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

FORM 10-K

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

For the year ended: December 31, 2020

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	000-55148	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 [X]

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 [X]

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the 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.
(1) Yes [X] No [ ] (2) Yes [X] 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 [X] No [ ]

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

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
Emerging Growth Company	[X]		

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [ ] No [X]

State the aggregate market value of the voting and non-voting common stock held by non-affiliates computed by reference to the price at which the common stock was last sold, or the average bid and asked price of such common stock, as of the last business day of the Registrant's most recently completed second fiscal quarter.

June 30, 2020 - $477,126. There are approximately 1,617,376 shares of common voting stock of the Registrant beneficially owned by non-affiliates on June 30, 2020. There is a limited public market for the common stock of the Registrant, so this computation is based upon the closing bid price of $0.295 per share of the Registrant's common stock on the OTCQB.

APPLICABLE ONLY TO REGISTRANTS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. [X] Yes [ ] No

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date:

April 14, 2021: Common – 27,497,850

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 technology;
- the ability of users of our products (when and as developed) to obtain third-party reimbursement;
- any failure to comply with rigorous FDA and other government regulations; and
- securing, maintaining and defending patent or other intellectual property protections for our technology.

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

MARKET DATA

Certain market and industry data included in this document is derived from information provided by third-party market research firms, or third-party financial or analytics firms that we believe to be reliable. Market estimates are calculated by using independent industry publications, government publications and third-party forecasts in conjunction with our assumptions about our markets. We have not independently verified such third-party information. The market data used in this document involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. While we are not aware of any misstatements regarding any market, industry or similar data presented herein, such data involves risks and uncertainties and are subject to change based on various factors, including those discussed below and set forth in the "Risk Factors" section of this document. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. Certain data are also based on our good faith estimates, which are derived from management's knowledge of the industry and independent

sources. Industry publications, surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but there can be no assurance as to the accuracy or completeness of included information. We have not independently verified any of the data from third-party sources nor have we ascertained the underlying economic assumptions relied upon therein. Statements as to our market position are based on market data currently available to us. While we are not aware of any misstatements regarding the industry data presented herein, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "Risk Factors" in this document. Similarly, we believe our internal research is reliable, even though such research has not been verified by any independent sources.

JUMPSTART OUR BUSINESS STARTUPS ACT DISCLOSURE

We qualify as an "emerging growth company," as defined in Section 2(a)(19) of the Securities Act by the Jumpstart Our Business Startups Act (the "JOBS Act"). An issuer qualifies as an "emerging growth company" if it has total annual gross revenues of less than $1.0 billion during its most recently completed fiscal year, and will continue to be deemed an emerging growth company until the earliest of:

- the last day of the fiscal year of the issuer during which it had total annual gross revenues of $1.0 billion or more;
- the last day of the fiscal year of the issuer following the fifth anniversary of the date of the first sale of common equity securities of the issuer pursuant to an effective registration statement;
- the date on which the issuer has, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or
- the date on which the issuer is deemed to be a "large accelerated filer," as defined in Section 240.12b-2 of the Exchange Act.

As an emerging growth company, we are exempt from various reporting requirements. Specifically, we are exempt from the following provisions:

- Section 404(b) of the Sarbanes-Oxley Act of 2002, which requires evaluations and reporting related to an issuer's internal controls;
- Section 14A(a) of the Exchange Act, which requires an issuer to seek shareholder approval of the compensation of its executives not less frequently than once every three years; and
- Section 14A(b) of the Exchange Act, which requires an issuer to seek shareholder approval of its so-called "golden parachute" compensation, or compensation upon termination of an employee's employment.

Under the JOBS Act, emerging growth companies may delay adopting new or revised accounting standards that have different effective dates for public and private companies until such time as those standards apply to private companies.

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.

Organizational History

The Company, formerly known as Q2Earth, Inc. ("Q2Earth"), was organized pursuant of the laws of the State of Delaware on August 26, 2004. Since 2015, the Company has transformed its business model, operations and management several times, most relevantly commencing with the November 12, 2015 merger of Q2Power Corp. into a newly formed and wholly-owned subsidiary of the Company, then called Ampath Group Inc. In August 2017, the Company sold the waste-to-power technology that it was then developing to a licensee and re-focused its efforts and resources to the pursuit of acquisitions and management of companies and assets in the business of compost and soil manufacturing. In June 2017, the Company changed its name to Q2Earth, Inc. to better reflect its new business model.

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

The Separation Agreement marked a discontinuance of the Company's compost operations to focus solely on the development of its exclusively licensed radiopharmaceutical drug candidate, Samarium-153-DOTMP, aka CycloSam® ("CycloSam" or the "New Technology"), as well as other drug candidates that it may license or otherwise secure in the future.

Pursuant to the Separation Agreement:

- The Management Agreement, dated January 18, 2019, as amended, between EPH and the Company was terminated by mutual agreement of the parties. Fees from this agreement constituted most of the Company's revenue over the prior two years.
- In lieu of any severance or other termination payments due under the Management Agreement, EPH released the Company from a total of $993,985 in liabilities, inclusive of advanced management fees and multiple promissory notes, including accrued and unpaid interest. An additional $114,700 in promissory notes plus accrued interest owed to an affiliate of EPH were converted into Company common stock at a price of $0.22 per share, and consequently, was retired as of December 31, 2020.
- The prior officers and employees of the Company engaged in the compost and soil manufacturing business were released from any non-competition, non-solicitation or other restricted covenant pursuant to their respective employment agreements. Several of these employees solely engaged in the legacy compost business had been removed from payroll as of October 1, 2020.
- The Company agreed to transfer to EPH the License Agreement with Agrarian Technologies LLC and Mulch Masters Inc. for the ABS product and all associated knowhow, trade secrets and trademark/service marks (the "ABS License"). All liabilities associated with the ABS License were also transferred to and assumed by EPH.

- EPH received the right in its sole discretion to use the name "Q2Earth" in all jurisdictions of the United States and worldwide.

At the end of 2020, the Company held approximately an 18% subordinated equity interest in EPH and accounted for EPH as an unconsolidated investee entity. In March 2021, the Company sold these equity units to an unaffiliated third party for $100,000. Kevin Bolin, the prior Chairman and CEO of the Company, also serves as President of EPH; and Christopher Nelson, General Counsel and Director of the Company, also serves as General Counsel and Secretary of EPH.

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 the conversion of approximately $156,000 in debt. The 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 flagship drug candidate CycloSam, as well as for general working capital and overhead.

The shares of Series B Preferred Stock are convertible into an aggregate of approximately 16.6 million shares of common stock of the Company and have voting rights alongside common stockholders on an as-converted basis. In January 2021, our Board approved a modification to the Series B Preferred Stock offering terms, and investors in the offering were issued in 2021 non-registered warrants to purchase an aggregate of up to 6.27 million shares of common stock at $0.35 per share prior to July 8, 2021. For its performance in support of the offering, Checkmate Capital earned in January 2021 a 12 month warrant to acquire 475,000 shares of common stock at $0.45 per share.

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.

Current Drug Development Business

The Company's current business is the development of Samarium-153 DOTMP aka CycloSam® ("CycloSam" or the "New Technology"), a novel radiopharmaceutical being developed for the treatment of bone cancers and related diseases. The Company seeks to enter clinical trials this year for CycloSam as a treatment for cancer that has metastasized to the bone from the lung, breast, prostate and other areas, as well as for certain primary bone cancers such as osteosarcoma. Ultimately, the Company may seek to commercialize CycloSam for one or more market indications or license the technology to a larger pharmaceutical partner.

What is CycloSam. CycloSam is comprised of a combination of the radioactive isotope Samarium-153 and the chelant DOTMP (1,4,7,10-tetraazacyclododecanetetramethylene-phosphonic acid). 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 and emits both medium-energy beta particles which produce the therapeutic effect, and gamma photons that make it possible to locate the anatomical distribution. Projected use of CycloSam as either a monotherapy or in combination with other more widely used treatments has the potential to minimize the amount and use of toxic modalities.

How is CycloSam believed to work. Through current research and studies, we believe CycloSam seeks out locations of high bone turnover which are adjacent to the tumor. The radiation from the Samarium-153 has the effect of killing the cancer cells or slowing their growth by damaging their DNA with minimal damage observed to healthy cells. Cancer cells, whose DNA is damaged beyond repair, stop dividing or die. When the damaged cells die, they are broken down and removed by the body. Generally, radiation therapy does not kill cancer cells right away and more than one treatment is expected to be needed to kill a tumor or dramatically reduce its size using CycloSam. Samarium-153 has a short half-life (46 hours), which means it can be rapidly eliminated from the body, avoiding an undesirable radioactive buildup in key organs when used in multiple treatments.

History of CycloSam development and past studies and trials

CycloSam was developed at IsoTherapeutics Group, LLC ("IsoTherapeutics") by its founders Jim Simone, PhD and R. Keith Frank, PhD, who also developed one of the first commercial radiopharmaceuticals on the market, called Quadramet®. Messrs. Simone and Frank each have over 30 years of experience in radiopharmaceuticals and have published more than 100 papers and authored over 60 patents in the field. According to the inventors, CycloSam was developed to address the shortcomings of other radiopharmaceuticals such as toxicity, saturation effects and long-lived impurities.

CycloSam has completed extensive animal studies in both small and large animals, as well as treating bone cancer in actual patient dogs at a university veterinary clinic. In addition to the extensive animal work, the Company has treated one human patient under a Single Patient Investigational New Drug (IND) for Emergency Use at the Cleveland Clinic where CycloSam showed promising results in connection with a bone marrow ablation procedure.

How is CycloSam differentiated in the market. CycloSam is believed to have significant advantages over current radiopharmaceutical offerings. Key differentiators are believed to include a short half-life (46 hours), minimal radionuclidic impurities, and no or minimal saturation effect allowing for repeated dosing. Its novel chelant delivers the radioactive "payload" adjacent to the tumor and, Samaium-153 being a beta emitter, is believed to enable it to travel farther than competitive alpha emitters. Thus, CycloSam is believed to be able to deeply penetrate the target tumor.

Potential Market Indications. CycloSam's therapeutic profile and presumed advantages over other radiopharmaceuticals translate to several potential key indications as detailed in the following table:

Market	Estimated Patients (US)
Primary Bone Cancer - Osteosarcoma	850
Other Primary Bone Cancers	2,400
Bone Metastases (Breast, Prostate, Lung)	280,000
Bone Marrow Ablation	15,000

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

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 systemic toxicity. Skeletal uptake has also been studied in rats over a wide range of doses to determine whether Samarium-153 DOTMP 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 Samarium-153 DOTMP. Additionally, a proof of concept study was conducted in ten dogs with spontaneously occurring bone cancer treated with 1-2 mCi/kg of Samarium-153 DOTMP. 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 Samarium-153 DOTMP has potential as a therapeutic agent in the treatment of primary bone cancer and metastatic bone disease.

***Clinical Studies*.** Samarium-153 DOTMP has recently been 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 Samarium-153 DOTMP 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 Samarium-153 DOTMP. 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. 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 with no complications.

There were no adverse events or serious adverse events observed that were considered related to infusion of Samarium-153 DOTMP, nor was there evidence of osteosarcoma relapse at any point following Samarium-153 DOTMP infusion. The investigator concluded that high-dose Samarium-153 DOTMP can be given safely with no apparent renal toxicity and no unexpected adverse events attributable to Samarium-153 DOTMP. The investigator also concluded that the appearance of engraftment was indicative that Samarium-153 DOTMP had an effect on MDS. Skeletal targeting with sparing of other tissues was observed after the high dose.

Collaborations, Partnerships and Agreements

Collaborations, partnerships and 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 (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.

The License Agreement, unless sooner terminated in accordance with its terms, terminates upon the latter of (a) the expiration of the last to expire of the IGL/ISO patent rights; or (b) twenty years after the effective date of the license. IGL may terminate the License Agreement early upon the occurrence of certain defaults by the Company, including, but not limited to, a material breach by us that is not cured within a predefined period of time after notice of the breach is provided to us.

The License Agreement provides the Company with the exclusive commercial rights to the patent portfolio developed by IGL as of the effective date of the license and requires us to pay various milestone, legal, filing and licensing payments to commercialize the technology. Furthermore, IGL is entitled to receive a non-refundable initial license fee, royalty payments and milestone payments based on net sales and percentages of sublicense fees and certain regulatory and commercial milestones.

Contracted Research Organization. In February 2020 the Company 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 CRO has a full-time staff of project managers, statisticians, physicians, nurses and other regulatory and operational personnel to support the company's 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. The MSA was amended in February 2021 and includes a fixed monthly retainer for regulatory and clinical trial consulting services as well as specific work orders for clinical trial execution services.

Patents and IP

Pursuant to the License Agreement, the Company's IP estate includes 15 total patents issued and pending across 3 distinct patent families that we believe provide protection for the use of CycloSam as a radiopharmaceutical in the U.S. and internationally. Under the License Agreement, the Company holds two issued patents in the US, one allowed patent in Europe, and 11 pending patents in international jurisdictions. Notably, the CycloSam kit that will be commercialized is protected by the extensive patent estate that broadly protects DOTMP kit formulations for radioisotopes, potentially allowing for efficient distribution of the product and widespread use. Additionally, the patents cover the use of low-specific activity Samarium-153 allowing for daily supply of the isotope, and methods relating to repeat dosing regimens for therapeutic radiopharmaceutical agents, which suggest increased efficacy based on prior research. Taken together, management believes that the patent family provides for a significant barrier to entry for a competitor as it is expected to prevent a generic product from being developed; however, we cannot guarantee that a competitor will not or cannot challenge our patents or otherwise circumvent our patents, or that we would have the resources to defend any patent infringement.

