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, 2022

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	001-41337	20-1602779
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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	□	Accelerated filer	□
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging Growth Company	□		

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. □

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. Yes □ No □

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). Yes □ No □

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 $4.26, as of the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $3.53 million.

As of March 27, 2023, there were issued and outstanding 2,335,520 shares of the registrant's common stock.

Documents incorporated by reference: None.

QSAM Biosciences, Inc.
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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 technologies and standards of care;
- 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 to date we have dosed three patients, and have opened two other trial sites at Rutgers Cancer Institute of New Jersey and the Ellis Fischel Cancer Center at the University of Missouri. We expect all 17 patients to be enrolled in our Phase 1 trial by the end of 2023, at which time we will seek to advance the study into a Phase 2 efficacy program.

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; and in February 2022, the FDA granted Rare Pediatric Disease Designation for the same indication. Although patients with osteosarcoma or Ewing's sarcoma are eligible to participate in our initial Phase 1 trials, we anticipate filing a separate protocol in the future 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.

What is CycloSam®. CycloSam® is a targeted, bone seeking radiopharmaceutical that combines the beta-emitting radioisotope Samarium-153 (^{153}Sm) 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.

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 Samraium-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 ^{153}SmCl 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 patented in the U.S. and other jurisdictions, and was 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, and such manufacturing is currently covered under our master services agreement, we plan to secure secondary manufacturing partners for the kits in the future. MURR has been our source of Samarium-153 used in our animal studies, our Single Patient IND for Emergency Use at the Cleveland Clinic, and our current clinical trials, and MURR has verbally committed to supply us Samarium-153 in the future. Although we expect MURR to be a key supplier of Samarium-153 in the U.S., 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 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 three issued patents in the US, three issued patents in Japan, one issued patent in Canada, two allowed patents in Europe, and six pending patents in international jurisdictions. Notably, the patents cover the use of low-specific activity Samarium-153, allowing for daily supply of the highly toxicity-reduced isotope, which we believe is the key to allowing for multi-dose regimens of CycloSam® that could have a positive therapeutic effect. Also, 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. Finally, methods relating to repeat dosing regimens for therapeutic radiopharmaceutical agents, which suggest increased efficacy based on prior research is also covered under patent applications. 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	Owner	Status	App No	Filing Date	Pub No	Pub Date	Patent No	Issue Date	Expiration Date
ITG-16 CA	Canada	IGL PHARMA, INC.	**ISSUED**	CA2926652A1	7-Oct-14	CA2926652A1	16-Apr-15	CA2926652	20-Jul-21	7-Oct-34
ITG-16 EP	Europe	IGL PHARMA, INC.	**ALLOWED 01/16/2023**	EP14852866A	7-Oct-14	EP3054996A1	17-Aug-16			
ITG-16 JP	Japan	IGL PHARMA, INC.	**ISSUED**	JP 2016-521278	6-Jun-16	JP2016-532652	20-Oct-16	JP 6787781 B2	18-Nov-20	7-Oct-34
ITG-16 JP 1	Japan	IGL PHARMA, INC.	**ISSUED**	2019-061398	27-Mar-19	JP2019123731A and JP2019123731A5	2-Jul-16 and 20-Feb-20	JP 7068222 B2	16-May-22	7-Oct-34
ITG-16 US	United States	IGL PHARMA, INC.	**ISSUED**	15/027,280	5-Apr-16	US2016/0250359 A1	1-Sep-16	US 10,172,965 B2	8-Jan-19	19-Nov-34
ITG-16 US 1	United States	IGL PHARMA, INC.	**ISSUED**	16/194,324	17-Nov-18	US2019/0083661 A1	21-Mar-19	US 10,596,277 B2	24-Mar-2020	05-Apr-36
ITG-17 CA	Canada	IGL PHARMA, INC.	Pending		24-May-16	CA2987242A1	1-Dec-16			
ITG-17 EP	Europe	IGL PHARMA, INC.	**ISSUED**	16800631	24-May-16	EP3302496	11-Apr-18	EP3302496A4	20-Jan-21	24-May-36
ITG-17 JP	Japan	IGL PHARMA, INC.	**ISSUED**	2017-561326	24-May-16	2018-515585	14-Jun-18	JP 6930922 B2	1-Sep-21	24-May-36
ITG-17 US	United States	IsoTherapeutics Group, LLC	Consolidated into ITG-17	15/821,983	24-Nov-17	Consolidated into ITG-17		n/a		
ITG-17 US	United States	IGL PHARMA, INC.	Abandoned	15/821,974	24-Nov-17	US2018/0104366	19-Apr-18			
ITG-17 US 1	United States	IGL PHARMA, INC.	**ISSUED**	16/866,001	4-May-20	US2020/0261607 A1	20-Aug-20	US 11,369,700 B2	28-Jun-22	25-Jul-36
ITG-18 CA	Canada	IGL PHARMA, INC.	Pending		6-Feb-18	CA3052973A1	16-Aug-18			
ITG-18 EP	Europe	IGL PHARMA, INC.	Pending	18751017	6-Feb-18	EP3579886	18-Dec-19			
ITG-18 JP	Japan	IGL PHARMA, INC.	Pending	JP2019-563340	20-Sep-19	JP 2020-506239 A and US 2021-0138095 A5	27-Feb-20 and 21-Jan-21			
ITG-18 US	United States	IGL PHARMA, INC.	Pending	16/484,706	8-Aug-19	US 2021-0138095 A1	13-May-21			

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 competitors to be other companies developing targeted 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, 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 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 Novartis AG and POINT Biopharma Global. Novartis recently received FDA approval for Pluvicto, a radiopharmaceutical medication used for the treatment of prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer. Pluvicto uses the beta-emitter Lutetium-177. Another competitive company, POINT Biopharma, has two indications using beta-emitting particles in Phase 3 trials, and which were recently licensed by Lantheus. 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 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 and safety precautions 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: Surveilance, 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. Novartis' Pluvicto, a beta-emitter, was approved by the FDA in late 2022 for the treatment of prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer. Novartis reported sales in its first full quarter of commercial release of over $80 million, and the company reported in a recent conference that they expect sales to reach $2 billion in the coming years.

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. We are currently enrolling patients in a Phase 1 multiple center, open label, dose escalation clinical trial intended to determine the maximum tolerated dose of CycloSam® in participants, and also assess early efficacy signals. Participants with bone cancer that has metastasized from the breast, lungs, prostate or other organs, as well as participants with cancer that has originated in the bone such as osteosarcoma and Ewing's Sarcoma – diseases that mostly affect children and young adults — are eligible subject to the trial's inclusion and exclusion criteria.

To date, we have completed the first of four patient groupings ("cohorts"), with a total of up to 17 participants expected to be enrolled. The completed cohort of three participants received the lowest dosage of CycloSam® in the study. The total dosage of the active radioisotope Samarium-153 to be received by the second cohort, expected to commence in early Q2 2023, will be 50% higher. The most recent participant in QSAM's clinical trial was a patient with breast cancer that had metastasized to the bone, a serious and life-threatening disease for which there is an unmet need by patients and an area of high interest by management for the clinical trials and product development of CycloSam®.

Safety data from the first three patients in our clinical trial showed no Serious Adverse Events (SAE's), and no clinically significant adverse events. Significantly, there was no clinically significant white, red, or platelet blood cell suppression to date, no Grade 3 adverse events, and no irreversible adverse events. These results are preliminary and may not be indicative of future results in the trial.

In February 2022, the FDA cleared our amended protocol increasing the age criteria to participants 75 years old from the prior age limitation of 65. This amendment to the enrollment criteria expands the population of potential participants in QSAM's Phase 1 study evaluating CycloSam® in the treatment of bone cancer.

In 2020, CycloSam® was 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 12,500 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 that continued through April 2022. We now contract directly with IsoTherapeutics for monthly consulting services at $8,500 per month under our Master Services Agreement. Pursuant to this arrangement, IsoTherapeutics provides 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 from IGL, 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.

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 ("*FDCA*"), 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.

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 know 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.

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 CFO is currently part-time, but has agreed to join the Company on a full time basis upon the closing of the Company's next significant fund raising and Nasdaq uplisting.

In 2023 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

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.

For nearly the past three years, the ongoing COVID-19 pandemic and efforts to control its spread have significantly impacted the movement of people, goods and services worldwide, including the conduct of our business operations. The COVID-19 pandemic 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.

Although the immediate impacts of the COVID-19 pandemic have been assessed and mitigated, the ultimate extent of the impact of this ongoing pandemic, including as a result of possible subsequent outbreaks of Coronavirus or of new variants thereof and measures taken in response thereto, will depend on future developments, which remain highly uncertain and cannot currently be predicted. While many health and safety restrictions have been lifted and vaccine distribution has increased, certain adverse consequences of the pandemic continue to impact the macroeconomic environment and may persist for some time. Any negative impact on our business, financial condition, results of operations and cash flows cannot be reasonably estimated at this time, but the ongoing COVID-19 pandemic could lead to extended disruption of economic activity and the impact on our business, financial condition, results of operations and cash flows could be material.

Given the ongoing dynamic nature of variants of the COVID-19 pandemic, it is difficult to predict its full impact on our business, 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.

Unfavorable global economic, geopolitical conflicts and other political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy, the global financial markets and global political conditions. The United States and global economies are facing growing inflation, higher interest rates and potential recession. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from the ongoing Covid-19 pandemic or political disruption, such as the war between Ukraine and Russia or political conflict between China and Taiwan, could result in a variety of risks to our business, including increased costs as well as our ability to raise additional capital on acceptable terms. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause delays in completion of clinical trials. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

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 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 early-stage clinical trials 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.

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.

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.

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.

- 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 patient data. 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. We cannot assure that such breaches, failures or interruptions will not occur or, if they do occur, that they will be adequately addressed by us or the third parties on which we rely. We may not be insured against all types of losses as a result of third-party failures, and insurance coverage may be inadequate to cover all losses resulting from breaches, systems failures or other disruptions. 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.

