020 through December 31, 2020	\$	0.57	\$	0.15
January 1, 2021 through March 31, 2021	\$	0.98	\$	0.40
April 1, 2021 through June 30, 2021	\$	0.84	\$	0.31
July 1, 2021 through September 30, 2021	\$	0.49	\$	0.25
October 1, 2021 through December 31, 2021	\$	0.40	\$	0.15

Holders

The number of record holders of our common stock as of the date of this Annual Report is 315. This figure does not include beneficial owners who may hold their shares in “street name”.

Dividends

We have not declared any cash dividends with respect to our common stock, and do not intend to declare dividends in the foreseeable future. Our future dividend policy cannot be ascertained with any certainty, and if and until we determine to engage in any business or we complete any acquisition, reorganization or merger, no such policy will be formulated. There are material restrictions limiting our ability to pay dividends on our securities, including state law and provisions under our Class A Preferred Stock and various debt instruments.

Recent Sales of Unregistered Securities

The following table sets forth the sales of unregistered securities by the Company in 2021:

Purpose / Holder	Number of Shares of Common Stock		Total Price/Amount	
Conversion into common stock of promissory notes among multiple note holders (1)		6,627,692	\$	1,447,315
Sale of Series B Shares to multiple investors (2)		2,219	\$	2,219,000
Common stock warrants issued to investors in Series B Offering (3)		6,743,575		-
Common stock warrants issued to service provider (4)		750,000	\$	120,000
Common stock issued to service providers for services (5)		750,000	\$	132,500
Grant of Series E-1 Preferred Shares to director (6)		850		-

Conversion of Series A Preferred Stock with unrelated party (7)	750,000	\$	120,000
Common stock issued to service provider for services (8)	700,000	\$	210,000
Conversion of Series B preferred shares and accrued dividends into common stock (9)	6,525,378	\$	1,344,068
Common stock options issued to directors (10)	644,000		-
Series B warrant exercise (11)	1,871,432	\$	467,858
Convertible Note Warrants (12)	925,001	\$	555,000
Common shares issued in exchange for Series E-1 preferred shares (13)	28,839,428	\$	8,651,829

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- (1) Shares of common stock issued to six holders of the Company's Bridge Notes.
- (2) Shares of common stock sold to 25 unaffiliated accredited investors as part of Series B financing.
- (3) 6,268,575 warrants issued to 27 investors who participated in Series B financing at an exercise price of \$0.35, expiring July 8, 2021 (subsequently amended to October 15, 2021 with reduced \$0.25 exercise price – see Note 11 below); and 475,000 warrants issued to Checkmate Capital Group LLC at an exercise price of \$0.45, expiring January 15, 2022 (subsequently amended to January 15, 2023).
- (4) Warrants issued to Sterling Management Inc. at an exercise price of \$0.22 per share, expiring July 8, 2021 (subsequently amended to expire October 15, 2021; expired on October 15, 2021).
- (5) 250,000 shares of common stock issued to Sterling Management, and 500,000 shares of common stock issued to IGL Pharma, Inc. under our License Agreement as amended.
- (6) Series E-1 preferred shares issued to Charles J. Link Jr. (Director) (subsequently exchanged for common shares – see Note 13 below).
- (7) Conversion of preferred shares by Alpha Capital Anstalt.
- (8) Common shares issued to Redstone Communications and affiliate for investor relations services pursuant to contract.
- (9) Common shares issued to nine unaffiliated parties upon conversion of Series B preferred shares and accrued unpaid dividends (see Note 2 above).
- (10) Options granted to directors, officers, and certain service providers of the Company under its Equity Incentive Plan.
- (11) Common stock issued to 8 non-affiliate investors upon exercise of warrants.
- (12) Issued in connection with Convertible Promissory Notes in the total principal amount of \$605,000 among six non-affiliated accredited investors. Warrants are exercisable prior to October 31, 2022 at \$0.60 per share.
- (13) Issued pursuant to exchange agreement and plan of reorganization dated December 6, 2021, between the Company and six officers, directors and key employee holders of the Series E-1 Preferred Stock.

We issued all securities reported to persons who were “accredited investors” as that term is defined in Rule 501 of Regulation D of the SEC, or to “sophisticated investors” or key employees; and each such person had prior access to all material information about us prior to the offer and sale of these securities, and had the right to consult legal and accounting professionals. We believe that the offer and sale of these securities were exempt from the registration requirements of the Securities Act, pursuant to Sections 4(a)(2) and Rule 506 of Regulation D of the SEC.

Purchases of Equity Securities by Us and Affiliated Purchasers

None.

ITEM 6: SELECTED FINANCIAL DATA

Not required for smaller reporting companies.

ITEM 7: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

A. Plan of Operation

Overview

The Company's business is the development of next-generation nuclear medicines for the treatment of cancer and related diseases. Our initial technology is Samarium-153 DOTMP, a/k/a CycloSam[®] (“CycloSam[®]” or the “New Technology”), a clinical-stage bone targeting radiopharmaceutical. The FDA cleared our IND in August 2021 to commence clinical trials of CycloSam[®] on patients with metastatic bone cancer, an open-label, dose escalating trial that may result in sufficient data to move subsequently into a pivotal trial.

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On April 20, 2020, we executed a Patent and Technology License Agreement and Trademark Assignment (the “License Agreement”) with IGL Pharma Inc. (“IGL”), through a newly created, wholly-owned subsidiary called QSAM Therapeutics Inc. (“QSAM Therapeutics”), which License Agreement was mutually amended on November 24, 2021. The License Agreement provides QSAM Therapeutics with exclusive, worldwide and sub-licensable rights to all of IGL's patents, product data and knowhow with respect to CycloSam[®]. The License Agreement also transfers to QSAM Therapeutics the rights to the product name CycloSam[®] for the technology, and provides QSAM Therapeutics a first right of refusal to license other technologies from IGL in the future.

On November 6, 2020, the Company entered into an Omnibus Separation Agreement (the “Separation Agreement”) with its unconsolidated investee, Earth Property Holdings LLC (“EPH”). Our board of directors approved the Separation Agreement in furtherance of its previously disclosed plan to secure new technologies and business opportunities in the broader biosciences sector, and to significantly reduce debt and liabilities of the Company and eliminate under-performing assets and agreements.

The Separation Agreement marked a discontinuance of the Company's soil health operations (the “Legacy Business”) to focus solely on the development of its exclusively licensed radiopharmaceutical drug candidate, CycloSam[®], as well as other drug candidates that it may license or otherwise secure in the future. Revenue and expenses from the Legacy Business are presented on our consolidated financial statements as “Discontinued Operations.”

New Equity and Debt Financings; S-1 Registration

To advance the development of the New Technology, in November 2020 we commenced a \$2.5 million Series B Preferred stock offering (the “Series B Offering”). We completed the Series B Offering in January 2021, raising \$2.5 million inclusive of \$156,000 in debt conversion, and issuing a total of 2,500 shares of Series B Preferred Stock.

In connection with this Series B Offering closing, our Board approved a modification to the offering terms in January 2021, and we issued in that month a total of 6.27 million common stock warrants. These warrants were originally exercisable prior to July 8, 2021 at an exercise price of \$0.35 per share, and later modified by our Board to expire on October 15, 2021 and be exercisable at \$0.25 per share. As of October 15, 2021, seven holders of the Series B warrants exercised those warrants and received a total of 1,871,431 common shares for total consideration to the Company of \$467,858. Also in 2021, our lead investor in the Series B Offering earned a warrant for 475,000 shares

exercisable at \$0.45 per share, which warrant was to expire January 15, 2022, but modified in 2022 to expire January 15, 2023.

In the fourth quarter of 2021, we entered into convertible note purchase agreements with eight accredited investors, pursuant to which we issued an aggregate of \$605,000 of convertible notes (the “Notes”). The Notes mature on December 31, 2023 and are convertible into shares of common stock of the Company in the event of future equity financing of \$5 million or greater, NASDAQ uplisting, or at the discretion of the noteholders, at a conversion price of \$0.20 per share. The obligations under the Notes are unsecured. The Company has agreed to pay simple interest at the rate of 6% per annum on the outstanding amount of the Notes until fully repaid or converted. In connection with the Notes offering, the Company issued 1,008,334 warrants to the noteholders, with each warrant convertible into one share of common stock at an exercise price of \$0.60 per share beginning from the date of the warrant until October 31, 2022. The outstanding balance of the Notes as of December 31, 2021 was \$605,000, exclusive of accrued interest.

In December 2021, the Company filed a registration statement on Form S-1 with the SEC to raise up to \$20 million through a common stock offering underwritten by Think Equity LLC, an investment bank based in New York. Concurrently, the Company submitted an application with the NASDAQ Stock Market LLC to list its common shares on that national exchange. While management believes these transactions could be completed in the first quarter of 2022, there is no guarantee that the Company will be able to complete the equity offering or have its shares listed on NASDAQ.

The process of developing pharmaceutical products is extremely costly, especially as such programs enter clinical trials, as our radiopharmaceutical candidate has. The Company will need to raise additional capital to continue these activities in 2022 and beyond. As of the end of 2021, the Company had approximately \$1.5 million in cash. Such funds are sufficient to cover the Company’s current operational burn through 2022; however, given the additional costs of conducting our clinical trials, such funds will likely be extinguished in the first two quarters of 2022. It is critical, therefore, for the Company to complete its currently anticipated registered, underwritten equity offering to maintain our clinical trials, or otherwise raise additional capital through equity or debt offerings. There is no guarantee that the Company will be successful in these efforts.

B. Management’s Discussion and Analysis of Financial Condition and Results of Operations

COVID-19

In March 2020, the World Health Organization declared COVID-19 a global pandemic and recommended containment and mitigation measures worldwide. Although our operations were not materially affected by the Covid outbreak, in the recent months, Covid has had direct impact on the commencement of our clinical trials. Due to Covid infections at one of our vendor labs, team members leading certain startup activities for our project were sent home and work could only be initiated upon their return, causing us to delay a key procedure, which was ultimately completed. General conditions around Covid have also created supply chain delays with certain of our manufacturers and distributors. Lastly, there remains a risk with the rise of Covid cases in the US could delay enrollment of patients into our clinical trials, interrupt treatment, or cause a patient to withdraw due to prolonged effects of infection. To mitigate these risks, we have worked with our vendors and suppliers to designate and train additional staff to support our project, and we have ordered sufficient supplies to support our entire Phase I trial. We are also securing secondary suppliers to ensure supply chain resilience. Additionally, we are working with our clinical trial site to screen more patients in order to have a sufficient volume of qualified patients waiting to enroll.

Results of Operations for the years ended December 31, 2021 and 2020

For the years ended December 31, 2021 and 2020, we recorded no revenue from continuing operations. Revenue from a management agreement with EPH and other Legacy Business operations have been reclassified in our Statement of Operations on our Consolidated Financial Statements as “discontinued operations.”

For the year ended December 31, 2021, we recorded a net loss from continuing operations of \$11,977,065, an increase of \$6,157,128 (105.8%) from our net loss from continuing operations of \$5,819,937 for the same period in 2020. Basic and diluted net loss per share was \$0.43 and \$0.89 for the years ended December 31, 2021 and 2020, respectively. The primary reasons for the increase in the net loss for 2021 over 2020 were an increase of \$7,917,761 in compensation and related expenses (mainly non-cash items as discussed below), as well as an increase in professional fees of \$1,542,985; offset slightly by a decrease of \$28,724 in general and administrative expenses.

Financial Condition, Liquidity and Capital Resources

For year ended December 31, 2021, cash increased by \$1,491,562 from \$8,304 as of December 31, 2020 to \$1,499,866 at the end of 2021. This increase was primarily the result of cash provided by financing activities of \$3,260,364, offset by cash used in operating activities of \$1,768,803.

Net cash used by operating activities was \$1,768,803 for the year ended December 31, 2021, which reflected our net loss during the period of \$11,977,065, non-cash adjustments of \$10,034,326, a net increase in operating liabilities of \$331,055, and a net increase in operating assets of \$157,118. The majority of non-cash adjustments consists of a \$7,826,779 stock-based compensation for the issuance of Series E-1 shares and the subsequent exchange of the Series E-1 shares into common stock, \$744,505 on the loss on conversion of bridge notes and accrued interest into common stock, and \$390,069 on the loss on conversion of debentures into common stock. Our net loss resulted largely from these non-cash items. Net cash used in investing activities during year ended December 31, 2021 consisted of \$0.

At December 31, 2021, our cash totaled \$1,499,866. Our cash is currently held at large U.S. banks.

Based on our current strategy and operating plan, at the end of 2020 we needed to raise additional capital to support operations through the coming year. This was accomplished during 2021; however, at the end of 2021 there was still substantial doubt about our ability to operate as a going concern. See “Note 2 – Basis of Presentation and Going Concern” in our consolidated financial statements.

As the Company enters its clinical trials, management expects expenses to increase materially. These expenses include dosing and monitoring of patients who participate in our clinical trials, manufacturing expenses, payment of fees to our CRO and other service providers, and other general overhead expenses including additional public company costs. We anticipate that we will be able to proceed with these plans if we are successful in raising additional funds through our planned underwritten equity offering. There is no guarantee, however, that we can complete this offering on terms suitable to the Company and its shareholders if at all.

Series B Financing. In January 2021, the Company closed a Series B Convertible Preferred Stock private placement (the “Series B Offering”) and issued a total of 2,500 shares at a price of \$1,000 per share, raising an aggregate amount of \$2.5 million, inclusive of \$156,000 in debt conversion. The Series B Offering, which commenced in 2020, was led by Checkmate Capital Group, LLC, a California based investment firm focused on biotechnology and other technology investments. The Company completed the offering primarily to advance its new business of drug development including funding the Company’s upcoming clinical trials for its drug candidate CycloSam, as well as for general working capital and overhead.

Warrant Conversion. In connection with this Series B Offering closing, we issued in 2021 a total of 6.27 million common stock warrants, which were originally exercisable prior to July 8, 2021 at an exercise price of \$0.35 per share, and later modified by our Board to expire on October 15, 2021 and be exercisable at \$0.25 per share. As of October 15, 2021, seven holders of the Series B warrants exercised those warrants and received a total of 1,871,431 common shares for total consideration to the Company of \$467,858.

Convertible Note Financing. In the fourth quarter of 2021, we entered into convertible note purchase agreements with eight accredited investors, pursuant to which we issued an aggregate of \$605,000 of convertible notes (the “Notes”). The Notes mature on December 31, 2023 and are convertible into shares of common stock of the Company in the event of future equity financing of \$5 million or greater, NASDAQ uplisting, or at the discretion of the noteholders, at a conversion price of \$0.20 per share. The obligations under the Notes are unsecured. The Company has agreed to pay simple interest at the rate of 6% per annum on the outstanding amount of the Notes until fully repaid or converted. In connection with the Notes offering, the Company issued 1,008,334 warrants to the noteholders, with each warrant convertible into one share of common stock at an exercise price of \$0.60 per share beginning from the date of the warrant until October 31, 2022. The outstanding balance of the Notes as of December 31, 2021 was \$605,000, exclusive of accrued interest.

Prior Bridge Note Financing. The Company issued a total of \$2,851,908 in Convertible Promissory Notes (the “Bridge Notes”) during 2017, 2018 and 2019. Proceeds from the Bridge Notes were used to for the Company’s Legacy Business. As of December 31, 2020, a total of \$1,965,030 plus \$964,525 in accrued interest on the Bridge Notes were converted into approximately 13.3 million shares of common stock. As of March 31, 2021, the remaining \$1,447,312 of principal and interest was converted into 6,578,702 shares of common stock, and no Bridge Notes currently remain outstanding.

Prior Series A Preferred Stock Financing. The Company raised \$600,000 in our Series A 6% Convertible Preferred Stock (the “Series A Preferred Stock”) from two separate accredited investors in November 2015 and January 2016, respectively. The Series A Preferred Stock bears a 6% dividend per annum, calculable and payable per quarter in cash or additional shares of common stock as determined in the Certificate of Designation. The Series A Preferred Stock was originally convertible at \$6.50 per share at the discretion of the holders and contains price protection provisions in the instance that we issue shares at a lower price, subject to certain exemptions. The price has been reset several times since the issuance of the Series A Preferred Stock. Most currently, as a result of the closing of the Series B preferred stock offering in January 2021, the conversion price was reset to \$0.16 per share. Series A Preferred Stock holders also received other rights and protections including piggy-back registration rights, rights of first refusal to invest in subsequent offerings, security over our assets (secondary to our debt holders), and certain negative covenant guaranties that we will not incur non-ordinary debt, enter into variable pricing security sales, redeem or repurchase stock or make distributions, and other similar warranties. The Series A Preferred Stock was redeemable on July 1, 2019 per a March 2019 modification and is currently in technical default. The Series A Preferred Stock has no voting rights until converted to common stock. The Series A Preferred Stockholders also received warrants in connection with their investment, all of which had expired in January 2021.

All promissory notes and shares in these offerings were sold pursuant to an exemption from the registration requirements of the Securities Exchange Commission under Regulation D to accredited or sophisticated investors who completed questionnaires confirming their status. Unless otherwise described in this Quarterly Report, reference to “restricted” common stock means that the shares have not been registered and are restricted from resale pursuant to Rule 144 of the Securities Act of 1933, as amended.

Cash and Working Capital

We have incurred negative cash flows from operations since inception. As of December 31, 2021, we had an accumulated deficit of \$29,281,674 and working capital of \$276,916.

Critical Accounting Policies

Our financial statements are prepared in conformity with U.S. generally accepted accounting principles (GAAP). Disclosures regarding our Critical Accounting Policies are provided in Note 3 – Summary of Significant Accounting Policies of the footnotes to our consolidated financial statements.

Off-Balance Sheet Arrangements

The Company did not engage in any “off-balance sheet arrangements” (as that term is defined in Item 303(a)(4)(ii) of Regulation S-K) as of December 31, 2021.

ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required for smaller reporting companies.

ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and the reports of our independent registered accounting firm required pursuant to this item are included in Item 15 of this report and are presented beginning on page F-1.

ITEM 9: CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A: CONTROLS AND PROCEDURES

In connection with the preparation of this Annual Report, management, under the supervision and with the participation of the Company’s Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the Company’s disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), as of the end of the period covered by this Annual Report. Disclosure controls and procedures are designed to ensure that information required to be disclosed in 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 and that such information is accumulated and communicated to management, including the Chief Executive Officer, General Counsel and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Management concluded that, as of December 31, 2021, the Company’s disclosure controls and procedure were effective based on the criteria in *Internal Control – Integrated Framework* issued by the COSO, version 2013.

Management’s Annual Report on Internal Control Over Financial Reporting

The Company’s management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Securities Exchange Act Rule 13a-15(f). The Company carried out an evaluation under the supervision and with the participation of the Company’s management, including the Company’s Chief Executive Officer and Chief Financial Officer, of the effectiveness of the Company’s internal control over financial reporting. The Company’s management used the framework in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations (COSO) to perform this evaluation. Based on that evaluation, the Company’s management concluded that the Company’s internal control over financial reporting was effective as of December 31, 2021. The Company’s management determined that previously identified material weaknesses (as described below) had been remediated as of December 31, 2021.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company’s annual or interim financial statements will not be prevented or detected on a timely basis.

During 2020, the Company did not have a full time CFO or adequate accounting function personnel to support the operations of the Company. As a result, management noted:

- Due to the size of the Company and available resources, in 2020 there were limited personnel to assist with the accounting and financial reporting function, which resulted in a lack of segregation of duties.
- The Company has experienced significant turnover in the role that oversees the day-to-day accounting and financial reporting functions, which increases the risk of a material misstatement in the financial statements.
- The Company prior to the end of 2021 lacked knowledge and expertise with accounting for stock-based compensation arrangements.