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

	Country/ Region	Status	App No	Filing Date	Pub No	Pub Date	Patent No	Issue Date	Expiration Date
"High purity therapeutic bone agents"									
ITG-16 CA	Canada	Pending	2,926,652	6-Apr-2016					
ITG-16 EP	Europe	Pending	14852866.4	5-May-2016	EP3054996	17-Aug-2016			
ITG-16 JP	Japan	Pending	2016-521278	7-Apr-2016	2016-532652	20-Oct-2016			
ITG-16 JP 1	Japan	Pending	2019-061398	27-Mar-2019					
ITG-16 US	**United States**	**ISSUED**	**15/027,280**	**5-Apr-2016**	**US2016/0250359**	**1-Sep-2016**	**10,172,965**	**8-Jan-2019**	**19-Nov-2034**
ITG-16 US 1	**United States**	**ISSUED**	**16/194,324**	**17-Nov-2018**	**US2019/0083661**	**21-Mar-2019**	**10,596,277**	**24-Mar-2020**	**05-Apr-2036**
"DOTMP kit formulations for radioisotopes"									
ITG-17 CA	Canada	Pending	2987242	23-Nov-2017					
ITG-17 EP	**Europe**	**ALLOWED**	**16800631**	**20-Nov-2017**	**EP3302496**	**11-Apr-2018**		**ALLOWED**	
ITG-17 JP	Japan	Pending	2017-561326	24-Nov-2017	2018-515585	14-Jun-2018			
ITG-17 US	United States	n/a	15/821,983	24-Nov-2017	Consolidated into ITG-17		n/a		
ITG-17 US	United States	Pending	15/821,974	24-Nov-2017	US2018/0104366	19-Apr-2018			

"Method of use for therapeutic bone agents"

ITG-18 CA	Canada	Pending		7-Aug-2019
ITG-18 EP	Europe	Pending	18751017.7	22-Aug-2019
ITG-18 JP	Japan	Pending		7-Aug-2019
ITG-18 US	United States	Pending	16/484,706	8-Aug-2019

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

Manufacturing

The Company has an established and validated process, as well as key partnerships in place for the just-in-time production of CycloSam on a named patient basis. Once prescribed by radiation oncologists and nuclear medicine physicians, the Company expects that it will 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. MURR has been the source of supply for the Samarium-153 used in both animal studies and the single patient IND. MURR has verbally committed to supply Samarium-153 to the Company in the future, has the capability to produce the CycloSam product on a commercial scale for U.S. distribution, and is expected to be the primary supplier of the radionuclide to the Company in the U.S. subject to definitive agreements that management expects to complete in 2021. Management also plans to qualify additional suppliers in 2021 as part of a supply chain and general business risk diversification strategy.

The patented "cold kit" was developed and issupplied to nuclear pharmacies by IsoTherapeutics, the inventors of CycloSam. The IsoTherapeutics cGMP manufacturing facility has the capacity to manufacture sufficient supply for initial rollout. Secondary manufacturing partners are concurrently being secured. While CycloSam is still in clinical development, the Company believes it has already established an efficient and cost-effective manufacturing process, allowing the clinician to treat the patient within approximately three days from order.

Competition

Bone cancer treatment often relies on combinations of treatments and experimental approaches. Over the years, several treatment options that include chemotherapy (docetaxel, cabazitaxel), external beam radiotherapy, surgery, bisphosphonates (zoledronate), hormone therapy, monoclonal antibody therapy (XGEVA), immunotherapies (Sipulecel-T), SRC inhibitors, and radiopharmaceuticals have been introduced for bone pain palliation or the treatment of primary and secondary bone cancers. Most fail to significantly improve overall survival of patients, tumor regression or quality of life.

Compared with almost all other systemic cancer treatment options, use of therapeutic radiopharmaceuticals has shown efficacy with minimal toxicity. Bone-seeking radiopharmaceuticals have been cleared by the FDA for bone pain palliation and are showing promise for treating bone cancer. Though many bone-seeking radiopharmaceuticals with therapeutic potential have been investigated, to management's knowledge there are currently three agents approved for bone cancer, Quadramet®, Metastron™, and Xofigo®, though none are without shortcomings such as myelotoxicity, cost, and long-lived radioactive impurities.

CycloSam uses Samarium-153, which is a 46.3-hr half-life radionuclide, whereas Metastron uses Sr-89, with a half-life of 50.6 days. The shorter half-life of Samarium-153 is believed to more readily accommodate retreatments and administration of subsequent chemotherapy. Another proposed advantage is that CycloSam has a shorter range beta particle than does Metastron. The use of shorter range beta particles is believed to help to lessen damage to non-target tissue.

While CycloSam uses the beta-emitting radionuclide Samarium-153, Xofigo uses the alpha-emitting radionuclide Ra-223. Although both agents localize in osteoblastic bone, the therapeutic effect of CycloSam's beta particles appears to extend to nearby cancer cells, whereas the effect of Xofigo's alpha particles is limited to the site of uptake.

CycloSam and Quadramet both share the same beta-emitting isotope, Samarium-153. CycloSam, however, can be made with low specific-activity Samarium-153, which enables seven-day-a-week availability and contains negligible long-lived impurities, allowing multiple dosing regimens. Quadramet requires high specific-activity Samarium-153, which is available only once a week, contains much higher levels of long-lived impurities and has a higher cost. CycloSam and Quadramet also use different chelating agents. The chelator in CycloSam, DOTMP, forms a much more stable complex with samarium than the complex formed in Quadramet. Tests have shown that CycloSam requires a far lower chelant-to-metal ratio (3:1 vs 270:1) in the formulation, which thereby allows for much higher administered dosages without saturation of the uptake sites.

Management believes that CycloSam has advantageous half-life, radiation penetration, chelation efficiency, impurity profile and availability that makes it abetter tolerated and more efficacious option for treating bone cancer.

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 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;
- submission of an 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 an 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 in the United States. 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.

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. 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

In March 2010, the Affordable Care Act was enacted, which includes measures that have or will significantly change the way health care is financed by both governmental and private insurers. The fees, discounts, and other provisions of this law are expected to have a significant negative effect on the profitability of pharmaceuticals. This legislation is expected to impact the scope of healthcare insurance, the insurance refunds from the insurance companies and possibly also on the costs of medical products.

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.

Exchange Act

We are subject to the following regulations of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), and applicable securities laws, rules and regulations promulgated under the Exchange Act by the SEC. Compliance with these requirements of the Exchange Act increases our legal and accounting costs.

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.

Emerging Growth Company

We are also an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or "JOBS Act." As long as we remain an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not an "emerging growth company," like those applicable to a "smaller reporting company," including, but not limited to, a scaled down description of our business in SEC filings; no requirements to include risk factors in Exchange Act filings; no requirement to include certain selected financial data and supplementary financial information in SEC filings; not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act; reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements that we file under the Exchange Act; no requirement for Sarbanes-Oxley Act Section 404(b) auditor attestations of internal control over financial reporting; and exemptions from the requirements of holding an annual nonbinding advisory vote on executive compensation and seeking nonbinding stockholder approval of any golden parachute payments not previously approved. We are also only required to file audited financial statements for the previous two fiscal years when filing registration statements, together with reviewed financial statements of any applicable subsequent quarter.

We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We can remain an "emerging growth company" for up to five years. We would cease to be an "emerging growth company" prior to such time if we have total annual gross revenues of $1 billion or more and when we become a "larger accelerated filer," have a public float of $700 million or more or we issue more than $1 billion of non-convertible debt over a three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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 and one part-time employee who handles our accounting operations.

Reports to Security Holders

You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may also find all of the reports that we have filed electronically with the SEC at their Internet site www.sec.gov.

ITEM 1A. RISK FACTORS

General Risks Related to our Business and Technology

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

Drug development is a highly uncertain scientific and medical endeavor, and failure can unexpectedly occur at any stage of clinical development. Typically, there is a high rate of attrition for product candidates in preclinical and clinical trials due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. Pre-clinical studies and clinical trials are long, expensive and highly uncertain processes that can take many years. It will take us several years to complete our clinical trials and the time required for completing, testing and obtaining approvals is uncertain. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes, or financial constraints. The FDA and other U.S. and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical trials, require additional clinical development or other testing, delay, condition or withhold registration and marketing approval and mandate product withdrawals, including recalls. Additionally, we may also amend, suspend or terminate clinical trials at any time if we believe that the participating patients are being exposed to unacceptable health risks. Results attained in our single early human clinical trial may not be indicative of results in later clinical trials. Our failure to demonstrate adequately the safety and efficacy of a product under development would delay or prevent marketing approval, which could adversely affect our operating results and credibility. The failure of one or more of our product candidates could have a material adverse effect on our business, financial condition and results of operations.

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

Our business and operations entail a variety of serious risks and uncertainties and are inherently risky. The development programs on which we focus involve novel approaches to treating bone cancer and related diseases. Our product candidates are in clinical development, and in some respects, involve technologies with which we have limited prior experience. We are subject to the risks of failure inherent in the development and commercialization of product candidates based on new technologies. There is some precedent for the successful commercialization of products based on our technologies, but there are still a number of technological challenges that we must overcome to complete our clinical trials and development efforts. We may not be able to successfully further 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.

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.

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, 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.

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

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

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

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

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

Even if our product candidates obtain marketing approval, our ability to generate revenue will 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.

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, it cannot be marketed until pricing and reimbursement for the product is also approved.

- 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.

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 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. 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 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 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 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.

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 agreements from which we derive or out-license intellectual property provide for various royalty, milestone and other payment, commercialization, sublicensing, patent prosecution and enforcement, insurance, indemnification and other obligations and rights, and are 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 third parties. 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 have been and expect to continue to be dependent on collaborators for the development, manufacturing and sales of certain products and product candidates, which expose us to the risk of reliance on these collaborators.

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

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

for which they are responsible. Setbacks of these types to our collaborators could have a material adverse effect on our business, results of operations and financial condition.

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

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

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 remain as a going concern or become profitable.

We recently began operations under our new business model and anticipate that we will operate at a loss for some time. Since we have limited operating history and no history of profitability, we have limited financial results upon which you may judge our potential. There can be no guarantee that we will become a going concern or ever become profitable. In the future, we may experience under-capitalization, development delays, set-backs with our drug development programs, lack of funding options, setbacks and many of the problems, delays and expenses encountered by any early stage business, many of which are beyond our control. These include, but are not limited to:

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

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

Because we are a company with limited operational history and no profitability, our business activity is early-staged and subject to numerous risks. The pharmaceutical development business is highly competitive with many companies having access to the same 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.

We will require additional financing.

For the foreseeable future, we expect to rely on funds that may be raised from future equity or debt offerings to provide growth and operating capital for the Company. Pharmaceutical development is inherently costly, and requires significant capital. We will have to obtain additional financing in order to continue clinical trials in the future. There can be no guaranty that additional funds will be available when and if needed. 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.

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

The Report of Independent Registered Public Accounting Firm issued in connection with our audited consolidated financial statements for the calendar year ended December 31, 2020 expressed substantial doubt about our ability to continue as a going concern, due to the fact that we have recurring operating losses and our lack of liquidity and working capital.

Our significant indebtedness and current and pending defaults under several of our debt instruments raise substantial doubt about our solvency and ability to continue operations.

We have a substantial amount of debt. At December 31, 2020, we had approximately $1.55 million of debt principal and accrued interest owed, outstanding and in default under our Bridge Notes and convertible debentures (however, at March 31, 2021, our debt position had been reduced to approximately $35,000 which is still in default). Our debt load could have important consequences to investors, including the following:

- it may be difficult for us to satisfy our obligations, including debt service requirements under our outstanding debt,
- our ability to obtain additional financing for working capital, capital expenditures, debt service requirements or other general corporate purposes may be impaired,
- we may not have the funds to service this debt as it matures,
- we are more vulnerable to economic downturns and adverse industry conditions and our flexibility to plan for, or react to, changes in our business or industry is more limited,
- our ability to capitalize on business opportunities and to react to competitive pressures, as compared to our competitors, may be compromised due to our high level of debt, and
- our ability to borrow additional funds or to refinance debt may be limited.

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 either 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.

Liquidity risks associated with our common stock.

Limited Public Market. There is a limited trading market for our shares of common stock and a robust trading market for our securities may not develop in the foreseeable future. If no market develops, it may be difficult or impossible for you to sell your shares if you should desire to do so. Our common stock is quoted on the OTCQB. There is limited and sporadic trading of our common stock and no assurance can be given, when, if ever, an active trading market will develop or, if developed, that it will be sustained.

No Trading of Stock. Current rules promulgated by the SEC may prohibit shareholders from trading their shares of common stock under Rule 144 for at least six months unless registered. We have heard from shareholders trying to deposit their previously restricted stock certificates into brokerage accounts that they were unable to do so, or have only been able to deposit such shares at substantial expense of time and money.

Limited Marketability, Transferability and Liquidity. There is a limited market through which our common stock may be sold, and transfer of these shares is subject to significant restrictions. Unless our shares are registered with the Securities and Exchange Commission and any required state authorities, or an appropriate exemption from registration is available, a holder of the shares may be unable to liquidate an investment in such securities, even though his or her personal financial condition may dictate such a liquidation. In addition, the shares will likely not be readily acceptable as collateral for loans. Therefore, prospective stockholders who require immediate liquidity in their investments should not invest in our common stock.

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.

As long as the trading price of our common stock is below $5.00 per share, the open-market trading of our common stock will be subject to the "penny stock" rules. The penny stock rules impose additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with assets in excess of $1 million or annual income exceeding $200,000 or $300,000 together with their spouses). For transactions covered by these rules, the broker-dealer must make a special suitability determination for the purchase of securities and have received the purchaser's written consent to the transaction before the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the broker-dealer must deliver, before the transaction, a disclosure schedule prescribed by the Commission relating to the penny stock market. The broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information on the limited market in penny stocks. These additional burdens imposed on broker-dealers may restrict the ability or decrease the willingness of broker-dealers to sell our common stock, and may result in decreased liquidity of our common stock and increased transaction costs for sales and purchases of our common stock as compared to other securities.

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 currently control approximately 18% of the voting stock of the Company, mainly through their ownership of the Series E-1 Preferred Shares. Our Bridge Note holders converted their debt principal and interest into common or preferred stock at prices significantly less than current market prices which has resulted in significant dilution. One of these former Bridge Note holders, Checkmate Capital and its affiliates, control approximately 13.4% of the voting stock of the Company. The Company has employee options and warrants and incentive preferred stock that could result in further dilution. Our business plan entails conducting multiple funding rounds, much of which may utilize our common stock. In this regard, management, Bridge Note holders, 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 three classes of preferred stock which contain voting, approval, liquidation, conversion, earnout and other rights that are senior to the common stock of the Company. As a result, the preferred stockholders can exert significant influence over the Company and can dilute the financial interests of the common stockholders. Following are certain material terms of these preferred shares:

In January 2021, the Company completed a $2.5 million offering of its Series B Preferred Stock (the "Series B Shares"). The Series B Shares provide the holders a 10% annual paid-in-kind dividend, a liquidation preference equal to the par value of the shares ($1,000 per share) followed by the right to participate with the common stockholders in the instance of a liquidation or other exit event, and provide the holders the right to vote along with the common holders based on the common conversion amount of their holdings. The Series B Preferred Shares are convertible into common stock at a price of $0.16 per share, subject to anti-dilution protections in the case of certain issuances of securities below that conversion price. The Series B Preferred Shares are not redeemable.