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 began operations in late 2020 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 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 and standards of care;
- 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, 2022 and 2021 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 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.

Based upon our current operating plan, we believe that the net proceeds from our current private placement, if completed in full, together with our existing cash and cash equivalents, will enable us to fund our operations through the third quarter of 2023. In particular, we expect that the net proceeds from such offering and our existing cash and cash equivalents will allow us to advance the Phase 1 portion of our clinical trials for CycloSam® used in connection with metastatic bone cancer. 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. This is particularly uncertain in the current environment of rising inflation and increasing interest rates. 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 their 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.

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 when and if we commercialize our drug candidate. We also plan to qualify additional suppliers in 2023 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®. IsoTherapuetics currently produces all of our needed supply of DOTMP cold kits, and if they are not able to continue to supply such kits, or if we cannot obtain kits from other sources, our clinical trials may be delayed.

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.

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 in the future for injuries resulting from hazardous materials; 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.

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.

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.

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.

Our stock currently trades on OTCQB and our shares of common stock are thinly traded. While management would like to pursue a listing on NASDAQ Capital Market or other national exchange for its common stock in the future, there can be no assurance that (1) such plan will be achieved, (2) an active trading market will be developed or sustained, (3) the liquidity of such market will increase, (4) our stockholders will be able sell their shares of common stock, or (5) 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.

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;

* 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 accredited investors. 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. Penny stocks generally do not have a very high trading volume. 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 38% of the common stock of the Company inclusive of vested options; David H. Clarke, a major investor in our last three offerings and a consultant to the Company, and certain entities that he controls holds 23% of the Company inclusive of convertible Series B preferred stock and warrants; and Checkmate Capital and its affiliates, one of our former debt holders and lead investors in the Series B round, control approximately 12% of the Company inclusive of convertible Series B preferred stock and warrants. The Company has employee options, 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.

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 216,577 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 currently convertible into approximately 292,990 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 720,986 shares of common stock, and Series E-1 preferred stock was retired thereafter.

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, 2022, 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.

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 historically identified certain material weaknesses in our internal control over financial reporting and 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 weakness 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 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 taken 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. 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.

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 office in Austin, Texas. The Company's office space in Austin is leased month-to-month at a rate of $255 per month.

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.

Our common stock is quoted on OTCQB under the symbol "QSAM". Set forth below are the high and low closing bid prices for our common stock for each quarter of the years 2021 and 2022, reflecting a 40:1 reverse stock split that took place in March 2022. 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, 2021 through March 31, 2021	$ 39.20	$ 15.94
April 1, 2021 through June 30, 2021	$ 33.60	$ 12.40
July 1, 2021 through September 30, 2021	$ 19.60	$ 10.00
October 1, 2021 through December 31, 2021	$ 15.97	$ 6.00
January 1, 2022 through March 31, 2022	$ 14.00	$ 6.00
April 1, 2022 through June 30, 2022	$ 9.00	$ 4.26
July 1, 2022 through September 30, 2022	$ 6.00	$ 3.50
October 1, 2022 through December 31, 2022	$ 5.96	$ 4.25

Holders

The number of record holders of our common stock as of March 27, 2023 is 309. 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 2022:

Purpose / Holder	Number of Shares of Common Stock		Total Price/Amount
Sale of common stock in private placement (1)	311,666	$	1,402,497
Common shares issued to service provider (2)	60,000	$	209,661
Conversion of debenture, inclusive of accrued interest (3)	5,469	$	132,932
Common shares issued to former director for services (4)	10,000	$	71,000
Common shares issued under consulting agreement to affiliate (5)	30,000	$	106,500
Common shares issued under service agreement (6)	18,750	$	254,750
Common shares issued to management in lieu of deferred salary (7)	168,611	$	598,389
Conversion of notes (8)	22,155	$	132,931

(1) Issued to 15 accredited investors, who also received 311,666 warrants exercisable for 24-months.
(2) Issued to service provider (Alta Capital) and its affiliate for shareholder communications services pursuant to agreement.
(3) Converted by Brio Capital Management LLC.
(4) Issued to Joel Mayersohn, former director for past services.
(5) Issued to GSB Holdings, Inc., controlled by David Clarke, for general consulting services.
(6) Issued to Sterling Management for general consulting services.
(7) Issued to the Company's Executive Chairman, CEO, General Counsel and VP of Operations in lieu of deferred salary.
(8) Converted by two accredited investors in the Company's convertible note round.

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

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 "Technology"), a clinical-stage bone targeting therapeutic 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 (Quadramet®) utilizing the same radioisotope 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 in multi-dose regimens 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 dosed our first patient in this open-label, dose escalating study in April 2022. As of March 27, 2023, we have dosed a total of three patients, in completion of the first cohort grouping in this study. This phase of our clinical trials is expected to conclude by the end of 2023, at which time we expect to seek approval from the FDA to commence Phase 2 efficacy trials of CycloSam®.

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, and in January 2022, the FDA granted us Rare Pediatric Disease Designation for that indication. Although patients with osteosarcoma or Ewing's sarcoma are eligible to participate in our initial Phase 1 trials, we anticipate filing a separate protocol IND application in the future, subject to funding, to commence clinical trials specifically for these primary, pediatric bone cancers. In March 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, and human Phase 1 trials have commenced.

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 ("FDCA"), 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.

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 those that form around 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 "theragnostics" and is a rapidly growing area of medical discovery.

License Agreement

Through our wholly-owned subsidiary, QSAM Therapeutics, we entered into an exclusive worldwide patent and technology license agreement (the "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 also serves as our Executive Chairman.

Our License Agreement with IGL, as amended in November 2021, is for 20 years or until the expiration of the multiple patents covered under the license, and requires multiple milestone-based payments up to $410,000 as CycloSam® advances through multiple stages of clinical trials, and $2 million upon commercialization. IGL also received 12,500 shares of common stock of the Company. Upon commercialization, IGL will receive an on-going royalty equal to 4.5% of Net Sales, as defined in the License Agreement, and will receive 5% of any consideration we receive pursuant to a sublicense, sale of the asset, or sale of the QSAM subsidiary. 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. We 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 starting 60 days after signing. 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®. Required monthly payments under the Consulting Agreement expired in April 2022, however, we continue to utilize the services of IGL through our master services agreement at a rate of $8,500 per month. Our Executive Chairman serves as President of IGL, receives a $500 per month fee, and holds options to acquire less than a 1% equity stake in IGL.

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 are not currently affected by the Covid outbreak, Covid previously had a 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, 2022 and 2021

For the years ended December 31, 2022 and 2021, we recorded no revenue from operations.

For the year ended December 31, 2022, we recorded a net loss from operations of $5,481,291, a decrease of $6,495,774 (-54.2%) from our net loss from operations of $11,977,065 for the same period in 2021. Basic and diluted net loss per share was $3.24 and $17.12 for the years ended December 31, 2022 and 2021, respectively. The primary reasons for the decrease in the net loss for 2022 over 2021 were as follows:

(1) FY 2022 decrease in compensation and related expenses of $5,390,712 is driven by a decrease in Series E Preferred Stock expense of $6,887,085, offset by an increase in Stock Option expense of $595,270 for options issued to the executive team in 2022 and an increase in wages, benefits and taxes of $735,841 for the executive team in 2022. Additionally, our independent directors were approved for compensation for their services of $94,875 starting in 2022.

(2) FY 2022 increase in General & Administrative costs of $158,440 is driven primarily by an increase in filling fees of $66,998 due to the NASDAQ uplisting effort in Q2 2022, an increase in D&O insurance of $82,354, and an increase in website expenses of $10,801.

(3) FY 2022 decrease in Other Expenses of $915,692 is driven primarily by a 2022 gain of $54,281 on the conversion of convertible notes versus a total expense in 2021 of $1,134,572 on the conversion of notes and debentures, offset in 2021 by a gain on the forgiveness of PPP loans of $142,942 and a gain on the divesture of a minority investment in the company that acquired our legacy business of $100,000.

(4) FY 2022 decrease in Professional Fees of $722,290 is primarily driven by a decrease in stock option and stock based consulting expense of $761,771, offset by an increase in consulting, legal and accounting $45,851.

(5) FY 2022 increase in Research and Development of $375,110 is driven by an increase in vendor expenses related to the clinical trial enrolling multiple patients during 2022.

Financial Condition, Liquidity and Capital Resources

For the year ended December 31, 2022, cash decreased by $1,274,590 from $1,499,866 as of December 31, 2021 to $225,276 at the end of 2022. This decrease was primarily the result of cash used in operating activities of $2,712,090, offset by cash provided by financing activities of $1,437,500.

Net cash used by operating activities was $2,712,090 for the year ended December 31, 2022, which reflected our net loss during the period of $5,481,291, non-cash adjustments of $1,999,145, a net increase in operating liabilities of $774,387, and a net decrease in operating assets of $4,331. The majority of non-cash adjustments consists of $1,534,964 of stock-based compensation to employees and directors, $482,162 of stock-based compensation for services, $36,300 of amortization of debt issuance costs, and a gain on the conversion of convertible notes of $54,281. Net cash provided by financing activities was $1,437,500 for the year ended December 31, 2022, which reflected the proceeds received from the issuance of common stock and the recognition of deferred offering costs of $35,000. Net cash used in investing activities during year ended December 31, 2022 consisted of $0.

At December 31, 2022, our cash totaled $225,276. Our cash is currently held at large U.S. banks.

Based on our current strategy and operating plan, at the end of 2022 we needed to raise additional capital to support operations through the coming year. This process is ongoing and there is 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 advances its clinical trials, management expects expenses to increase. 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 have under $100,000 in commitments to contractors and third-parties, not including employees, that we must pay even if we do not advance the clinical trials. We anticipate that we will be continue the clinical trials without material interruption or delay if we are successful in raising additional funds through our current and future offerings. There is no guarantee, however, that we can complete our current or any future offerings on terms suitable to the Company and its shareholders if at all.