During 2021, the Company engaged a consulting firm to assist with the back-office accounting, evaluation of internal controls, and updating of documentation. Additionally, the Company hired a part time CFO with extensive public accounting background to support the business and apply knowledge and expertise to the daily operations of the Company. As of December 31, 2021, the Company had implemented an effective segregation of duties in the accounting and financial reporting function by the use of the consulting firm and part time CFO. Additionally, the consulting firm and part time CFO reduces the risk of a material misstatement due to the experience of the firm and its associates working on the Company. Finally, with the addition of the part time CFO, the Company now has the knowledge and expertise for technical accounting matters including stock-based compensation arrangements. This part time CFO has agreed to assume a full time CFO position upon the completion of the Company's listing on NASDAQ. If such event occurs, the Company believes it will further strengthen its accounting, financial reporting and internal controls.

While the Company is still in the process of documenting risks and controls related to the Company and its operations, the addition of the CFO will allow management to be more diligent in its efforts to continue to improve the reporting processes of the Company, including the addition of accounting resources and the continued development of proper accounting policies and procedures.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. We were not required to have, nor have we, engaged our independent registered public accounting firm to perform an audit of internal control over financial reporting pursuant to the rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

Changes in Internal Control Over Financial Reporting

Except for controls implemented to address the deficiencies described above, there have been no other changes in our internal control over financial reporting in connection with the evaluation required by Rule 13a-15(d) of the Exchange Act that occurred during 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B: OTHER INFORMATION

There was no other information required to be disclosed in the fourth quarter of 2021 that was not filed by the Company in a Current Report on Form 8-K.

PART III

ITEM 10: DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Identification of Directors and Executive Officers

The following table sets forth the names of all of our current directors and executive officers. The Directors will serve until the next annual meeting of the shareholders or until their successors are elected or appointed and qualified, or their prior resignation or termination.

Name	Positions Held	Age	Date of Election or Designation	Date of Termination or Resignation
C. Richard Piazza	Executive Chairman	73	November 2020	*
Douglas R. Baum	Chief Executive Officer & Director	54	January 2020 (1)	*
Christopher Nelson	General Counsel & Director	52	July 2014	*
Adam King	Interim Chief Financial Officer	36	December 2021	*
Joel Mayersohn	Director	63	July 2014	*
Charles J. Link, Jr.	Director	62	February 2021	*
Adriann Sax	Director	60	January 2022	*

(1) Mr. Baum was appointed director in January 2020 and CEO in November 2020.

Business Experience

C. Richard Piazza, Ph.D. – Executive Chairman. Mr. Piazza was appointed as a member and the Executive Chairman of the board of the Company in November 2020. Mr. Piazza has also served since 2017 as President and CEO of IGL Pharma Inc., the licensor of CycloSam®, and a consultant to IsoTherapeutics Group, LLC, the inventors of the technology. Mr. Piazza also currently serves on the board of directors of NovaScan LLC, a privately-held cancer detection and diagnostics company. Prior to his work with IGL Pharma, from 2014 to 2016, he was CEO of SynVivo, Inc., a cancer diagnostics company. Mr. Piazza has more than 48 years of healthcare experience in both medical devices and pharmaceutical/biotech and has led several technology companies to market success including numerous FDA approvals in both sectors. Previously, he served in general management positions in both public and private international companies including Ohmeda, Smith & Nephew Pharmaceuticals, Marquest and VitaGen (world's first bioartificial liver). Over his career, he has provided advisory services to some of world's leading institutions including MD Anderson Cancer Center, Baylor College of Medicine, University of California San Diego, University of Chicago and Kings College Hospital (London). In 2019, he co-founded QSAM Therapeutics, Inc. with Douglas Baum, our CEO. Mr. Piazza obtained a BS in Economics and a BS in Speech Pathology from the State University of New York and MA & PhD in Economics from the University of Buffalo and Leeds University.

We believe Mr. Piazza is qualified to serve on our board of directors due to his significant experience in the pharmaceutical and biotech industry, and his experience

serving of the boards and in senior management positions in several publicly traded companies.

Douglas R. Baum – Chief Executive Officer & Director. Mr. Baum was appointed to the board of the Company in January 2020 and to the position of CEO in November 2020. He brings to the Company over 30 years of experience in the bioscience and biotech industries, including development, FDA/EMA approval and commercialization of multiple drugs and medical devices. Over his long senior executive tenure, he has overseen 15 product approvals through the FDA and EMA and raised over \$85 million in capital to fund breakthrough technologies. Between 2017 and 2020, Mr. Baum consulted with multiple medical schools, biotech and pharmaceutical companies; and between 2012 and 2017, he served as President, Chief Executive Officer and Director of Xeris Pharmaceuticals Inc. (currently, NASDAQ: XERS). Previously, he served as Executive Vice President and Chief Operating Officer of Macular Inc., and other executive level positions with clinical trial research firms including SCIREX and Premier Research Group, Inc. He holds a Master's of Science in Technology Commercialization and BBA in International Business and Marketing from the University of Texas.

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Mr. Baum's extensive experience in the biotech industry as a senior level executive and vast exposure to the lifecycle of healthcare products from trials to commercialization makes him qualified to serve on our board of directors.

Christopher Nelson – General Counsel & Director. Mr. Nelson has been General Counsel and director of the Company since 2015, and was also its President from 2016 to November 2020. In these roles, he has overseen corporate and governance legal matters, finance and business development for the Company. He has also served since 2016 as Managing Director of GreenBlock Capital LLC in Palm Beach, Florida, a boutique mergers and acquisitions advisory firm specializing in bio-technology, ag-technology and similar sector business combination transactions; and since 2019 as General Counsel for Earth Property Holdings, LLC, a private equity-backed company engaged in soil health and compost manufacturing in Texas and Florida. Mr. Nelson has practiced law in Florida for over 26 years, and during that time has represented many start-up, early stage and established businesses seeking financing, acquisitions and general growth management counseling. Early in his career, Mr. Nelson was an associate with Greenberg Traurig PA, and with Akerman Senterfitt PA, both in Miami, Florida. At both firms he served in their corporate and securities practice, representing NYSE and NASDAQ companies. Mr. Nelson received a BA from Princeton University, and JD from University of Miami School of Law, and is a member of the Florida Bar.

Mr. Nelson's extensive experience representing public companies in capital markets finance, mergers and acquisitions, and general corporate and governance matters, makes him qualified to serve on our board of directors.

Adam King, CPA – Interim Chief Financial Officer. Mr. King currently serves as Interim CFO for the Company, a position he has held since December 6, 2021. Mr. King is the founder and CEO of King Consulting Group, where he provides a range of financial and reporting services for clients that include Vice President of Finance for large private equity-backed international companies to CFO of small start-ups. Before founding King Consulting Group in January 2021, Mr. King was the CFO for Netsertive, a venture-backed digital marketing company in Research Triangle Park, North Carolina. From 2016 to 2018, he was the Office Managing Audit Director for BDO's Greenville, SC office, in addition to Audit Director in Raleigh, NC, and Boston. While at BDO, Mr. King worked with various clients, from Tech and Life Science start-ups to large billion-dollar publicly traded companies. Before his time at BDO, he served as the Director of Revenue Assurance and Internal Controls at Bandwidth.com and an Audit Manager at Ernst & Young. Mr. King holds a Bachelor of Science in Accounting from Elon University and is a CPA in Raleigh, NC. In October 2019, Mr. King and his wife filed for personal bankruptcy under chapter 13 of the United States Bankruptcy Code due to excessive medical expenses incurred by the family in connection with their child's medical diagnosis and treatment. The final payment under their bankruptcy plan is scheduled to end in September 2024.

Joel Mayersohn – Director. Mr. Mayersohn has been a director of the Company since 2015. Mr. Mayersohn is a Partner in the Ft. Lauderdale, FL office of Dickinson Wright PLLC since 2016, where he specializes in corporate, securities and business law. Over the last 30 years, he has advised a diversified client base in private placements, public offerings, mergers and acquisitions, financing transactions and general securities law matters. He also has experience in venture capital, bridge loans and pipe financings. He is a member of the Florida and New York Bars. Mr. Mayersohn received a Bachelor of Arts and Juris Doctorate from State University of New York at Buffalo.

Mr. Mayersohn's almost 40 years of experience of advising public and private companies in all areas of corporate and securities law, including representing technology and healthcare companies make him qualified to serve on our board of directors.

Charles J. Link, Jr. – Director. Dr. Link was appointed to the Board in February 2021, and brings decades of biotech and drug development experience to the Company. He currently serves on the executive committee of the Board of Directors at NovaScan Inc., a clinical-stage company focused on cancer detection. Dr. Link also serves on the Board of Directors for Viewpoint Molecular Targeting, a clinical stage company developing alpha-particle radiopharmaceuticals; and is the founder and Executive Director of biotech startup Synchronum. He is also a founder of biotech startup ChainLink Pharma. Previously, Dr. Link was the CEO, CSO, Chairman, and founder of NewLink Genetics, a NASDAQ-listed immunotherapy company focused on developing novel immuno-oncology product candidates, from 1999 until his retirement in 2019. During his tenure at NewLink, Dr. Link led a series of collaborative transactions totaling hundreds of millions of dollars with Merck, Roche and the United States government. He also oversaw the collaboration with Merck to develop EVERBO, the first Ebola vaccine to receive FDA approval. Prior to founding NewLink Genetics, Dr. Link was an attending physician at the National Cancer Institute. He has authored more than 100 peer-reviewed papers. Dr. Link received an M.D. from Stanford University, and he attended the U.S. Air Force Academy.

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Dr. Link's experience as CEO and Chairman of a NASDAQ-listed biotechnology company where he led several multi-party drug development programs and successfully raised significant funding in the capital markets, as well as his service as an oncology physician and senior government researcher, qualifies him to serve on our board of directors.

Adriann Sax – Director. Ms. Sax was appointed Director in January 2022. She has a distinguished 30+ year career in biotech and life sciences, serving in leadership, operational and business development roles with a focus on oncology for both Fortune 100 and start-up companies. Since May 2020, she has served as CEO and co-founder of Vetigenics LLC, an animal health biotech company, where she has secured partnerships with Merck, obtained federal grants, and was named 2021 Start-up of the Year by the Penn Center for Innovation at the University of Pennsylvania. From 2019 to 2020, she served as CEO and Director of Orsenix LLC, a clinical staged oncology biotech, and from 2014 through 2019, as Entrepreneur in Residence at Fortress Biotech. Previously she was EVP and Chief Commercial Officer at Kadmon Corp., a division of Sanofi Company, and before that served in various leadership capacities at large pharmaceutical companies, notably Vice President at Bristol Myers Squibb, Executive Director at Merck & Co., and Executive Vice President in charge of Business Development and Strategic Planning at King Pharmaceuticals, leading to its \$6.5 Billion acquisition by Pfizer. Ms. Sax holds an MBA from the Keller Graduate School and a BS in Animal Science from the University of Delaware. She is an active advisor and board member for many industry associations, academic institutions, and nonpublic company boards.

Ms. Sax's extensive experience in biotech and life sciences, serving in leadership, operational, business development, and board of director roles for both Fortune 100 and start-up companies qualifies him to serve on our board of directors.

Other Key Employees and Advisors

Namrata Chand – VP Operations. Age 41. Ms. Chand has held the position of VP - Operations with the Company since November 2020. Ms. Chand brings 20 years of experience and a diverse foundation in administration, marketing, operations and business development within non-profit and for-profit sectors. Initially focusing her career in large organizations, she held leadership positions in marketing and corporate relations at Nestle, Beam Suntory, Aetna and BFAS, a leading national animal welfare organization, to build brand awareness, improve operational efficiency and drive overall growth. Ms. Chand later entered the life science space and joined La Jolla Capital

Partners in 2011 where she assisted small to midsize healthcare companies through various stages of development with special emphasis on capital formation, operations, supply chain, clinical trials, marketing and business development. Most recently, Ms. Chand led Investor Relations and Business Development for Ryca International, an innovative dental product company that entered into a joint venture with a leading global medtech company. In addition to leading operations at the Company, Ms. Chand serves on the Advisory Board of a number of early-stage biotech companies.

Barry Sugarman – Scientific Advisor. Age 63. Mr. Sugarman has held the position of senior regulatory and scientific advisor with the Company since November 2020. Mr. Sugarman has over 30 years of experience spanning public and private companies in the pharmaceutical, medical device, dietary supplement and cosmetic industries. Mr. Sugarman has considerable direct experience in pharmaceutical product development, manufacturing, clinical trials, regulatory affairs, FDA and government relations, marketing, and distribution; as well as Good Manufacturing Practices (GMP's), Good Clinical Practices (GCP's), Good Laboratory Practices (GLP's), and International Conference for Harmonization (ICH) requirements. He is an author and co-author of numerous FDA filings and approvals including Investigational New Drug Applications, New Drug Applications, Abbreviated New Drug Applications, and Medical Device Applications 510(k)'s. Mr. Sugarman is a member of the Regulatory Affairs Professional Society, American Association of Pharmaceutical Scientists, Association of Clinical Research Professionals, and the National Association of Corporate Directors. He is a co-author of "Prompt, Accurate Diagnosis of Pediatric Cancer and Leukemia for Pediatricians, Orthopedists, and Family Practitioners" (2007).

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Richard "Keith" Frank – Scientific Advisor. Age 65. Dr. Frank has served as scientific advisor to the Company since April 2020. Since 2006, he has served as CEO, President and co-founder of IsoTherapeutics LLC, a radiopharmaceutical R&D and contract manufacturing company that invented CycloSam[®] and provides services for both large and small biotechnology companies. He also serves as Chairman of IGL Pharma, Inc., the Company's licensor of CycloSam[®]. Prior to these positions, Dr. Frank spent over 20 years in numerous senior scientific positions at Dow Chemical Company. At Dow, he was a collaborator in the development of bone-seeking radiopharmaceuticals Quadramet (Sm-153-EDTMP) and STR (Ho-166-DOTMP). Additionally, Dr. Frank was the lead inventor of Iotrex[™] for use in the GliSite[®] Radiation Therapy System. He also initiated and was the technical leader of Dow's ChelaMedSM Radiopharmaceutical Services offering.

Jaime "Jim" Simon – Scientific Advisor. Age 68. Dr. Simon has served as scientific advisor to the Company since April 2020. Since 2006, he has served as Vice President and Chief Science Officer, and co-founder of IsoTherapeutics LLC, a radiopharmaceutical R&D and contract manufacturing company that invented CycloSam[®] and provides services for both large and small biotechnology companies. Prior to co-founding IsoTherapeutics, Dr. Simon spent over 25 years as a senior scientist at Dow Chemical Company where his initial proposals led to the creation of Dow's radiopharmaceutical group. At Dow, Dr. Simon was the lead inventor for all bone agent patents including Sm-153-EDTMP and Ho-166-DOTMP. Dr. Simon has been involved in numerous FDA submissions for clinical trials, and has coordinated the radioisotope activities at the University of Missouri Research Reactor (isotope production), the University of Missouri Veterinary School (dog studies), and The Harry S. Truman Veterans Administration Hospital (human clinical studies).

Family Relationships

There are no family relationships between any of the Company's directors or executive officers or any person nominated or chosen by the Company to become a director or executive officer.

Directorships

None of our directors is a director of a company or has been in the last five years the director of any other reporting company or registered investment company.

Involvement in Certain Legal Proceedings

Except as disclosed under Mr. King's biographical information pertaining to Mr. King's and his wife's filing of personal bankruptcy under the United States Bankruptcy Code in 2019, during the past 10 years, none of our present or former directors, executive officers or persons nominated to become directors or executive officers or control person of our Company:

- has filed a petition under federal bankruptcy laws or any state insolvency laws, nor had a receiver, fiscal agent or similar officer appointed by a court for the business or property of such person, or any partnership in which he was a general partner at or within two years before the time of such filing, or any corporation or business association of which he was an executive officer at or within two years before the time of such filing;
- was convicted in a criminal proceeding or named subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- was the subject of any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining him or her from or otherwise limiting the following activities:

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Acting as a futures commission merchant, introducing broker, commodity trading advisor, commodity pool operator, floor broker, leverage transaction merchant, any other person regulated by the Commodity Futures Trading Commission, or an associated person of any of the foregoing, or as an investment adviser, underwriter, broker or dealer in securities, or as an affiliated person, director or employee of any investment company, bank, savings and loan association or insurance company, or engaging in or continuing any conduct or practice in connection with such activity;

Engaging in any type of business practice; or

Engaging in any activity in connection with the purchase or sale of any security or commodity or in connection with any violation of Federal or State securities laws or Federal commodities laws;

- was the subject of any order, judgment or decree, not subsequently reversed, suspended or vacated, of any Federal or State authority barring, suspending or otherwise limiting for more than 60 days the right of such person to engage in any activity described in the preceding bullet point, or to be associated with persons engaged in any such activity;
- was found by a court of competent jurisdiction in a civil action or by the SEC to have violated any Federal or State securities law, and the judgment in such civil action or finding by the SEC has not been subsequently reversed, suspended, or vacated;
- was found by a court of competent jurisdiction in a civil action or by the Commodity Futures Trading Commission to have violated any Federal commodities law, and the judgment in such civil action or finding by the Commodity Futures Trading Commission has not been subsequently reversed, suspended or vacated;
- was the subject of, or a party to, any Federal or State judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of:

any Federal or State securities or commodities law or regulation; or

any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order; or

any law or regulation prohibiting mail or wire fraud in connection with any business activity; or

- was the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, or any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Promoters and Control Person

To the best of our management's knowledge, no person who may be deemed to have been a promoter or founder of our Company was the subject of any of the legal proceedings listed under the heading "Involvement in Certain Legal Proceedings" above.

Section 16(a) Beneficial Ownership Reporting Compliance

Our shares of common stock are registered under the Exchange Act, and therefore the officers, directors and holders of more than 10% of our outstanding shares are subject to the provisions of Section 16(a), which requires them to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and our other equity securities. Officers, directors and greater than 10% beneficial owners are required by SEC regulations to furnish us with copies of all Section 16(a) reports they file. Based solely upon review of the copies of such forms furnished to us during the fiscal year ended December 31, 2021, we have determined that the following officers and directors failed to timely file reports under Section 16. All directors and officers have filed Form 5s as of February 15, 2022 reporting all missed transactions.

- Mr. Piazza failed to file a total of four reports, one of which was in connection with his appointment as director of the Company, and three others involving three unique transactions with respect to the grant of stock options, issuance of Series E-1 preferred shares and exchange of those shares into common stock;
- Mr. Baum failed to file a total of five reports, one of which was in connection with his appointment as director of the Company, and four others involving four unique transactions with respect to the grant of stock options, issuance of Series E-1 preferred shares and exchange of those shares into common stock;
- Dr. Link failed to file a total of four reports, one of which was in connection with his appointment as director of the Company, and three others involving three unique transactions with respect to the grant of stock options, issuance of Series E-1 preferred shares and exchange of those shares into common stock;
- Mr. Nelson failed to file a total of three reports involving three unique transactions with respect to the grant of stock options, issuance of Series E-1 preferred shares and exchange of those shares into common stock;
- Mr. Mayersohn failed to file a total of two reports involving two unique transactions with respect to the grant of stock options and restricted common shares.

All transactions were timely disclosed by the Company on Forms 8-K with respect to officer/director appointments, and issuances of preferred shares and exchange of those shares into common stock; and also with respect to option grants, which were disclosed by the Company in quarterly or annual reports filed for the period when such transactions occurred.

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Code of Ethics

On January 13, 2022, we adopted a revised code of ethics for our principal executive and financial officers, directors and employees. Our code of ethics, as amended, was posted to our web site on January 13, 2022, updating a prior version that was originally posted as of November 2015. On January 13, 2022, we also adopted a Policy on Insider Trading.

Corporate Governance

Audit Committee. Our Audit Committee is currently comprised of its Chairman, Joel Mayersohn, and Adriann Sax. We have determined that Mr. Mayersohn is not independent under Rule 10A-3 of the Exchange Act; however, pursuant to OTCQB rules, the Company is not currently required to have an audit committee. Ms. Sax qualifies as an independent director with financial experience to serve on the Audit Committee. We are in the process of appointing one additional independent director who will be qualified as a "financial expert" as required under NASDAQ rules to serve as the Audit Committee Chair, and intend on appointing a third independent director to the Audit Committee. The Company may not be approved for NASDAQ listing and may not appoint additional directors if the NASDAQ listing is not approved. Upon such new appointment if required, Mr. Mayersohn has agreed to resign from the Audit Committee.