Investors in the Series B Stock offering also received six-month, non-registered warrants to purchase an aggregate of up to approximately 6.27 million shares of Common Stock at $0.35 per share; however, these warrants were not agreed to nor yet issued as of December 31, 2020. The lead investor in the offering received a 12 month warrant convertible into 475,000 shares of Common Stock at $0.45 per share, which was also approved by our Board and issued in 2021.

In December 2020, the Company issued 7,650 shares of Series E-1 Preferred Stock (the "Series E-1 Stock"). Another 850 shares of Series E-1 Stock were issued in the first quarter of 2021. 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 leading to the earnout into an aggregate of 8.5 million common shares based on a conversion rate of 1,000 shares for each share of Series E-1 Stock. 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.

The Company has 600 shares of Series A Convertible Preferred Stock (the "Preferred Stock") outstanding at December 31, 2020 (520 shares as of March 31, 2021), with a purchase value of $600,000, held by two institutional investors. The Preferred Stock currently converts into common stock at $0.16 per share, subject to price protection provisions in the instance certain shares are issued at a lower price. The Preferred Stock is technically in default as the Company was required to redeem all 600 shares on July 1, 2019, per a modification agreement signed in March 2019. Holders of the Preferred Stock have additional rights to approve extraordinary transactions, including a sale or merger, additional debt and other similar items. While the Preferred Stock does not vote, the holders of the Preferred Stock can control significant influence over the Company.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None. Not required for smaller reporting companies.

ITEM 2. PROPERTIES

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

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

None; not applicable.

PART II

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

Market Information

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

Set forth below are the high and low closing bid prices for our common stock for each quarter of the years 2019 and 2020. 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. All prices reflect a 25:1 reverse split of the Company's common stock effected as of September 10, 2020.

Period	High	Low
January 1, 2019 through March 31, 2019	$ 1.70	$ 0.50
April 1, 2019 through June 30, 2019	$ 1.45	$ 0.30
July 1, 2019 through September 30, 2019	$ 1.50	$ 0.32
October 1, 2019 through December 31, 2019	$ 0.70	$ 0.14
January 1, 2020 through March 31, 2020	$ 0.58	$ 0.16
April 1, 2020 through June 30, 2020	$ 0.50	$ 0.24
July 1, 2020 through September 30, 2020	$ 0.55	$ 0.20
October 1, 2020 through December 31, 2020	$ 0.57	$ 0.15

Rule 144

The following is a summary of the current requirements of Rule 144:

	Affiliate or Person Selling on Behalf of an Affiliate	Non-Affiliate (and has not been an Affiliate During the Prior Three Months)
Restricted Securities of Reporting Issuers	During six-month holding period – no resales under Rule 144 permitted.	During six- month holding period – no resales under Rule 144 permitted.

After six-month holding period – may resell in accordance with all Rule 144 requirements including:
- Current public information,
- Volume limitations,
- Manner of sale requirements for equity securities, and
- Filing of Form 144.

After six-month holding period but before one year – unlimited public resales under Rule 144 except that the current public information requirement still applies.

After one-year holding period – unlimited public resales under Rule 144; need not comply with any other Rule 144 requirements.

Holders

The number of record holders of our common stock as of the date of this Annual Report is 322. 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.

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	356,000	$ 0.50	44,000
Equity compensation plans not approved by security holders	112,619	$ 5.25	None
Total	468,619	$ 0.50	3,850,000

* Information provided as of December 31, 2020. In January 2020, the Company's shareholders approved the 2016 Omnibus Plan, as amended. In February 2021, the Board approved an increase in the number of shares eligible to be issued under the 2016 Omnibus Equity Plan, as amended, from 400,000 shares to 1 million shares.

Recent Sales of Unregistered Securities

The following table sets forth the sales of unregistered securities by the Company in 2020 and up to the date of filing that were not previously reported in Form 10-Q or 8-K filings.

During the year ended December 31, 2020, the Company made the following sales of unregistered securities:

Purpose / Holder	Number of Shares	Total Price/Amount
Conversion into common shares of promissory notes among multiple note holders (1)	13,312,175	$ 2,928,679
Conversion into common shares of related party notes (2)	696,159	$ 153,155
Issuance of common shares to officers and directors in lieu of salary and bonus (3)	1,277,226	280,990
Common shares issued to related party for services (4)	227,273	$ 50,000
Common shares issued to one service provider (5)	800,000	$ 200,000
Common shares issued to one service provider (6)	150,000	$ 30,000
Conversion of debt into Series B shares (7)	156	$ 156,000
Sale of Series B Preferred Shares to multiple investors (8)	125	$ 125,000
Grant of Series E-1 Preferred Shares to management (9)	7,650	-

(1) Shares issued to 27 holders of the Company's Bridge Notes.
(2) Shares issued to Kevin Bolin, Joel Mayersohn, Scott Whitney (all current or former directors of the Company) and Checkmate Capital Group LLC or its affiliated entity (a 10% holder of the Company).
(3) Shares issued to Kevin Bolin (former Chairman and CEO), Christopher Nelson (Director and General Counsel), Joel Mayersohn (Director) and Scott Whitney and Tristan Peitz (former directors).
(4) Shares issued to Checkmate Capital Group LLC or its affiliate.
(5) Shares issued to Redstone Communications Inc. or its affiliate.
(6) Shares issued to Atlanta Capital Partners LLC.
(7) Shares issued to Checkmate Capital Group LLC or its affiliate.
(8) Shares issued to two unaffiliated parties.
(9) Series E-1 preferred shares issued to C. Richard Piazza (Executive Chairman), Douglas Baum (CEO and Director), Christopher Nelson (General Counsel and Director), and two non-executive management / advisors of the Company.

Subsequent to the year ended December 31, 2020, the Company made the following sales of unregistered securities:

Purpose / Holder	Number of Shares	Total Price/Amount
Conversion into common shares of promissory notes among multiple note holders (1)	6,578,702	$ 1,447,312
Sale of Series B Shares to multiple investors (2)	2,219	$ 2,219,000
Common stock warrants issued to investors in Series B Offering (3)	6,743,575	-
Common stock warrants issued to service provider (4)	750,000	-
Common shares issued to service provider for services (5)	250,000	-

Grant of Series E-1 Preferred Shares to director (6)	850	-

(1) Shares issued to six holders of the Company's Bridge Notes.
(2) Shares issued to 25 unaffiliated parties.
(3) 6,268,575 warrants issued to 27 investors at $0.35, expiring July 8, 2021; and 475,000 warrants issued to one investor at $0.45, expiring January 15, 2021.
(4) Warrants issued to Sterling Asset Management Inc. at $0.22 per share, expiring July 8, 2021.
(5) Common shares issued to Sterling Asset Management Inc.
(6) Series E-1 preferred shares issued to Charles J Link (Director)

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 4(6) thereof, 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

Legacy Business

Until November 2020, our primary business was acquiring and overseeing the acquisition of companies in the compost and soil health sector (the "Legacy Business"). Through an affiliated company, Earth Property Holdings LLC ("EPH"), we completed two acquisitions of compost facilities in Austin, Texas and Jacksonville, Florida, and had been managing all the operations of those entities through an eight-year Management Agreement providing us $700,000 per year in fees. Prior to these operations, we were developing waste-to-power technology with the goal of pursuing business opportunities in the clean energy sector. In 2017 we raised funding through our Bridge Offering (see "Financial Condition, Liquidity and Capital Resources" below) to transition into the soil health sector, and sold our prior waste-to-power technology to a licensee.

EPH is an unconsolidated investee entity in which we owned approximately an 18% Class B subordinated equity stake as of December 31, 2020. Class A equity holders comprised of one primary institutional investor and two follow-on investors who have collectively provided approximately $7 million to EPH, own the other 82% of EPH. As of March 23, 2021, we sold our Class B equity stake in EPH to an unaffiliated party for $100,000, and currently hold no equity in and have no affiliation with EPH.

New Strategic Plan

In January 2020, our Board of Directors authorized a strategic plan comprised of: (1) securing new technologies and business opportunities in the broader biosciences sector, including both human and soil health; and (2) significantly reducing debt and liabilities of the Company (including over $4 million in the Company's convertible bridge notes (the "Bridge Notes") which were in default in 2020) and eliminating under-performing assets and agreements. The successful results of these actions were intended to attract new capital to fund long term growth opportunities for the Company, reduce the significant debt burden of the Company, and provide shareholders with new opportunities for growth and value appreciation. We believe we were successful in these efforts.

In January 2020, we appointed Douglas R. Baum to our Board of Directors. Mr. Baum has over 28 years of experience in the bioscience and biotech industries, including development, commercialization and marketing of multiple drugs and medical devices. After his appointment to the Board, Mr. Baum secured for the Company an Exclusive Dealing Option Agreement to provide us a 90-day period to negotiate with IGL Pharma Inc. ("IGL") for a license to the radiopharmaceutical Samarium-153 DOTMP aka CycloSam® ("CycloSam" or the "New Technology"). CycloSam is a promising drug with initial indications for pediatric osteosarcoma, a devastating form of bone cancer afflicting children, as well as a broader market in bone marrow ablation and other metastasized bone cancers. IGL is an affiliated entity of IsoTherapeutics Group LLC, whose founders created Quadramet® (Samarium-153-EDTMP) one of the first effective commercial radiopharmaceuticals. After signing the option agreement for the licensing of CycloSam, we provided IGL with $50,000 of advanced support fees to fund a single patient test for the drug, which was approved by the FDA to treat a patient in a bone marrow ablation procedure and was performed with technical success.

On April 20, 2020, we exercised our option and executed a Patent and Technology License Agreement and Trademark Assignment (the "License Agreement") with IGL, through a newly created, wholly-owned subsidiary called QSAM Therapeutics Inc. ("QSAM"). The License Agreement provides our subsidiary QSAM with exclusive, worldwide and sub-licensable rights to all of IGL's patents, product data and knowhow with respect to CycloSam. The License Agreement also transfers to QSAM the rights to the product name CycloSam for the technology, and provides QSAM a first right of refusal to license other IGL/ISO technologies in the future.

The License Agreement is for 20 years or until the expiration of the multiple patents covered under the license, and requires multiple milestone-based payments including: $60,000 and other expense reimbursements within 60 days of signing (such expenses have been paid), up to $150,000 as CycloSam advances through multiple stages of clinical trials, and $1.5 million upon commercialization. IGL will also receive equity in QSAM equal to 5% of the company to be issued within 60 days of signing. This equity has not yet been issued. Upon commercialization, IGL will receive an on-going royalty equal to 4.5% of Net Sales, as defined in the License Agreement, and up to 50% of any sublicense consideration received by QSAM, as defined in the License Agreement. QSAM will also pay for ongoing patent filing and maintenance fees, and has 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 may terminate for any reason upon 30 days' notice. In the case IGL terminates due to an uncured QSAM breach, IGL will repay to QSAM 25% of its direct clinical costs to assume ownership of data and other information gained in that process.

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. 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.

Separation from EPH and New Business Path

Our Board of Directors determined in the fourth quarter of 2020 that the opportunities presented through the development of the New Technology present shareholders with the best path forward. As a result, on November 6, 2020, we entered into an Omnibus Separation Agreement (the "Separation Agreement") with EPH. Under the terms of the Separation Agreement, the parties agreed that we will continue to operate and pursue opportunities in the biosciences and pharmaceutical fields while EPH will continue to operate in the compost and soil manufacturing fields. More specifically:

- The Management Agreement, dated January 18, 2019, as amended, between EPH and the Company was terminated by mutual agreement of the parties. Fees from this agreement constituted most of the Company's revenue over the prior two years. We have presented revenue and expenses related to the Management Agreement, as well as other expenses, assets and liabilities related to the Legacy Business, as "discontinued operations" in our consolidated financial statements.

- In lieu of any severance or other termination payments due under the Management Agreement, EPH released the Company from a total of $993,985 in liabilities, inclusive of advanced management fees and multiple promissory notes, including accrued and unpaid interest. An additional $114,700 in promissory notes plus accrued interest owed to an affiliate of EPH were converted into Company common stock at a price of $0.22 per share.

- The Company agreed to transfer to EPH the license agreement with Agrarian Technologies LLC and Mulch Masters Inc. for the ABS soil enhancement product and all associated knowhow, trade secrets and trademark/service marks. Accrued license fees in connection with that license agreement were also transferred to and assumed by EPH.

- The prior officers and employees of the Company engaged in the Legacy Business were released from any non-competition, non-solicitation or other restricted covenant pursuant to their respective employment agreements. Several of these employees had already been removed from the Company's payroll as of October 1, 2020.

- EPH received the right in its sole discretion to use the name "Q2Earth" in all jurisdictions of the United States and worldwide.

New Equity Financing and Debt Conversions

To advance the development of the New Technology, in November 2020 we commenced a $2.5 million Series B Preferred stock offering (the "Series B Offering"), issuing 281 shares of Series B Preferred stock for $125,000 ($25,000 of which was recorded as a subscription receivable at the end of 2020) and $156,000 in debt conversion. In January 2021, we completed the Series B Offering, raising $2.5 million (inclusive of the debt conversion) and issuing a total of 2,500 shares of Series B Preferred Stock.

In connection with this Series B Offering closing, our Board approved a modification to the offering terms and we issued in 2021 a total of 6.27 million common stock warrants, which are exercisable prior to July 8, 2021 at an exercise price of $0.35 per share. Also in 2021, our lead investor in the Series B Offering earned a warrant for 475,000 shares which expire January 15, 2022 and are exercisable at $0.45 per share. None of these warrants provide a cashless exercise option nor any registration rights, and none of these warrants were issued or approved in 2020.

In the fourth quarter of 2020, we also further advanced the conversion of Bridge Notes and other liabilities into equity. 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. Officers, directors and related parties of the Company converted $346,867 in accrued compensation, unpaid bonuses and other notes payable into 1,576,668 shares of common stock. This is in addition to the $993,985 in liabilities owed to EPH that were forgiven and additional $117,659 note principal and accrued interest converted into 534,814 shares of common stock.

As of the first quarter of 2021, all remaining Bridge Note holders converted their notes, representing $1,447,312 in principal and accrued interest, into 6,578,702 shares of common stock. Also in December 2020 and January 2021, one of the Company convertible debenture holders converted the remaining balance of $27,500 and $72,500 of its debenture into 125,000 and 329,545 shares of common stock, respectively; and in February 2021, converted $120,000 of its Series A Preferred stock into 750,000 shares of common stock. In February 2021, a second debenture holder converted $30,000 of its debenture into 187,541 shares of common stock.