We have raised capital through debt and equity fundings over the last two years to advance the development of the Technology. As of December 31, 2022, we raised $1,402,500 in a private placement, and issued a total of 311,666 shares of common stock and 311,666 common stock warrants that may be exercised any time during the following 24 months at $6.00 per share; and as of the filing of this annual report, we have raised a total of $1,656,751 the private placement.

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 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. Due to market conditions, in May 2022, the Company terminated this offering; however, management plans to pursue a NASDAQ uplisting in the future.

As of December 31, 2022, the Company had $225,276 in cash, and $513,005 in debt from convertible notes inclusive of accrued interest, but not including trade payables which are also significant. Management agreed in December 2022 to convert $758,750 of their accrued but unpaid salaries into 168,611 shares of common stock, and at the end of 2022, the Company had $79,166 of accrued but unpaid salary remaining on its balance sheet. In July 2021, our loan from the Payroll Protection Program loan was forgiven. The Series A Stock, which is still outstanding and subject to a redemption clause, is in default; however, the Company has a conversion agreement with these two holders that is valid through March 2023.

We have limited operations and are not currently generating any revenues from our business operations. Our independent registered public accounting firm has issued a going concern opinion for the year ended December 31, 2022. This means that our auditors believe there is substantial doubt that we can continue as an on-going business for the next 12 months. Our consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties. The ability of the Company to continue as a going concern is dependent on the success of management's plans, which is not guaranteed. The Company has supported operations through the issuance of common stock, preferred stock and debt over the last 12 months. This includes the current common stock and warrant offering, the Series B Preferred Stock offering in the first quarter of 2021, the exercise of warrants issued in connection with the Series B offering, and also the convertible debt offering conducted in the fourth quarter of 2021. Management expects expenses to increase in 2023 as our drug technology advances through clinical trials, and as a result, we will need to raise additional capital to support these operations. 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. Management believes that is has cash to support operations into the second quarter of 2023, and if the current common stock offering is fully subscribed, that it can continue to support operations through the third quarter of 2023; however, there is no guarantee that such plan will be successful. We currently have accounts payable and accrued expenses that are significantly greater than our cash on hand, and to extend our ability to operate under these conditions, management has deferred or converted to equity a large part of their salaries and we are working with vendors to delay payments until we are able to raise additional capital. Management understands that such efforts cannot be sustained indefinitely. If we are not successful in raising additional capital, we may need to delay clinical trials, reduce overhead, or in the most extreme scenario, shut down operations.

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. There are currently 1,509 shares of Series B Stock outstanding, and as a result of the current common stock private placement, the conversion price of the Series B Stock has been reset to $4.50 per share multiplied by the issuance price.

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 $14.00 per share, and later modified by our Board to expire on October 15, 2021 and be exercisable at $10.00 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 11,875 shares exercisable at $18.00 per share, which warrant was to expire January 15, 2022, but modified in January 2022 to expire January 15, 2023 and be exercisable at $10.00 per share. These warrants expired in January 2023.

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 $24.00 per share beginning from the date of the warrant until October 31, 2022. In the fourth quarter of 2022, $125,000 of the principal amount under the Notes plus $7,932 of accrued interest was converted into 16,616 shares of common stock, at a reduced conversion price of $6.00 per share, as approved by the Board. The outstanding balance of the Notes as of December 31, 2022 was $480,000, exclusive of $33,005 of accrued interest through the end of 2022.

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 financing was used to support the prior, discontinued business and operations of the Company. 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 current private placement offering, the conversion price was reset to $4.50 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, 2022, we had an accumulated deficit of $35,177,625 and negative working capital of $1,215,409.

Critical Accounting Policies

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the revenue and expenses incurred during the reported periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known.

Accrued Research and Development Expenses

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on the facts and circumstances known to us at that time. Our expense accruals for contract research, contract manufacturing and other contract services are based on estimates of the fees associated with services provided by the contracting organizations. Payments under some of the contracts we have with such parties depend on factors such as successful enrollment of patients, site initiation and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from these service providers. However, we may be required to estimate these services based on other information available to us. If we underestimate or overestimate the activity or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Subsequent changes in estimates may result in a material change in our accruals.

Stock-Based Compensation

We recognize stock-based compensation expense for grants of stock option awards, restricted stock units and restricted stock under our Incentive Plan to employees, nonemployees and nonemployee members of our board of directors based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period. In addition, in the past we have granted performance-based stock option awards and restricted stock grants, which vest based upon our satisfying certain performance conditions. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, we estimate that these options will vest, which is based on whether we consider the options' performance conditions to be probable of attainment. Our estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods.

We use the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our common stock price, (ii) the periods of time over which employees and members of the board of directors are expected to hold their options prior to exercise (expected term), (iii) expected dividend yield on the common stock, and (iv) risk-free interest rates. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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, 2022.

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. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures are designed only to provide reasonable assurance, and no matter how well designed and operated, there can be no assurance that disclosure controls and procedures will operate effectively in all circumstances. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that as of December 31, 2022, the Company's disclosure controls and procedure were not effective based on the criteria in Internal Control – Integrated Framework issued by the COSO, version 2013 , as discussed below.

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. As a result of this assessment, management identified a material weaknesses in internal control over financial reporting. A material weakness is a control deficiency, or a 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. The identified material weakness is disclosed below:

- Due to the size of the Company and available resources, there are limited personnel to assist with the accounting and financial reporting function, which results in a lack of segregation of duties.

As a result of the material weakness in internal control over financial reporting described above, management concluded that, as of December 31, 2022, the Company's internal control over financial reporting was not effective based on the criteria in *Internal Control – Integrated Framework* issued by the COSO. Management notes that upon subsequent funding, the Company expects to have the available resources in order to hire additional personnel to expand the finance and accounting department in order to mitigate the material weakness noted above.

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

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the 2022 other than noted above 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 2022 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	75	November 2020	*
Douglas R. Baum	Chief Executive Officer & Director	56	January 2020 (1)	*
Adam King	Chief Financial Officer	37	December 2021	*
Christopher Nelson	General Counsel	53	July 2014	*
Charles J. Link, Jr.	Director	63	February 2021	*
Adriann Sax	Director	61	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 bioartifical 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 Macuclear 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.

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. Mr. Nelson has been General Counsel of the Company since 2015, and was also its Director from 2016 to January 2022, and 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 from 2019 to 2022, 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 practiced law in Florida for over 27 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.

Adam King, CPA – Chief Financial Officer. Mr. King currently serves as 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 extensive medical expenses incurred by the family in connection with their child's medical diagnosis and treatment. The repayment plan was completed in full in March 2022.

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 is also the founder and Executive Chairman of privately-held Syncromune Inc., a cancer immunotherapy company and a founder of biotech startup ChainLink Pharma. Dr. Link served on the Board of Directors for Viewpoint Molecular Targeting, a clinical stage company developing alpha-particle radiopharmaceuticals until its recent merger into a NASDAQ-listed corporation to form Perspective Therapeutics. 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.

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 43. 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 65. 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).

Richard "Keith" Frank – Scientific Advisor. Age 67. 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 GliaSite® Radiation Therapy System. He also initiated and was the technical leader of Dow's ChelaMed℠ Radiopharmaceutical Services offering.

Jaime "Jim" Simon – Scientific Advisor. Age 69. 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

Dr. Link served as Chairman of the Board of Directors of NewLink Genetics, a NASDAQ-listed company from 1999 until his retirement in 2019. None of our other 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:

  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.

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, 2022, we have determined that that all officers and directors except the following directors timely filed their reports under Section 16:

1. Charles Link Jr. – Form 4 reporting grant of options to buy common stock of the Company on February 21, 2022 was reported on March 8, 2022;

2. Adriann Sax – Ms. Sax was appointed as director of the Company on January 22, 2022. Ms. Sax's Form 3 was filed on February 17, 2022. Ms Sax's Form 4 reporting grant of options to buy common stock of the Company on January 25, 2022 was reported on February 17, 2022.

Corporate Governance

Audit Committee. Our Audit Committee is currently comprised of Dr. Charles Link and Adriann Sax. We have determined that both Dr. Link and Ms. Sax are independent under Rule 10A-3 of the Exchange Act, and have the financial experience to serve of the Audit Committee; however, pursuant to OTCQB rules, the Company is not currently required to have an audit committee. We may appoint one additional independent director who would be qualified as a "financial expert" as required under NASDAQ rules to serve as the Audit Committee Chair, if necessary, however since the Company is not required to have an audit committee under the SEC or OTCQB rules, its audit committee currently does not have a "financial expert", as that term is defined under the SEC rules.

Under the Audit Committee's 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.

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

Under the Compensation Committee's 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.

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.

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 website (www.qsambio.com) 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.

ITEM 11: EXECUTIVE COMPENSATION

The following table sets forth information regarding compensation earned in or with respect to our fiscal year 2022 and 2021 for the following persons ("Names Executive Officers"):

(i) our principal executive officer, or other individual serving in a similar capacity during the fiscal year 2022 and 2021;
(ii) our two most highly compensated executive officers other than our principal executive officer who were serving as executive officers at December 31, 2022, and 2021; 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, 2022.