On January 13, 2022, our Board adopted a new formal charter for the Audit Committee pursuant to NASDAQ rules. Under this new charter, the Audit Committee is responsible for assisting with the Board's oversight of: (1) the quality and integrity of the Company's financial statements and related disclosure; (2) the Company's compliance with legal and regulatory requirements relating to financial and accounting matters; (3) the independent auditor's qualifications, performance and independence; (4) the integrity of the internal controls at the Company; and (5) the administration of the Company's conflicts of interest and related party transactions policies and procedures. The Committee is also responsible for providing an avenue for effective communication among the Audit Committee, the independent auditor, management and the Board.

Under the new charter, the Audit Committee shall be comprised of three or more directors as determined by the Board, each of whom shall be an "independent director" for purposes of Audit Committee membership in accordance with the rules of NASDAQ or any successor national securities exchange on which the Company's stock is listed, and meet the criteria for independence set forth in Rule 10A-3(b)(1) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") (subject to the exemptions provided in Rule 10A-3(c) under the Exchange Act), and any other applicable laws, rules and regulations. No member of the Audit Committee shall have participated in the preparation of the financial statements of the Company or any subsidiary during the prior three-year period. Each member of the Audit Committee shall be free from any relationship (including disallowed compensatory arrangements) that, in the opinion of the Board, would interfere with the exercise of his or her independent judgment as a member of the Audit Committee. Each member of the Audit Committee shall be able to read and understand fundamental financial statements, including a company's balance sheet, income statement and cash flow statement, and have a working familiarity with basic finance and accounting practices, and at least one member of the Audit Committee shall be a "financial expert" in compliance with the criteria established by the SEC.

Compensation Committee. Our Compensation Committee is currently comprised of Douglas Baum, Joel Mayersohn, and Charles J. Link Jr., of whom only Dr. Link is an independent director under the board independence standards set forth by NASDAQ. The Compensation Committee formally instituted its governance procedures in 2017, and actively oversees all executive-level salary and compensation matters for the Company.

On January 13, 2022, our Board adopted a new formal charter for the Compensation Committee pursuant to NASDAQ rules and regulations. As defined in its Charter, the purpose of the Compensation Committee is to assist the Board in carrying out its responsibilities relating to compensation and benefits for the Company's directors, officers and employees. The Compensation Committee is also responsible for performing the duties relating to executive compensation provided for in the rules of the national securities exchange on which the Company's stock may be listed. The Committee is also responsible for preparing any compensation committee reports required in the Company's annual report and proxy materials by the rules of the SEC. The Compensation Committee also oversees the performance of the Audit Committee.

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Under the new Charter, the Compensation Committee shall consist of no fewer than two directors. Each member of the Compensation Committee shall be an “independent director” as that term is defined in the applicable rules of NASDAQ, or any successor national securities exchange on which the Company’s stock is listed. Each member of the Compensation Committee shall be free from any relationship (including disallowed compensatory arrangements) that in the opinion of the Board would interfere with the exercise of his or her independent judgment as a member of the Committee. All of the members of the Committee must qualify as “non-employee directors” for the purposes of Rule 16b-3 under the Exchange Act.

Nominating and Corporate Governance Committee. We have not yet established a Nominating and Corporate Governance Committee (“Nominating Committee”). Up to this time, we believe that we have been able to effectively manage the issues normally considered by a Nominating Committee through the Board of Directors. If the Company is approved for listing on NASDAQ, the Company will constitute its Nominating Committee. The Company may not be approved for NASDAQ listing and may not appoint additional directors if the NASDAQ listing is not approved.

On January 13, 2022, our Board adopted a new formal charter for the Nominating and Corporate Governance Committee pursuant to NASDAQ rules. The purpose of the Nominating Committee is to carry out the responsibilities delegated by the board of directors relating to the Company’s director nominations process, developing and maintaining the Company’s corporate governance policies and any related matters required by the federal securities laws. The Nominating Committee shall consist of two or more directors. Each member of the Committee shall be independent in accordance with the rules of NASDAQ and SEC rules and regulations.

ITEM 11: EXECUTIVE COMPENSATION

The following table sets forth information regarding compensation earned in or with respect to our fiscal year 2021 and 2020 for the following persons (“Names Executive Officers”):

- (i) our principal executive officer, or other individual serving in a similar capacity during the fiscal year 2021 and 2020;
- (ii) our two most highly compensated executive officers other than our principal executive officers who were serving as executive officers at December 31, 2021, and 2020; and
- (iii) up to two additional individuals for whom disclosure would have been required but for the fact that the individual was not serving as an executive officer at December 31, 2021.

Summary Executive Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation	All Other Compensation	Total Earnings
		(\$) (a)	(\$) (b)	(\$) (c)	(\$) (d)	(\$) (e)	(\$) (f)	(\$) (g)	(\$) (h)
C. Richard Piazza, Executive Chairman (1)	2021	\$ 127,083		\$ 2,082,500	\$ 41,250				\$ 2,250,833
	2020	-							-
Douglas Baum, CEO and Director (2)	2021	\$ 137,500		\$ 2,082,500	\$ 41,250				\$ 2,261,250
	2020	-			100				100
Christopher Nelson, General Counsel (former President) (3)	2021	\$ 108,333		\$ 595,000	\$ 37,950				\$ 741,283
	2020	107,895	50,000	43,194				11,743	212,832
Adam King, CFO (4)	2021	-	-	-	-	-	-	10,820	10,820
	2020	-	-	-	-	-	-	-	-

- (a) Salaries include those amounts paid and accrued as an expense on the books of the Company.
- (c)(d) Stock and Option Awards are calculated based on the face value of awards as of the date of grant.
- (g) Other Compensation is comprised of healthcare costs or consulting fees in the case of Mr. King.

- (1) Mr. Piazza signed his employment agreement with the Company on November 1, 2020; however, per understanding of the parties, no salary or other compensation accrued under that agreement until after the completion of the Company’s Series B offering in January 2021. Further, Mr. Piazza received only partial salary during all of 2021, which per an agreement of the parties did not start accruing unpaid salary until December 1, 2021, when his employment agreement was amended and restated. Included in the table are 2,975 shares of Series E-1 Preferred Stock issued to Mr. Piazza on December 30, 2020, which were exchanged into 10,093,800 shares of common stock on December 6, 2021 per the terms of an Exchange Agreement and Plan of Reorganization, and which equity based compensation comprises a substantial portion of his Total Earnings in 2021.
- (2) Mr. Baum signed his employment agreement with the Company on November 1, 2020; however, per understanding of the parties, no salary or other compensation accrued under that agreement until after the completion of the Company’s Series B offering in January 2021. Further, Mr. Baum received only partial salary during all of 2021, which per an agreement of the parties did not start accruing unpaid salary until December 1, 2021, when his employment agreement was amended and restated. Included in the table are 2,975 shares of Series E-1 Preferred Stock issued to Mr. Baum on December 30, 2020, which were exchanged into 10,093,800 shares of common stock on December 6, 2021 per the terms of an Exchange Agreement and Plan of Reorganization, and which equity based compensation comprises a substantial portion of his Total Earnings in 2021.

- (3) In 2020, Mr. Nelson received \$43,194 of his annual salary paid in 196,336 shares of common stock, and his deferred bonus of \$50,000 paid in 227,273 shares of common stock. Mr. Nelson also waived \$13,911 of compensation due to him in 2020. Mr. Nelson received only partial salary during all of 2021, which per an agreement of the parties did not start accruing unpaid salary until December 1, 2021, when his employment agreement was amended and restated. Included in the table are 850 shares of Series E-1 Preferred Stock issued to Mr. Nelson on December 30, 2020, which were exchanged into 2,883,943 shares of common stock on December 6, 2021 per the terms of an Exchange Agreement and Plan of Reorganization, and which equity based compensation comprises a substantial portion of his Total Earnings in 2021.
- (4) Mr. King was appointed to the position of interim CFO in December 2021, and was compensated as an independent contractor during 2021.

Executive Employment Agreements

C. Richard Piazza – Executive Chairman. Mr. Piazza signed his employment agreement with the Company on November 1, 2020, with an effective date of November

6, 2020. This agreement was amended and restated on December 6, 2021. The term is three years, with extensions at the agreement of the parties. His base salary is \$400,000 per year, however, he is currently receiving a partial salary of \$112,500 until the Company's next financing is completed. Under the amended agreement, Mr. Piazza is entitled to receive regular company benefits, including annual bonuses and salary increases, participation in management incentive plans involving cash or stock bonuses ranging from 25% and 125% of base salary, vacations, sick leave and PTO. Mr. Piazza is also entitled to receive a transaction bonus in the instance any of the Company's assets are sold or sublicensed or if the Company or its subsidiary is acquired, equal to 1.75% of the consideration received by the Company. If he is terminated for cause, as defined in the agreement, or he leaves the employment of the Company on his own volition, Mr. Piazza shall receive salary and benefits that have accrued up to the date of termination. If he is terminated without cause or following a material change, as defined in the agreement, Mr. Piazza will receive salary through the date of termination plus a pro-rated portion of bonus that would be earned during the full year when the termination became effective (or a lump sum of 50% of the full target bonus), all stock options shall vest immediately, and base salary and healthcare benefits will continue for 24 months. Mr. Piazza also agreed to a 12 month non-compete / non-solicitation, and signed a separate Proprietary Information and Inventions Agreement with his employment agreement which assigns to the Company any intellectual property developed by him during his employment.

Douglas Baum, CEO. Mr. Baum signed his employment agreement with the Company on November 1, 2020, with an effective date of November 6, 2020. This agreement was amended and restated on December 6, 2021. The term is three years, with extensions at the agreement of the parties. His base salary is \$400,000 per year, however, he is currently receiving partial salary of \$125,000 until the Company's next financing is completed. Under the amended agreement, Mr. Baum is entitled to receive regular company benefits, including annual bonuses and salary increases, participation in management incentive plans involving cash or stock bonuses ranging from 25% and 125% of base salary, vacations, sick leave and PTO. Mr. Baum is also entitled to receive a transaction bonus in the instance any of the Company's assets are sold or sublicensed or if the Company or its subsidiary is acquired, equal to 1.75% of the consideration received by the Company. If he is terminated for cause, as defined in the agreement, or he leaves the employment of the Company on his own volition, Mr. Baum shall receive salary and benefits that have accrued up to the date of termination. If he is terminated without cause or following a material change, as defined in the agreement, Mr. Baum will receive salary through the date of termination plus a pro-rated portion of bonus that would be earned during the full year when the termination became effective (or a lump sum of 50% of the full target bonus), all stock options shall vest immediately and salary and healthcare benefits will continue for 24 months. Mr. Baum also agreed to a 12 month non-compete / non-solicitation, and signed a separate Proprietary Information and Inventions Agreement with his employment agreement which assigns to the Company any intellectual property developed by him during his employment.

Christopher Nelson, General Counsel. Mr. Nelson initially signed his employment agreement in 2017, which renewed on a year-to-year basis on April 1 each year. On December 6, 2021, Mr. Nelson signed an amended and restated employment agreement with the Company providing for a term of three years, with extensions at the agreement of the parties. His base salary is \$300,000 per year; however, he is currently receiving partial salary of \$100,000 until the Company's next financing is completed. Under the amended agreement, Mr. Nelson is entitled to receive regular company benefits, including annual bonuses and salary increases, vacations, sick leave and PTO. Mr. Nelson is also entitled to receive a transaction bonus in the instance any of the Company's assets are sold or sublicensed or if the Company or its subsidiary is acquired, equal to 0.5% of the consideration received by the Company. If he is terminated for cause, as defined in the agreement, or he leaves the employment of the Company on his own volition, Mr. Nelson shall receive salary and benefits that have accrued up to the date of termination. If he is terminated without cause or following a material change, as defined in the agreement, Mr. Nelson will receive salary through the date of termination plus a pro-rated portion of bonus that would be earned during the full year when the termination became effective (or a lump sum of 50% of the full target bonus), all stock options shall vest immediately and salary and healthcare benefits will continue for 18 months. Mr. Nelson also agreed to a 12 month non-compete / non-solicitation, and signed a separate Proprietary Information and Inventions Agreement with his employment agreement which assigns to the Company any intellectual property developed by him during his employment.

Proprietary Information and Inventions Agreement

All officers, directors (except Joel Mayersohn), and other key employees and consultants have signed a Proprietary Information and Invention Agreement ("PIIA") with the Company that provides in material part the following:

- All inventions and discoveries made by them during their employment or using Company resources shall be assigned to the Company.
- They will not interfere in customer relationships during the term of employment plus 12 months after termination for any reason.
- They will not solicit other employees of the Company during the term of employment plus 12 months after termination for any reason.
- They will not compete with the business of the Company during the term of employment plus 12 months after termination for any reason.

Outstanding Option and Stock Awards

The following table presents information concerning unexercised options and unvested restricted stock awards for the named executive officer outstanding as of December 31, 2021.

Outstanding Option and Stock Awards

Name (a)	Option Awards					Stock Awards				
	Number of Securities Underlying Unexercised Options (#) (b)	Number of Securities Underlying Unexercised Options (#) (c)	Equity Incentive Plan Awards Number of Securities Underlying Unexercised Options (#) (d)	Option Exercise Price (\$) (e)	Option Expiration Date (f)	Number of Shares or Units of Stock That Have Not Vested (#) (g)	Market Value of Shares or Units of Stock That Have Not Vested (\$) (h)	Equity Incentive Plan Awards: Number of Unearned Units or Rights That Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$) (j)	
C. Richard Piazza (1) Executive Chairman	-	125,000	-	-	-	-	-	-	-	
Douglas Baum (2) CEO and Director	8,000	125,000	-	\$ 0.50	1/14/2025	-	-	-	-	
Christopher Nelson (3) General Counsel	10,200	-	-	\$ 0.50	7/30/24	-	-	-	-	
	2,400	115,000	-	\$ 0.50	11/17/25	-	-	-	-	
			-	\$ 0.36	8/24/31					

- (1) In December 2020, Mr. Piazza received a grant of 2,975 shares of Series E-1 Preferred Stock. All of these shares vested on July 1, 2021, and were subsequently exchanged into 10,093,800 shares of common stock on December 6, 2021 per the terms of an Exchange Agreement and Plan of Reorganization.
- (2) In December 2020, Mr. Baum received a grant of 2,975 shares of Series E-1 Preferred Stock. All of these shares vested on July 1, 2021, and were subsequently exchanged into 10,093,800 shares of common stock on December 6, 2021 per the terms of an Exchange Agreement and Plan of Reorganization.
- (3) In December 2020, Mr. Nelson received a grant of 850 shares of Series E-1 Preferred Stock. Half of these shares vested on July 1, 2021, and the balance on December 31, 2021. All Mr. Nelson's Series E-1 shares were subsequently exchanged into 2,883,943 shares of common stock on December 6, 2021 per the terms of an Exchange Agreement and Plan of Reorganization

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Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

Plan Category	Number of Securities to be issued upon exercise of outstanding options, stock appreciation rights and common stock awards*	Weighted-average exercise price of outstanding options, stock appreciation rights and common stock awards	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 security holders	1,000,000	\$ 0.43	None
Equity compensation plans not approved by security holders	112,619	\$ 3.67	None
Total	1,112,619		None

* Information provided as of December 31, 2021. In January 2022, the Board approved an increase in the number of shares eligible to be issued under the 2016 Omnibus Equity Plan, as amended, from 1 million shares to 8 million shares.

Director Compensation

On January 21, 2022, the Board approved a plan of compensation for independent directors, which provides: an annual retainer of \$30,000; additional annual fees of \$20,000, \$15,000 and \$10,000 for serving as Chair of the Audit Committee, Compensation Committee and Nominating & Governance Committee, respectively; and annual fees of \$7,500, \$5,000 and \$3,500 for serving as members of the Audit Committee, Compensation Committee and Nominating & Governance Committee, respectively. Upon appointment to our Board, non-employee directors receive 250,000 stock options, exercisable for 10 years at a price equal to the closing price of our common stock on the date of appointment, and vesting 50% in 12 months and the balance in 24 months. Additional annual option awards are granted at the discretion of the Compensation Committee. All cash fees are annual and paid quarterly.

On January 15, 2022, Joel Mayersohn received a stock grant of 400,000 common shares for his prior services on the Board.

On January 25, 2022, Adriann Sax received a grant of 250,000 stock options exercisable at \$0.20, and vesting half on January 25, 2023, and the balance on January 25, 2024. The options are exercisable for 10 years following the grant date.

On August 24, 2021, our directors received a grant of stock options as follows: Mr. Baum – 125,000 options, Mr. Piazza – 125,000 options, Dr. Link – 55,000 options, Mr. Nelson – 115,000 options, and Mr. Mayersohn – 54,000 options. All options were issued under our 2016 Omnibus Equity Incentive Plan, as amended. Each of the options shall have a ten (10) year term, vest 50% six months after grant and 50% twelve months after grant, and exercisable at the closing price of the Company's common stock as of the date of grant of \$0.36 per share.

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In February 2021, in connection with the appointment of Dr. Link to our Board, he received as compensation 850 shares of our Series E-1 Preferred Stock. These shares, along with all other outstanding Series E-1 Preferred shares were exchanged for common stock as of December 6, 2021. Dr. Link received an additional 1 million options on February 21, 2022 that are exercisable for 10 years at \$0.20 per share, and vest December 31, 2022.

The following table provides all fees paid to all directors in 2021, but excludes fees paid to the inside directors, Messrs. Baum, Piazza and Nelson, for their services in 2021 in their respective officer capacities. Messrs. Baum, Piazza and Nelson did not receive additional fees specifically for their services as directors of the Company.

Name	Fees Earned or Paid in Cash (\$)(1)	Stock Awards (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Joel Mayersohn	\$ -	-	\$ 17,820	-	-	-	\$ 17,820
Charles J. Link		\$ 865,183(1)	\$ 37,950	-	-		\$ 903,133

(1) Includes issuance of Series E-1 shares and exchange of those shares into common stock.

Exchange Agreement and Plan of Reorganization

On December 31, 2020, the Company reported on Form 8-K an amendment to its Certificate of Incorporation authorizing the issuance of up to 8,500 shares of Series E-1 Preferred Stock (the "E-1 Stock") and issuance of 7,650 shares of E-1 Stock to certain officers, directors and key personnel of the Company. The Company issued the remaining 850 shares of E-1 Stock to a newly appointed independent director in February 2021. The E-1 Stock carried certain rights and priorities over the Company's common stockholders, such as the right to receive in the aggregate and on a first priority non-dilutable basis 20% of the value of the ultimate sale, licensing or commercialization of the Company's radiopharmaceutical technology. In light of the progress the Company made during 2021 in advancing its radiopharmaceutical technology into clinical trials and the additional equity funding that management anticipates will be required to continue to advance this technology through possible commercialization, the Company's Board determined that such rights and priorities may have the unintended effect of complicating the Company's future fund raising efforts, and as a result, create unintended impediments to ultimately maximizing the potential value of the Company's assets for all shareholders. After significant analysis and discussion in the fourth quarter of 2021, the Board approved a plan to exchange the E-1 Stock for common stock and to retire all the shares of E-1 Stock.

On December 6, 2021, the Company entered into an Exchange Agreement and Plan of Reorganization (the “Exchange Agreement”) with all E-1 Stock holders pursuant to which all shares of series E-1 Stock were exchanged into an aggregate of 28,839,428 shares of common stock of the Company. The value of the E-1 Stock was determined to be approximately \$8.65 million based on the value of common stock and 20% non-dilutable earnout feature, as well as a 40% control premium reflecting the ability of the E-1 Stock holders to nominate board members, approve the sale of the Company’s technology and other factors. The valuation was approved for fairness by the chairman of the Compensation Committee, who did not hold any E-1 Stock. The common stock was valued at \$0.30 per share based on a 30-day weighted average closing price calculation, and was issued proportionately to each holder based on their individual holdings of E-1 Stock. All shares of common stock issued to the shareholders are subject to the same vesting schedules as was originally provided in each shareholder’s E-1 Stock issuance agreement, meaning that such shares are forfeitable if certain conditions of employment are not met by the holders, and as further described in the Exchange Agreement.