As of the end of the first quarter of 2021, the Company had approximately $2 million in cash and only approximately $35,000 in debt, not including trade payables and the Series A Preferred stock which is still outstanding and subject to a redemption clause in default. Management is in discussions with the Series Preferred A stockholders to convert the remaining balance of these securities into common stock or otherwise amend the redemption terms of their securities.

We believe our transition plan, including the execution of the Separation Agreement and the subsequent debt reduction and equity raise, has significantly strengthened our balance sheet and provided us the funding to pursue the New Technology. Management believes these results have materially improved the chance for shareholder value appreciation in the following periods.

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. We are monitoring this closely, and although operations have not been materially affected by the COVID-19 outbreak to date, the ultimate duration and severity of the outbreak and its impact on the economic environment and our business is uncertain. Accordingly, while we do not anticipate an impact on our operations, we cannot estimate the duration of the pandemic and potential impact on our business. In addition, a severe or prolonged economic downturn could result in a variety of risks to our business, including a possible delay in our ability to raise money. At this time, the Company is unable to estimate the impact of this event on its operations.

Results of Operations for the years ended December 31, 2020 and 2019

For the years ended December 31, 2020 and 2019, we recorded no revenue from continuing operations. Revenue from the Management Agreement and other Legacy Business operations have been reclassified in our Statement of Operations on our Consolidated Financial Statements as "discontinued operations."

For the year ended December 31, 2020, we recorded a net loss from continuing operations of $4,898,123, an increase of $4,180,144 (582%) from our net loss from continuing operations of $717,979 for the same period in 2019. Basic and diluted net loss per share was $0.88 and $0.34 for the years ended December 31, 2020 and 2019, respectively. The primary reasons for the increase in the net loss for 2020 over 2019 were an increase of $194,702 in operating expenses, as well as an increase in the loss recognized due to the change in the fair value of the convertible bridge notes of $4,228,113 and the loss of $834,903 on convertible debt and other liabilities converted to equity; offset slightly by a decrease of $50,475 in financing costs. Expenses from the Legacy Business operations have been reclassified in our Statement of Operations on our Consolidated Financial Statements as "discontinued operations."

The majority of the $194,702 increase in operating expenses was due to the research and development expenses of $362,456 and higher general and administrative expenses of $103,955 (246%); offset by lower payroll and related expenses of $277,222 (43%) to $372,938 in the year ended December 31, 2020 from $650,160 for the year ended December 31, 2019.

Financial Condition, Liquidity and Capital Resources

For year ended December 31, 2020, cash increased by $7,826 from $478 as of December 31, 2019 to $8,304 at the end of 2020. This increase was primarily the result of cash provided by financing activities of $750,725, offset by cash used in operating activities of $742,899.

Net cash used by operating activities was $742,899 for the year ended December 31, 2020, which reflected our net loss during the period of $4,862,683, non-cash adjustments of $3,741,254, and a net increase in operating liabilities of $378,530. The majority of non-cash adjustments consists of a $3,170,236 loss on change in fair value of the Bridge Notes primarily as a result of our higher stock price and proximity to maturity, $484,031 in paid-in-kind interest related to the Bridge Notes, the loss on conversion into common stock of the Bridge Notes and accrued interest of $495,320, the loss on conversion of accrued salary and bonus, director fees and promissory notes with related parties of $271,210 and $258,667 of stock based compensation; offset by the gain on forgiveness of promissory notes and accrued expenses.

Our net loss resulted largely from the non-cash items of the change in fair value of the Bridge Notes and loss on convertible debt and other liabilities that were converted to equity.

Net cash used in investing activities during year ended December 31, 2020 consisted of $0.

Net cash provided by financing activities during the year ended December 31, 2019 consisted of additional notes from EPH of $788,500 and additional convertible Bridge Note of $30,000.

At December 31, 2020, our cash totaled $8,304. Our cash is currently held at large U.S. banks.

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

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 flagship drug candidate CycloSam, as well as for general working capital and overhead.

The shares of Series B Preferred Stock are convertible into an aggregate of approximately 16.6 million shares of common stock of the Company and have voting rights alongside common stockholders on an as-converted basis. In 2021, our Board approved a modification to the offering and issued to investors six-month, non-registered warrants to purchase an aggregate of up to 6.27 million shares of Common Stock at $0.35 per share. For the performance of its lead investor commitment in 2021, Checkmate Capital also earned a 12 month warrant convertible into 475,000 shares of Common Stock at $0.45 per share. All warrants were approved and issued in 2021 at the closing of the offering, and therefore were not outstanding at the end of 2020.

Funds received from the Series B Offering are expected to support operations through the end of 2021. Furthermore, if Series B warrants are exercised, the Company expects to have the capital needed to fund both operations and the start of clinical trials of CycloSam at least into the beginning of 2022.

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.

Additional Debt Settlement. As of December 31, 2020, officers, directors and related parties of the Company converted $346,867 in accrued compensation, unpaid bonuses and other notes payable into 1,576,668 shares of common stock. This is in addition to the $993,985 in liabilities owed to EPH that were forgiven pursuant to the Separation Agreement, and additional $117,659 note principal and accrued interest converted into 534,814 shares of common stock.

Company’s Prior Series A Preferred Stock Financing.

We raised $600,000 in our Series A 6% Convertible Preferred Stock (the “Preferred Stock”) from two separate accredited investors in November 2015 and January 2016, respectively. The 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 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 Preferred Stock. Most currently, as a result of the recent debt conversions, the conversation price for these Preferred Shares automatically reduced to $0.22 per share, and as a result of the closing of the Series B preferred stock offering in January 2021, the conversion price was reset to $0.16 per share. 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 Preferred Stock was redeemable on July 1, 2019 per a March 2019 modification and is currently in technical default. The Preferred Stock has no voting rights until converted to common stock. The 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, 2020, we had an accumulated deficit of $15,911,895 and working capital deficit of $4,168,618.

Critical Accounting Policies

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

Off-Balance Sheet Arrangements

The Company did not engage in any "off-balance sheet arrangements" (as that term is defined in Item 303(a)(4)(ii) of Regulation S-K) as of December 31, 2020.

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, President and Principal Accounting Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this Annual Report. Disclosure controls and procedures are designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to management, including the Chief Executive Officer, General Counsel and the Principal Accounting Officer, to allow timely decisions regarding required disclosures. Management concluded that, as of December 31, 2020, 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.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process, under the supervision of the Chief Executive Officer, the General Counsel and the Principal Accounting Officer, designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external purposes in accordance with generally accepted accounting principles in the United States (GAAP). Internal control over financial reporting includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the Company's assets;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of management and the Board of Directors; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management conducted an assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in 2013. As a result of this assessment, management identified certain 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 weaknesses are 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.

- The Company has experienced significant turnover in the role that oversees the day-to-day accounting and financial reporting functions, which increases the risk of a material misstatement in the financial statements.

- The Company lacks knowledge and expertise with accounting for stock -based compensation arrangements.

As a result of the material weaknesses in internal control over financial reporting described above, management concluded that, as of December 31, 2020, the Company's internal control over financial reporting was not effective based on the criteria in *Internal Control – Integrated Framework* issued by the COSO.

The Company is in the process of addressing and correcting these material weaknesses, including drafting, formalizing and implementing greater internal controls to assure proper financial reporting. As the Company retained but then lost its acting CFO in early 2020, and its Principal Accounting Officer has not had the resources to implement proper controls, these weaknesses still exist. Management will be diligent in its efforts to continue to improve the reporting processes of the Company, including the addition of accounting resources and the continued development of proper accounting policies and procedures.

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

Changes in Internal Control Over Financial Reporting

There were no other changes in our internal control over financial reporting in connection with the evaluation required by Rule 13a-15(d) of the Exchange Act that occurred during 2020 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 2020 that was not filed by the Company in a Current Report on Form 8-K.

PART III

ITEM 10: DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Identification of Directors and Executive Officers

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

Name	Positions Held	Age	Date of Election or Designation	Date of Termination or Resignation
C. Richard Piazza	Executive Chairman	73	November 2020	*
Douglas R. Baum	Chief Executive Officer & Director	54	January 2020 (1)	*
Christopher Nelson	General Counsel & Director	51	July 2014	*
Joel Mayersohn	Director	62	July 2014	*
Charles J. Link, Jr.	Director	61	February 2021	*

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

Business Experience

C. Richard Piazza – 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 more than 45 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. During his career running both public and private companies he has raised more than a $120 million in capital. Mr. Piazza also serves as President, and is a minority shareholder, of IGL Pharma Inc., the licensor of the Company's drug technology, and a consultant to IsoTherapeutics Group, LLC, the inventors of the technology.

Douglas R. Baum – Chief Executive Officer & Director. Mr. Baum was appointed to the Board in January 2020 and to the position of CEO in November 2020. He brings to the Company over 28 years of experience in the bioscience and biotech industries, including development, commercialization and marketing of multiple drugs and medical devices. Over his long senior executive tenure, he has overseen 15 product approvals through the FDA and raised over $80 million in capital to fund breakthrough technologies. Between 2012 and 2017, he served as President, Chief Executive Officer and Director of Xeris Pharmaceuticals Inc.; and from 2007 to 2012 as Executive Vice President and Chief Operating Officer of Macuclear Inc. Prior to that, Mr. Baum held several executive level positions with clinical trial research firms. He holds an MSTC in Technology Commercialization and BBS in International Sales and Marketing from the University of Texas.

Christopher Nelson – General Counsel & Director. Mr. Nelson oversees finance, business development, and legal aspects for the Company, a role he has provided since the Company's inception in 2014. He also serves as Managing Director of GreenBlock Capital LLC in Palm Beach, Florida, a boutique mergers and acquisitions firm specializing in ag-technology and bio-technology transactions, and as General Counsel for Earth Property Holdings, LLC. Mr. Nelson has practiced law in Florida for over 26 years, and since 2001 has represented many start-up, early stage and established businesses seeking financing, acquisitions and general growth management counseling. Between 1997 and 2000, Mr. Nelson was an associate with Greenberg Traurig PA, and between 1995 and 1997 an associate 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.

Joel Mayersohn – Director. Mr. Mayersohn is a Partner in the Ft. Lauderdale, FL, office of Dickinson Wright PLLC, where he specializes in corporate, securities and business law. Over the last 30 years, he has advised a diversified client base in private placements, public offerings, mergers and acquisitions, financing transactions and general securities law matters. He also has experience in venture capital, bridge loans and pipe financings. He is a member of the Florida and New York Bars.

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; and is the founder and President of biotech startup Syncromune. 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. 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 150 peer-reviewed papers. He previously received funding from the National Institute of Health, the National Cancer Institute, the American Cancer Society, and others. Dr. Link received an M.D. from Stanford University, and he attended the U.S. Air Force Academy.

Executive Recruitment

Management is currently in discussions with several individuals to fill other key positions including Chief Financial Officer. The Board will make its decision to hire executive personnel based upon experience, knowledge of the industry, professional reputation and performance history. All members of senior management are expected to have employments agreements with non-compete provisions similar to current executives.

Family Relationships

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

Directorships

None of our directors or executive officers is a director of a company that is required to file reports under Sections 15 or 13(d) of the Exchange Act.

Involvement in Certain Legal Proceedings

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.

Promoters and Control Person

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

Section 16(a) Beneficial Ownership Reporting Compliance

Our shares of common stock are registered under the Exchange Act, and therefore the officers, directors and holders of more than 10% of our outstanding shares are subject to the provisions of Section 16(a), which requires them to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and our other equity securities. Officers, directors and greater than 10% beneficial owners are required by SEC regulations to furnish us with copies of all Section 16(a) reports they file. Based solely upon review of the copies of such forms furnished to us during the fiscal year ended December 31, 2020, we have determined that our Chairman, CEO and one new director will need to file appropriate forms in 2021.

Code of Ethics

We have adopted a code of ethics for our principal executive and financial officers. Our code of ethics was initially posted to our web site as November 2015.

Corporate Governance

Audit Committee. Our Audit Committee is currently comprised of one independent Director and our Executive Chairman. The Audit Committee formally instituted its governance procedures in 2017, and actively oversees the quarterly and year-end review and audit process.

Compensation Committee. Our Compensation Committee is currently comprised of one independent Director and our CEO/Director. The Compensation Committee formally instituted its governance procedures in 2017, and actively oversees all executive-level salary and compensation matters for the Company.

Nominating Committee. We have not established a Nominating Committee. We believe that we are able to effectively manage the issues normally considered by a Nominating Committee through the Board of Directors. If we do establish a Nominating Committee, we will disclose this change to our procedures in recommending nominees to our Board of Directors.

Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law provides, in general, that a corporation incorporated under the laws of the State of Delaware, such as the Company, may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than a derivative action by or in the right of the corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. In the case of a derivative action, a Delaware corporation may indemnify any such person against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification will be made in respect of any claim, issue or matter as to which such person will have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery of the State of Delaware or any other court in which such action was brought determines such person is fairly and reasonably entitled to indemnity for such expenses.

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide that we will indemnify our directors, officers, employees and agents to the extent and in the manner permitted by the provisions of the Delaware General Corporation Law. Any repeal or modification of these provisions shall be prospective only, and shall not adversely affect any limitation on the liability of our directors or officers existing prior to the time of such repeal or modification. We are also permitted to apply for insurance on behalf of any director, officer, employee or other agent for liability arising out of his actions, whether or not the Delaware General Corporation Law would permit indemnification.

ITEM 11: EXECUTIVE COMPENSATION

The following table sets forth information regarding compensation earned in or with respect to our fiscal year 2020 and 2019 for:

(i) our principal executive officer, or other individual serving in a similar capacity during the fiscal year 2020 and 2019;
(ii) our two most highly compensated executive officers other than our principal executive officers who were serving as executive officers at December 31, 2020, and 2019 whose compensation exceed $100,000; 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, 2020.

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,	2020	-							-
Executive Chairman (1)	2019	-							-
Douglas Baum,	2020	-			100				100
CEO and Director (2)	2019	-							-
Christopher Nelson,	2020	107,895	50,000	43,194				11,743	212,832
General Counsel (former President) (3)	2019	245,000	-					16,626	261,626
Kevin Bolin,	2020	132,105	50,000	97,796				14,151	294,052
Former Chairman & CEO (4)	2019	295,000	-	-	-	-	-	17,853	312,853

(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) All Other Compensation is comprised of healthcare costs.