Summary Executive Compensation Table

Name and Principal Position	Year	Salary ($) (a)	Bonus ($) (b)	Stock Awards ($) (c)	Option Awards ($) (d)	Non-Equity Incentive Plan Compensation ($) (e)	Nonqualified Deferred Compensation ($) (f)	All Other Compensation ($) (g)	Total Earnings ($) (h)
C. Richard Piazza,	2022	$ 163,021	-	$ 188,949	$ 116,500	-	-	-	$ 468,470
Executive Chairman (1)	2021	$ 127,083	-	$ 2,082,500	$ 41,250	-	-	-	$ 2,250,833
Douglas Baum,	2022	$ 170,833	-	$ 180,733	$ 116,500	-	-	-	$ 468,066
CEO and Director (2)	2021	$ 137,500	-	$ 2,082,500	$ 41,250	-	-	-	$ 2,261,250
Christopher Nelson,	2022	$ 133,333	-	$ 131,442	$ 116,500	-	-	-	$ 381,275
General Counsel (3)	2021	$ 108,333	-	$ 595,000	$ 37,950	-	-	-	$ 741,283
Adam King,	2022	-	-	-	$ 117,000	-	-	$ 208,200	$ 325,200
CFO (4)	2021	-	-	-	-	-	-	$ 10,820	$ 10,820

(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 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. Per a November 14, 2022 second amendment, Mr. Piazza accepted as payment in full for $239,583 in deferred salary that had accrued through September 30, 2022, a cash amount of $47,917 and 53,241 shares of common stock, subject to restrictions and forfeiture. Included in the table are 252,345 shares of common stock issued 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 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. Per a November 14, 2022 second amendment, Mr. Baum accepted as payment in full for $229,167 in deferred salary that had accrued through September 30, 2022, a cash amount of $45,833, which was not paid as of December 31, 2022, and 50,926 shares of common stock, subject to restrictions and forfeiture. Included in the table are 252,345 shares of common stock issued 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) 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. Per a November 14, 2022 second amendment, Mr. Nelson accepted as payment in full for $166,667 in deferred salary that had accrued through September 30, 2022, a cash amount of $33,333, which was not paid as of December 31, 2022, and 37,037 shares of common stock, subject to restrictions and forfeiture. Included in the table are 70,099 shares of common stock issued 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 and 2022. He now serves as CFO in a parttime role.

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, and then amended again on November 14, 2022. The term is three years from December 2021, with extensions at the agreement of the parties. His base salary, as amended, is $300,000 per year, however, that base salary will not commence until the Company successfully raises a minimum of $7.5 million in a single offering. He is currently receiving an annualized base salary of $125,000 until the Company raises $2 million, at which time the annualized base salary will be increased to $160,000, and then increased again to $225,000 upon the Company raising $5 million. Pursuant to the November 14, 2022 amendment, Mr. Piazza accepted as payment in full for $239,583 in deferred salary that had accrued through September 30, 2022, a cash amount of $47,917 and 53,241 shares of common stock, subject to restrictions and forfeiture.

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, and then amended again on November 14, 2022. The term is three years from December 2021, with extensions at the agreement of the parties. His base salary, as amended, is $300,000 per year, however, that base salary will not commence until the Company successfully raises a minimum of $7.5 million in a single offering. He is currently receiving an annualized base salary of $125,000 until the Company raises $2 million, at which time the annualized base salary will be increased to $160,000, and then increased again to $225,000 upon the Company raising $5 million. Pursuant to the November 14, 2022 amendment, Mr. Baum accepted as payment in full for $229,167 in deferred salary that had accrued through September 30, 2022, a cash amount of $45,833, which has not been paid as of December 31, 2022, and 50,926 shares of common stock, subject to restrictions and forfeiture.

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. This agreement was amended again on November 14, 2022. His base salary, as amended, is $225,000 per year, however, that base salary will not commence until the Company successfully raises a minimum of $7.5 million in a single offering. He is currently receiving an annualized base salary of $100,000 until the Company raises $2 million, at which time the annualized base salary will be increased to $125,000, and then increased again to $170,000 upon the Company raising $5 million. Pursuant to the November 14, 2022 amendment, Mr. Nelson accepted as payment in full for $166,667 in deferred salary that had accrued through September 30, 2022, a cash amount of $33,333, which has not been paid as of December 31, 2022, and 37,037 shares of common stock, subject to restrictions and forfeiture.

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, 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 officers outstanding as of December 31, 2022.

Outstanding Option and Stock Awards

	Option Awards					Stock Awards			
Name (a)	Number of Securities Underlying Unexercised Options (#) Exercisable (b)	Number of Securities Underlying Unexercised Options (#) Unexercisable (c)	Equity Incentive Plan Awards Number of Securities Underlying Unexercised Unearned 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 Shares, Vested Units or Other 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	3,125	-	-	$14.40	8/21/31	-	-	-	-
Executive Chairman	-	12,500		$ 10.00	3/3/32	-	-	-	-
Douglas Baum	200	-	-	$ 20.00	1/14/2025	-	-	-	-
CEO and Director	3,125	-	-	$ 14.40	8/24/31	-	-	-	-
	-	12,500	-	$ 10.00	3/3/32	-	-	-	-
Christopher Nelson	255	-	-	$ 20.00	7/30/24	-	-	-	-
General Counsel	60	-	-	$ 20.00	11/17/25	-	-	-	-
	2,875	-	-	$ 14.40	8/24/31	-	-	-	-
	-	12,500	-	$ 10.00	3/3/32	-	-	-	-

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	175,000	$ 10.41	25,000
Equity compensation plans not approved by security holders	2,815	$ 146.86	None
Total	177,815		25,000

* Information provided as of December 31, 2022.

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 6,250 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 10,000 common shares for his prior services on the Board.

On January 25, 2022, Adriann Sax received a grant of 6,250 stock options exercisable at $8.00, 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 March 3, 2022, Adriann Sax received a grant of 18,750 stock options exercisable at $10.00, and vesting half on March 3, 2023, and the balance on March 3, 2024. The options are exercisable for 10 years following the grant date.

On February 21, 2022, Dr. Link received a grant of 25,000 stock options exercisable at $8.00, and all in 2022. The stock options are exercisable for 10 years following the date of grant.

The following table provides all fees paid to all directors in 2022, but excludes fees paid to the inside directors, Messrs. Baum and Piazza, for their services in 2022 in their respective officer capacities. Messrs. Baum and Piazza 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 ($)
Charles J. Link	-	-	$ 129,000	-	$ 51,333	-	$ 180,333
Adriann Sax	-	-	$ 214,375	-	$ 43,542	-	$ 257,917

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 720,986 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 at that time, who did not hold any E-1 Stock. The common stock was valued at $12.00 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 March 27, 2023 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 March 27, 2023. 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 2,335,520 shares of our common stock outstanding as of March 27, 2023. 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 March 27, 2023. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. We also deemed outstanding any shares issued to officers and directors that contain a forfeiture clause which is not tied to a specific vesting date.

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	314,961[2]	13.4%
Douglas Baum	313,432[3]	13.4%
Christopher Nelson	140,302[4]	6.0%
Adam King	9,613[5]	0.4%
Charles J. Link, Jr.	98,384	4.2%
Adriann Sax	12,500[6]	0.5%
All Officers and Directors (as a group, 6 persons)	889,192	37.9%

(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 March 27, 2023 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	Option Shares
C. Richard Piazza	9,375
Douglas Baum	9,575
Christopher Nelson	9,440
Adam King	9,613
Charles J. Link Jr.	26,375
Adriann Sax	12,500

(2) Excludes 6,250 options that vest on March 3, 2024.
(3) Includes 586 shares of common stock receivable upon the conversion of Series B preferred stock at $6.19 per share with accrued dividends through February 2023. Excludes 6,250 options that vest on March 3, 2024.
(4) Includes 3,910 shares of common stock receivable upon conversion of Series B preferred stock at $6.19 per share with accrued dividends through February 2023. Excludes 6,250 options that vest on March 3, 2024.
(5) Excludes 2,888 options that vest monthly starting July 1, 2023 through March 1, 2026.
(6) Excludes 3,125 options that vest on January 21, 2024 and 9,375 options that vest on March 3, 2024.
(7) The percentages shown are based on the 2,335,520 shares of our common stock outstanding as of March 27, 2023, plus the number of shares that the named person or group has the right to acquire within 60 days of March 27, 2023. 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 March 27, 2023 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. We also deemed outstanding any shares issued to officers and directors that contain a forfeiture clause which is not tied to a specific vesting date.

More than 5% Beneficial Holders

Name of beneficial owner	Amount beneficially owned	Percent of Class Beneficially Owned[4]
David H. Clarke	584,214[1]	22.5%
Checkmate Capital Group LLC, Checkmate Strategic Capital 2, LLC, Checkmate Strategic Capital Holdings LLC, and Charles Thomas Paschall	280,816[2]	11.5%
Alpha Capital Anstalt	174,174[3]	6.9%

(1) The information is based on a Schedule 13G/A filed by David Howard Clarke, GSB Holdings Inc., Bounty Hunter LLC, and supplemented and updated to reflect accrued dividends through February 2023 and a modified conversion price of $6.19 on Series B preferred stock, and additional issued common stock warrants. The address for each is 14179 Laurel Trail, Wellington, FL 33414. Includes 49,052 and 4,903 shares of common stock receivable by certain members of the group upon of conversion of Series B preferred stock with accrued dividends through February 2023; and 177,778, 11,111, and 23,000 shares of common stock receivable from the exercise of common stock warrants by members of the group.

(2) 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, and supplemented and updated to reflect accrued dividends through February 2023 and a modified conversion price of $6.19 on Series B preferred stock, and additional issued common stock warrants. Includes 31,276 and 29,371 shares of common stock receivable by certain members of the group upon of conversion of Series B preferred stock with accrued dividends through February 2023; and 50,000 shares of common stock receivable from the exercise of common stock warrants. 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.

(3) Based on 380 shares of Series A preferred stock and accrued dividends through February 2023, at a conversion price of $3.33. Their address is Altenbach 8, FL-9490 Vaduz, Liechtenstein.

(4) The percentages shown are based on the 2,335,520 shares of our common stock outstanding as of March 27, 2023, plus the number of shares that the named person or group has the right to acquire within 60 days of March 27, 2023. 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 March 27, 2023 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.

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 had a material interest 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:

C. Richard Piazza, our Executive Chairman, also serves as the 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 monthly fee from IGL Pharma and holds options to acquire less than 1% of that company.

GSB Holdings, Inc, which holds along with its affiliated persons approximately 22.5% equity in the Company, has a month-to-month Consulting Agreement with the Company pursuant to which it receives $12,000 and 5,000 shares of common stock per month. GSB Holdings is controlled by David H. Clarke but maintains no equity interest in GSB Holdings, Inc. The Consulting Agreement is cancellable at any time by the Company.