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

The following table sets forth certain information regarding the beneficial ownership of our common stock as of February 15, 2022 for:

- each person, or group of affiliated persons, known to us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership of our common stock is determined under the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power, or of which a person has a right to acquire ownership at any time within 60 days of the date of this prospectus. Except as indicated by footnote, and subject to applicable community property laws, we believe the persons identified in the table have sole voting and investment power with respect to all shares of common stock beneficially owned by them.

In the following table, percentage ownership is based on 66,484,085 shares of our common stock outstanding as of February 15, 2022. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of voting securities subject to options or other convertible securities held by that person or entity that are currently exercisable or releasable or that will become exercisable or releasable within 60 days of February 15, 2022. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each of the following persons is c/o. QSAM Biosciences, Inc., 9442 Capital of Texas Hwy N, Plaza 1, Suite 500, Austin, TX 78759.

Except as otherwise noted, the persons named in the table have sole voting and dispositive power with respect to all shares beneficially owned, subject to community property laws where applicable.

Executive Officers and Directors

Name of beneficial owner	Amount beneficially owned ⁽¹⁾	Percent of Class Beneficially Owned ⁽⁷⁾
C. Richard Piazza	10,156,300 ⁽²⁾	15.3%
Douglas Baum	10,183,050 ⁽³⁾	15.3%
Christopher Nelson	3,761,607 ⁽⁴⁾	5.7%
Joel Mayersohn	935,456 ⁽⁵⁾	1.4%
Charles J. Link, Jr.	2,911,443 ⁽⁶⁾	4.4%
Adriann Sax	-	-
Adam King	-	-
All Officers and Directors (as a group, 7 persons)	27,947,856	42.0%

(1) The number of shares beneficially owned includes any shares over which the person has sole or shared voting power or investment power and also any shares that the person can acquire within 60 days of February 15, 2022 through the exercise of any stock options or other right. Unless otherwise indicated, each person has sole investment and voting power (or shares such power with his or her spouse) over the shares set forth in the table. For each person, the number of shares that is included in the table because the person has options to acquire the shares is set forth below.

Name	Shares
C. Richard Piazza	62,500
Douglas Baum	70,500
Christopher Nelson	70,100
Joel Mayersohn	106,840
Charles J. Link Jr.	27,500

(2) Excludes 62,500 options that vest on August 24, 2022.

(3) Includes 18,750 shares of common stock receivable upon the exercise of Series B preferred stock. Excludes 62,500 options that vest on August 24, 2022.

(4) Includes 125,000 shares of common stock receivable upon exercise of Series B preferred stock. Excludes 57,500 options that vest on August 24, 2022. Mr. Nelson’s address is 420 Royal Palm Way, Suite 100, Palm Beach, FL 33480.

(5) Includes 400,000 shares of restricted stock issued on January 15, 2021. Excludes 27,000 options that vest on August 24, 2022. Mr. Mayersohn’s address is 350 East Las Olas Blvd., Suite 1750, Ft. Lauderdale, FL 33301.

(6) Excludes 27,500 options that vest on August 24, 2022.

(7) The percentages shown are based on the 66,484,085 shares of our common stock outstanding as of February 15, 2022, plus the number of shares that the named person or group has the right to acquire within 60 days of February 15, 2022. For purposes of computing the percentages of outstanding shares of common stock held by each person, any shares that the person has the right to acquire within 60 days after February 15, 2022 are deemed to be outstanding with respect to such person but are not deemed to be outstanding for the purpose of computing the percentage of ownership of any other person.

More than 5% Beneficial Holders

Name of beneficial owner	Amount beneficially owned	Percent of Class Beneficially Owned ⁽⁴⁾
Checkmate Capital Group LLC, Checkmate Strategic Capital 2, LLC, Checkmate Strategic Capital Holdings LLC, and Charles Thomas Paschall	9,169,193 ⁽¹⁾	13.8%
GSB Holdings, Inc.	4,107,911 ⁽²⁾	6.2%
Strategic Assets Planning Ltd.	3,430,632 ⁽³⁾	5.2%

- (1) The information is based on a Schedule 13D filed by Checkmate Strategic Capital 2, LLC with the SEC on January 26, 2021, reporting its beneficial ownership along with Checkmate Capital Group LLC, Checkmate Strategic Capital Holdings LLC, and Charles Thomas Paschall, members of its “group” as that term is defined in Section 13(d) of the Exchange Act. Includes 475,000 and 1,912,500 shares of common stock receivable by certain members of the group upon exercise of warrants and conversion of Series B preferred stock, respectively. Mr. Paschall and Checkmate Strategic Capital 2, LLC each have disclaimed beneficial ownership with respect to certain securities of the Company as reported on Schedule 13D except to the extent of their pecuniary interest therein. Their address is 595 E. Colorado Blvd., Suite 530, Pasadena, CA 91101.
- (2) The address for GSB Holdings, Inc. is: 14179 Laurel Trail, Wellington, FL 33414. Includes 166,667, 1,562,500, and 500,000 shares of common stock receivable upon exercise of warrants, and conversion of Series B preferred stock and convertible notes, respectively.
- (3) The address for Strategic Assets Planning Ltd. is: Suite 122, 12/F, Wing On Centre, 111 Connaught Road Central, Hong Kong. Includes 1,562,500 shares of common stock receivable upon conversion of Series B preferred stock.
- (4) The percentages shown are based on the 66,484,085 shares of our common stock outstanding as of February 15, 2022.

ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTORS INDEPENDENCE

Transactions with Related Persons

A transaction may be a related person transaction if any of our directors, executive officers, owners of more than 5% of our common stock, or their immediate family were involved in a transaction in the last fiscal year or in any currently proposed transaction in which the Company was or is to be a participant, and the amount involved exceeds the lesser of \$120,000 or 1% of the average of the Company’s total assets at year end for the last two completed fiscal years. The Company engaged in or expects to engage in the following related persons transactions during the period set forth above:

Joel Mayersohn, our Director, is also a partner in the law firm of Dickinson Wright PLLC, which provides legal services for the Company, including federal and state securities law work.

C. Richard Piazza, our Executive Chairman, also serves as President of IGL Pharma Inc., the licensor of the Company’s drug technology, and a consultant to IsoTherapeutics Group, LLC, the inventors of the technology. Mr. Piazza receives a \$500 per month fee from IGL Pharma and holds options to acquire less than 1% of that company.

Director Independence

Two of our currently serving Board members, Dr. Link and Ms. Sax, are independent under director independence standards set forth by NASDAQ. For committee memberships of each of the directors and their independence status, please see “Corporate Governance” beginning on page 43 of this annual report.

ITEM 14: PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following is a summary of the fees billed and unbilled to the Company by our independent registered public accounting firm for professional services rendered for 2021 and 2020:

Fee Category	2021		2020	
Audit Fees	\$	61,000	\$	56,000
Audit-related Fees		-		-
Tax Fees		-		-
All Other Fees		-		-

Audit fees - Consists of fees for professional services rendered by D. Brooks and Associates CPAs, P.A. in 2021 and 2020 for the audit of our annual consolidated financial statements, and the review of interim consolidated financial statements included in our quarterly reports and services that are normally provided by our principal accountants in connection with statutory and regulatory filings or engagements.

Audit-related fees - Consists of fees for assurance and related services by our principal accountants that are reasonably related to the performance of the audit or review of the Company’s consolidated financial statements and are not reported under “Audit fees.”

Tax fees - Consists of fees for professional services rendered by our principal accountants for tax compliance, tax advice and tax planning.

All other fees - Consists of fees for products and services provided by our principal accountants, other than the services reported under “Audit fees,” “Audit-related fees” and “Tax fees” above.

The audit fees for 2021 and 2020 were not reviewed or approved by our Audit Committee. Under the Company’s newly adopted Audit Committee charter, such future fees will be reviewed and approved by the Audit Committee.

PART IV

ITEM 15: EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

- (a)(1) Financial Statements.

The following financial statements of QSAM Biosciences Inc., together with the report thereon of D. Brooks and Associates, CPAs, P.A., an independent registered public accounting firm, are included in this Annual Report on Form 10-K:

Report of Registered Independent Public Accounting Firm	F-1
Consolidated Balance Sheets as of December 31, 2021 and 2020	F-3
Consolidated Statements of Operations for the years ended December 31, 2021 and 2020	F-4
Consolidated Statements of Stockholders' Deficit for the years ended December 31, 2021 and 2020	F-5
Statements of Cash Flows for the years ended December 31, 2021 and 2020	F-6
Notes to Consolidated Financial Statements	F-7

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes thereto set forth under Item 8 above.

(a)(3) Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to the Form 8-K filed December 15, 2015 and Form 8-K filed December 23, 2010)
3.2	Certificate of Amendment of the Amended and Restated Articles of Incorporation of Q2Earth, Inc. (incorporated by reference to the Form 8-K dated September 4, 2020)
3.3	Amended and Restated Bylaws (incorporated by reference to the Form 8-K filed December 23, 2010)
4.1	Certificate of Designation of Preferences, Rights and Limitations of Series A 6% Convertible Preferred Stock (incorporated by reference to the Form 8-K filed November 18, 2015)
4.2	Certificate of Designation for the Series B Convertible Preferred Stock (incorporated by reference to Form 8-K dated December 31, 2020)
4.3	Certificate of Designation for the Series E-1 Incentive Preferred Stock (incorporated by reference to Form 8-K dated December 31, 2020)
10.01	Securities Purchase Agreement for Convertible Debentures (incorporated by reference to the Form 8-K filed July 2, 2014)
10.02	Original Issue Discount Senior Secured Convertible Debentures (incorporated by reference to the Form 8-K filed July 2, 2014)
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10.03	Form of Subscription Agreement for Convertible Note Bridge Offering (incorporated by reference to the Form 8-K filed April 4, 2017)
10.04	Form of Promissory Note for Convertible Note Bridge Offering (incorporated by reference to the Form 8-K filed April 4, 2017)
10.05	2016 Omnibus Equity Incentive Plan (incorporated by reference in the Form 10-K filed for the year ended December 31, 2017)
10.06	Employment Agreement with Christopher Nelson (incorporated by reference in the Form 10-K filed for the year ended December 31, 2017)
10.07	Management Agreement dated November 9, 2018 between Q2Earth, Inc. and Earth Property Holdings, Inc. (incorporated by reference in the Form 8-K filed on November 13, 2018)
10.08	Limited Liability Company Agreement of Earth Property Holdings, Inc. dated November 9, 2018 (incorporated by reference in the Form 8-K filed on November 13, 2018)
10.09	Subscription Agreement for Class B Units in Earth Property Holdings LLC (incorporated by reference in the Form 8-K filed January 23, 2019)
10.10	Form of Amended and Restated Limited Liability Company Agreement of Earth Property Holdings LLC (incorporated by reference in the Form 8-K filed January 23, 2019)
10.11	Omnibus Separation Agreement, dated November 6, 2020, between the Company and Earth Property Holdings, LLC incorporated by reference in the Form 8-K dated November 6, 2020
10.12	Employment Agreement dated November 6, 2020, between the Company and C. Richard Piazza incorporated by reference in the Form 8-K dated November 6, 2020
10.13	Employment Agreement dated November 6, 2020, between the Company and Douglas Baum incorporated by reference in the Form 8-K dated November 6, 2020
10.14	Form of Issuance Agreement for the Series E-1 Incentive Preferred Stock (incorporated by reference in the Form 8-K dated December 31, 2020)
10.15	Independent Director Compensation Plan (incorporated by reference in the Form 8-K dated January 28, 2022)
14	Code of Ethics Policy
21.1	Subsidiaries of the Company
31.1	302 Certification of Douglas Baum, CEO
31.2	302 Certification of Principal Accounting Officer
32	906 Certification

101 The following information from the Company's Annual Report on Form 10-K for the year ended December 31, 2021, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Income, (iii) the Consolidated Statements of Comprehensive Income, (iv) the Consolidated Statements of Changes in Shareholders' Equity, (v) the Consolidated Statements of Cash Flows, and (vi) the Notes to Consolidated Financial Statements.

104 Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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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.

QSAM BIOSCIENCES, INC.

Date: February 24, 2022

By: /s/ Douglas Baum
Douglas Baum
Director and Chief Executive Officer

Date: February 24, 2022

By: /s/ Adam King
Adam King
Interim Chief Financial Officer and Principal Accounting 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: February 24, 2022

By: /s/ C. Richard Piazza
C. Richard Piazza
Executive Chairman of the Board of Directors

Date: February 24, 2022

By: /s/ Douglas Baum
Douglas Baum
Director and Chief Executive Officer

Date: February 24, 2022

By: /s/ Christopher M. Nelson
Christopher M. Nelson
General Counsel and Director

Date: February 24, 2022

By: /s/ Joel D. Mayersohn
Joel D. Mayersohn
Director

Date: February 24, 2022

By: /s/ Charles J. Link Jr.
Charles J. Link Jr.
Director

Date: February 24, 2022

By: /s/ Adriann Sax
Adriann Sax
Director

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of QSAM Biosciences, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of QSAM Biosciences, Inc (f/k/a Q2Earth, Inc., and referred to as the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended and the related notes to the consolidated financial statements (collectively referred to as the consolidated financial statements). In our opinion, the consolidated 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 the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt Regarding Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred operating losses, has incurred negative cash flows from operations and has an accumulated deficit. These and other factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plan regarding these matters is also described in Note 2 to the

consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 consolidated 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 audit includes performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

4440 PGA Blvd, Suite 104 ■ Palm Beach Gardens, Florida 33410 ■ Main Office: 561.429.6225 ■ Fax: 561.282.3444

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Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated 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.

Series E-1 Preferred Stock ("Series E-1 Stock")

As disclosed in Note 10 to the consolidated financial statements, during the years ended 2021 and 2020, the Company issued Series E-1 Stock to executives and directors of the Company as compensation for their services. The Company computed the total grant date fair value of the Series E-1 Stock to be approximately \$6,528,000 using the Black Scholes option pricing model which requires management's assumptions regarding expected term and stock volatility using guideline public companies. Further, on December 6, 2021, the Company entered into an Exchange Agreement and Plan of Reorganization (the "Exchange") with all E-1 Stockholders pursuant to which all shares of Series E-1 Stock were exchanged into an aggregate of 28,839,428 shares of common stock of the Company. The fair value of the Series E-1 Stock was determined to be approximately \$8.65 million at the time of the exchange based on the market price of the underlying common stock on the date of the exchange. We identified the initial fair value of the Series E-1 Stock and the accounting for the Exchange has a critical audit matter given its significance and unusual nature.

Our audit procedures related to the critical audit matter identified included the following, among others:

With the assistance of our valuation specialist, we performed the following:

- Evaluated selected guideline public companies by reading the business descriptions and examining financial metrics of the comparable public companies.
- Evaluated the reasonableness of assumptions related to expected term and volatility.
- Evaluated the reasonableness and accuracy of the Company's valuation techniques.
- Reviewed management's technical accounting memo for the accounting for the Exchange against technical authoritative accounting guidance.
- Recomputed the fair value of the shares of common stock issued in the Exchange.

Warrant Modifications

As disclosed in Note 10 to the consolidated financial statements, during the year ended December 31, 2021, the Company issued 6,743,575 warrants in connection with a Series B Preferred Stock offering and 750,000 warrants to a service provider. The terms of the warrants were modified twice in 2021 by resolution of the Company's board of directors, first to extend the termination date from July 8, 2021 to September 30, 2021 and then to extend the termination date to October 15, 2021. As part of the second modification, the exercise price of the warrants issued with the Series B Preferred Stock was reduced from \$0.35 per share to \$0.25 per share. The Company computed the incremental value derived from the modifications utilizing a Black Scholes option pricing model which requires certain management assumptions. We identified the accounting for the modifications has a critical audit matter given its unusual nature.

With the assistance of our valuation specialist, we performed the following:

- Evaluated the reasonableness of assumptions related to expected term and volatility.
- Evaluated the reasonableness and accuracy of the Company's valuation techniques.
- Reviewed management's technical accounting memo for the accounting for the modifications against technical authoritative accounting guidance.
- Performed an independent computation of incremental value in connection with the modifications.

We have served as the Company's auditor since 2019.

 D. Brooks and Associates CPAs, P.A.

QSAM BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash	\$ 1,499,866	\$ 8,304
Prepaid expenses and other assets	135,014	12,896
Deferred offering costs	35,000	-
TOTAL CURRENT ASSETS	1,669,880	21,200
TOTAL ASSETS	\$ 1,669,880	\$ 21,200
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 569,321	\$ 308,157
Accrued payroll and related expenses	95,400	48,006
Accrued series B preferred stock dividends	153,343	-
Notes payable, net of discount	532,400	-
Notes payable - related parties	7,500	63,992
Paycheck Protection Program Loan - current portion	-	34,163
Debentures	35,000	137,500
Convertible bridge notes, at fair value	-	3,598,000
TOTAL CURRENT LIABILITIES	1,392,964	4,189,818
Paycheck Protection Program Loan - net of current portion	-	108,779
Total Liabilities	1,392,964	4,298,597
Redeemable convertible preferred stock - Series A; \$0.0001 par value, 1,500 designated Series A, and 480 and 600 shares issued and outstanding (liquidation preference of \$693,580 and \$784,044) as of December 31, 2021 and December 31, 2020, respectively	693,580	784,044
Stockholders' Deficit		
Preferred stock, Series B, \$0.001 par value; 2,500 shares authorized, 1,509 and 281 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	2	-
Preferred stock, Series E-1, \$0.0001 par value; 8,500 shares authorized, 0 and 7,650 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	-	-
Common stock, \$0.0001 par value, 300,000,000 shares authorized, 66,084,085 and 19,472,241 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	6,608	1,947
Unearned deferred compensation	(900,742)	(148,333)
Subscription receivable	-	(25,000)
Additional paid-in capital	29,759,142	11,021,840
Accumulated deficit	(29,281,674)	(15,911,895)
Total Stockholders' Deficit	(416,664)	(5,061,441)
Total Liabilities & Stockholders' Deficit	\$ 1,669,880	\$ 21,200

See notes to the consolidated financial statements.