(1) Mr. Piazza signed his employment agreement with the Company on November 1, 2020; however, per understanding of the parties, no salary or other compensation accrued under that agreement until after the completion of the Company's Series B offering in January 2021. Mr. Piazza was not employed by the Company in 2019. Not included in the table are 2,975 shares of Series E-1 Preferred Stock issued to Mr. Piazza on December 30, 2020, which do not vest and have not been fully earned until July 1, 2021.
(2) Mr. Baum signed his employment agreement with the Company on November 1, 2020; however, per understanding of the parties, no salary or other compensation accrued under that agreement until after the completion of the Company's Series B offering in January 2021. Mr. Baum was not employed by the Company in 2019. Not included in the table are 2,975 shares of Series E-1 Preferred Stock issued to Mr. Baum on December 30, 2020, which do not vest and have not been fully earned until July 1, 2021.
(3) Mr. Nelson received $43,194 of his annual salary paid in 196,336 shares of common stock, and his deferred bonus of $50,000 paid in 227,273 shares of common stock. Mr. Nelson also waived $13,911 of compensation due to him in 2020. Not included in the table are 850 shares of Series E-1 Preferred Stock issued to Mr. Nelson on December 30, 2020, which do not vest and have not been fully earned until half on July 1, 2021 and the balance on December 31, 2021.
(4) Mr. Bolin's employment with the Company terminated by mutual agreement on November 6, 2020. Mr. Bolin received $97,796 of his deferred annual salary paid in 444,527 shares of common stock, and his deferred bonus of $50,000 paid in 227,273 shares of common stock. Mr. Bolin also waived $32,598 of deferred compensation due to him in 2020.

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. The term is three years, with extensions at the agreement of the parties. His base salary is $225,000 per year, however, the parties agreed that no salary was paid or accrued in 2020. Under the agreement, Mr. Piazza is entitled to receive regular company benefits, including vacations, sick leave and PTO. If he is terminated for cause, as defined therein, 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 therein, Mr. Piazza will receive salary through the date of termination plus an additional 12 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 12 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 1, 2020. The term is three years, with extensions at the agreement of the parties. His base salary is $250,000 per year, however, the parties agreed that no salary was paid or accrued in 2020. Under the agreement, Mr. Baum is entitled to receive regular company benefits, including vacations, sick leave and PTO. If he is terminated for cause, as defined therein, 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 therein, Mr. Baum will receive salary through the date of termination plus an additional 12 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 12 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, the term of which is currently on a year-to-year basis renewing on April 1 each year. Mr. Nelson's annual salary is $220,000, however the parties agreed that no salary was paid in the fourth quarter of 2020. His agreement provides for a 12 month severance in the instance of a termination without cause, as defined therein. Mr. Nelson also agreed to a 12 month non-compete / non-solicitation and proprietary information and inventions covenant under his employment agreement which assigns to the Company any intellectual property developed by him during his employment.

Outstanding Option and Stock Awards

The following table presents information concerning unexercised options and unvested restricted stock awards for the named executive officer outstanding as of December 31, 2020.

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 (1) Executive Chairman	-	-	-	-	-	-	-	-	-
Douglas Baum (2) CEO and Director	4,000	4,000	-	$ 0.50	1/14/2025	-	-	-	-
Christopher Nelson (3)	10,200	-	-	$ 0.50	7/30/24	-	-	-	-
General Counsel	2,400	-	-	$ 0.50	11/17/25	-	-	-	-
Kevin Bolin	16,000	-	-	$ 0.50	2/29/26	-	-	-	-
Former Chairman & CEO	72,000	-	-	$ 0.50	12/28/26	-	-	-	-

(1) In December 2020, Mr. Piazza received a grant of 2,975 shares of Series E-1 Preferred Stock. All of these shares vest on July 1, 2021.
(2) In December 2020, Mr. Baum received a grant of 2,975 shares of Series E-1 Preferred Stock. All of these shares vest on July 1, 2021.
(3) In December 2020, Mr. Nelson received a grant of 850 shares of Series E-1 Preferred Stock. Half of these shares vest on July 1, 2021, and the balance on December 31, 2021.

Director Compensation

In June 2019, the Board approved payment to the independent directors of $500 per month plus an additional $500 per month for committee chairs. These fees were accrued but not paid in 2019 and 2020. In December 2020, all directors converted their respective accrued fees totaling $40,000 into 181,818 shares of common stock of the Company. These fees terminated in the fourth quarter of 2020 and will not be paid in 2021 unless re-established by the Board.

In 2020, two of our independent directors received a grant of 40,000 stock options each, one director received a grant of 20,000 stock options, and a newly appointed director received a grant of 8,000 stock options. No option grants were made in 2019. Directors are also able to be reimbursed for reasonable travel expenses incurred in connection with meetings of the Board of Directors, but no such expenses were incurred in 2020 or 2019.

In February 2021, in connection with the appointment of Dr. Link to our Board, he received as compensation 850 shares of our Series E-1 Preferred Stock.

The following table provides all fees paid to all directors in 2020, but excludes fees paid to the inside directors, Messrs. Baum, Piazza and Nelson, for their services in 2020 in their respective officer capacities. It also excludes fees paid to Mr. Bolin for his services as Chairman and CEO, which terminated in November 2020.

Name	Fees Earned or Paid in Cash ($) (1)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Joel Mayersohn	$ 12,000	-	$ 5,319	-	-	-	$ 17,319
Scott Whitney	$ 12,000	-	$ 5,319	-	-	-	$ 17,319
Tristan Peitz (2)	$ 6,000	-	$ 2,660	-	-	-	$ 8,660

(1) As of December 2020, all accrued fees earned in cash were converted to common stock at a price of $0.22 per share.
(2) Mr. Peitz resigned from the Board on December 9, 2020.

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 April 14, 2021 for:

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

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

In the following table, percentage ownership is based on 27,497,850 shares of our common stock, 520 shares of Series A Preferred Stock, 2,500 shares of Series B Preferred Stock, and 8,500 Shares of Series E-1 Preferred Stock outstanding as of April 14, 2021. 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 April 14, 2021. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

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

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

Executive Officers and Directors

(1) Title of class	(2) Name of beneficial owner		(3) Amount and nature of beneficial ownership	(4) Percent of class
	C. Richard Piazza (1)	Executive Chairman		
Common			-	-
Series A			-	-
Series B			-	-
Series E-1			-	--
	Douglas Baum (2)	CEO and Director		
Common			4,000	*
Series A			-	-
Series B			3	*
Series E-1			-	--
	Christopher Nelson (3)	General Counsel and Director		
Common			725,164	2.6%
Series A			-	-
Series B			20	*
Series E-1			-	--
	Joel Mayersohn (4)	Director		
Common			508,674	1.8%
Series A			-	-
Series B			-	-
Series E-1			-	--
	Charles J. Link, Jr. (5)	Director		
Common			-	-
Series A			-	-
Series B			-	-
Series E-1			-	-
	All Officers and Directors			
Common			1,237,838	4.5%
Series A			-	-
Series B			23	*
Series E-1			-	-

* Less than 1%

(1) Mr. Piazza's holdings do not include 2,975 shares of Series E-1 preferred stock that vest on July 1, 2021.
(2) Mr. Baum's holdings do not include 2,975 shares of Series E-1 preferred stock that vest on July 1, 2021. His common holdings include 4,000 vested stock options but does not include 4,000 unvested stock options.
(3) Mr. Nelson's holdings do not include 850 shares of Series E-1 preferred stock that vest half on July 1, 2021 and the balance on December 31, 2021. His common holdings include 12,600 vested stock options. Mr. Nelson's address is 420 Royal Palm Way, Suite 100, Palm Beach, FL 33480.
(4) Mr. Mayersohn's holdings include 79,840 vested stock options. Mr. Mayersohn's address is 350 East Las Olas Blvd., Suite 1750, Ft. Lauderdale, FL 33301.
(5) Dr. Link's holdings do not include 850 shares of Series E-1 preferred stock that vest half on February 1, 2022 and the balance on February 1, 2023.

More than 5% Beneficial Holders

(1) Title of class	(2) Name of beneficial owner	(3) Amount and nature of beneficial ownership	(4) Percent of class
	Checkmate Capital Group LLC (1)		
Common		6,806,693	24.8%
Series A		-	
Series B		306	6.2%
Series E-1		-	
	Alpha Capital Anstalt (2)		
Common		1,230	*
Series A		420	80.7%
Series B		-	-
Series E-1		-	
	Kevin Bolin (3)		
Common		2,075,239	7.5%
Series A		-	
Series B		-	
Series E-1		-	

(1) Checkmate Capital Group LLC directly owns 762,088 common shares; through its affiliated entity Checkmate Strategic Capital 2, LLC, 6,044,605 common shares and 156 Series B Preferred shares; and through its affiliated entity Checkmate Strategic Capital Holdings LLC, 150 Series B Preferred shares. The address for Checkmate is 595 E. Colorado Blvd., Suite 530, Pasadena, CA 91101.
(2) The Company is not aware of any common shares currently held by Alpha Capital in street name. Their address is: 510 Madison Avenue, New York, NY, 10022
(3) Mr. Bolin's shares include 88,000 vested stock options. In November 2020 as part of his severance, the Company terminated the forfeiture provisions on 400,000 shares issued to him in 2017. The address for Mr. Bolin is 420 Royal Palm Way, Palm Beach, FL 33480.

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

Transactions with Related Persons

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

C. Richard Piazza, our Executive Chairman, also serves as President, and is a minority shareholder, of IGL Pharma Inc., the licensor of the Company's drug technology, and a consultant to IsoTherapeutics Group, LLC, the inventors of the technology.

Promoters and Certain Control Persons

See the heading "Transactions with Related Persons" above.

The Company signed a three-month investor relations agreement with Atlanta Capital Partners LLC in November 2020. The Company paid 150,000 in restricted common shares in considerations for their services.

Parents of the Smaller Reporting Company

We have no parents.

Director Independence

We had two independent directors serving on our Board of Directors as of the end of 2020 – Messrs. Whitney and Mayersohn. While Mr. Mayersohn's firm also serves as the Company's corporate counsel, it was determined that the payments made for services from the Company to his firm are not material enough to create an issue with Mr. Mayersohn's independence. In 2021, Mr. Whitney resigned from the Board and was replaced with another independent director, Dr. Charles Link.

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 2020 and 2019:

Fee Category	2020	2019
Audit Fees	$ 56,000	$ 56,000
Audit-related Fees	-	-

Tax Fees	-	-
All Other Fees	-	-

Audit fees - Consists of fees for professional services rendered by D. Brooks and Associates CPAs, P.A. in 2020 and 2019 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.

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 Articles of Incorporation of Q2Earth, Inc. (incorporated by reference to the Form 8-K dated September 4, 2020)
3.3	Amended and Restated Bylaws (incorporated by reference to the Form 8-K filed December 23, 2010)
4.1	Certificate of Designation of Preferences, Rights and Limitations of Series A 6% Convertible Preferred Stock (incorporated by reference to the Form 8-K filed November 18, 2015)
4.2	Certificate of Designation for the Series B Convertible Preferred Stock (incorporated by reference to Form 8-K dated December 31, 2020)
4.3	Certificate of Designation for the Series E-1 Incentive Preferred Stock (incorporated by reference to Form 8-K dated December 31, 2020)
10.01	Securities Purchase Agreement for Convertible Debentures (incorporated by reference to the Form 8-K filed July 2, 2014)
10.02	Original Issue Discount Senior Secured Convertible Debentures (incorporated by reference to the Form 8-K filed July 2, 2014)

10.03	Form of Subscription Agreement for Convertible Note Bridge Offering (incorporated by reference to the Form 8-K filed April 4, 2017)
10.04	Form of Promissory Note for Convertible Note Bridge Offering (incorporated by reference to the Form 8-K filed April 4, 2017)
10.05	2016 Omnibus Equity Incentive Plan (incorporated by reference in the Form 10-K filed for the year ended December 31, 2017)
10.06	Employment Agreement with Christopher Nelson (incorporated by reference in the Form 10-K filed for the year ended December 31, 2017)
10.07	Management Agreement dated November 9, 2018 between Q2Earth, Inc. and Earth Property Holdings, Inc. (incorporated by reference in the Form 8-K filed on November 13, 2018)

10.08	Limited Liability Company Agreement of Earth Property Holdings, Inc. dated November 9, 2018 (incorporated by reference in the Form 8-K filed on November 13, 2018)
10.09	Subscription Agreement for Class B Units in Earth Property Holdings LLC (incorporated by reference in the Form 8-K filed January 23, 2019)
10.10	Form of Amended and Restated Limited Liability Company Agreement of Earth Property Holdings LLC (incorporated by reference in the Form 8-K filed January 23, 2019)
10.11	Omnibus Separation Agreement, dated November 6, 2020, between the Company and Earth Property Holdings, LLC incorporated by reference in the Form 8-K dated November 6, 2020
10.12	Employment Agreement dated November 6, 2020, between the Company and C. Richard Piazza incorporated by reference in the Form 8-K dated November 6, 2020
10.13	Employment Agreement dated November 6, 2020, between the Company and Douglas Baum incorporated by reference in the Form 8-K dated November 6, 2020
10.14	Form of Issuance Agreement for the Series E-1 Incentive Preferred Stock (incorporated by reference in the Form 8-K dated December 31, 2020)
21.1	Subsidiaries of the Company
31.1	302 Certification of Douglas Baum, CEO
31.2	302 Certification of Principal Accounting Officer
32	906 Certification
101.INS#	XBRL Instance Document.
101.SCH#	XBRL Taxonomy Extension Schema Document.
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF#	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB#	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document.