Policies and Procedures for Related Party Transactions

Our Audit Committee has the primary responsibility for the review, approval and oversight of any "related party transaction," which is any transaction, arrangement, or relationship (or series of similar transactions, arrangements, or relationships) in which we are, were, or will be a participant and the amount involved exceeds $120,000, and in which the related person has, had, or will have a direct or indirect material interest. In approving or rejecting the proposed transactions, our Audit Committee will take into account all of the relevant facts and circumstances available. No member of the Audit Committee will participate in any review, consideration or approval of any related person transaction with respect to which such member or any of his or her immediate family members is the related person.

Director Independence

While we are not subject to NASDAQ rules, the Board uses the standards set forth by NASDAQ for determination of director independence. Our current board members consist of Richard Piazza, Douglas Baum, Charles Link Jr. and Adriann Sax. Two of our currently serving Board members, Dr. Link and Ms. Sax, are independent under director independence standards set forth by NASDAQ. For membership information of our audit and compensation committee, and each of their independence status, please see "Corporate Governance" beginning on page 47 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 2022 and 2021:

Fee Category	2022	2021
Audit Fees	$ 77,643	$ 56,000
Audit-related Fees	-	-
Tax Fees	$ 35,800	-
All Other Fees	-	-

Audit fees - Consists of fees for professional services rendered by D. Brooks and Associates CPAs, P.A. in 2022 and 2021 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 2022 and 2021 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:

(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 Certificate of Incorporation dated November 18, 2015 (incorporated by reference to the Form 8-K dated December 15, 2015)
3.3	Certificate of Amendment of the Amended and Restated Certificate of Incorporation dated August 18, 2017 (incorporated by reference to the Form 8-K dated August 23, 2017)
3.4	Certificate of Amendment of the Amended and Restated Articles of Incorporation of Q2Earth, Inc. (incorporated by reference to the Form 8-K dated September 11, 2020)
3.5	Certificate of Amendment of the Amended and Restated Certificate of Incorporation dated March 4, 2022 (incorporated by reference to the Form 8-K dated March 9, 2022)
3.6	Amended and Restated Bylaws Dated March 23, 2022 (incorporated by reference to the Company's registration statement on Form S-1/A dated March 24, 2022)
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)

10.01	Original Issue Discount Senior Secured Convertible Debentures (incorporated by reference to the Form 8-K filed July 2, 2014)
10.02	Patent and Technology License Agreement and Trademark Assignment between IGL Pharma, Inc. and QSAM Therapeutics Inc., dated April 20, 2020 (incorporated by reference to the Form 8-K dated April 24, 2020)
10.03	Form of Securities Purchase Agreement for Series B Convertible Preferred Stock (incorporated by reference to the Form 8-K dated January 28, 2021)
10.04	Form of Convertible Note (incorporated by reference to the Form 8-K dated December 8, 2021)
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	First Amendment to the Patent and Technology License Agreement and Trademark Assignment between IGL Pharma, Inc. and QSAM Therapeutics Inc., dated April 20, 2020 effective November 17, 2021 (incorporated by reference to the Form 8-K dated November 30, 2021)
10.07	Amended and Restated Employment Agreement dated December 6, 2021 with C. Richard Piazza, Executive Chairman (incorporated by reference to the Form 8-K dated December 10, 2021)
10.08	Amended and Restated Employment Agreement dated December 6, 2021 with Douglas R. Baum, CEO (incorporated by reference to the Form 8-K dated December 10, 2021)
10.09	Amended and Restated Employment Agreement dated December 6, 2021 with Christopher Nelson, General Counsel (incorporated by reference to the Form 8-K dated December 10, 2021)
10.10	Amendment to Employment Agreement for the Company's Executive Chairman dated November 14, 2022 (incorporated by reference to the Form 8-K dated November 14, 2022)
10.11	Amendment to Employment Agreement for the Company's CEO dated November 14, 2022 (incorporated by reference to the Form 8-K dated November 14, 2022)
10.12	Amendment to Employment Agreement for the Company's General Counsel dated November 14, 2022 (incorporated by reference to the Form 8-K dated November 14, 2022)
10.13	Form of Common Stock Securities Purchase Agreement (incorporated by reference to the Form 8-K dated September 30, 2022)
10.14	Form of Common Stock Warrant (incorporated by reference to the Form 8-K dated September 30, 2022)
10.15	Independent Director Compensation Plan (incorporated by reference to the Form 8-K dated January 28, 2022)
14	Code of Ethics Policy (incorporated by reference to the Company's registration statement on Form S-1/A dated March 10, 2022)
21.1	Subsidiaries of the Company
31.1	302 Certification of Douglas Baum, CEO
31.2	302 Certification of Adam King, CFO
32	906 Certification
101	The following information from the Company's Annual Report on Form 10-K for the year ended December 31, 2022, 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)

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: March 30, 2023 *By:* */s/ Douglas Baum*
Douglas Baum
Director and Chief Executive Officer

Date: March 30, 2023 *By:* */s/ Adam King*
Adam King
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: March 30, 2023 *By:* */s/ C. Richard Piazza*
C. Richard Piazza
Executive Chairman of the Board of Directors

Date: March 30, 2023 *By:* */s/ Douglas Baum*
Douglas Baum
Director and Chief Executive Officer

Date: March 30, 2023 *By*: */s/ Charles J. Link Jr.*
Charles J. Link Jr.
Director

Date: March 30, 2023 *By*: */s/ Adriann Sax*
Adriann Sax
Director

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 (the "Company") as of December 31, 2022 and 2021, 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, 2022 and 2021, 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 audits include 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.

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. We determined that there were no critical audit matters.

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

Palm Beach Gardens, FL
March 30, 2023

QSAM BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash	$ 225,276	$ 1,499,866
Prepaid expenses and other assets	139,345	135,014
Deferred offering costs	-	35,000
TOTAL CURRENT ASSETS	364,621	1,669,880
TOTAL ASSETS	**$ 364,621**	**$ 1,669,880**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 745,011	$ 569,321
Accrued payroll and related expenses	79,166	95,400
Accrued Series B preferred stock dividends	304,653	153,343
Notes payable, net of discount	443,700	-
Notes payable - related parties	7,500	7,500
Debentures	-	35,000
TOTAL CURRENT LIABILITIES	1,580,030	860,564
Notes payable, net of discount	-	532,400
Total Liabilities	**1,580,030**	**1,392,964**
Redeemable convertible preferred stock - Series A; $0.0001 par value, 1,500 designated Series A, and 480 shares issued and outstanding (liquidation preference of $721,200 and $693,580) as of December 31, 2022 and December 31, 2021, respectively	721,200	693,580
Stockholders' Deficit		
Preferred stock, Series B, $0.001 par value; 2,500 shares authorized, 1,509 shares issued and outstanding (liquidation preference of $1,813,607 and $1,662,711) as of December 31, 2022 and December 31, 2021, respectively	2	2
Preferred stock, Series E-1, $0.0001 par value; 8,500 shares authorized, 0 shares issued and outstanding as of December 31, 2022 and December 31, 2021	-	-
Common stock, $0.0001 par value, 100,000,000 shares authorized, 2,279,019 and 1,652,102 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	228	165
Unearned deferred compensation	(187,329)	(900,742)
Additional paid-in capital	33,428,115	29,765,585
Accumulated deficit	(35,177,625)	(29,281,674)
Total Stockholders' Deficit	**(1,936,609)**	**(416,664)**
Total Liabilities & Stockholders' Deficit	**$ 364,621**	**$ 1,669,880**

See notes to the consolidated financial statements.

QSAM BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the years ended December 31,	
	2022	**2021**
REVENUES	$ -	$ -
Operating Expenses		
Compensation and related expenses	2,899,987	8,290,699
Professional Fees	1,262,860	1,985,780
General and administrative	275,923	117,483
Research and development	1,022,412	647,302
Total Operating Expenses	5,461,182	11,041,264
Loss from Operations	**(5,461,182)**	**(11,041,264)**
Other Income (Expense) from operations		
Financing costs including interest	(74,390)	(44,171)
Gain on sale of equity method investment	-	100,000
Loss on conversion of bridge notes and accrued interest	-	(744,505)
Gain on conversion of convertible debt	54,281	-
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	(20,109)	(935,801)
Loss from operations before income taxes	(5,481,291)	(11,977,065)
Income Taxes	-	-
NET LOSS	(5,481,291)	(11,977,065)
PREFERRED STOCK		
Series A convertible contractual dividends	(27,620)	(29,538)
Series B convertible contractual dividends	(151,310)	(153,343)
Deemed dividend Series B warrant modification	(41,225)	(850,214)
Deemed dividends on Series A conversion to common stock	-	(542,500)
Deemed dividends from Series A and B conversion price reduction	(373,435)	-
NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (6,074,881)	$ (13,552,660)
NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS: BASIC AND DILUTED:	$ (3.45)	$ (17.20)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING: BASIC AND DILUTED	1,762,160	791,599

See notes to the consolidated financial statements.