QSAM BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the years ended December 31,	
	2021	2020
REVENUES	\$ -	\$ -
Operating Expenses		
Compensation and related expenses	8,290,699	379,242
Professional Fees	1,985,780	442,795
General and administrative	117,483	139,903
Research and development	647,302	362,456
Total Operating Expenses	11,041,264	1,324,396

Loss from Continuing Operations	(11,041,264)	(1,324,396)
Other Income (Expense) from continuing operations		
Financing costs including interest	(44,171)	(490,402)
Change in fair value of convertible bridge notes	-	(3,170,236)
Gain on sale of equity method investment	100,000	-
Loss on conversion of bridge notes and accrued interest	(744,505)	(495,320)
Loss on conversion of debentures and notes payable with unrelated parties	-	(68,373)
Loss on conversion of accrued salary and bonus, director fees, and notes payable with related parties	-	(271,210)
Loss on debentures and accrued expenses converted to common stock	(390,067)	-
Gain on forgiveness of debt from Paycheck Protection Program	142,942	-
Total Other Expenses, net	<u>(935,801)</u>	<u>(4,495,541)</u>
Loss from continuing operations before income taxes	(11,977,065)	(5,819,937)
Income Taxes	-	-
Income from discontinued operations	-	<u>957,254</u>
NET LOSS	(11,977,065)	(4,862,683)
PREFERRED STOCK		
Series A convertible contractual dividends	(29,538)	(35,440)
Series B convertible contractual dividends	(153,343)	-
Deemed dividend series B warrant modification	(850,214)	-
Deemed dividends on series A conversion to common stock	(542,500)	-
NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ (13,552,660)	\$ (4,898,123)
NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS: BASIC AND DILUTED:		
CONTINUING OPERATIONS	\$ (0.43)	\$ (1.06)
DISCONTINUED OPERATIONS	\$ -	\$ 0.17
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING: BASIC AND DILUTED	<u>31,663,946</u>	<u>5,522,771</u>

See notes to the consolidated financial statements

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**QSAM BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT**

	Preferred Stock		Series E-1 Preferred Stock		Common Stock		Additional Paid In Capital	Deferred Stock-based Compensation	Stock Subscription	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Value	Shares	Value	Shares	Value					
Balance, December 31, 2019	-	-	-	-	2,079,898	\$ 208	\$ 6,475,667	\$ -	\$ -	\$(11,049,212)	\$ (4,573,337)
Stock-based compensation for services	-	-	-	-	1,750,000	175	406,825	(148,333)	-	-	258,667
Stock-based compensation expense and stock option modification	-	-	-	-	-	-	24,327	-	-	-	24,327
Conversion of debentures and promissory note with unrelated parties	-	-	-	-	218,686	22	116,508	-	-	-	116,530
Conversion of bridge notes and accrued interest to common stock	-	-	-	-	13,312,175	1,331	3,016,168	-	-	-	3,017,499
Conversion of accrued salary and bonus, directors fees, and promissory notes with related parties	-	-	-	-	2,111,482	211	736,785	-	-	-	736,996
Series A, preferred stock contractual dividends	-	-	-	-	-	-	(35,440)	-	-	-	(35,440)
Conversion of debt to Series B preferred stock	156	-	-	-	-	-	156,000	-	-	-	156,000
Sale of Series B preferred stock	125	-	-	-	-	-	125,000	-	(25,000)	-	100,000
Issuance of Series E-1 shares to employees and directors	-	-	7,650	-	-	-	-	-	-	-	-
Net loss year ended December 31, 2020	-	-	-	-	-	-	-	-	-	(4,862,683)	(4,862,683)
Balance, December 31, 2020	<u>281</u>	<u>-</u>	<u>7,650</u>	<u>-</u>	<u>19,472,241</u>	<u>1,947</u>	<u>11,021,840</u>	<u>(148,333)</u>	<u>(25,000)</u>	<u>(15,911,895)</u>	<u>(5,061,441)</u>
Adjustment to common stock to reconcile to transfer agent	-	-	-	-	(85,079)	(9)	9	-	-	-	-
Compensation expense due to warrant modification	-	-	-	-	-	-	109,206	-	-	-	109,206
Conversion of bridge notes and accrued interest to common stock	-	-	-	-	6,627,692	664	4,377,824	-	-	-	4,378,488
Conversion of debentures and accrued expenses	-	-	-	-	632,995	63	515,006	-	-	-	515,069
Conversion of Series A preferred stock to common stock	-	-	-	-	750,000	75	662,425	-	-	(542,500)	120,000
Exercise of Series B Warrants to common stock	-	-	-	-	1,871,430	187	467,669	-	-	-	467,857

Series B, preferred stock contractual dividends	-	-	-	-	-	-	(153,343)	-	-	-	(153,343)
Incremental value from warrant modifications	-	-	-	-	-	-	850,214	-	-	(850,214)	-
Fair value allocation of warrants issued with convertible notes	-	-	-	-	-	-	72,600	-	-	-	72,600
Issuance of Series B, conversion of notes payable with directors to preferred stock	23	-	-	-	-	-	23,000	-	-	-	23,000
Issuance of Series B, preferred stock for cash	2,196	2	-	-	-	-	2,195,998	-	25,000	-	2,221,000
Conversion of Series B preferred stock to common stock	(991)	-	-	-	6,525,378	652	(652)	-	-	-	-
Series A, preferred stock contractual dividends	-	-	-	-	-	-	(29,538)	-	-	-	(29,538)
Common stock and warrants issued for services	-	-	-	-	1,450,000	145	922,247	148,333	-	-	1,070,725
Stock-based compensation to employees and directors	-	-	850	-	-	-	6,603,691	(1,307,593)	-	-	5,296,098
Conversion of Series E Preferred Stock to common stock	-	(8,500)	-	-	28,839,428	2,884	2,120,946	406,851	-	-	2,530,679
Net loss year ended December 31, 2021	-	-	-	-	-	-	-	-	-	(11,977,065)	(11,977,065)
Balance, December 31, 2021	1,509	\$ 2	-	-	66,084,085	\$ 6,608	\$29,759,142	\$ (900,742)	\$ -	(29,281,674)	\$ (416,664)

See notes to the consolidated financial statements.

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QSAM BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the years ended December 31,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (11,977,065)	\$ (4,862,683)
Adjustments to reconcile net loss to net cash provided by operations:		
Stock-based compensation for services and warrant modification	1,179,932	258,667
Stock-based compensation to employees and directors	7,826,779	24,327
Loss on conversion of bridge notes and accrued interest	744,505	495,320
Loss on conversion of debentures and accrued expenses to common stock	390,069	68,373
Loss on conversion of accrued salary and bonus, director fees, and promissory notes with related parties	-	271,210
Change in fair value of convertible bridge notes	-	3,170,236
Amortization of debt issuance costs	-	1,250
Paid-in-kind interest - convertible bridge notes	35,983	484,031
Gain on forgiveness or assumption of promissory notes and accrued expenses	-	(1,032,160)
Gain on forgiveness of Paycheck Protection Program	(142,942)	-
Changes in operating assets and liabilities		
Increase in prepaid expenses and other current assets	(122,118)	(5,231)
Increase in accounts payable and accrued expenses	283,660	174,690
Increase accrued payroll and related expenses	47,394	152,657
Deferred offering costs	(35,000)	-
Increase in accrued interest	-	50,803
Increase in accrued interest - related party	-	5,611
Net cash used in operating activities	<u>(1,768,803)</u>	<u>(742,899)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from promissory notes - related parties	-	338,373
Repayments on promissory notes - related parties	(33,492)	(1,590)
Proceeds from promissory notes - unrelated parties	-	171,000
Proceeds from convertible notes payable	605,000	-
Proceeds from conversion of warrants	467,857	-
Proceeds from issuance of preferred stock - Series B	2,221,000	100,000
Proceeds from Paycheck Protection Program	-	142,942
Net cash provided by financing activities	<u>3,260,365</u>	<u>750,725</u>
NET INCREASE IN CASH	1,491,562	7,826
CASH - Beginning of year	<u>8,304</u>	<u>478</u>
CASH - End of year	<u>\$ 1,499,866</u>	<u>\$ 8,304</u>
SUPPLEMENTAL CASH FLOW DISCLOSURES:		
Payment of interest in cash	\$ -	\$ -
Payment of income taxes	\$ -	\$ -
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Accrual of contractual dividends on Series A convertible preferred stock	\$ 29,538	\$ 35,440

Accrual of contractual dividends on Series B convertible preferred stock	\$ 153,343	\$ -
Fair value allocation of warrants issued with debt	\$ 72,600	\$ -
Deemed dividend on warrant modifications	\$ 850,214	\$ -
Deemed dividend on conversion of Series A	\$ 542,500	\$ -
Conversion of convertible Bridge Notes and accrued interest to 6,627,692 and 11,418,069 shares of common stock, respectively	\$ 3,633,983	\$ 2,531,438
Conversion of debentures and accrued expenses to common stock	\$ 125,000	\$ 48,811
Conversion of accrued salary and bonus, director fees, and notes payable with related parties to common stock	\$ -	\$ 464,526
Conversion of notes payable to Series B Preferred Stock	\$ -	\$ 156,000
Conversion of Series A preferred stock to common stock	\$ 120,000	\$ -
Series B Preferred Stock purchased with a stock subscription receivable	\$ -	\$ 25,000
Conversion of notes payable with related parties to Series B preferred stock and warrants	\$ 23,000	\$ -

See notes to the consolidated financial statements.

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QSAM BIOSCIENCES INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – ORGANIZATION AND DESCRIPTION OF BUSINESS

QSAM Biosciences Inc. (hereinafter the “Company”, “we”, “our”, “us”), incorporated in Delaware on August 26, 2004, is currently engaged in the business of developing a novel radiopharmaceutical drug candidate for the treatment of bone cancer. This business line commenced in earnest in the fourth fiscal quarter of 2020 as a result of the separation and transfer pursuant to an Omnibus Separation Agreement dated November 6, 2020 (the “Separation Agreement”) of the Company’s prior business of managing compost and soil manufacturing facilities (the “Legacy Business”) through an unconsolidated investee entity called Earth Property Holdings LLC, a Delaware limited liability company (“EPH”). Pursuant to the Separation Agreement, the Company transferred to EPH all assets and related liabilities in connection with the Legacy Business in return for a forgiveness of debt. The financial statements presented herein have been adjusted to account for the Legacy Business as discontinued operations (see Note 4 – Separation Agreement and Note 9 – Discontinued Operations). The Company sold its entire equity interest in EPH to a third party in the first quarter of 2021 for \$100,000, and currently holds no ownership in EPH.

In April 2020, the Company established QSAM Therapeutics Inc. (“QSAM”) as a wholly-owned subsidiary incorporated in the state of Texas, and through QSAM, executed a Patent and Technology License Agreement and Trademark Assignment (the “License Agreement”) with IGL Pharma, Inc. (“IGL”). The License Agreement, as amended in November 2021, provides QSAM with exclusive, worldwide and sub-licensable rights to all of IGL’s patents, product data and knowhow with respect to Samarium-153 DOTMP aka CycloSam® (the “Technology”), a clinical stage novel radiopharmaceutical meant to treat different types of bone cancer and related diseases.

In connection with the transition to the biosciences sector, the Company changed its name to QSAM Biosciences Inc. on September 4, 2020, and subsequently changed its stock symbol to QSAM, to better reflect its business moving forward.

On September 4, 2020, the Company completed a 25:1 reverse stock split of its common shares. All shares and share prices set forth in this report have been adjusted to account for this reverse stock split as if it had occurred at the beginning of the earliest period presented.

Prior to 2017, the Company owned and licensed technology that converts waste fuels and heat to power, which it sold to a licensee in August of that year. Much of these operations were conducted through a wholly-owned subsidiary of the Company called Q2Power Corp. (“Q2P”), which still exists but has no current operations.

The recent outbreak of the novel coronavirus (COVID-19) is impacting worldwide economic activity. COVID-19 poses the risk that we or our employees and our other partners may be prevented from conducting business activities for an indefinite period of time, including due to the spread of the disease or shutdowns that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the full impact that COVID-19 could have on our business, the continued spread of COVID-19 could disrupt our research and development of CycloSam and other related activities, which could have a material adverse effect on our business, financial condition and results of operations. In addition, a severe or prolonged economic downturn could result in a variety of risks to the business. While we have not yet experienced any material disruptions in our business or other material negative consequences relating to COVID-19, the extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted.

NOTE 2 – BASIS OF PRESENTATION AND GOING CONCERN

For the year ended December 31, 2021, the Company used net cash in operating activities for its continuing operations of \$1,768,803 and incurred a loss from its continuing operations of \$11,977,065. As of December 31, 2021, the Company’s accumulated deficit is \$29,281,674 and has cash of \$1,499,866. As of December 31, 2021, the Company’s has working capital of \$276,916. These conditions raise substantial doubt about the Company’s ability to continue as a going concern.

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The Company’s convertible debentures of \$35,000 and \$480,000 of redeemable convertible preferred stock were both in default as of December 31, 2021. At the end of 2021, management was in discussions with the holders of these debt and equity securities to reach an agreement to convert the outstanding balances into common stock or otherwise amend the respective maturity and redemption. On February 22, 2022, the holder of the debenture converted the full balance of \$35,000 into 218,750 shares of common stock at \$0.16 per share, and the balance on the convertible debenture is currently \$0 (see Note 14 - Subsequent Events).

The Company has supported operations through the issuance of common stock, preferred stock and debt over the last 12 months. This includes the \$5 million Series B preferred stock offering in the first quarter of 2021, the recent exercise of approximately \$470,000 in warrants issued in connection with the Series B offering, and also a convertible debt offering in the amount of \$605,000 conducted in the fourth quarter of 2021. With respect to the convertible notes, they are convertible into common stock prior to the maturity date of December 31, 2023, or automatically upon the Company completing a qualified offering in the amount of \$5 million or uplisting its common shares to NASDAQ; and bear interest at the rate of 6% per annum, with all interest and principal due at maturity, unless earlier converted. The note holders also received a total of 1,008,334 common stock warrants. See Notes 7 and 10 for further discussion.

Management expects expenses to increase in 2022 as our drug technology enters into clinical trials, and as a result, we will need to raise additional capital to support these operations. Management believes that it can do so through equity raises in 2022, and in December 2021, filed an initial S-1 registration statement with the Securities Exchange Commission to raise additional equity capital in an offering underwritten by an investment bank. There is no guarantee, however, that such offering will be successful. If the Company is not successful in raising additional capital, it may need to delay clinical trials, reduce overhead, or in the most extreme scenario, shut down operations.

There is no guarantee whether the Company will be able to generate revenue and/or raise capital sufficient to support its continuing operations. The ability of the Company to continue as a going concern is dependent on management's plans which include implementation of its business model to develop and commercialize its drug candidate, seek strategic partnerships to advance clinical trials and other research endeavors which could provide additional capital to the Company, and continue to raise funds for the Company through equity or debt offerings. There is no assurance, however, that the Company will be successful in raising the needed capital and, if funding is available, that it will be available on terms acceptable to the Company. The consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The consolidated financial statements include the accounts of QSAM Biosciences Inc. and its wholly-owned subsidiaries QSAM Therapeutics Inc and Q2Power Corp (currently inactive). All significant inter-company transactions and balances have been eliminated in consolidation. References herein to the Company include the Company and its Subsidiaries unless the context otherwise requires.

Cash and Cash Equivalents

The Company considers cash, short-term deposits, and other investments with original maturities of no more than ninety days when acquired to be cash and cash equivalents for the purposes of the statement of cash flows. The Company maintains cash balances at one financial institution and has experienced no losses with respect to amounts on deposit. The Company held no cash equivalents as of December 31, 2021 and 2020.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, "Revenue from Contracts with Customers ("ASC 606") and all the related amendments.

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The core principle of ASC 606 requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than previously required under U.S. GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation.

The Company had no revenue in 2021 and 2020 from continuing operations.

Stock Based Compensation

The Company applies the fair value method of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 718, "Share Based Payment", in accounting for its stock-based compensation with employees and non-employees. This standard states that compensation cost is measured at the grant date based on the fair value of the award and is recognized over the service period, which is usually the vesting period. The Company values stock-based compensation at the market price for the Company's common stock and other pertinent factors at the grant date.

The Black-Scholes option pricing valuation method is used to determine fair value of stock options consistent with ASC 718, 'Share Based Payment'. Use of this method requires that the Company make assumptions regarding stock volatility, dividend yields, expected term of the awards and risk-free interest rates.

Research and Development

Research and development costs are expensed as incurred. Research and development costs were \$647,302 for the year ended December 31, 2021, and are a result of the Company's activities to commence clinical trials of its drug Technology, as secured by the Company under a License Agreement executed in the second quarter of 2020. Research and development costs were \$362,456 for the year ended December 31, 2020, and are also a result of the License Agreement as well as expenses incurred on the Technology prior to the signing of the License Agreement (see Note 13 – Commitments and Contingencies).

Fair Value Measurement

The Company measures fair value in accordance with a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure 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). The Company's convertible Bridge Notes are valued by using Monte Carlo Simulation methods and discounted future cash flow models. Where possible, the Company verifies the values produced by its pricing models to market prices. Valuation models require a variety of inputs, including contractual terms, market prices, yield curves, credit spreads, measures of volatility and correlations of such inputs. These convertible Bridge Notes do not trade in liquid markets, and as such, model inputs cannot generally be verified and do involve significant management judgment. Such instruments are typically classified within Level 3 of the fair value hierarchy.

Equity Method Investment

Investments in partnerships, joint ventures and less-than majority-owned subsidiaries in which we have significant influence are accounted for under the equity method. The Company's consolidated net income includes the Company's proportionate share of the net income or loss of our equity method investee. When we record our proportionate share of net income, it increases income (loss) — net in our consolidated statements of operations and our carrying value in that investment. Conversely, when we record our proportionate share of a net loss, it decreases income (loss) — net in our consolidated statements of income and our carrying value in that investment. The Company's proportionate share of the net income or loss of our equity method investees includes significant operating and nonoperating items recorded by our equity method investee. These items can have a significant impact on the amount of income (loss) — net in our consolidated statements of operations and our carrying value in those investments. The Company divested its investment in its equity method investee in March 2021.

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Discontinued Operations

In accordance with ASC 205-20 *Presentation of Financial Statements: Discontinued Operations*, a disposal of a component of an entity or a group of components of an entity is required to be reported as discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results when the components of an entity meets the criteria in paragraph 205-20-45-10. In the period in which the component meets held-for-sale or discontinued operations criteria the major current assets, other assets, current liabilities, and noncurrent liabilities shall be reported as components of total assets and liabilities separate from those balances of the continuing operations. At the same time, the results of all discontinued operations, less applicable income taxes (benefit), shall be reported as components

of net income (loss) separate from the net income (loss) of continuing operations.

The Company disposed of a component of its business pursuant to a Separation Agreement in November 2020, which met the definition of a discontinued operation. Accordingly, the operating results of the business disposed are reported as income (loss) from discontinued operations in the accompanying consolidated statements of operations for the years ended December 31, 2021 and 2020. For additional information, see Note 4 – Separation Agreement and Note 9 - Discontinued Operations.

Income Taxes

Income taxes are accounted for under the asset and liability method as stipulated by FASB ASC 740, “Income Taxes” (“ASC 740”). 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 and operating loss and tax credit carry forwards. 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, the effect on deferred tax assets and liabilities or a change in tax rate is recognized in income in the period that includes the enactment date. Deferred tax assets are reduced to estimated amounts to be realized by the use of a valuation allowance. A valuation allowance is applied when in management’s view it is more likely than not (50%) that such deferred tax will not be utilized.

In the event that an uncertain tax position exists in which the Company could incur income taxes, the Company would evaluate whether there is a probability that the uncertain tax position taken would be sustained upon examination by the taxing authorities. Reserves for uncertain tax positions would be recorded if the Company determined it is probable that a position would not be sustained upon examination or if payment would have to be made to a taxing authority and the amount is reasonably estimated. As of December 31, 2021, the Company does not believe it has any uncertain tax positions that would result in the Company having a liability to the taxing authorities; however, federal returns have not been filed since the Company’s inception in 2014. Such delinquencies are being resolved by management and a retained tax expert. Interest and penalties related to any unrecognized tax benefits is recognized in the consolidated financial statements as a component of income taxes. The Company will need to be in compliance with the tax authorities by filing past federal and state income tax returns.

Basic and Diluted Loss Per Share

Net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period plus any potentially dilutive shares related to the issuance of stock options, shares from the issuance of stock warrants, shares issued from the conversion of redeemable convertible preferred stock and shares issued for the conversion of convertible debt.