XBRL (Extensible Business Reporting Language) information is furnished and not filed herewith, is not a part of a registration statement or Prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

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: April 15, 2021 *By:* */s/ Douglas Baum*
Douglas Baum
Director and Chief Executive Officer

Date: April 15, 2021 *By:* */s/ Thomas Knight*
Thomas Knight
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: April 15, 2021 *By:* */s/ C. Richard Piazza*
C. Richard Piazza
Executive Chairman of the Board of Directors

Date: April 15, 2021 *By:* */s/ Douglas Baum*
Douglas Baum
Director and Chief Executive Officer

Date: April 15, 2021 *By:* */s/ Christopher M. Nelson*
Christopher M. Nelson
General Counsel and Director

Date: April 15, 2021 *By:* */s/ Joel Mayersohn*
Joel Mayersohn
Director

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of QSAM Biosciences, Inc (f/k/a Q2Earth, Inc., and referred to as the "Company") as of December 31, 2020 and 2019, 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, 2020 and 2019, and the results of its operations and its cash flows for the year 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 a working capital deficit. These and other factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plan regarding these matters is also described in Note 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

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

Palm Beach Gardens, FL
April 15, 2021

QSAM BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash	$ 8,304	$ 478
Prepaid expenses and other assets	12,896	7,665
TOTAL CURRENT ASSETS	21,200	8,143
TOTAL ASSETS	$ 21,200	$ 8,143
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 308,157	$ 189,611
Accrued payroll and related expenses	48,006	36,337
Accrued bonus	-	150,000
Notes payable - related parties	63,992	-
Debentures	137,500	165,000
Paycheck protection program loan - current portion	34,163	-
Convertible bridge notes, at fair value	3,598,000	2,440,090
Current liabilities held for disposal	-	818,926
TOTAL CURRENT LIABILITIES	4,189,818	3,799,964
Paycheck protection program loan - net of current portion	108,779	-
Convertible bridge notes, at fair value	-	32,910
TOTAL LIABILITIES	4,298,597	3,832,874

Redeemable convertible preferred stock - Series A; $0.0001 par value, 1,500 designated Series A, 600 shares issued and outstanding (liquidation preference of $784,044)	784,044	748,604
STOCKHOLDERS' DEFICIT		
Preferred stock, Series B, $0.001 par value; 250,000 shares authorized, 281 and 0 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	-	-
Preferred stock, Series E-1, $0.0001 par value; 8,500 shares authorized, 7,650 and 0 shares issued and outstanding at December 31, 2020, and December 31, 2019, respectively	-	-
Common stock, $0.0001 par value, 300,000,000 shares authorized, 19,512,517 and 2,079,898 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	1,947	208
Unearned deferred compensation	(148,333)	-
Subscription receivable	(25,000)	-
Additional paid-in capital	11,021,840	6,475,667
Accumulated deficit	(15,911,895)	(11,049,210)
TOTAL STOCKHOLDERS' DEFICIT	(5,061,441)	(4,573,335)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 21,200	$ 8,143

See notes to the consolidated financial statements.

QSAM BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the years ended December 31,	
	2020	2019
REVENUES	$ -	$ -
OPERATING EXPENSES FROM CONTINUED OPERATIONS		
Payroll and related expenses	372,938	650,160
Professional fees	442,795	437,282
General and administrative	146,207	42,251
Research and development expenses	362,456	-
Total Operating Expenses	1,324,396	1,129,693
LOSS FROM CONTINUING OPERATIONS	(1,324,396)	(1,129,693)
OTHER INCOME (EXPENSE) FROM CONTINUING OPERATIONS		
Financing costs including interest	(490,402)	(540,877)
Change in fair value of convertible bridge notes	(3,170,236)	1,057,877
Loss on equity method investment	-	(21,588)
Loss on convertible debt and other liabilities converted to equity	(834,903)	-
Total Other (Expense) Income	(4,495,541)	495,412
Loss from continuing operations before income taxes	(5,819,937)	(634,281)
INCOME TAXES	-	-
Loss from continuing operations	(5,819,937)	(634,281)
DISCONTINUED OPERATIONS:		
Income (Loss) from discontinued operations before income taxes	957,254	(47,698)
INCOME TAXES	-	-
Income (Loss) from discontinued operations	957,254	(47,698)
NET LOSS	(4,862,683)	(681,979)
PREFERRED STOCK		
Series A convertible contractual dividends	(35,440)	(36,000)
NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (4,898,123)	$ (717,979)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS: BASIC AND DILUTED:		
CONTINUING OPERATIONS	$ (1.06)	$ (0.32)
DISCONTINUED OPERATIONS	0.17	(0.02)
	$ (0.88)	$ (0.34)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING: BASIC AND DILUTED	5,522,771	2,079,898

See notes to the consolidated financial statements

QSAM BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT

	Preferred Stock		Common Stock		Additional Paid In	Deferred Stock-based	Subscription	Accumulated	Total Stockholders'
	Shares	Value	Shares	Value	Capital	Compensation	Receivable	Deficit	Deficit
Balance, December 31, 2018	-	-	2,079,898	$ 208	$ 6,395,952	$ -	$ -	$ (10,367,231)	$ (3,971,071)
Issuance of stock to consultants for services	-	-	-	-	115,715	-		-	115,715
Series A, preferred stock contractual dividends	-	-	-	-	(36,000)	-		-	(36,000)
Net loss period ended December 31, 2019	-	-	-	-	-	-		(681,979)	(681,979)
Balance, December 31, 2019	-	-	2,079,898	$ 208	$ 6,475,667	$ -	$ -	$ (11,049,210)	$ (4,573,335)
Stock-based compensation for services	-	-	1,750,000	175	406,825	(148,333)	-	-	258,667
Stock-based compensation expense and stock option modification	-	-	-	-	24,327	-	-	-	24,327
Conversion of debenture and promissory note with unrelated parties	-	-	218,686	22	116,508	-	-	-	116,530
Conversion of bridge notes and accrued interest to common stock	-	-	13,312,175	1,331	3,016,168	-		-	3,017,499
Conversion of accrued salary and bonus, director fees, and promissory notes with related parties	-	-	2,111,482	211	736,785	-		-	736,996
Series A, preferred stock contractual dividends	-	-	-	-	(35,440)	-	-	-	(35,440)
Conversion of debt to Series B preferred stock	156	-	-	-	156,000	-	-	-	156,000
Sale of Series B preferred stock	125	-	-	-	125,000	-	(25,000)	-	100,000
Net loss period ended December 31, 2020	-	-	-	-	-	-	-	(4,862,683)	(4,862,683)
Balance, December 31, 2020	281	-	19,472,241	$ 1,947	$ 11,021,840	$ (148,333)	$ (25,000)	$ (15,911,893)	$ (5,061,439)

See notes to the consolidated financial statements.

QSAM BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the years ended December 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (4,862,683)	$ (681,979)
Adjustments to reconcile net loss to net cash provided by operations:		
Depreciation	-	354
Loss on equity investment	-	21,588
Stock-based compensation for services	258,667	115,715
Stock-based compensation and stock option modification	24,327	-
Loss on conversion of bridge notes and accrued interest	495,320	-
Loss on conversion of debentures and notes payable with unrelated parties	68,373	-
Loss on conversion of accrued salary and bonus, director fees, and notes payable with related parties	271,210	-
Change in fair value of convertible bridge notes	3,170,236	(1,057,877)
Amortization of debt issuance costs	1,250	5,000
Paid-in-kind interest - convertible bridge notes	484,031	535,877
Gain on forgiveness or assumption of notes payable and accrued expenses	(1,032,160)	-
Changes in operating assets and liabilities		
Increase in prepaid expenses and other current assets	(5,231)	(7,665)
Increase in accounts payable and accrued expenses	174,690	43,171
Increase accrued payroll and related expenses	152,657	150,000
Increase in contract liabilities - related party	-	(117,667)

Increase in accrued interest – related party	50,803	15,426
Increase in accrued interest	5,611	-
Net cash used in operating activities	(742,899)	(978,057)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from notes payable - related parties	338,373	788,500
Repayments on notes payable - related parties	(1,590)	
Proceeds from notes payable - unrelated parties	171,000	-
Proceeds from convertible notes payable	-	30,000
Proceeds from issuance of Series B Preferred Stock	100,000	-
Proceeds from Paycheck Protection Program	142,942	-
Net cash provided by financing activities	750,725	818,500
NET INCREASE (DECREASE) IN CASH	7,826	(159,557)
CASH - Beginning of year	478	160,035
CASH - End of year	$ 8,304	$ 478
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	$ 35,440	$ 36,000
Investment purchased with a subscription payable	$ -	$ 21,588
Conversion of convertible bridge notes and accrued interest of common stock, fair value	$ 2,531,438	$ -
Conversion of debentures and notes payable with unrelated parties to common stock	$ 48,811	$ -
Conversion of accrued salary and bonus, director fees, and notes payable with related parties to common stock	$ 464,526	$ -
Conversion of notes payable to Series B Preferred Stock	$ 156,000	$ -
Series B Preferred Stock purchased with a stock subscription receivable	$ 25,000	$ -

See notes to the consolidated financial statements.

QSAM BIOSCIENCES INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – ORGANIZATION AND DESCRIPTION OF BUSINESS

QSAM Biosciences Inc. (f/k/a Q2Earth, Inc.) (hereinafter the "Company", "we", "our", "us"), incorporated in Delaware on August 26, 2004, is currently engaged in the business of developing a novel radiopharmaceutical drug candidate for the treatment of bone cancer. This business line commenced in earnest in the fourth fiscal quarter of 2020 as a result of the separation and transfer pursuant to an Omnibus Separation Agreement dated November 6, 2020 (the "Separation Agreement") of the Company's prior business of managing compost and soil manufacturing facilities (the "Legacy Business") through an unconsolidated investee entity called Earth Property Holdings LLC, a Delaware limited liability company ("EPH"). Pursuant to the Separation Agreement, the Company transferred to EPH all assets and related liabilities in connection with the Legacy Business in return for a forgiveness of debt. The financial statements presented herein have been adjusted to account for the Legacy Business as discontinued operations (see Notes 4 – Separation Agreement and 9 – Discontinued Operations). The Company owns approximately an 18% subordinated equity interest in EPH as of December 31, 2020, which was sold to a third party in 2021 for $100,000 (see Note 14 – Subsequent Events).

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 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. The establishment of QSAM and execution of the License Agreement and the Separation Agreement are part of the Company's strategic plan to transition its business into the broader biosciences sector which currently is the Company's focus.

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

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

Prior to 2017, the Company owned and licensed technology that converts waste fuels and heat to power, which it sold to a licensee in August of that year. Much of these operations were conducted through a wholly-owned subsidiary of the Company called Q2Power Corp. ("Q2P"), which still exists but has no current operations. Q2P and QSAM are sometimes referred to herein as the "Subsidiaries". Formerly, the Company's name was Q2Power Technologies, Inc., and before that, Anpath Group, Inc.

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 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 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, 2020, the Company used cash in operating activities for its continuing operations of $742,899 and incurred a loss from its continuing operations of $4,862,683. The accumulated deficit since inception is $15,911,895, which was comprised of operating losses and other expenses for both the continuing and

discontinued operations.

The Company raised a total of $2,851,908 in convertible bridge notes (the "Bridge Notes") starting in March 2017 and ending in 2019. In 2020, $2,928,679 of the Bridge Notes inclusive of principal and accrued and capitalized interest were converted by the holders into 13,312,175 shares of common stock. As of December 31, 2020, approximately $1.4 million of Bridge Notes inclusive of principal and accrued and capitalized interest remained outstanding and in default. As of March 31, 2021, all remaining Bridge Notes including principal and accrued and capitalized interest were converted into common stock (see Note 14 - Subsequent Events).

The Company's convertible debentures totaling $137,500 and $600,000 of redeemable convertible preferred stock were in default as of December 31, 2020. Management is in discussions with the holders of these debt and equity securities to reach an agreement to convert the outstanding balances into common stock. As of March 31, 2021, only $35,000 of the debentures and $480,000 of the preferred stock remained outstanding and in default (see Note 14 - Subsequent Events).

As of December 31, 2020, the Company had a working capital deficit of $4,168,618.

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

In 2018, the Company signed an eight-year Management Agreement with EPH to oversee all of the operations of EPH and its acquired subsidiaries for an initial annual fee of $200,000, and acquired 124,999 Class B Membership Units of EPH, equal to 19.9% of the voting interests of EPH, for $50,000. In January 2019, the Company acquired an additional 53,970 Class B Membership Units in EPH for $21,588 through a subscription payable which was paid off in April 2020, and received an additional annual management fee of $500,000 plus expenses. Pursuant to the Separation Agreement (see Note 4 – Separation Agreement), the Management Agreement was terminated in November 2020, and operations from the Management Agreement have been included in discontinued operations on the accompanying statements of operations and are not part of the continuing operation of the Company (see Note 9 - Discontinued Operations). The Company evaluated its ownership interest held in EPH and concluded that EPH is an equity method investment. The primary investor, and not the Company, has ultimate control over major decisions affecting EPH and the greatest economic risk. In 2021, the Company divested its equity interest in EPH completely (see Note 14 – Subsequent Events).

Our net loss from continuing operations in 2020 and 2019 resulted largely from activities related to the public company and in 2020 also from certain license and research expenses in connection with the continuing operations of the Company's drug development business. All income and losses related to expenses from the Legacy Business are included in discontinued operations (see Note 9 - Discontinued Operations).

Management is taking steps to improve its balance sheet and negative cashflow. Commencing in December 2020 and closing in February 2021, management raised $2.5 million in Series B Preferred Stock to support its new business model, which is expected to support continuing operations through the end of 2021 (see Note 14 – Subsequent Events). In 2020, management also was able to reduce debt significantly, in part from the forgiveness of notes payable owed to EPH (see Note 4 – Separation Agreement) and also by converting a portion of additional liabilities into common stock (see Note 7 – Debentures, Convertible Bridge Notes and Notes Payable).

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its Subsidiaries. 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

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 two financial institutions and has experienced no losses with respect to amounts on deposit. The Company held no cash equivalents as of December 31, 2020 and 2019.

Revenue Recognition

On January 1, 2018, the Company adopted ASC Topic 606, "Revenue from Contracts with Customers ("ASC 606") and all the related amendments. The Company elected to adopt this guidance using the modified retrospective method. The adoption of this guidance did not have a material effect on the Company's financial position, results of operations, or cash flows.

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 2020 and 2019 from continuing operations.

Stock Based Compensation

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

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

Research and Development

Research and development costs are expensed as incurred. Research and development costs were $362,456 for year ended December 31, 2020, and are a result of the License Agreement for the Company's drug Technology executed during the period (see Note 13 – Commitments and Contingencies). The Company did not incur any research and development costs during 2019.

Fair Value Measurement

The Company measures fair value in accordance with a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The Company's convertible Bridge Notes are valued by using Monte Carlo Simulation methods and discounted future cash flow models. Where possible, the Company verifies the values produced by its pricing models to market prices. Valuation models require a variety of inputs, including contractual terms, market prices, yield curves, credit spreads, measures of volatility and correlations of such inputs. These convertible Bridge Notes do not trade in liquid markets, and as such, model inputs cannot generally be verified and do involve significant management judgment. Such instruments are typically classified within Level 3 of the fair value hierarchy.