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, 2020	281	-	7,650	-	486,806	49	11,023,738	(148,333)	(25,000)	(15,911,895)	(5,061,441)
Adjustment to common stock to reconcile to transfer agent	-	-	-	-	(2,127)	-		-	-	-	-
Compensation expense due to warrant modification	-	-	-	-	-	-	109,206	-	-	-	109,206
Conversion of bridge notes and accrued interest to common stock	-	-	-	-	165,692	17	4,378,471	-	-	-	4,378,488
Conversion of debentures and accrued expenses	-	-	-	-	15,825	2	515,067	-	-	-	515,069
Conversion of Series A preferred stock to common stock	-	-	-	-	18,750	2	662,498	-	-	(542,500)	120,000
Exercise of Series B Warrants to common stock					46,786	5	467,852	-	-		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)	-	-	-	163,134	16	(16)	-	-	-	-
Series A, preferred stock contractual dividends	-	-	-	-	-	-	(29,538)	-	-	-	(29,538)
Common stock and warrants issued for services	-	-	-	-	36,250	4	922,388	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)		720,986	72	2,123,756	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	-	-	1,652,102	$ 165	$ 29,765,585	$ (900,742)	$ -	(29,281,674)	$ (416,664)
Common stock issued for services, including a director	-	-	-	-	118,750	12	632,739	(150,589)	-	-	482,162
Conversion of debentures and accrued expenses	-	-	-	-	27,624	3	113,648	-	-	-	113,651
Incremental value from warrant modifications	-	-	-	-	-	-	41,225	-	-	(41,225)	-
Deemed dividend from Series A conversion price adjustment	-	-	-	-	-	-	342,497	-	-	(342,497)	-
Deemed dividend from Series B conversion price adjustment	-	-	-	-	-	-	30,938	-	-	(30,938)	-
Series A, preferred stock contractual dividends	-	-	-	-	-	-	(27,620)	-	-	-	(27,620)
Series B, preferred stock contractual dividends	-	-	-	-	-	-	(151,309)	-	-	-	(151,309)
Accretion of stock-based compensation to employees and directors	-	-	-	-	-	-	670,962	864,002	-	-	1,534,964
40:1 Reverse Split Fractional Shares Adjustment	-	-	-	-	266	-	-	-	-	-	-
Issuance of common stock for cash	-	-	-	-	311,666	31	1,402,469	-	-	-	1,402,500
Conversion of deferred employee compensation	-	-	-	-	168,611	17	606,981	-	-	-	606,998
Net loss for the year ended December 31, 2022	-	-	-	-	-	-	-	-	-	(5,481,291)	(5,481,291)
Balance, December 31, 2022	1,509	$ 2	-	$ -	2,279,019	$ 228	$ 33,428,115	$ (187,329)	$ -	$ (35,177,625)	$ (1,936,609)

See notes to the consolidated financial statements.

QSAM BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the years ended December 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (5,481,291)	$ (11,977,065)
Adjustments to reconcile net loss to net cash provided by operations:		
Stock-based compensation for services and warrant modification	482,162	1,179,932
Stock-based compensation to employees and directors	1,534,964	7,826,779
Loss on conversion of bridge notes and accrued interest	-	744,505
Loss on conversion of debentures and accrued expenses to common stock	-	390,069
Amortization of debt issuance costs	36,300	-
Paid-in-kind interest - convertible bridge notes	-	35,983
Gain on conversion of convertible debt	(54,281)	-
Gain on forgiveness of Paycheck Protection Program	-	(142,942)
Changes in operating assets and liabilities		
Increase in prepaid expenses and other current assets	(4,331)	(122,118)
Increase in accounts payable and accrued expenses	155,833	283,660
Increase accrued payroll and related expenses	590,763	47,394
Increase in accrued interest	27,791	-
Net cash used in operating activities	(2,712,090)	(1,733,803)
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayments on promissory notes - related parties	-	(33,492)
Deferred offering costs	35,000	(35,000)
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
Proceeds from issuance of common stock	1,402,500	-
Net cash provided by financing activities	1,437,500	3,225,365
NET (DECREASE) INCREASE IN CASH	(1,274,590)	1,491,562
CASH - Beginning of year	1,499,866	8,304
CASH - End of year	$ 225,276	$ 1,499,866
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	$ 27,620	$ 29,538
Accrual of contractual dividends on Series B convertible preferred stock	$ 151,309	$ 153,343
Fair value allocation of warrants issued with debt	$ -	$ 72,600
Deemed dividend on warrant modifications	$ 41,225	$ 850,214
Deemed dividend on Series A conversion price modifications	$ 342,497	$ -
Deemed dividend on Series B conversion price modifications	$ 30,938	$ -
Deemed dividend on conversion of Series A	$ -	$ 542,500
Conversion of convertible Bridge Notes and accrued interest to 165,692 shares of common stock	$ -	$ 3,633,983
Conversion of debentures and accrued expenses to common stock	$ 35,000	$ 125,000
Conversion of accrued salary and bonus to common stock	$ 606,981	$ -
Conversion of convertible debt and accrued interest	$ 132,934	$ -
Conversion of Series A preferred stock to common stock	$ -	$ 120,000
Conversion of notes payable with related parties to Series B preferred stock and warrants	$ -	$ 23,000

See 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 (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 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 Samaium-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 divestiture of the Legacy Business, 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 March 4, 2022, the Company completed a 40:1 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.

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, 2022, the Company used net cash in operating activities for its operations of $2,712,090 and incurred a loss from its operations of $5,481,291. As of December 31, 2022, the Company's accumulated deficit is $35,177,625. As of December 31, 2022, the Company has negative working capital of $1,215,409 and cash of $225,276. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company's $480,000 of Series A redeemable convertible preferred stock was in default as of December 31, 2022, but the holders of the Series A stock have agreed to stay any action pursuant to a conditional conversion agreement until the end of March 2023, and management is in discussions with these holders to extend those agreements.

The Company has supported operations through the issuance of common stock, preferred stock and debt over the last 12 months. This includes the current $3.5 million common stock and warrant offering, of which $1,405,500 has been raised as of December 31, 2022; the $2.5 million Series B preferred stock offering in the first quarter of 2021; the exercise in late 2021 of approximately $470,000 in warrants issued in connection with the Series B offering; and 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. See Note 6 for further discussion.

Management expects expenses to increase in 2023 as our drug technology continues 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 2023. 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 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. Any loss incurred or a lack of access to such funds above the FDIC limit could have a significant adverse impact on the Company's financial condition, results of operations and cash flows. The Company held no cash equivalents as of December 31, 2022 and 2021.

Revenue Recognition

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

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 2022 and 2021 from 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 $1,022,412 for the year ended December 31, 2022, 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 $647,302 for the year ended December 31, 2021, 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 10 – Commitments and Contingencies).

Fair Value Measurement

The Company has determined the fair value of certain assets and liabilities in accordance with generally accepted accounting principles, which provides a framework for measuring fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques should maximize the use of observable inputs and minimize the use of unobservable inputs.

A fair value hierarchy has been established, which prioritizes the valuation inputs into three broad levels. Level 1 inputs consist of quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the related asset or liability. Level 3 inputs are unobservable inputs related to the asset or liability.

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.

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, 2022, the Company does not believe it has any uncertain tax positions that would result in the Company having a liability to the taxing authorities.

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.

As of December 31, 2022, 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 inclusive of accrued dividends ($6.19 conversion price)	292,990
Shares from common stock options	177,815
Shares from common stock warrants	323,543
Shares from conversion of convertible notes inclusive of accrued interest ($8.00 conversion price)	64,126
Shares from the conversion of Series A Preferred stock (calculated from liquidation value and assumed conversion price at December 31, 2022 of $3.33 per share)	216,577

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	235,774
Shares from common stock options	27,815
Shares from common stock warrants	37,083
Shares from conversion of convertible notes not inclusive of accrued interest	75,625
Shares from the conversion of debentures	5,469
Shares from the conversion of Series A Preferred Stock (calculated from liquidation value and an assumed conversion price at December 31, 2021 of $6.40 per share)	108,231

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 an 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.

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, 2022 does not exceed the FDIC limits.

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 operations for the year periods ended December 31, 2022 and 2021.

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.

Reclassifications

Certain reclassifications of prior year amounts have been made which consisted of the reclassification of the convertible notes payable outstanding as of December 31, 2021 with a maturity date of December 2023 as long-term which were incorrectly presented as current in the prior year. These reclassifications had no effect on net loss or loss per share as previously reported.

NOTE 4 – 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 2022 or 2021.

Christopher Nelson, General Counsel of the Company, also serves as General Counsel and Secretary of EPH. See Note 5 – Related Party Transactions for transactions with our equity method investment during the years ended December 31, 2022 and 2021.

NOTE 5 – 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 12,500 shares of the Company to IGL Pharma, Inc (see Note 7). The associated expense of $140,000 was recorded in Professional Fees. Under the License Agreement, the Company incurred research and development related expenses of $105,382 during the year ended December 31 2022 which have been included in research and development expenses on the consolidated financial statements and reimbursed IGL for direct expenses totaling $39,499. As of December 31, 2022, amounts outstanding due IGL Pharma, Inc, for their services amounted to $13,900.

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.

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.

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, 2022 and 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 $14.00 per share, which resulted in no gain or loss on conversion (see Note 7).

During the years ended December 31, 2022 and 2021, the Company incurred $238,401 and $77,064, respectively, in legal fees with a law firm in which the Company's former Director and audit committee chair (resigned from the Board in February 2021) is a partner. As of December 31, 2022 and 2021, accounts payable and accrued expenses include $219,459 and $195,000 for legal fees due to the law firm for services, respectively.

NOTE 6 – 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 $0 and $35,000 outstanding as of December 31, 2022 and 2021, respectively. In the first quarter of 2021, the two institutional holders of the debentures converted an aggregate of $102,500 into 12,927 shares of common stock, and the Company recognized a loss on the two debenture conversions of $356,454 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 5,469 shares of common stock at $6.40 per share, and the balance as of December 31, 2022 on the convertible debenture is currently $0.

Convertible Bridge Notes

In prior years, 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, $2.9 million of the Bridge Notes, inclusive of principal and accrued and capitalized interest, was converted into 332,804 shares of common stock at $8.80 per share. 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 165,692 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.

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, any time prior to maturity at a conversion price of $8.00. 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. In the fourth quarter of 2022, two note holders converted $132,932 of principal and interest on their notes into 22,155 shares of common stock, at a reduced conversion price approved by the Board of $6.00. In addition to the notes payable, each holder received a warrant for the purchase of shares of common stock with a purchase price of $24.00, which expired in 2022. In accordance with accounting standards, the warrants were 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. During the years ended December 31, 2022 and 2021, the Company recorded interest expense related to the amortization of the discount of $36,300 and $0, respectively. As of December 31, 2022 and 2021, unamortized debt discount was $72,600 and $36,300, respectively, and the convertible liability balance, net of a discount was $443,700 and $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) on the consolidated statements of operations.