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As of December 31, 2021, there were the following potentially dilutive securities that were excluded from diluted net loss per share because their effect would be anti-dilutive:

Shares from the conversion of Series B Preferred Stock not inclusive of accrued dividends	9,430,963
Shares from common stock options	1,112,619
Shares from common stock warrants	1,483,333
Shares from conversion of convertible notes not inclusive of accrued interest	3,025,000
Shares from the conversion of debentures	218,750
Shares from the conversion of redeemable convertible preferred stock (based upon an assumed conversion price at December 31, 2021 of \$0.16 per share; inclusive of cumulative dividends which may be converted to shares of common stock under certain conditions)	4,329,250

As of December 31, 2020, there were the following potentially dilutive securities that were excluded from diluted net loss per share because their effect would be anti-dilutive:

Shares from the conversion of Series B Preferred Stock	1,756,250
Shares from the conversion of Series E-1 Preferred Stock	7,650,000
Shares from common stock options	468,619
Shares from common stock warrants	46,154
Shares from the conversion of debentures	625,000
Shares that may be converted from Bridge Notes (based upon an assumed conversion price at December 31, 2020 of \$0.22 per share)	6,578,702
Shares from the conversion of redeemable convertible preferred stock (based upon an assumed conversion price at December 31, 2020 of \$0.22 per share; inclusive of cumulative dividends which may be converted to shares of common stock under certain conditions)	2,727,273

Significant Estimates

U.S. Generally Accepted Accounting Principles (“GAAP”) requires the Company to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, the reported amounts of revenues and expenses, cash flows and the related footnote disclosures during the period. On an on-going basis, the Company reviews and evaluates its estimates and assumptions, including, but not limited to, those that relate to the fair value of stock-based compensation fair value of convertible bridge notes, and a valuation allowance on deferred tax assets and contingencies. Actual results could differ from these estimates.

Recent Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2020-06, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity’s Own Equity (Subtopic 815-40) (“ASU 2020-06”) to simplify accounting for certain financial instruments. ASU 2020-06 eliminates the current models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity’s own equity. The new standard also introduces additional disclosures for convertible debt and freestanding instruments that are indexed to and settled in an entity’s own equity. ASU 2020-06 amends the diluted earnings per share guidance, including the requirement to use the if-converted method for all convertible instruments. ASU 2020-06 is effective January 1, 2022 and should be applied on a full or modified retrospective basis, with early adoption permitted beginning on January 1, 2021. The Company adopted ASU 2020-06 effective January 1, 2021 which was applied to convertible debt notes issued in 2021 (see Note 7). The adoption of ASU 2020-06 did not have a material impact on the Company’s consolidated financial statements.

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material effect on its consolidated financial statements.

Reclassifications

Certain reclassifications of prior year amounts including loss on conversion of bridge notes and accrued interest, loss on conversion of debentures and notes payable with unrelated parties, loss on conversion of accrued salary and bonus, director fees, and notes payable with related parties, and stock based compensation on the consolidated statements of operations have been made to conform to the 2021 presentation. These reclassifications had no effect on net loss or loss per share as previously reported.

Concentration of Risk

The Company expects cash to be the asset most likely to subject the Company to concentrations of credit risk. The Company's bank deposits may at times exceed federally insured limits. The Company's policy is to maintain its cash with high credit quality financial institutions to limit its risk of loss exposure. The Company's cash balance as of December 31, 2021, is in excess of FDIC limits in the amount of approximately \$1,249,866.

The Company is subject to a number of risks similar to those of other companies at a clinical-stage for radiopharmaceutical drug candidates, including dependence on key individuals; the need to develop commercially viable therapeutics; competition from other companies, many of which are larger and better capitalized; and the need to obtain adequate additional financing to fund the development of its products. The Company currently depends on third-party suppliers for key materials and services used in its research and development manufacturing process, and is subject to certain risks related to the loss of these third-party suppliers or their inability to supply the Company with adequate materials and services.

The Company had no revenue from its continuing operations for the year periods ended December 31, 2021 and 2020. Revenue included in discontinued operations was generated from one related customer in the 2020 period.

Fair Value of Financial Instruments

In accordance with Accounting Standards Codification ("ASC") 825, *Financial Instruments*, disclosures of fair value information about financial instruments are required, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. Cash is carried fair value.

Other financial instruments, including accounts payable, accrued liabilities and short-term debt, are carried at cost, which approximates fair value given their short-term nature.

Deferred Offering Cost

Costs incurred prior to an equity offering are capitalized until the offering occurs. Upon the equity offering, all accumulated costs are charged against proceeds. If the Company determines that the equity offering will not occur, the accumulated costs are charged to operations.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, the Company views its operations and manages its business as one segment.

NOTE 4 – SEPARATION AGREEMENT

On November 6, 2020, the Company entered into the Separation Agreement with its unconsolidated investee, EPH. The Company's board of directors approved the Separation Agreement in support of the Company's previously disclosed plan to secure new technologies and business opportunities in the broader biosciences sector, and to significantly reduce debt and liabilities of the Company and eliminate under-performing assets and agreements. The Separation Agreement resulted in the discontinuance of the Company's management of businesses and assets focused on compost and soil manufacturing to focus solely on the development of its exclusively licensed pharmaceutical Technology, as well as other drug candidates that it may license or otherwise secure in the future. Pursuant to the Separation Agreement:

- The Management Agreement, dated January 18, 2019, as amended, between EPH and the Company was terminated by mutual agreement of the parties. Fees from this agreement constituted most of the Company's revenue over the prior two years.

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- In lieu of any severance or other termination payments due under the Management Agreement, EPH released the Company from a total of \$993,985 in liabilities, inclusive of advanced management fees and multiple promissory notes, including accrued and unpaid interest. An additional \$114,700 in promissory notes owed to an affiliate of EPH were converted into Company common stock at a price of \$0.22 per share.
- The Company agreed to transfer to EPH its license agreement with Agrarian Technologies LLC and Mulch Masters Inc. for the ABS soil enhancement product and all associated knowhow, trade secrets and trademark/service marks. Accrued license fees in connection with this license agreement were also assumed by EPH in the amount of \$37,500.
- The prior officers and employees of the Company engaged in the Legacy Business were released from any non-competition, non-solicitation or other restricted covenant pursuant to their respective employment agreements. Effective October 1, 2020, several of these employees had already separated from the Company.

Pursuant to ASC 205-20 *Presentation of Financial Statements: Discontinued Operations* and amended by ASU No. 2014-08, management has determined that the Separation Agreement results in the disposal of a component that represents a strategic shift in the Company's business operations that will have a major effect on the Company's operations and financial results. Therefore, the net income (loss) generated from this disposed component have been presented as discontinued operations for the period ended December 31, 2020 on the statement of operations, including any gains or losses resulting from the forgiveness of liabilities and conversion liabilities to equity.

NOTE 5 – EQUITY METHOD INVESTMENT

During November 2018, the Company invested \$50,000 for a 19.9% Class B limited liability membership interest in EPH and recorded this transaction as an equity method investment due to the Company's ability to exercise significant influence over EPH. The carrying value of the investment at December 31, 2020 was zero due to continued losses incurred by EPH. In the first quarter of 2021, the Company sold this equity interest to an unrelated third party for \$100,000. There were no distributions received from the equity method investment in 2021 or 2020. See Note 4 for discussion of the Separation Agreement with our equity method investment in November 2020.

Our prior Chairman and CEO of the Company who resigned in 2020, also serves as President of EPH; and Christopher Nelson, General Counsel and Director of the Company, also serves as General Counsel and Secretary of EPH. See Note 6 – Related Party Transactions for transactions with our equity method investment during the years ended December 31, 2021 and 2020.

NOTE 6 – RELATED PARTY TRANSACTIONS

The Company currently has a License Agreement with IGL Pharma, Inc., an entity in which the Company's Executive Chairman serves as President. Effective November 17, 2021, the Company amended the license agreement with IGL Pharma, Inc which adjusted milestone payment amounts during the course of the agreement term. Additionally, the Company issued 500,000 shares of the Company to IGL Pharma, Inc (see Note 12). The associated expense of \$140,000 was recorded in Professional Fees.

The Company currently maintains an executive office in Florida, which is leased by an investment firm in which the Company's General Counsel serves as an officer but does not hold any equity or voting rights. The Company has no formal agreement for this space and pays no rent.

During the year ended December 31, 2020, the Company received \$250,000 from its equity method investee, EPH, as management fee revenue. The Company did not receive any revenue from EPH for any period in 2021. Due to the Separation Agreement disclosed in Note 4, management fee revenues received during 2020 have been presented on the statement of operations as discontinued operations (see Note 9 – Discontinued Operations). Management fee revenues were the Company's primary source of revenue during the prior year.

In 2021, the Company paid to EPH \$34,136 arising from notes payable and accrued interest which was included in notes payable-related parties in prior periods in the consolidated balance sheet.

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During the year ended December 31, 2020, the Company received \$45,500 of proceeds from short-term notes payable with officers and directors of the Company bearing interest at 10%. As of December 31, 2021, \$7,500 of principal remains outstanding on certain of these short-term notes payable. During 2021, \$23,000 of these short-term notes payable were converted into 23 shares of the Company's Series B preferred stock at a conversion ratio of \$1,000 per share and warrants to purchase 65,714 shares of common stock at an exercise price of \$0.35 per share, which resulted in no gain or loss on conversion (see Note 9).

During the year ended December 31, 2021, the Company incurred \$77,064 in legal fees with a law firm in which the Company's audit committee chair is an employee. During the year ended December 31, 2020, the Company incurred \$67,147 of legal services with this related party. As of December 31, 2021 and 2020, accounts payable and accrued expenses include \$195,000 and \$32,716 for legal fees due to the law firm for services, respectively.

NOTE 7 – DEBENTURES, CONVERTIBLE BRIDGE NOTES, AND NOTES PAYABLE

Debentures

The Company has Original Issue Discount Senior Secured Convertible Debentures (the "Debentures") in the aggregate amount of \$5,000 and \$137,500 outstanding as of December 31, 2021 and 2020, respectively. All assets of the Company are secured under the Debentures. The Debentures contain certain anti-dilutive protection provisions in the instance that the Company issues stock at a price below the conversion price of the Debentures, as adjusted from time to time, as well as other standard protections for the holder. There is no interest on these notes. On December 28, 2020, \$27,500 of these Debentures was converted into common stock at a price of \$0.22 per share resulting in the issuance of 125,000 shares of common stock and the recognition of a loss on conversion of \$1,250 which is included in loss on convertible debt and other liabilities converted to common stock on the consolidated statements of operations. In the first quarter of 2021, the two institutional holders of the debentures converted an aggregate of \$102,500 into 517,086 shares of common stock, and the Company recognized a loss on the two debenture conversions of \$56,454 which is included in loss on debentures and accrued expenses converted to common stock on the consolidated statements of operations. As of December 31, 2021, the outstanding amount of \$35,000 was in default. On February 22, 2022, the holder of the debenture converted the full balance of \$35,000 into 218,750 shares of common stock at \$0.16 per share, and the balance on the convertible debenture is currently \$0 (see Note 14 - Subsequent Events).

Convertible Bridge Notes

In 2017, 2018 and 2019, the Company issued a total of \$2,801,908 in a convertible promissory note (the "Bridge Notes") offering, which included three of the Company's directors converting \$156,368 and one shareholder converting \$11,784 of prior notes and cash advances, including interest thereon, into the offering. In 2020, \$9 million of the Bridge Notes, inclusive of principal and accrued and capitalized interest, was converted into 13,312,175 shares of common stock at \$0.22 per share. The Company recorded a loss on extinguishment of these Bridge Notes of \$495,320, which is included in the loss on conversion of bridge notes and accrued interest. As of March 31, 2021, all remaining Bridge Notes inclusive of principal and accrued and capitalized interest, were settled with the holders of these notes converting their debt into a total of 6,627,692 shares of common stock of the Company with a fair value of \$4,378,488 based on the stock price of the Company on the date of conversion. The Company recorded a loss on extinguishment of these Bridge Notes of \$744,205 for the year ended December 31, 2021, which is included in loss on conversion of bridge notes and accrued interest, as other income expenses in the statements of operations.

Pursuant to ASC 825-10-25-1, Fair Value Option, the Company made an irrevocable election at the time of issuance to report the Bridge Notes at fair value, with changes in fair value recorded through the Company's condensed consolidated statements of operations as other income (expense) in each reporting period. The estimated fair value of the remaining outstanding Bridge Notes as of December 31, 2021 and 2020 was \$0 and \$3,598,000 (see Note 8 – Fair Value Measurement), respectively. During 2020, the change in fair value resulted in a loss of \$3,170,236, which is presented as change in fair value of convertible bridge notes on the consolidated statements of operations (see Note 8 - Fair Value Measurement).

Convertible Promissory Notes

In the fourth quarter of 2021, the Company issued a total of \$605,000 in convertible notes payable. The convertible notes mature on December 31, 2023, and include a 6% simple interest rate per annum payable upon maturity. The notes are convertible, at the option of the holder, anything prior to maturity at a conversion price of \$0. Each of the convertible notes have an automatic conversion feature in the event that the Company completes an equity offering resulting in gross proceeds to the Company of at least \$5,000,000 or lists its equity securities on NASDAQ or NYSE. The conversion of notes will be at \$0.20 per share and adjusted for stock splits, stock dividends or other recapitalizations. In addition to the notes payable, each holder received a warrant for the purchase of shares of common stock with a purchase price of \$0.60 per share. The exercise period for the warrant holder expires on October 31, 2022. In accordance with accounting standards, the warrant was valued using a Black Scholes Model and the relative fair value of the warrant was applied against the convertible note for a debt discount of \$72,600 for a net Convertible note liability on the balance sheet of \$532,400.

Paycheck Protection Program

On April 14, 2020, the Company received \$142,942 under the Paycheck Protection Program (PPP) overseen by the U.S. Small Business Administration. The loan has an annual interest rate of 1% with loan payments being deferred six months from the date of the loan with a maturity date of April 2022. On July 14, 2021, the Company's PPP loan was forgiven, resulting in \$142,492 gain on forgiveness of debt which is included as other income (expense) in the consolidated statements of operations.

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NOTE 8 – FAIR VALUE MEASUREMENT

The Company measures fair value in accordance with a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure 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). The three levels of the fair value hierarchy are described below:

Level 1 Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

- Level 2 Quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability; and
- Level 3 Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity).

As disclosed in Note 7, the Bridge Notes are reported at fair value, with changes in fair value recorded through the Company's consolidated statements of operations as a component of other income (expense) in each reporting period. All Bridge Notes were converted to shares of common stock as of December 31, 2021.

The following tables set forth the Company's financial assets and liabilities measured at fair value by level within the fair value hierarchy as of December 31, 2021 and December 31, 2020. Assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Convertible Bridge Notes	\$ -	\$ -	\$ -	\$ -
Fair value as of December 31 2021	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>
	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Convertible Bridge Notes	\$ 3,598,000	\$ -	\$ -	\$ 3,598,000
Fair value as of December 31, 2020	<u>\$ 3,598,000</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 3,598,000</u>

The following tables present a reconciliation of the beginning and ending balances of items measured at fair value on a recurring basis that use significant unobservable inputs (Level 3) that has been recorded in the condensed consolidated balance sheets which is as follows:

Fair value, December 31, 2020	\$ 3,598,000
Accrued interest	35,983
Conversion to shares of common stock	(3,633,983)
Fair value, December 31, 2021	<u>\$ -</u>

NOTE 9 – DISCONTINUED OPERATIONS

On November 6, 2020, the Company executed a Separation Agreement (see Note 4 – Separation Agreement), whereby the Company transferred its Legacy Business and the related assets and liabilities to EPH, a related party and equity method investee.

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ASC 205-20 “Discontinued Operations” establishes that the disposal or abandonment of a component of an entity or a group of components of an entity should be reported in discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results. As a result, the component's results of operations have been reclassified as discontinued operations on a retrospective basis for the period ended December 31, 2020. There were no results of operations from the component in the current period. As of December 31, 2021, there were no assets or liabilities held associated with this business. The results of operations of this component, for all periods, are separately reported as “discontinued operations” on the consolidated statements of operations.

As disclosed in Note 4 – Separation Agreement, the Company sold its equity interest in EPH as of March 31, 2021. There have been no transactions between the Company and EPH since the Separation Agreement.

A reconciliation of the major classes of line items constituting the income (loss) from discontinued operations, net of income taxes as is presented in the consolidated statements of operations for the year ended December 31, 2020, are summarized below:

Reconciliation of revenue and expense items in discontinued operations in the consolidated statements of operations:

	Year Ended December 31, 2020
REVENUES	<u>\$ 541,200</u>
OPERATING EXPENSES	
Payroll and related expenses	515,741
General and administrative	53,398
Total operating expenses	<u>569,139</u>
Financing costs including interest	46,967
Gain on debt extinguishment	(1,032,160)
INCOME FROM DISCONTINUED OPERATIONS	<u>\$ 957,254</u>

Reconciliation of cash flows from operating activities and financing activities on the statements of cash flows:

	Year Ended December 31, 2020
CASH FLOWS FROM OPERATING ACTIVITIES	
Net income from discontinued operations	\$ 957,254
Adjustments to reconcile net income to net cash provided by discontinued operations:	
Gain on forgiveness or assumption of promissory notes and accrued expenses	(1,032,160)
Changes in operating assets and liabilities	
Increase in accounts payable and accrued expenses	22,500
Increase in accrued interest - related party	46,967
Net cash provided by operating activities	<u>(5,439)</u>
CASH FLOWS FROM FINANCING ACTIVITIES	
Proceeds from promissory notes - related parties	338,373
Repayments on promissory notes – related parties	<u>(1,590)</u>

Net cash provided by financing activities	336,783
Net cash provided by discontinued operations	\$ 331,344

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NOTE 10 – PREFERRED STOCK, COMMON STOCK, AND WARRANTS

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

As of December 31, 2021 and 2020, the Company has 480 and 600 shares of Series A Stock issued and outstanding, respectively. During the year ended December 31, 2020, the Company converted 120 shares of Series A Stock with a stated value of \$120,000 into 750,000 shares of common stock with a fair value of \$662,425 at a conversion ratio of \$0.16. A deemed dividend was recognized in the amount of \$542,500 for the difference between the value of the common shares using the market price on the date of conversion and the \$120,000 stated value of the Series A Stock upon conversion into common stock, which has been presented as an increase to the net loss available to common stockholders in the consolidated statement of operations.

The remaining outstanding shares of Series A Stock are convertible at \$0.16 per share of the Company’s common stock (the “Conversion Price”), which was adjusted to match the conversion price of the Company’s Series B Preferred Stock. The Series A Stock bears a 6% dividend per annum, calculable and payable per quarter in cash or additional shares of common stock as determined in the Certificate of Designation. The Series A Stock has no voting rights until converted to common stock and has a liquidation preference equal to the aggregate purchase price of \$480,000 plus accrued dividends. The Series A Stock was in default at the end of 2021, and the Company is negotiating a modification with the holders, including the conversion of these shares into common stock. Each share of Series A Stock received warrants, all of which had expired as of the first quarter of 2021.

The Series A Stock has price protection provisions in the case that the Company issues any shares of stock not pursuant to an “Exempt Issuance” at a price below the Conversion Price. Exempt Issuances include: (i) shares of common stock or common stock equivalents issued pursuant to the original merger of the company or any funding contemplated by that transaction; (ii) any common stock or convertible securities outstanding as of the date of closing; (iii) common stock or common stock equivalents issued in connection with strategic acquisitions; (iv) shares of common stock or equivalents issued to employees, directors or consultants pursuant to a plan, subject to limitations in amount and price; and (v) other similar transactions. The Certificate of Designation contains restrictive covenants not to incur certain debt, repurchase shares of common stock, pay dividends or enter into certain transactions with affiliates without consent of holders of 67% of the Series A Stock.

Management has determined that the Series A Stock is more akin to a debt security than equity primarily because it contains a mandatory 2-year redemption at the option of the holder, which only occurs if the Series A Stock is not converted to common stock. Therefore, management has presented the Series A Stock outside of permanent equity as mezzanine equity, which does not factor into the totals of either liabilities or equity.

The Series A Stock carries a 6% per annum dividend calculated on the stated value of the stock and is cumulative and payable quarterly beginning July 1, 2016. These dividends are accrued at each reporting period and are added to the redemption value of the stock; however, since the Company has an accumulated deficit, the charge has been recognized in additional paid-in capital. The accrued dividends are \$213,580 and \$184,044 as of December 31, 2021 and 2020, respectively.