Equity Method Investment

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

Discontinued Operations

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

The Company disposed of a component of its business pursuant to a Separation Agreement in November 2020, which met the definition of a discontinued operation. Accordingly, the operating results of the business disposed are reported as income (loss) from discontinued operations in the accompanying consolidated statements of operations for the years ended December 31, 2020, and 2019. For additional information, see Note 4 – Separation Agreement and Note 14 - Discontinued Operations.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is computed on the straight-line method, based on the estimated useful lives of the assets as follows:

	Years
Furniture and equipment	7
Computers	5

Expenditures for maintenance and repairs are charged to operations as incurred.

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, 2020, the Company does not believe it has any uncertain tax positions that would result in the Company having a liability to the taxing authorities; however, federal returns have not been filed since the Company's inception in 2014. Such delinquencies are being resolved by management and a retained tax expert. Interest and penalties related to any unrecognized tax benefits is recognized in the consolidated financial statements as a component of income taxes.

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.

At December 31, 2020, there were the following potentially dilutive securities that were excluded from diluted net loss per share because their effect would be anti-dilutive (all shares adjusted to reflect a 25:1 reverse stock split effected on September 4, 2020):

Shares from the conversion of Series B Preferred Stock	1,756,250
Shares from the conversion of Series E-1 Preferred Stock (subject to vesting in 2021 through 2023 and potential forfeiture)	7,650,000
Shares from common stock options	468,619

Shares from common stock warrants	46,154
Shares from the conversion of debentures	625,000
Shares that may be converted from Bridge Notes (based upon an assumed conversion price at December 31, 2020 of $0.22 per share)	6,578,702
Shares from the conversion of redeemable convertible preferred stock (based upon an assumed conversion price at December 31, 2020 of $0.22 per share; not inclusive of cumulative dividends which may be converted to shares of common stock under certain conditions)	2,727,273

At December 31, 2019, there were the following potentially dilutive securities that were excluded from diluted net loss per share because their effect would be anti-dilutive (all shares adjusted to reflect a 25:1 reverse stock split effected on September 4, 2020):

Shares from common stock options	340,619
Shares from common stock warrants	126,154
Shares from the conversion of debentures	66,000
Shares that may be converted from Bridge Notes (based upon an assumed conversion price at December 31, 2019 of $2.10 per share);	2,858,671
Shares from the conversion of redeemable convertible preferred stock (not inclusive of cumulative dividends which may be converted to shares of common stock under certain conditions).	299,442

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 deferred the valuation allowance on deferred tax assets and contingencies. Actual results could differ from these estimates.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*", requiring management to recognize any right-to-use-asset and lease liability on the statement of financial position for those leases previously classified as operating leases. The criteria used to determine such classification is essentially the same as under the previous guidance, but it is more subjective. The lessee would classify the lease as a finance lease if certain criteria at lease commencement are met. This ASU is effective for fiscal years beginning after December 15, 2018. Effective January 1, 2019 the Company adopted ASU 2016-02 which did not have an impact on the consolidated financial statements of the Company as the Company has no leases that meet the scope of ASC 842.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting*, which is intended to simplify the accounting for nonemployee share-based payment transactions by expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2018. Early adoption is permitted, but no earlier than an entity's adoption date of ASC 606. Effective January 1, 2019 the Company adopted ASC 2018-07 and it did not have an impact on the Company's consolidated financial statements.

In August 2018, the FASB issued guidance that amends fair value disclosure requirements. The guidance removes disclosure requirements on the transfers between Level 1 and Level 2 of the fair value hierarchy in addition to the disclosure requirements on the policy for timing of transfers between levels and the valuation process for Level 3 fair value measurements. The guidance clarifies the measurement uncertainty disclosure and adds disclosure requirements for Level 3 unrealized gains and losses and significant unobservable inputs used to develop Level 3 fair value measurements. The guidance is effective for fiscal years beginning after December 15, 2019. Entities are permitted to early adopt any removed or modified disclosures upon issuance and delay adoption of the additional disclosures until the effective date. The Company is currently evaluating the impact of this new guidance on its consolidated financial statements and disclosures.

Reclassifications

Certain reclassifications of prior year amounts have been made to conform to the 2020 presentation. These reclassifications had no effect on net loss or loss per share as previously reported.

Concentration of Risk

The Company expects cash to be the asset most likely to subject the Company to concentrations of credit risk. The Company's bank deposits may at times exceed federally insured limits. The Company's policy is to maintain its cash with high credit quality financial institutions to limit its risk of loss exposure.

The Company had no revenue from its continuing operations in 2020 and 2019. Revenue included in discontinued operations was generated from one related customer in 2020 and two related customers in 2019.

NOTE 4 – SEPARATION AGREEMENT

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

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

- In lieu of any severance or other termination payments due under the Management Agreement, EPH released the Company from a total of $993,985 in liabilities, inclusive of advanced management fees and multiple promissory notes, including accrued and unpaid interest. An additional $114,700 in promissory notes owed to an affiliate of EPH were converted into Company common stock at a price of $0.22 per share.

- The Company agreed to transfer to EPH its license agreement with Agrarian Technologies LLC and Mulch Masters Inc. for the ABS soil enhancement product and all associated knowhow, trade secrets and trademark/service marks. Accrued license fees in connection with this license agreement were also assumed by EPH in the amount of $37,500.

- The prior officers and employees of the Company engaged in the Legacy Business were released from any non-competition, non-solicitation or other restricted covenant pursuant to their respective employment agreements. Effective October 1, 2020, several of these employees had already separated from the Company.

- EPH received the right in its sole discretion to use the name "Q2Earth" in all jurisdictions of the United States and worldwide.

Pursuant to ASC 205-20 *Presentation of Financial Statements: Discontinued Operations* and amended by ASU No. 2014-08, management has determined that the Separation Agreement results in the disposal of a component that represents a strategic shift in the Company's business operations that will have a major effect on the Company's operations and financial results. Therefore, the net income (loss) generated from this disposed component have been presented as discontinued operations for the years ended December 31, 2020 and 2019 on the statement of operations. Further, liabilities forgiven or assumed in connection with the Separation Agreement have been presented as liabilities held for disposal as of December 31, 2019 on the accompanying balance sheet (see Note 9 – Discontinued Operations).

NOTE 5 – EQUITY METHOD INVESTMENT

During November 2018, the Company invested $50,000 for a 19.9% Class B limited liability membership interest in EPH and recorded this transaction as an equity method investment due to the Company's ability to exercise significant influence over EPH. The carrying value of the investment in EPH was reduced to zero after recording the proportionate share of the investee's net loss for the 2018 fiscal year. In January 2019, the Company committed an additional $21,588 through a subscription payable to maintain its 19.9% Class B limited liability interests in EPH, after additional Class A units were sold to investors, which was fully paid in April 2020. The carrying value of the investment at December 31, 2019 was zero and remains at zero at December 31, 2020 due to continued losses incurred by EPH. The loss on equity investment has been presented on the consolidated statement of operations for the year ended December 31, 2019. There were no distributions received from the equity method investment in 2020 or 2019. See Note 4 for discussion of the Separation Agreement with our equity method investment in November 2020.

For the year ended December 31, 2020, EPH generated $11,676,137 in revenue and had a loss prior to income taxes of $2,121,397. Of this loss, $1,110,674 was from the write-off of notes payable due from the Company inclusive of a transfer of the $114,700 note plus interest to a related party, pursuant to the Separation Agreement (see Note 4 – Separation Agreement).

Our prior Chairman and CEO of the Company, also serves as President of EPH; and Christopher Nelson, General Counsel and Director of the Company, also serves as General Counsel and Secretary of EPH. See Note 6 – Related Party Transactions for transactions with our equity method investment during the years ended December 31, 2020 and 2019.

NOTE 6 – RELATED PARTY TRANSACTIONS

The Company currently has a License Agreement with IGL Pharma, Inc., an entity in which the Company's Executive Chairman serves as President and holds a non-controlling equity interest.

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

During the years ended December 31, 2020 and 2019, the Company received $525,000 and $549,000 from its equity method investee, EPH, as management fee revenue. Due to the Separation Agreement disclosed in Note 4, management fee revenues received during the years ended December 31, 2010 and 2019 have been presented on the statement of operations as discontinued operations (see Note 9 – Discontinued Operations). Management fee revenues were the Company's primary source of revenue during the years ended December 31, 2020 and 2019. During 2019, the Company also received a fee of $250,000 for advisory services related to an acquisition completed by a related party which was also included in the Company's discontinued operations.

During the years ended December 31, 2020 and 2019, the Company received $291,283 and $788,500 from EPH under multiple demand notes payable with interest payable at 6% annually. As of November 6, 2020, pursuant to the Separation Agreement, the amount of $993,985, inclusive of all unpaid accrued interest, of these notes was terminated; and $37,500 of accrued royalties under the Company's license agreement with Agrarian Technologies were assumed by EPH. As of December 31, 2020, $117,659 of additional debt, inclusive of all unpaid accrued interest, was converted into 534,815 shares of common stock. The Company recorded a gain of $1,032,160 in connection with this forgiveness and assumption of debt which has been presented within discontinued operations, and a loss of $155,096 in connection with the conversion of notes into common stock which is included in loss on convertible debt and other liabilities converted to common stock on the consolidated statements of operations. As of December 31, 2020, the Company owes to EPH $33,492 of notes payable and accrued interest which is included in notes payable-related parties on the consolidated balance sheet. As of December 31, 2019, $788,500 and $15,426 of principal and accrued interest remained outstanding on these demand notes payable. Due to the Separation Agreement which resulted in the forgiveness of these demand notes payable, including interest, these amounts have been presented in current liabilities held for disposal on the consolidated balance sheet (see Note 9 – Discontinued Operations).

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, 2020, $30,500 of principal remains outstanding on certain of these short-term notes payable. See Note 14 – Subsequent Events for conversion of certain of these short-term notes payable into shares of Series B preferred stock.

During the years ended December 31, 2020 and 2019, the Company incurred approximately $67,147 and $12,000 in legal fees with a law firm in which the Company's audit committee chair is an employee. As of December 31, 2020 and 2019, accounts payable and accrued expenses include $32,716 and $10,575, respectively, for legal fees due to the law firm for services.

In 2020, a total of approximately $413,000 in principal and accrued interest from Bridge Notes held by officers and directors of the Company were converted into shares of common stock; and an additional $346,867 of deferred salary and bonuses, accrued director fees and short-term notes payable were also converted by related parties into 1,576,668 shares of common stock in 2020 which resulted in a loss of $309,430 which is included in loss on convertible debt and other liabilities converted to common stock on the consolidated statements of operations.

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

Debentures

The Company has Original Issue Discount Senior Secured Convertible Debentures (the "Debentures") with two holders in the aggregate amount of $137,500 and $165,000 as of December 31, 2020 and 2019, respectively. On December 28, 2020, $27,500 of these Debentures was converted into common stock at a price of $0.22 per share resulting in the issuance of 125,000 shares of common stock and the recognition of a loss on conversion of $41,250 which is included in loss on convertible debt and other liabilities converted to common stock on the consolidated statements of operations. All assets of the Company are secured under the Debentures. The Debentures contain certain anti-dilutive protection provisions in the instance that the Company issues stock at a price below the conversion price of the Debentures, as adjusted from time to time, as well as other standard protections for the holder. As of December 31, 2020, the outstanding amount of $137,500 is in default. See Note 14 – Subsequent Events for the conversion in 2021 of a portion of the amount still owed into shares of common stock.

Convertible Bridge Notes

In 2017 and 2018, the Company issued a total of $2,771,908 in a convertible promissory note (the "Bridge Notes") offering (collectively, the "Bridge 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 Bridge Offering. In 2019, an additional $30,000 Bridge Note was issued to one investor. In June 2018, one of the original Bridge Notes for $50,000 plus $7,664 accrued interest was converted by its holder into 24,538 shares of common stock. Maturity for the Bridge Notes was 36 months from issuance (24 months for the Bridge Notes issued in 2018 and 2019) with 15% annual interest which is capitalized each year into the principal of the Bridge Notes and paid in kind.

As of December 31, 2020, approximately $1.4 million of principal and accrued capitalized interest under the Bridge Notes was in default; and $2.9 million in principal and accrued and capitalized interest under additional Bridge Notes was settled with the holders of these notes converting their debt into 13,312,175 shares of common stock of the Company with a fair value of $3,017,499 based on the stock price of the Company on the date of conversion. These Bridge Note conversions included $413,469 of aggregate principal and accrued interest from officers and directors of the Company. The Company recorded a loss on extinguishment of these Bridge Notes of $495,320 which is included in loss on convertible debt and other liabilities converted to common stock on the consolidated statements of operations.

Pursuant to ASC 825-10-25-1, Fair Value Option, the Company made an irrevocable election at the time of issuance to report the Bridge Notes at fair value, with changes in fair value recorded through the Company's condensed consolidated statements of operations as other income (expense) in each reporting period. The estimated fair value of the remaining outstanding Bridge Notes as of December 31, 2020 and 2019 was $3,598,000 and $2,981,000 (see Note 8 – Fair Value Measurement), and the principal amount due was $836,878 and $2,801,908, respectively. During the year ended December 31, 2020 and 2019, the change in fair value resulted in a (loss) gain of $(3,170,236) and $1,057,877, respectively, which is presented as change in fair value of convertible bridge notes on the consolidated statements of operations (see Note 8 - Fair Value Measurement).

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 14, 2022. The Company used these funds for payroll costs only and will apply for forgiveness of the loan under the program once the U.S. Small Business Administration starts accepting the forgiveness applications. As of December 31, 2020, the amount due on the loan of $142,929. Under the terms of the PPP, principal payments are due as follows: $34,163 in 2021 and $108,779 in 2022. PPP.

Notes Payable

Between June and November 2020, the Company received a total of $171,000 under a promissory note with an unrelated third party with multiple tranches with interest payable at 8% annually. All outstanding principal and interest accrued and unpaid on the note was due and payable twelve (12) months after the respective tranche date. As of December 31, 2020, the full balance of $171,000 plus $5,611 in interest was converted into 93,686 of shares of common stock and 156 shares of the Company's Series B Preferred stock. The Company recorded a loss of $27,169 on these notes payable converted to equity.

See Note 6 – Related Party Transactions for additional notes payable with related parties.