NOTE 7 – TEMPORARY EQUITY, PREFERRED STOCK, COMMON STOCK, AND WARRANTS

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

As of both December 31, 2022 and 2021, the Company has 480 shares of Series A Stock issued and outstanding. The outstanding shares of Series A Stock are currently convertible at $3.33 per share of the Company's common stock (the "Conversion Price"), which was reduced in 2022 pursuant to a price protection provision included in the Series A Certificate of Designation ("Series A Designation" as the Company began selling common stock and a warrant in an offering at $4.50 (see below). The Series A Designation requires an adjustment to the conversion price if a subsequent equity sale occurs at a price below the conversion rate. The Company recorded a deemed dividend within stockholders' equity associated with the reduction in conversion price from $6.40 to $3.33 of $342,497 based on the incremental value to the Series A holders due to the conversion price reduction. This incremental value has also been presented on the consolidated statement of operations as an addition to the net loss available to common stockholders. The incremental value was determined by computing the additional shares the Series A holders would receive based on the conversion price reduction multiplied by the estimated fair value of common stock of $3.33, based on the sale of common stock in a recent offering.

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 as of December 31, 2022, but the holders of the Series A stock have agreed to stay any action pursuant to a conditional conversion agreement until the end of March 2023, and management is in discussions with these holders to extend those agreements. 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. This price protection provision was triggered on September 30, 2022 when the Company sold common stock and a warrant for $4.50. 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 resides between liabilities and 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 as an accumulated deficit, the charge has been recognized in additional paid-in capital. The accrued dividends are $241,200 and $213,580 as of December 31, 2022 and 2021, respectively. As of December 31, 2022 and 2021, the stated value of the Series A and the accrued dividends was $721,200 and $693,580 which has been presented as mezzanine equity on the consolidated balance sheets, which resides between liabilities and stockholders' equity.

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. 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 163,134 shares of common stock, which included $53,061 of accrued dividends. As of December 31, 2022 and 2021, 1,509 shares of Series B Stock were issued and outstanding. The accrued dividends are $304,653 and $153,343 as of December 31, 2022 and 2021, respectively, which are presented on the consolidated balance sheets.

The Series B Stock was originally convertible into common stock at a ratio of $6.40 per share, subject to anti-dilution protections in the case of certain issuances of securities below that conversion price, and as a result of this price protection, the ratio was reduced to reduced to $6.19 per share based on the Series B Certificate of Designation ("Series B Designation") which define the adjustment to the conversion ratio and incremental shares when the Company issues common stock at a price below the conversion ratio. Based on the Series B Designation, the conversion ratio was reduced to $6.19. The Company recorded a deemed dividend within stockholders' equity associated with the reduction in conversion price from $6.40 to $6.19 of $30,938 based on the incremental value to the Series B holders due to the conversion price reduction. This incremental value has also been presented on the consolidated statement of operations as an addition to the net loss available to common stockholders. The incremental value was determined by computing the additional shares the Series B holders would receive based on the conversion price reduction multiplied by the estimated fair value of common stock of $3.33, based on the sale of common stock in a recent offering.

With respect to the Series B Preferred Stock, the Company recognized the incremental value associated with the downround of the conversion price due to the issuance of common stock at a lower price than Series B conversion price and associated adjustment of convertible shares as a deemed dividend charge of $30,938 within stockholders' equity and as a reduction of net loss available to common stockholders on the consolidated statement of operations in 2022. The incremental value associated with the Series B Preferred stock was determined using an adjusted conversion price of $6.19 and an adjusted common stock conversion of 290,965 shares.

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 .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 720,986 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 $12.00 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, 2022, approximately 717,924 common shares are fully vested and approximately 3,062 common shares are unvested, but have fully vested as of February 2023.

During the years ended December 31, 2022 and 2021, the Company recognized stock-based compensation to employees and directors totaling $864,002, and $7,751,087, respectively 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, 2022, approximately $37,000 of unrecognized compensation remains which will be recognized by February 1, 2023.

Common Stock

In 2022, the Company effected a 40:1 reverse stock split and all share numbers herein have been adjusted for that change.

In 2022 and 2021, the Company issued 626,917 and 1,167,423 shares of common stock, respectively, as follows:

	For the Years Ended December 31,	
	2022	2021
Adjustment for 40:1 Reverse Stock Split	266	-
Conversion of bridge notes and accrued interest to common stock	-	165,692
Conversion of debentures	5,469	15,825
Conversion of accrued salary to management	168,611	-
Conversion of Series A Stock to common stock	-	18,750
Conversion of Series B Stock to common stock	-	163,134
Exercise of Series B Warrants to common stock	-	46,786
Exchange of Series E-1 Stock to common stock	-	720,986
Conversion of convertible debt to common stock	22,155	-
Issuance of common stock for cash	311,666	-
Stock based compensation for services	118,750	36,250
Total Common Shares issued	626,917	1,167,423

During the year ended December 31, 2022, the Company issued 5,469 shares of common stock in connection with $35,000 of debentures that were converted at a price of $6.40 per share.

During the year ended December 31, 2022, the Company issued 168,611 shares of common stock in connection with conversion of management salaries that were deferred totaling $606,998. The salary was converted at a price of $3.55 per share based on a weighted average of the market price of common stock and the offering price of common stock of $3.33 sold during 2022 (see below). The fair value of the shares issued upon settlement was equal to the amount owed for the management salaries; thefore, no gain or loss was recorded on the settlement and the accrued salaries were reclassed to stockholders' equity. The shares of common stock issued in the settlement are restricted and shall be subject to forfeiture as follows: until such time that the Company successfully closes $5 million in a single fundraising (the "Trigger Event"), which may be completed in one or more closings over a period of 90 days, the shares of common stock may not be sold, transferred or otherwise disposed of by the holder. Upon the occurrence of the Trigger Event, the shares shall be fully vested. If the Trigger Event does not occur within 36 months of November 14, 2022, the shares of common stock shall be forfeited and returned to the Company. The shares issued with the settlement agreements have been presented as issued and outstanding on the statement of stockholders' equity as of December 31, 2022.

During the year ended December 31, 2022, the Company issued 22,155 shares of common stock in connection with conversion of convertible notes in the amount of $132,932 that were converted at a $6.00 price per share. The Company recorded a gain on the conversion of the debt to equity of $54,281 which was recorded in other income and expense. The gain was calculated by the difference between the total of the principal and accrued interest outstanding the estimated fair value of the shares issued upon conversion of $3.55 based on a weighted average of the market price of common stock and the offering price of common stock of $3.33 sold during 2022 (see below).

During the year ended December 31, 2022, the Company issued 311,666 shares of common stock in connection with its common stock private placement which included a unit which consisted of one share of common stock and one common stock warrant at a price per unit of $4.50. During the year ended December 31, 2022, the Company received cash proceeds of $1,402,500 from the sale of units. The common stock sold in the unit was determined to have an estimated fair value of $3.33 based on the fair value of one warrant of $1.17 which was determing using a Black-scholes pricing model and the following assumptions: exercise price $6.00, expected term of 2 years, volatility of 91.2%, dividend rate of 0%, and discount rate of 4.22%. The implied stock price of $3.33 was then determined based on the $4.50 offering price for one unit.

During the year ended December 31, 2022, the Company issued 118,750 shares of common stock for services with an estimated fair value of $632,750 based on the market price of stock or estimated value of a common stock shares sold in the private placement offering (see above) on the date of issuance. The shares are recognized as expense over the related service period. During the year ended December 31, 2022, the Company recognized $482,161 of stock-based compensation of which $411,161 has been reflected in professional fees and $71,000 reflected in compensation and related expenses for shares issued to a former director and audit committee chair of the Company for such services. As of December 31, 2022, unearned deferred compensation related to these shares issued for services to be provided through May 2023 was $150,589.

During the year ended December 31, 2021, the Company issued 163,134 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 $6.40. The Company also issued 36,250 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.

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 a total of 181,517 shares of common stock at a price of $6.40 per share. Further, $120,000 of Series A Stock was converted into 18,750 shares of common stock at a price of $6.40 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 $542,500 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 720,986 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, 46,786 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.

Warrants

In 2022, the Company effected a 40:1 reverse stock split and all warrant numbers herein have been adjusted for that change.

During the year ended December 31, 2022, the Company issued 311,666 warrants in connection with its private placement offering (the "Common Stock Warrants").

During the year ended December 31, 2021, the Company issued 168,589 warrants in connection with its Series B Stock offering (the "Series B Warrants"), 18,750 warrants to a service provider (the "Service Warrants"), and 25,208 warrants in connection with its convertible note offering (the "Note Warrants").

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 $14.00 per share to $10.00 per share. As of October 15, 2021, 46,786 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 with the exception of 11,875 for one warrant holder that expired in January 2023.

A summary of warrant activity and related information during the years ended December 31, 2022 and 2021 is as follows:

	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding as of December 31, 2020	1,154	$ 8.80	$ -
Issued	212,548	11.55	-
Exercised	46,786	10.00	-
Expired	129,832	9.82	-
Outstanding as of December 31, 2021	37,083	$ 19.52	$ -
Issued	311,668	6.00	-
Expired	25,208	24.00	-
Outstanding as of December 31, 2022	323,543	$ 6.15	$ -

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, 2022 and 2021.

The following is a summary of the outstanding common stock warrants as of December 31, 2022:

	Number of Warrants	Exercise price per share	Expiration Date
Warrants issued in connection with issuance of Series B Stock to lead investor	11,875	$ 10.00	January 15, 2023
Warrants issued in connection with common stock	311,668	$ 6.00	Sept. 30 – Dec. 31, 2024
Total Outstanding as of December 31, 2022	323,543		

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 an increase of net loss available to common stockholders on the consolidated statement of operations in 2021. 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 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 $41,225 within stockholders' equity and as a reduction of net loss available to common stockholders on the consolidated statement of operations in 2022. 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 .50 years, dividend yield of 0%, volatility of 224.2%%, and a risk-free rate of 0.51%.