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

In December 2020, the Company filed an amendment to its Articles of Incorporation to authorize the issuance of up to 2,500 shares of Series B Stock, par value \$0.001 per share, pursuant to a Certificate of Designation. The Series B Stock provides the holders a 10% annual paid-in-kind dividend, a liquidation preference equal to the purchase price of the shares (\$1,000 per share) followed by the right to participate with the common stockholders in the instance of a liquidation or other exit event, and provide the holders the right to vote along with the common holders based on the common conversion amount of their holdings. The Series B Stock is convertible into common stock at a ratio of \$0.16 per share, subject to anti-dilution protections in the case of certain issuances of securities below that conversion price. The Series B Stock is not redeemable.

In January 2021, the Company closed a private offering of its Series B Stock for \$1,000 per share, raising a total of \$2,500,000, inclusive of \$156,000 in prior debt conversion and \$23,000 of notes payable with directors converted to shares of Series B Stock and warrants. Between July 27 and August 24, 2021, 15 holders of an aggregate of 991 shares of Series B Stock converted their preferred shares into 6,525,378 shares of common stock, which included \$53,061 of accrued dividends. As of December 31, 2021, 1,509 shares of Series B Stock were issued and outstanding. The accrued dividends are \$153,757 and \$0 as of December 31, 2021 and 2020, respectively.

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Series E-1 Preferred Stock (“Series E-1 Stock”)

On December 3, 2020, the Company filed an amendment to its Articles of Incorporation to authorize the issuance of up to 8,500 shares of Series E-1 Stock pursuant to a Certificate of Designation. The shares of Series E-1 Stock are incentive-based, vesting and forfeitable securities that provide the holders the right in the aggregate to receive an “earnout” equal to 20% of the total consideration received by the Company in the instance of a sale or sub-license of its core licensed radiopharmaceutical technology, or sale or merger of the Company, which is paid on a priority, senior basis. In addition, the holders of the Series E-1 Stock can convert their vested preferred stock at anytime or after an event resulting in an earnout payment, such as an acquisition of the Company, into an aggregate of 8.5 million common shares. The holders of the Series E-1 Stock have the right to vote along with the common stockholders based on the common conversion amount of their holdings, and have the right to nominate two members of the Board of Directors.

On December 30, 2020, 7,650 shares of Series E-1 Stock were issued to five individuals, including the Company’s Executive Chairman, CEO and General Counsel which vest starting in July 2021 through January 2023 and are forfeitable by the holders prior to vesting. In February 2021, the remaining 850 shares of Series E-1 Stock were issued to one newly-appointed director, vesting half in February 2022 and the balance in February 2023.

The Company computed the total grant date fair value of the Series E-1 Stock to be approximately \$6,528,000 using an option pricing model and the following assumptions: (1) with respect to the shares granted in 2020: expected term of four years, dividend yield of 0%, volatility of 96.12%, and a risk-free rate of 0.27%; and (2) with respect to the shares granted in 2021: expected term of four years, dividend yield of 0%, volatility of 90.78%, and a risk-free rate of 0.29%.

On December 6, 2021, the Company entered into an Exchange Agreement and Plan of Reorganization (the “Exchange Agreement”) with all E-1 Stockholders pursuant to which all shares of Series E-1 Stock were exchanged into an aggregate of 28,839,428 shares of common stock of the Company. The fair value of the Series E-1 Stock was determined to be approximately \$8.65 million at the time of exchange, and was based upon a valuation report provided to the Board by an independent third party expert, and approved for fairness by the independent chairman of the Compensation Committee. The common stock issued in the exchange was based on a value of \$0.30 per share using a 30-day weighted average closing price calculation, and was issued proportionately to each holder based on their individual holdings of Series E-1 Stock. All shares of common stock issued to the shareholders are subject to the same vesting schedules as was originally provided in each shareholder’s Series E-1 Stock issuance agreement, meaning that such shares of common stock are forfeitable if certain conditions of employment are not met by the holders. As of December 31, 2021, approximately 23 million common shares are fully vested and approximately 6 million common shares are unvested.

During the year ended December 31, 2021, the Company recognized stock-based compensation to employees and directors totaling \$7,751,087 related to the Series E-

1 Stock, which is included in compensation and related expenses on the consolidated statements of operations. As of December 31, 2021, approximately \$0.9 million of unrecognized compensation remains which will be recognized over a twelve-month vesting period and has been presented as deferred compensation on the consolidated balance sheets.

Common Stock

In 2020, the Company effected a 25:1 reverse stock split and all share numbers herein have been adjusted for that change.

In 2021 and 2020, the Company issued 44,696,923 and 17,392,343 shares of common stock, respectively, as follows:

	For the Years Ended December 31,	
	2021	2020
Conversion of bridge notes and accrued interest to common stock	6,627,692	13,312,175
Conversion of debentures and accrued expenses	632,995	218,686
Conversion of accrued salary and bonus, directors fees, and promissory notes with related parties	-	2,111,482
Conversion of Series A Stock to common stock	750,000	-
Conversion of Series B Stock to common stock	6,525,378	-
Exercise of Series B Warrants to common stock	1,871,430	-
Exchange of Series E-1 Stock to common stock	28,839,428	-
Stock based compensation for services	1,450,000	1,750,000
Total Common Shares issued	44,696,923	17,392,343

During the year ended December 31, 2021, the Company issued 6,525,378 shares of common stock in connection with the conversion of Series B Stock with an original investment amount of \$911,000 plus \$53,061 in accrued dividends at the original stated conversion rate of \$0.16. The Company also issued 1,450,000 shares of common stock to service providers during the period. The fair market value of the common stock was \$517,500 which was recorded as stock compensation expense under Professional fees.

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As of December 31, 2021, \$125,007 of debentures and accrued expenses plus bridge notes with principal and accrued interest of \$1,447,315 for an aggregate of \$1,572,315 of obligations were converted into 7,260,687 shares of common stock at a price of \$0.16 per share. Further, \$120,000 of Series A Stock was converted into 750,000 shares of common stock at a price of \$0.16 per share. Due to the timing of the conversions and the Company's stock price at that time of conversion, the Company recorded the following losses from liability conversions in the twelve months ended December 31, 2021: \$744,505 from the conversion of Bridge Notes including accrued interest, and \$390,068 from the conversion of a debenture and accrued expenses. A deemed dividend was recognized in the amount of \$42,500 for the difference between the value of the common shares using market price on the date of conversion and the \$120,000 stated value of the Series A Stock upon conversion into common stock which has been presented as an increase to the net loss available to common stockholders in the consolidated statement of operations. Further, on December 6, 2021, the Company entered into an Exchange Agreement and Plan of Reorganization (the "Exchange Agreement") with all E-1 Stockholders pursuant to which all shares of Series E-1 Stock were exchanged into an aggregate of 28,839,428 shares of common stock of the Company. As part of the exchange, the Company recognized stock-based compensation to employees and directors totaling \$7,751,087 related to the Series E-1 Stock, which is included in compensation and related expenses on the consolidated statements of operations. Further, on October 15, 2021, 1,871,431 of the Series B Warrants were exercised for proceeds to the Company of \$467,858, and the remaining Series B Warrants and the Service Warrants expired.

For the years ended December 31, 2021 and 2020, the Company recognized \$1,070,725 and \$406,825 of compensation expense for several service agreements which is included in professional fees.

For the year ended December 31, 2020, \$3,441,401 of total obligations were converted into shares of common stock at a price of \$0.22 per share. Due to the timing of the conversions and the Company's stock price at that time of conversion, the Company recorded the following losses from liability conversions in 2020: \$495,320 from the conversion of Bridge Notes including accrued interest, \$68,373 from the conversion of a debenture and note payable with unrelated parties, and \$71,210 from the conversion of accrued salary, bonus, directors' fees and notes payable with related parties.

Warrants

During the year ended December 31, 2021, the Company issued 6,743,575 warrants in connection with its Series B Stock offering (the "Series B Warrants"), 750,000 warrants to a service provider (the "Service Warrants"), and 1,008,334 warrants in connection with its convertible note offering (the "Note Warrants"), see Note 7.

The terms of the Series B Warrants and Service Warrants were modified twice in 2021 by resolution of the Company's board of directors, first to extend the termination date from July 8, 2021 to September 30, 2021 and then to extend the termination date to October 15, 2021. As part of the second modification, the exercise price of the Series B Warrants was reduced from \$0.35 per share to \$0.25 per share. As of October 15, 2021, 1,871,431 of the Series B Warrants were exercised for proceeds to the Company of \$467,855, and the remaining Series B Warrants and the Service Warrants expired.

A summary of warrant activity and related information during the years ended December 31, 2021 and 2020 is as follows:

	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding as of December 31, 2019	126,154	\$ 0.22	\$ -
Issued	-	-	-
Exercised	-	-	-
Expired	80,000	-	-
Outstanding as of December 31, 2020	46,154	\$ 0.22	\$ -
Issued	8,501,908	0.29	-
Exercised	1,871,432	0.25	-
Expired	5,193,297	0.25	-
Outstanding as of December 31, 2021	1,483,333	\$ 0.49	\$ -

The aggregate intrinsic value of the warrants is the difference between the fair market value of the Company's closing price of its common stock at each reporting date, less the exercise price multiplied by the number of warrants outstanding, which was \$0 at December 31, 2021.

The following is a summary of the outstanding common stock warrants as of December 31, 2021:

	Number of Warrants	Exercise price per share	Expiration Date
Warrants issued in connection with issuance of Series B Stock to lead investor	475,000	\$ 0.25	January 15, 2022
Warrants issued in connection with convertible notes	1,008,333	\$ 0.60	October 31, 2022
Total Outstanding as of December 31, 2021	1,483,333		

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With respect to the Series B Warrants, the Company recognized the incremental value associated with the two modifications for term extension and exercise price reduction as a deemed dividend charge of \$850,214 within stockholders' equity and as a reduction of net loss available to common stockholders on the consolidated statement of operations. The incremental value associated with these warrant modifications was determined using a Black-Scholes pricing model using the original terms of the warrants and the modified terms and the following assumptions: expected term of 0.0- .25 years, dividend yield of 0%, volatility of 6.5-183.2%, and a risk-free rate of 0.04%-0.07%.

With respect to the Service Warrants, the Company computed the total grant date fair value of the warrants to be approximately \$405,000 using a Black-Scholes option pricing model and the following assumptions: expected term of 0.5 years, dividend yield of -0%-, volatility of 129.81%, and a risk-free rate of .08%. The value of these warrants was recognized as stock-based compensation expense on the date of grant and is included in professional fees on the consolidated statement of operations for year ended December 31, 2021, as the warrants were fully earned upon issuance. On June 17, 2021 and September 22, 2021, the term of these warrants was extended, resulting in incremental compensation expense of \$109,208, has been included in professional fees on the consolidated statement of operations for the year ended December 31, 2021. The incremental value associated with these modified warrants was determined using a Black-Scholes pricing model using the original terms of the warrants and the modified terms and the following assumptions: expected term of 0.00 – 0.04 years, dividend yield of 0%, volatility of 106.5% -183.2%, and a risk-free rate of 0.05-0.07%.

With respect to the Note Warrants, the Company computed the total grant dates fair value of the warrants to be \$82,522 using a Black-Scholes option pricing model and the following assumptions: expected term of 0.5 years, dividend yield of 0%, volatility of 175.7% to 184.4% and a risk-free rate of .11% to .14%. The value of these warrants was recorded against the convertible notes as a debt discount using the relative fair value method and included in additional paid-in capital.

NOTE 11 – STOCK OPTIONS AND RESTRICTED STOCK UNITS

To compensate officers, directors and other key service providers with equity grants, the Board approved the 2016 Omnibus Equity Incentive Plan ("2016 Plan") in 2016, which initially allowed for 160,000 shares of common stock, stock options, stock rights (restricted stock units), or stock appreciation rights to be granted by the Board in its discretion. This authorized amount was increased to 400,000 shares by Board resolution and amendment in 2017, and further increased to 1 million shares by Board resolution in 2021. As of December 31, 2021, there are no shares available under the 2016 Plan for future issuance; however, the Board approved an increase in the authorized shares available to 8 million by resolution on January 13, 2022, as provided under the 2016 Plan (See Note 14 – Subsequent Events).

The Company issued 644,000 options to purchase common stock to officers and directors of the Company during 2021. These options have a 10 year term, a vesting period of 50% six months after issuance and the balance 12 months after issuance, and an exercise price of \$0.36 per share.

A summary of stock option activity and related information during the years ended December 31, 2021 and 2020 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of December 31, 2019	340,619	\$ 3.00	3.9	\$ -
Granted	128,000	\$ 0.50	8.9	\$ -
Outstanding as of December 31, 2020	468,619	\$ 1.75	5.6	\$ -
Granted	644,000	\$ 0.36	10.0	\$ -
Outstanding as of December 31, 2021	1,112,619	\$ 0.76	7.9	\$ -
Exercisable as of December 31, 2021	468,619	\$ 1.31	5.5	\$ -

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The Company recorded \$75,692 and \$24,327 of stock-based compensation expense and one-time incremental charge for option repricing which is included in compensation and related expenses for the years ended December 31, 2021 and 2020, respectively, on the consolidated statement of operations.

The aggregate intrinsic value of options is the difference between the fair market value of the Company's closing price of its common stock at each reporting date, less the exercise price multiplied by the number of options granted, which was \$0 at December 31, 2021.

As of December 31, 2021, the unrecognized stock-based compensation of \$136,828 is expected to be expensed through August 2022 based on the option vesting requirements. The weighted average fair value of options granted was \$0.36 per share for the year ended December 31, 2021.

We estimate the fair value of stock-based awards on the date of grant using the Black-Scholes option pricing model using the fair market value of our common stock on the date of grant and a number of other assumptions. These assumptions include estimates regarding the expected term of the awards, estimates of the stock volatility over a duration that approximates the expected term of the awards, estimates of the risk-free rate, and estimates of expected dividend rates.

The assumptions that were used in Black-Scholes option pricing model for the year ended December 31, 2021 were as follows:

	For the years ended	
	2021	2020
Expected term (years)	5.38	5.0
Expected volatility	153.9%	149.67%
Risk-free interest rate	0.94%	1.610%
Expected dividend yield	0.0%	0.0%

Option Repricing

On January 6, 2020, the compensation committee of the Company's Board of Directors, approved a one-time stock option repricing program (the "Option Repricing") to permit the Company to reprice certain options to purchase the Company's Common Stock held by its current directors, officers and employees (the "Eligible Options"), which actions became effective on January 6, 2020. Under the Option Repricing, Eligible Options with an exercise price at or above \$2.50 per share (representing an aggregate of 252,440 options, or 54% of the total outstanding) were amended to reduce such exercise price to \$0.50 per share.

The impact of the Option Repricing was a one-time incremental non-cash charge of \$6,304, which was recorded as stock option expense for the year ended December

31, 2020 which was included in compensation and related expenses on the consolidated statements of operations.

NOTE 12 – INCOME TAXES

A reconciliation of the differences between the effective income tax rates and the statutory federal tax rates for the years ended December 31, 2021 and 2021 (computed by applying the U.S. Federal corporate tax rate of 21 percent to the loss before taxes) is as follows:

	2021	2020
Tax benefit at U.S. statutory rate	\$ (2,515,184)	\$ (1,021,163)
State taxes, net of federal benefit	(89,264)	(260,154)
Stock based compensation	1,875,514	
Change in fair value of convertible bridge notes and derivatives	-	792,877
PPP loan forgiveness	(30,018)	-
Gain on extinguishment of liabilities	238,260	-
Other permanent differences	-	60,941
Change in valuation allowance	520,692	427,499
	<u>\$ -</u>	<u>\$ -</u>

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The tax effect of temporary differences that give rise to significant portions of the deferred tax assets and liabilities for the years ended December 31, 2021 and 2020 consisted of the following:

	2021	2020
Net operating loss carry-forward	\$ 3,073,065	\$ 2,657,931
Accrued expenses	166,783	80,676
Stock based compensation	70,128	50,944
Charitable contribution	267	-
Net deferred tax assets	3,310,243	2,789,552
Valuation allowance	(3,310,243)	(2,789,552)
Total net deferred tax asset	<u>\$ -</u>	<u>\$ -</u>

At December 31, 2021 and 2020, the Company had net deferred tax assets of \$3,310,243 and \$2,789,552 principally arising from net operating loss carry-forwards for income tax purposes (“NOLs”). As management of the Company cannot determine that it is more likely than not that the Company will realize the benefit of the net deferred tax asset, a valuation allowance equal to the net deferred tax asset has been established at December 31, 2021 and 2020. At December 31, 2021, the Company has net operating loss carry forwards totaling approximately \$12,125,000. The potential tax benefit arising from NOLs generated of approximately \$4,474,000 prior to 2018 effective date will begin to expire in 2034. The potential tax benefit arising from the net operating loss carryforwards of approximately \$6,651,000 generated after 2018 can be carried forward indefinitely within the annual usage limitations. The Company is delinquent in filing its federal tax returns for several of the previous year periods since inception. Therefore, all tax years since the Company’s inception remain open for examination. Management expects to retain a tax professional to assist in bringing these filings current.

The Company’s NOL and tax credit carryovers may be significantly limited under the Internal Revenue Code (“IRC”). NOL and tax credit carryovers are limited under Section 382 when there is a significant “ownership change” as defined in the IRC. During the year ended December 31, 2021 and in prior years, the Company may have experienced such ownership changes, which could impose such limitations.

The limitations imposed by the IRC would place an annual limitation on the amount of NOL and tax credit carryovers that can be utilized. When the Company completes the necessary studies, the amount of NOL carryovers available may be reduced significantly. However, since the valuation allowance fully reserves for all available carryovers, the effect of the reduction would be offset by a reduction in the valuation allowance.

NOTE 13 – COMMITMENTS AND CONTINGENCIES

Employment Agreements

The employment agreements as amended for the Company’s Executive Chairman and CEO each contain termination provisions whereby if they are terminated without cause or following a material change, as defined therein, they will receive salary through the date of termination plus an additional 24 months, bonus that would be earned during the full year when the termination became effective (or a lump sum of 50% of the full target bonus), all stock options shall vest and healthcare benefits will continue for 24 months. The Company’s General Counsel’s employment agreement, as amended, contains an 18-month severance payment in the instance of a termination without cause or following a material change, as defined therein. Additionally, the management team are currently taking partial salary of their approved salary per their employment agreements and the difference is being accrued starting as of December 1, 2021. As of December 31, 2021, the accrued salary for the management team was \$83,731.

The employment agreements, as amended, for the Company’s Executive Chairman and CEO each contain a transaction bonus in the instance any of the Company’s assets are sold or sublicensed or if the Company or its subsidiary is acquired, equal to 1.75% of the consideration received by the Company. The employment agreement, as amended, for the Company’s General Counsel contains a similar transaction bonus equal to 0.5% of consideration received by the Company.

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License Agreement

The Company’s License Agreement for the Technology, as amended, with IGL is for 20 years or until the expiration of the multiple patents covered under the license and requires multiple milestone-based payments including: up to \$410,000 as CycloSam[®] advances through Phase 3 of clinical trials, and \$2 million upon commercialization. IGL has also received 500,000 shares of the Company as additional compensation. Upon commercialization, IGL will receive an on-going royalty equal to 4.5% of Net Sales, as defined in the License Agreement, and 5% of any consideration we receive pursuant to a sublicense, sale of the asset, or sale of QSAM Therapeutics. QSAM will also pay for ongoing patent filing and maintenance fees, and has certain requirements to defend the patents against infringement claims.

In connection with the License Agreement, QSAM signed a two-year Consulting and Confidentiality Agreement (the “Consulting Agreement”) with IGL, which provides IGL with payments of \$8,500 per month starting 60 days after signing through April 2022. The Consulting Agreement is to provide QSAM with additional consulting and advisory services from the technology’s founders to assist in the clinical development of CycloSam. As of December 31, 2021, the Company has paid \$ 15,101 in expense reimbursements required under the agreement. As of December 31, 2020, the Company paid \$60,000 under the License Agreement representing the full upfront license fee, as well \$97,999 in expense reimbursements required under that agreement. The drug development costs to service providers including the fixed \$,500 monthly consulting fee, which has been reflected as research and development expense on the consolidated statement of operations was \$647,302 and \$362,456 for the years ended December 31, 2021 and 2020, respectively.

NOTE 14 – SUBSEQUENT EVENTS

On January 13, 2022, by resolution of the Board of Directors, the Company increased the authorized shares issuable under its 2016 Omnibus Equity Incentive Plan, as amended, from 1 million to 8 million shares.

On January 15, 2022, the Company modified the terms of the warrant issued to Checkmate Capital Group LLC under a modification agreement, to extend the term of such warrant until January 15, 2023, in return for an agreement for the holder to sign a six-month lock-up agreement in the instance that the Company completes an upcoming underwritten equity offering and lists its shares on NASDAQ.

On January 15, 2022, the Company issued one of its Directors 400,000 shares of common stock for services previously rendered to the Company.

On January 24, 2022, the Board approved a plan of compensation for independent directors, which provides: an annual retainer of \$0,000; additional annual fees of \$20,000, \$15,000 and \$10,000 for serving as Chair of the Audit Committee, Compensation Committee and Nominating & Governance Committee, respectively; and annual fees of \$7,500, \$5,000 and \$3,500 for serving as members of the Audit Committee, Compensation Committee and Nominating & Governance Committee, respectively. Upon appointment to our Board, non-employee directors receive 250,000 stock options, exercisable for 10 years at a price equal to the closing price of our common stock on the date of appointment, and vesting 50% in 12 months and the balance in 24 months.

On January 25, 2022, the Company appointed Adriann Sax to the Board of Directors and issued her 250,000 stock options, exercisable at a price of \$0.20, and vesting half on January 25, 2023, and the balance on January 25, 2024. The options are exercisable for ten years from issuance. Ms. Sax was appointed to the Audit Committee and Chair of the Nominating & Governance Committee.

On February 21, 2022, one of the Company's independent directors was granted 1,000,000 stock options, exercisable at a price of \$0.20, and vesting on December 31, 2022. The options are exercisable for ten years from issuance.

On February 22, 2022, the holder of the Company's convertible debenture converted the \$35,000 principal balance of that debt security into 218,750 shares of common stock at \$0.16 per share. No convertible debentures remain outstanding.

On February 22, 2022, one of the Company's key employees was granted 1,000,000 stock options, exercisable at a price of \$0.20, and vesting in one-third increments over the following three years from grant. All options are exercisable for ten years from issuance.

QSAM Biosciences, Inc.
Code of Business Conduct and Ethics

This Code of Business Conduct and Ethics (the “Code”) sets forth legal and ethical standards of conduct for directors, officers and employees of QSAM Biosciences, Inc. and its subsidiaries (the “Company”). This Code is intended to: (i) promote honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest; (ii) promote full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with, or submits to, the Securities and Exchange Commission (the “SEC”) and in other public communications made by the Company; (iii) promote compliance with applicable governmental laws, rules and regulations; (iv) promote the protection of Company assets, including corporate opportunities and confidential information; (v) promote fair dealing practices; (vi) deter wrongdoing; and (vii) ensure accountability for adherence to the Code. This Code applies to the Company and all of its subsidiaries and other business entities controlled by it worldwide.

The Company’s policy is to promote high standards of integrity by conducting its affairs honestly and ethically. Each director, officer and employee of the Company must act with integrity and observe the highest ethical standards of business conduct in his or her dealings with the Company’s customers, suppliers, partners, service providers, competitors, employees and anyone else with whom he or she has contact in the course of performing his or her job.

If you have any questions regarding this Code or its application to you in any situation, you should contact your supervisor or the Company’s General Counsel.

1. Compliance with Laws, Rules and Regulations

1.1 The Company requires that all employees, officers and directors comply with all laws, rules and regulations applicable to the Company wherever it does business. You are expected to be familiar with the laws, rules and regulations applicable to your place of work, and such additional laws, rules and regulations which may apply and of which the Company gives you written notice. You are expected to use good judgment and common sense in seeking to comply with all applicable laws, rules and regulations and to ask for advice when you are uncertain about them.

1.2 If you become aware of the violation of any law, rule or regulation by the Company, whether by its officers, employees or directors, it is your responsibility to promptly report the matter to your supervisor, the Company’s General Counsel, or the Chairman of the Audit Committee. While it is the Company’s desire to address matters internally, nothing in this Code should discourage you from reporting any illegal activity, including any violation of the securities laws, antitrust laws, environmental laws or any other federal or state law, rule or regulation, to the appropriate regulatory authority.

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1.3 Employees, officers and directors should comply, both in letter and spirit, with all applicable laws, rules and regulations in the cities, states and countries in which the Company operates.

1.4 Although not all employees, officers and directors are expected to know the details of all applicable laws, rules and regulations, it is important to know enough to determine when to seek advice from appropriate personnel. Questions about compliance should be addressed to the General Counsel.

1.5 No director, officer or employee may purchase or sell any Company securities while in possession of material nonpublic information regarding the Company, nor may any director, officer or employee purchase or sell another company’s securities while in possession of material nonpublic information regarding that company. It is against Company policies and illegal for any director, officer or employee to use material nonpublic information regarding the Company or any other company to:

- (a) obtain profit for himself or herself; or
- (b) directly or indirectly “tip” others who might make an investment decision on the basis of that information.

Refer to Company’s Insider Trading Policies for more information.

1.6 Employees, officers and directors shall not discharge, demote, suspend, threaten, harass or in any other manner discriminate against an employee because he or she in good faith reports any such violation.

1.7 This Code should not be construed to prohibit you from testifying, participating or otherwise assisting in any state or federal administrative, judicial or legislative proceeding or investigation.

2. Conflicts of Interest

2.1 Employees, officers and directors must act in the best interests of the Company. You must refrain from engaging in any activity or having a personal interest that presents a conflict of interest.

2.2 A conflict of interest occurs when an individual’s private interest (or the interest of a member of his or her family) interferes, or even appears to interfere, with the interests of the Company as a whole. A conflict of interest can arise when an employee, officer or director (or a member of his or her family) takes actions or has interests that may make it difficult to perform his or her work for the Company objectively and effectively. Conflicts of interest also arise when an employee, officer or director (or a member of his or her family) receives improper personal benefits as a result of his or her position in the Company.

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2.3 Loans by the Company to, or guarantees by the Company of obligations of, employees or their family members are of special concern and could constitute improper personal benefits to the recipients of such loans or guarantees, depending on the facts and circumstances. Loans by the Company to, or guarantees by the Company of obligations of, any director or executive officer or their family members are expressly prohibited.

2.4 Whether or not a conflict of interest exists or will exist can be unclear. Conflicts of interest should be avoided unless specifically authorized as described in Section 2.5.

2.5 Persons other than directors and executive officers who have questions about a potential conflict of interest or who become aware of an actual or potential conflict should discuss the matter with, and seek a determination and prior authorization or approval from, their supervisor, the Company’s General Counsel, or the Chairman of the Audit Committee. A supervisor may not authorize or approve conflict of interest matters or make determinations as to whether a problematic conflict of interest exists without first providing the General Counsel or Chairman of the Audit Committee with a written description of the activity and seeking the Chairman’s or the General Counsel’s written approval. If the supervisor is himself or herself involved in the potential or actual conflict, the matter should instead be discussed directly with the General Counsel.

Directors and executive officers must seek determinations and prior authorizations or approvals of potential conflicts of interest exclusively from the Audit

3. Insider Trading

3.1 It is usually illegal to buy or sell securities using material information not available to the public. Persons who give such undisclosed “inside” information to others may be as liable as persons who trade securities while possessing such information. Securities laws may be violated if you, or any relatives or friends trade in securities of the Company, or any of its customers or vendors, while possessing inside information or unpublished knowledge. If you are uncertain about the constraints on your purchase or sale of any Company securities or the securities of any other company that you are familiar with by virtue of your relationship with the Company, you should consult with the Company’s General Counsel before making any such purchase or sale. Refer to Company’s Insider Trading Policy for more information.

4. Confidentiality

4.1 Employees, officers and directors must maintain the confidentiality of confidential information entrusted to them by the Company or other companies, including our suppliers and customers, except when disclosure is authorized by a supervisor or legally mandated. Unauthorized disclosure of any confidential information is prohibited. Additionally, employees should take appropriate precautions to ensure that confidential or sensitive business information, whether it is proprietary to the Company or another company, is not communicated within the Company except to employees who have a need to know such information to perform their responsibilities for the Company.

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4.2 Third parties may ask you for information concerning the Company. Employees, officers and directors (other than the Company’s authorized spokespersons) must not discuss internal Company matters with, or disseminate internal Company information to, anyone outside the Company, except as required in the performance of their Company duties and after an appropriate confidentiality agreement is in place. This prohibition applies particularly to inquiries concerning the Company from the media, market professionals (such as securities analysts, institutional investors, investment advisers, brokers and dealers) and security holders. All responses to inquiries on behalf of the Company must be made only by the Company’s authorized spokespersons. If you receive any inquiries of this nature, you must decline to comment and refer the inquirer to your supervisor or one of the Company’s authorized spokespersons. You also must abide by any lawful obligations that you have to your former employer. These obligations may include restrictions on the use and disclosure of confidential information, restrictions on the solicitation of former colleagues to work at the Company and non-competition obligations.

4.3 Finally, if you are involved in conducting business in the federal, state or local government marketplace(s), you may be subject to other obligations regarding the use, disclosure, safeguarding or receipt of particular types of information, including restrictions regarding competition-sensitive information such as government source selection or contractor bid and proposal information.

5. Corporate Opportunities

5.1 All directors, officers and employees owe a duty to the Company to advance its interests when the opportunity arises. Directors, officers and employees are prohibited from taking for themselves personally (or for the benefit of friends or family members) opportunities that are discovered through the use of Company assets, property, information or position. Directors, officers and employees may not use Company assets, property, information or position for personal gain (including gain of friends or family members). In addition, no director, officer or employee may compete with the Company.

6. Honest and Ethical Conduct and Fair Dealing

6.1 Employees, officers and directors should endeavor to deal honestly, ethically and fairly with the Company’s suppliers, customers, competitors and employees. Statements regarding the Company’s products and services must not be untrue, misleading, deceptive or fraudulent. You must not take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts or any other unfair dealing practice.

7. Protection and Proper Use of Corporate Assets

7.1 Employees, officers and directors should seek to protect the Company’s assets. Theft, carelessness and waste have a direct impact on the Company’s financial performance. Employees, officers and directors must use the Company’s assets and services solely for legitimate business purposes of the Company and not for any personal benefit or the personal benefit of anyone else.

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7.2 Employees, officers and directors must advance the Company’s legitimate interests when the opportunity to do so arises. You must not take advantage of opportunities for yourself or another person that are discovered through your position with the Company or the use of property or information of, or entrusted to, the Company.

8. Gifts and Gratuities

8.1 The use of Company funds or assets for gifts, gratuities or other favors to Company employees is prohibited, except to the extent such gifts are in compliance with applicable law, nominal in amount and not given in consideration or expectation of any action by the recipient. Note: Payments to Company employees under bonus, commission, incentive, or other bona-fide recognition and performance plans or programs are not considered gifts under this section.

8.2 Employees, officers and directors must not accept, or permit any member of his or her Immediate Family to accept, any gifts, gratuities or other favors from any customer, supplier or other person doing or seeking to do business with the Company, other than items of nominal value. Any gifts that are not of nominal value should be returned immediately and reported to your supervisor. If immediate return is not practical, they should be given to the Company for charitable disposition or such other disposition as the Company believes appropriate in its sole discretion. For purposes of this policy, nominal value is considered \$100 or less.

8.3 Common sense and moderation should prevail in business entertainment engaged in on behalf of the Company. Employees, officers and directors should provide, or accept, business entertainment to or from anyone doing business with the Company only if the entertainment is infrequent, modest and intended to serve legitimate business goals.

8.4 Bribes and kickbacks are criminal acts, strictly prohibited by law. You must not offer, give, solicit or receive any form of bribe or kickback anywhere in the world. You must also abide by the often stringent laws regulating gifts and gratuities to government officials and employees.

9. Accuracy of Books and Records and Public Reports

9.1 Employees, officers and directors must honestly and accurately report all business transactions. You are responsible for the material accuracy of your records and reports. Accurate record keeping and reporting are essential to the Company’s ability to meet legal and regulatory obligations, including specific obligations relating to the Company’s transactions with governments and governmental entities.

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9.2 All Company books, records and accounts shall be maintained in accordance with all applicable regulations and standards and accurately reflect the true nature of the transactions they record in all material respects. The financial statements of the Company shall conform in all material respects to generally accepted accounting principles and the Company's accounting policies. No undisclosed or unrecorded account shall be established for any purpose. No false or misleading entries shall be made in the Company's books or records for any reason, and no disbursement of corporate funds or other corporate property shall be made without adequate supporting documentation. It is the policy of the Company to provide full, fair, accurate, timely and understandable disclosure in reports and documents filed with, or submitted to, the Securities and Exchange Commission and in other public communications.

10. Concerns Regarding Accounting or Auditing Matters

10.1 Employees with concerns regarding questionable accounting or auditing matters or complaints regarding accounting, internal accounting controls or auditing matters may confidentially, and anonymously if they wish, submit such concerns or complaints in writing to the Chairman of the Audit Committee of the Board of Directors at the Company's headquarters address. *See Reporting and Compliance Procedures*. A complete record of all complaints will be prepared by the Audit Committee each fiscal quarter and reported to the Board of Directors.

10.2 The Audit Committee will evaluate the merits of any concerns or complaints received by it and authorize such follow-up actions, if any, as it deems necessary or appropriate to address the substance of the concern or complaint. The Company will not discipline, discriminate against or retaliate against any employee who reports a complaint or concern (unless the employee is found to have knowingly and willfully made a false report).

11. Waivers of this Code of Business Conduct and Ethics

11.1 While some of the policies contained in this Code must be strictly adhered to and no exceptions can be allowed, in other cases exceptions may be possible. Any employee or officer who believes that an exception to any of these policies is appropriate in his or her case should first contact his or her immediate supervisor. If the supervisor agrees that an exception is appropriate, the approval of the General Counsel must be obtained.

11.2 The General Counsel shall be responsible for maintaining a complete record of all requests for exceptions to any of these policies and the disposition of such requests and report such record to the Audit Committee each fiscal quarter.

11.3 Any executive officer or director who seeks an exception to any of these policies should contact the Chairman of the Audit Committee of the Board of Directors.

11.4 Any waiver of this Code for executive officers or directors or any change to this Code that applies to executive officers or directors may be made only by the Board of Directors of the Company and will be disclosed as required by law or stock market regulation.

11.5 Any waiver for a director or an executive officer shall be disclosed as required by the SEC.

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12. Reporting and Compliance Procedures

12.1 Every employee, officer and director has the responsibility to ask questions, seek guidance, and report suspected violations and express concerns regarding compliance with this Code. Any employee, officer or director who knows or believes that any other employee or representative of the Company has engaged or is engaging in Company related conduct that violates applicable law or this Code should report such information to his or her supervisor, the Company's General Counsel, as described below.

12.2 You may report such conduct openly or anonymously without fear of retaliation. The Company will not discipline, discriminate against or retaliate against any employee who reports such conduct in good faith, whether or not such information is ultimately proven to be correct, or who cooperates in any investigation or inquiry regarding such conduct. Any supervisor who receives a report of a violation of this Code must immediately inform the General Counsel.

12.3 You may report violations of this Code on a confidential or anonymous basis by calling the Company's Corporate Governance Hotline. Depending on the nature of the information you are providing, your message will be directed to either the General Counsel or the Chairman of the Audit Committee. While we prefer that you identify yourself when reporting violations so we may follow up with you as necessary for additional information, you may leave messages anonymously if you wish.

12.4 If either the General Counsel or the Chairman of the Audit Committee receives information regarding an alleged violation of this Code, he or she shall, as appropriate:

- (a) evaluate such information;
- (b) if the alleged violation involves an executive officer or a director, inform the Chief Executive Officer and Board of Directors of the alleged violation;
- (c) determine whether it is necessary to conduct an informal inquiry or a formal investigation and, if so, initiate such inquiry or investigation; and
- (d) report the results of any such inquiry or investigation, together with a recommendation as to disposition of the matter, to the Board of Directors or a committee thereof.

12.5 Employees, officers and directors are expected to cooperate fully with any inquiry or investigation by the Company regarding an alleged violation of this Code. Failure to cooperate with any such inquiry or investigation may result in disciplinary action, up to and including discharge.

12.6 The Company shall determine whether violations of this Code have occurred and, if so, shall determine the disciplinary measures to be taken against any employee who has violated this Code. In the event that the alleged violation involves an executive officer or a director, the Chief Executive Officer and the Board of Directors, respectively, shall determine whether a violation of this Code has occurred and, if so, shall determine the disciplinary measures to be taken against such executive officer or director.

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12.7 Failure to comply with the standards outlined in this Code will result in disciplinary action including, but not limited to, reprimands, warnings, probation or suspension without pay, demotions, reductions in salary, discharge and restitution.

12.8 Certain violations of this Code may require the Company to refer the matter to the appropriate governmental or regulating authorities for investigation or prosecution.

12.9 Any supervisor who directs or approves of any conduct in violation of this Code, or who has knowledge of such conduct and does not immediately report it, also

will be subject to disciplinary action, up to and including discharge.

12.10 All such disciplinary actions are to be taken in accordance with the laws pertaining to the place of employment of the subject party, including laws governing due process and employment, and such other agreements of employment as may exist between the Company and the subject employee.

13. Dissemination and Amendment

13.1 The Company reserves the right to amend, alter or terminate this Code at any time for any reason. This document is not an employment contract between the Company and any of its employees, officers or directors and does not alter any existing employment contract, if any, or, where no such employment contracts exists.

14. Definitions

For the purpose of this Code, the following definitions apply:

“**Close Relative**” means a spouse, domestic partner, dependent child (including step-child or foster child) or any other person living in the same home with the employee, officer or director.

“**Direct Competitor**” means any commercial business entity which directly competes with one or more of the Company’s product or service lines of business representing at least 5% (five percent) of the Company’s gross annual revenues.

“**Immediate Family**” means a Close Relative and a parent, sibling, child (including stepchild or foster child), mother- or father-in-law, son- or daughter-in-law, or brother- or sister-in-law.

ACKNOWLEDGMENT OF RECEIPT AND REVIEW

To be signed and returned to the Company’s General Counsel.

I, _____, acknowledge that I have received and read a copy of the QSAM Biosciences, Inc. Code of Ethics and Business Conduct. I understand the contents of the Code and I agree to comply with the policies and procedures set out in the Code.

I understand that I should approach Chairman of the Audit Committee or the General Counsel if I have any questions about the Code generally or any questions about reporting a suspected conflict of interest or other violation of the Code.

[NAME]

[PRINTED NAME]

[DATE]

Subsidiaries

QSAM Therapeutics, Inc., a Texas corporation
Q2Power Corp., a Delaware corporation

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002**

I, Douglas Baum, certify that:

1. I have reviewed this annual report on Form 10-K of QSAM Biosciences Inc. for the year ending December 31, 2021;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal controls over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: February 24, 2022

By: /s/ Douglas Baum
Douglas Baum
Chief Executive Officer

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002**

I, Adam King, certify that:

1. I have reviewed this annual report on Form 10-K of QSAM Biosciences Inc. for the year ending December 31, 2021;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal controls over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: February 24, 2022

By: /s/ Adam King
Adam King
Interim Chief Financial Officer and Principal Accounting Officer

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND
PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K for QSAM Biosciences Inc. (the "Company") for the year ended December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Douglas Baum, Chief Executive Officer and Adam King, Interim Chief Financial Officer/Principal Accounting Officer of the Company, certify pursuant to 18 U.S.C. section 1350 of the Sarbanes-Oxley Act of 2002 that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 24, 2022

By: /s/ Douglas Baum
Douglas Baum
Chief Executive Officer

By: /s/ Adam King
Adam King
Interim Chief Financial Officer and Principal Accounting Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