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 that 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%. As of December 31, 2022 and 2021, there were no service warrants outstanding as they were fully expired as of December 31, 2021.

With respect to the Note Warrants, the Company computed the total grant dates fair value of the warrants to be $72,600 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.

With respect to the Common Stock Warrants, the Company computed the total grant date fair value of the warrants to be $364,651 using a Black-Scholes option pricing model and the following assumptions: expected term of 2 years, dividend yield of 0%, volatility of 91.2% and a risk-free rate of 4.22% The value of these warrants was recorded using the relative fair value method and included in additional paid- in capital.

NOTE 8 – STOCK OPTIONS AND RESTRICTED STOCK UNITS

In 2016 to compensate officers, directors and other key service providers with equity grants, the Board approved the 2016 Omnibus Equity Incentive Plan (“2016 Plan”), which initially allowed for 4,000 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 multiple times by Board resolution, most recently to 200,000 shares on January 13, 2022. As of December 31, 2022, there are 25,000 shares available under the 2016 Plan for future issuance; however, the Board may increase the authorized shares under the 2016 Plan each year to an amount equal to 5% of the total issued and outstanding common shares of the Company or such other amount in its reasonable discretion. The Board has indicated that they intend to increase the authorized shares under the 2016 Plan in 2023.

The Company issued 150,000 stock options to purchase common stock to officers and directors of the Company during 2022. These options have a 10 year term. The options have the following vesting schedules:

Vesting Description	Number of Options
50% 12 months after issuance and the balance 24 months after issuance	87,500
100% 10 months after issuance	25,000
34% 12 months after issuance, 33% 24 months after issuance, and the remaining 36 months after issuance	25,000
Performance conditions set by Board of Directors	12,500

A summary of stock option activity and related information during the years ended December 31, 2022 and 2021 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of December 31, 2020	11,715	$ 70.00	5.6	$ -
Granted	16,100	$ 14.40	-	$ -
Outstanding as of December 31, 2021	27,815	$ 30.40	7.9	$ -
Granted	150,000	$ 9.25	-	$ -
Outstanding as of December 31, 2022	177,815	$ 12.57	8.8	$ -
Exercisable as of December 31, 2022	56,565	$ 30.46	8.0	$ -

The Company recorded $670,962 and $75,692 of stock-based compensation expense which is included in compensation and related expenses for the years ended December 31, 2022 and 2021, 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, 2022.

As of December 31, 2022, there was unrecognized stock-based compensation of $638,237 which is expected to be expensed through March 2024 based on the option vesting requirements. The weighted average fair value of options granted was $7.82 per share for the year ended December 31, 2022.

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, 2022 and 2021 were as follows:

	For the years ended	
	2022	**2021**
Expected term (years)	5.50	5.38
Expected volatility	130.6% - 166.7%	153.9%
Risk-free interest rate	1.65% - 1.86%	0.94%
Expected dividend yield	0.0%	0.0%

NOTE 9 – 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, 2022 and 2021 (computed by applying the U.S. Federal corporate tax rate of 21 percent to the loss before taxes) is as follows:

	2022	2021
Tax benefit at U.S. statutory rate	$ (1,151,071)	$ (2,515,184)
State taxes, net of federal benefit	-	(89,264)
Stock based compensation	423,597	1,875,514
PPP loan forgiveness	-	(30,018)
Gain on extinguishment of liabilities	(11,399)	238,260
Other permanent differences	592,659	-
Change in valuation allowance	146,214	520,692
	$ -	$ -

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, 2022 and 2021 consisted of the following:

	2022	2021
Net operating loss carry-forward	$ 3,204,894	$ 3,073,065
Accrued expenses	-	166,783
Stock based compensation	58,106	70,128
Section 174 R&D expenses	193,236	-
Charitable contribution	221	267
Net deferred tax assets	3,456,457	3,310,243
Valuation allowance	(3,456,457)	(3,310,243)
Total net deferred tax asset	$ —	$ —

At December 31, 2022 and 2021, the Company had net deferred tax assets of $3,456,457 and $3,310,243 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, 2022 and 2021. At December 31, 2022, the Company has net operating loss carry forwards totaling approximately $15,261,399. The potential tax benefit arising from NOLs generated of approximately $6,822,000 prior to 2018 effective date will begin to expire in 2034. The potential tax benefit arising from the net operating loss carryforwards of approximately $8,439,531 generated after 2018 can be carried forward indefinitely within the annual usage limitations. The Company is in compliance with filling its federal tax returns through December 31, 2021.

The Company's U.S. federal and state income tax returns are generally subject to tax examinations for the tax years ended December 31, 2019 through December 31, 2021. There are currently no pending income tax examinations. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service and state tax authorities to the extent utilized in a future period. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

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, 2022 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 10 – 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.

Pursuant to amendments dated November 14, 2022 to the three employment agreements of the Company's Executive Chairman, CEO and General Counsel, as well as an amendment to the employment agreement for the Company's VP Operations, each of these four employees have agreed to accept reduced salaries until the Company is successful in raising additional funds. Specifically, when the Company raises at least $7.5 million in a single offering, each employee's salary will be increased to the full contracted rate; and prior to that time, the reduced salaries will be gradually increased as the Company raises $2 million and then $5 million. During this time, the difference between the reduced salaries and the full contracted salaries will not accrue as liabilities for the Company. As of December 31, 2022 and 2021, the accrued salary for the management team was $79,166 and $83,731.

During the year ended December 31, 2022, the Company entered into settlement agreements with four employees of the Company who had accrued salaries at time of settlement of $758,748. Pursuant to the settlement agreements, the accrued salaries were settled with shares of common stock with an estimated fair value of $606,998 and cash payments of $151,750, of which $79,166 remains unpaid and has been accrued as of December 31, 2022. The Company issued 168,611 shares of common stock in connection with conversion of management salaries. The salary was converted at a price of $3.55 per share.

The shares of common stock issued in the settlement are restricted and shall be subject to forfeiture as follows: until such time that the Company successfully closes $5 million in a single fundraising (the "Trigger Event"), which may be completed in one or more closings over a period of 90 days, the shares of common stock may not be sold, transferred or otherwise disposed of by the holder. Upon the occurrence of the Trigger Event, the shares shall be fully vested. If the Trigger Event does not occur within 36 months of November 14, 2022, the shares of common stock shall be forfeited and returned to the Company. The shares issued with the settlement agreements have been presented as issued and outstanding on the statement of stockholders' equity as of December 31, 2022.

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 and for its VP Operations each contain a similar transaction bonus equal to 0.5% of consideration received by the Company.

Board of Director Agreements

In January 2022, Adriann Sax was appointed as a Director to the Board of Director and awarded an annual retainer of $30,000 per year with an additional $7,500 for serving as an Audit Committee member and an additional $10,000 for serving as the Nominating & Governance Committee Chair. Ms. Sax has agreed to defer compensation for serving as a Director until the completion of the next fundraising round. As such, the Company has accrued the director compensation for Ms. Sax monthly with a total accrued balance of $43,542 as of December 31, 2022.

In February 2022, Charles J. Link, Jr. was appointed as a Director to the Board of Director and awarded an annual retainer of $30,000 per year with an additional $7,500 for serving as an Audit Committee member and an additional $15,000 for serving as the Compensation Committee Chair, and $3,500 for serving as a member of the Nominating Committee. Dr. Link has agreed to defer compensation for serving as a Director until the completion of the next fundraising round. As such, the Company has accrued the director compensation for Dr. Link monthly with a total accrued balance of $51,333 as of December 31, 2022.

License Agreement

The License Agreement for the Technology, as amended, between the Company's wholly-owned subsidiary QSAM and 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 12,500 shares of the Company's common stock 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 the QSAM subsidiary. The Company 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, 2022, the Company has paid $39,499 in expense reimbursements required under the agreement. The drug development costs to IGL including the fixed $8,500 monthly consulting fee, which has been reflected as research and development expense on the consolidated statements of operations was $105,382 and $136,232 for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, $13,900 of these costs remained outstanding and included in accounts payable and accrued expenses on the consolidated balance sheets.

On July 1, 2022, QSAM signed a new work order under the Master Services Agreement dated August 31, 2020 with IsoTherapeutics Group, Inc.("ISO"), a company that has common ownership control with IGL. The new work order with ISO is a $8,500 per month consulting contract to utilize the knowledge and expertise of Drs. Keith Frank and Jim Simon, primary scientists and owners in ISO and IGL, and to provide scientific and manufacturing consulting support with the clinical trials as they progress through each phase. The work order is a 2 year term with a 15 day cancellation notice and the Company is only obligated for fees incurred for services performed to date under the work order.

NOTE 11 – SUBSEQUENT EVENTS

On January 15, 2023, the Company entered into a consulting agreement with Checkmate Capital Group LLC for advisory services related to foreign strategic partners, and under the agreement issued 50,000 common stock warrants that may be exercised at $6.00 per share at any time prior to January 15, 2025.

In the first quarter of 2023, the Company completed an additional $254,251 in investments under its common stock and warrant private placement, with an additional 56,500 shares of common stock and 56,500 common stock warrants issued to these accredited investors. The shares of common stock and common stock warrant were offered at $4.50. The warrants are exercisable for a period of two-years at a $6.00 exercise price.

Exhibit 21.1

Subsidiaries

QSAM Therapeutics, Inc., a Texas corporation
Q2Power Corp., a Delaware corporation (inactive)

Exhibit 31.1

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, 2022;

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: March 30, 2023

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

Exhibit 31.2

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, 2022;

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: March 30, 2023

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

Exhibit 32.1

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, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Douglas Baum, Chief Executive Officer and Adam King, 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.

March 30, 2023

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

By: */s/ Adam King*
Adam King
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.