NOTE 8 – FAIR VALUE MEASUREMENT

The Company measures fair value in accordance with a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

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

Level 2 Quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3 Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity).

As disclosed in Note 7, the Bridge Notes are reported at fair value, with changes in fair value recorded through the Company's consolidated statements of operations as other income (expense) in each reporting period.

The following tables set forth the Company's consolidated financial assets and liabilities measured at fair value by level within the fair value hierarchy at December 31, 2020 and 2019. Assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

	Fair value at December 31, 2020	Level 1	Level 2	Level 3
Convertible Bridge Notes	$ 3,598,000	$ -	$ -	$
Total	$ 3,598,000	$ -	$ -	$

	Fair value at December 31, 2019	Level 1	Level 2	Level 3
Convertible Bridge Notes	$ 2,473,000	$ -	$ -	$ 2,473,000
Total	$ 2,473,000	$ -	$ -	$ 2,473,000

The following tables present a reconciliation of the beginning and ending balances of items measured at fair value on a recurring basis that use significant unobservable inputs (Level 3) and the related realized and unrealized gains (losses) recorded in the consolidated statement of operations during the periods.

	Year Ended December 31, 2020
Fair value, December 31, 2019	$ 2,473,000
Accrued interest	485,336
Conversions of debt and accrued interest to shares of common stock	(2,530,572)
Amortization of debt issuance costs	-
Net unrealized loss on convertible bridge notes	3,170,236
Fair value, December 31, 2020	$ 3,598,000

	Year Ended December 31, 2019
Fair value, December 31, 2018	$ 2,960,000

Issuances of debt	30,000
Accrued interest	535,877
Amortization of debt issuance costs	5,000
Net unrealized gain on convertible bridge notes	(1,057,877)
Fair value, December 31, 2019	$ 2,473,000

The Company's convertible Bridge Notes are valued by using Monte Carlo Simulation methods and discounted future cash flow models. Where possible, the Company verifies the values produced by its pricing models to market prices. Valuation models require a variety of inputs, including contractual terms, market prices, yield curves, credit spreads, measures of volatility and correlations of such inputs. These convertible Bridge Notes do not trade in liquid markets, and as such, model inputs cannot generally be verified and do involve significant management judgment. Such instruments are typically classified within Level 3 of the fair value hierarchy. The following assumptions were used to value the Company's convertible Bridge Notes at December 31, 2020: dividend yield of -0-%, volatility of 66.7%, risk free rate of 0.09% and an expected term of 0.25 years. The fair value of the Bridge Note was estimated based on the present value expected future cash flows using a discount rate of 20%. The following assumptions were used to value the Company's convertible Bridge Notes at December 31, 2019: dividend yield of -0-%, volatility of 160.8%, risk free rate of 1.55% and an expected term of .25 years. The fair value of the Bridge Note was estimated based on the present value expected future cash flows using a discount rate of 20%.

NOTE 9 – DISCONTINUED OPERATIONS

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

ASC 205-20 "Discontinued Operations" establishes that the disposal or abandonment of a component of an entity or a group of components of an entity should be reported in discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results. As a result, the component's results of operations have been reclassified as discontinued operations on a retrospective basis for all periods presented. Accordingly, the liabilities forgiven or assumed by EPH in connection with the Separation Agreement separately reported as "liabilities held for disposal" as of December 31, 2019. As of December 31, 2020, there were no assets held associated with this business. The results of operations of this component, for all periods, are separately reported as "discontinued operations" on the consolidated statements of operations.

As disclosed in Note 5, the Company retained its equity interest in EPH as of December 31, 2020. This equity interest has been accounted for as an equity method investment for all periods. There have been no transactions between the Company and EPH since the Separation Agreement.

A reconciliation of the major classes of line items constituting the income (loss) from discontinued operations, net of income taxes as is presented in the consolidated statements of operations for the years ended December 31, 2020, and 2019 are summarized below:

Reconciliation of liabilities included in current liabilities held for disposal on the consolidated balance sheet:

	Year ended December 31,	
	2020	2019
Carrying amounts of major classes of liabilities included as part of liabilities held for disposal		
Accounts payable and accrued expenses	$ -	$ 15,000
Accrued interest - related parties	-	15,426
Notes payable - related parties	-	788,500
Total liabilities included in the liabilities held for disposal	$ -	$ 818,926

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

	Year ended December 31,	
	2020	2019
REVENUES	$ 541,200	$ 916,667
OPERATING EXPENSES		
Payroll and related expenses	515,741	835,183
Professional fees	-	7,500
General and administrative	53,398	106,256
Total Operating Expenses	569,139	948,939
Financing costs including interest	46,967	15,426
Gain on debt extinguishment	(1,032,160)	-
INCOME (LOSS) FROM DISCONTINUED OPERATIONS	$ 957,254	$ (47,698)

Reconciliation of cash flows from operating activities and financing activities on the consolidated statement of cash flow:

	Year ended December 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Income (Loss) from Discontinued Operations	$ 957,254	$ (47,698)
Adjustments to reconcile net loss to net cash provided by discontinued operations:		
Gain on forgiveness or assumption of promissory notes and accrued expenses	(1,032,160)	-
Changes in operating assets and liabilities		
Increase in accounts payable and accrued expenses	22,500	15,000
Increase in contract liabilities - related party	-	(117,667)
Increase in accrued interest - related party	46,967	15,426
Net cash used in operating activities	(5,439)	(134,939)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from promissory notes - related parties	338,373	788,500
Repayments on promissory notes - related parties	(1,590)	-
Net cash provided by financing activities	336,783	788,500

Net cash provided by discontinued operations	$ 331,344	$ 653,561

NOTE 10 – COMMON STOCK, PREFERRED STOCK AND WARRANTS

Common Stock

In 2020, the Company issued 17,392,343 shares of common stock as follows:

Stock based compensation for services	1,750,000
Conversions of debentures and notes with unrelated parties	218,686
Conversion of Bridge Notes	13,312,175
Conversion of accrued salary and bonus, directors' fees and notes with related parties	2,111,482
Total Common Shares issued in 2020	17,392,343

In total, $3,441,401 of obligations were converted into shares of common stock in 2020 at a price of $0.22 per share. Due to the timing of the conversions and the Company's stock price at that time of conversion, the Company recorded the following losses from liability conversions in 2020: $495,320 from the conversion of Bridge Notes including accrued interest, $68,373 from the conversion of a debenture and note payable with unrelated parties, and $271,210 from the conversion of accrued salary, bonus, directors' fees and notes payable with related parties. During the year ended December 31, 2020, the Company recorded a loss $834,903 on these obligations converted into shares of common stock as presented on the consolidated statements of operations.

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

The Company did not issue any common shares in 2019.

For the years ended December 31, 2020 and 2019, the Company recognized $258,667 and $115,714 of compensation expense for several service agreements.

Series A Redeemable Convertible Preferred Stock

The Company has 600 shares of Preferred Stock issued and outstanding as of December 31, 2020, which currently are convertible at $0.16 per share of the Company's common stock (the "Conversion Price"), which was adjusted to match the conversion price of the Company's Series B Preferred Stock. The 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 Preferred Stock has no voting rights until converted to common stock and has a liquidation preference equal to the aggregate purchase price of $600,000 plus accrued dividends. The Preferred Stock is currently in default, and the Company is negotiating a modification with the holders, including the conversion of these shares into common stock. Each share of Preferred Stock received warrants, of which all but 46,154 warrants expired in 2020.

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

Management has determined that the Preferred 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 Preferred Stock is not converted to common stock. Therefore, management has presented the Preferred Stock outside of permanent equity as mezzanine equity, which does not factor into the totals of either liabilities or equity.

The Preferred 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. They add to the redemption value of the stock; however, as the Company shows an accumulated deficit, the charge has been recognized in additional paid-in capital.

Series B Preferred Stock

On December 29, 2020, the Company filed an amendment to its Articles of Incorporation to authorize the issuance of up to 2,500 shares of Series B Convertible Preferred Stock (the "Series B Stock"), par value $0.001 per share, pursuant to a Certificate of Designation. The Series B Preferred Shares provide the holders a 10% annual paid-in-kind dividend, a liquidation preference equal to the purchase price of the shares ($1,000 per share) followed by the right to participate with the common stockholders in the instance of a liquidation or other exit event, and provide the holders the right to vote along with the common holders based on the common conversion amount of their holdings. The Series B Preferred Shares are convertible into common stock at a price of $0.16 per share, subject to anti-dilution protections in the case of certain issuances of securities below that conversion price. The Series B Preferred Shares are not redeemable.

In December 2020, the Company commenced a private offering of its Series B Stock for $1,000 per share. As of December 31, 2020, 281 shares of Series B Stock were issued and outstanding in connection with the issuance of 156 shares upon the conversion of a note payable in the amount $156,000, inclusive of unpaid and accrued interest and the sale of 125 shares for total prices of $125,000, $25,000 of which was received in 2021 and recorded as a subscription receivable as of December 31, 2020. There was no gain or loss recognized on the conversion of the notes payable into Series B Stock as the conversion rate was equal to the Series B per share purchase price.

Series E-1 Preferred 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 Preferred Stock (the "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 had been 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. Upon these shares of Series E-1 preferred stock becoming fully vested, they are convertible in the aggregate into 7,650,000 shares of common stock which had a value of approximately $3.9 million as of December 31, 2020. The Company computed the grant date fair value of the Series E-1 Stock to be approximately $5.34 million using an option pricing model and the following assumptions: expected term of four years, dividend yield of -0-%, volatility of 96.12%, and a risk-free rate of .27%, which will be recognized as stock-based compensation expense over the vesting period through January 2023. Since the vesting period began on December 30, 2020, compensation expense as of December 31, 2020 was not significant. As of December 31, 2020, all 7,650 Series E-1 Stock issued remains unvested.

Warrants

During the year ended December 31, 2020, the Company issued no warrants and 80,000 warrants expired. During the year ended December 31, 2019, the Company did not issue any warrants and 81,340 warrants expired. The following is a summary of all outstanding common stock warrants as of December 31, 2020:

	Number of Warrants	Exercise price per share	Average remaining term in years
Warrants issued in connection with issuance of Series A Preferred Stock	46,154	$ 0.22	0.005

During the year ended December 31, 2018, the Company committed to issuing warrants to purchase 6,000 shares of common stock at $1.00 per share and expiring in five years. These warrants are provisional and are not considered outstanding or granted as of December 31, 2020.

NOTE 11 – 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 160,000 shares of common stock, stock options, stock rights (restricted stock units), or stock appreciation rights to be granted by the Board in its discretion. This authorized amount was increased to 400,000 shares by Board resolution and amendment in 2017.

The Company issued 128,000 stock options in 2020, 40,000 each to two of the Company's independent directors, 20,000 each to one other independent director and one Board observer, and 8,000 to a new director. The options issued to the directors and Board observer were fully vested upon issuance, are exercisable at a price of $0.50 per share, and expire ten years after issuance. The 8,000 options to the new director vest half in 12 months and the balance in 24 months, expire in five years, and are exercisable at $0.50 per share. The options were valued at $18,023 (pursuant to the Black Scholes valuation model see below), based on an exercise price of $0.50 per share and estimated expected term of 5.0 years. This has been classified in general and administrative expense in the unaudited condensed consolidated statements of operations.

Option Repricing

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

The impact of the Option Repricing was a one-time incremental non-cash charge of $6,304, which was recorded as stock option expense in the first quarter of 2020 which is included in general and administrative expenses on the unaudited condensed consolidated statement of operations.

Total stock-based compensation for stock options issued and the one-time incremental charge for the Option Repricing for the year ended December 31, 2020 was $24,327. There was no stock-based compensation recognized in 2019 related to stock options.

A summary of the common stock options issued under the 2016 Plan and prior stock option plans for the year ended December 31, 2020 is as follows (shares and prices have been adjusted to account for a 25:1 reverse split):

	Number Outstanding	Weighted Avg. Exercise Price	Weighted Avg. Remaining Contractual Life (Years)
Balance, December 31, 2019	340,619	$ 3.00	3.9
Options issued	128,000	0.50	8.9
Balance, December 31, 2020	468,619	1.75	5.6

The vested and exercisable options at period end follows:

	Exercisable/ Vested Options Outstanding	Weighted Avg. Exercise Price	Weighted Avg. Remaining Contractual Life (Years)
Balance, December 31, 2020	464,619	$ 1.75	5.6

The fair value of new stock options granted and repriced stock options using the Black-Scholes option pricing model was calculated using the following assumptions for the year ended December 31, 2020:

	Year Ended December 31, 2020
Risk free interest rate	1.610%
Expected volatility	149.67%
Expected dividend yield	-%
Expected term in years	5.0

Expected volatility is based on historical volatility of a group of 4 comparable companies, due to the low trading volume of the Company's own stock. Short Term U.S. Treasury rates were utilized as the risk-free interest rate. The expected term of the options was calculated using the alternative simplified method codified as ASC 718 "*Accounting for Stock Based Compensation,*" which defines the expected life as the average of the contractual term of the options and the weighted average vesting period for all issuances.

NOTE 12 – INCOME TAXES

A reconciliation of the differences between the effective income tax rates and the statutory federal tax rates for the years ended December 31, 2020 and 2019 (computed by applying the U.S. Federal corporate tax rate of 21 percent to the loss before taxes) is as follows:

	2020	2019
Tax benefit at U.S. statutory rate	$ (1,021,163)	$ 143,216
State taxes, net of federal benefit	(260,154)	35,189
Change in fair value of convertible bridge notes and derivatives	792,877	222,129
Other permanent differences	60,941	37,509
Change in valuation allowance	427,499	(438,042)
	$ —	$ —

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, 2020 and 2019 consisted of the following:

	2020	2019
Net operating loss carry-forward	$ 2,657,931	$ 2,229,303
Accrued expenses	80,676	87,888
Stock based compensation	50,944	44,861
Deferred revenue	-	—
Depreciation expense	-	—
Net deferred tax assets	2,789,552	2,362,052
Valuation allowance	(2,789,552)	(2,362,052)
Total net deferred tax asset	$ —	$ —

At December 31, 2020 and 2019, the Company had net deferred tax assets of $2,789,552 and $2,362,052 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, 2020 and 2019. At December 31, 2020, the Company has net operating loss carry forwards totaling approximately $10,487,000. The potential tax benefit arising from NOLs generated of approximately $5,474,000 prior to 2018 effective date will begin to expire in 2034. The potential tax benefit arising from the net operating loss carryforward of approximately $5,013,005 generated after 2018 can be carried forward indefinitely within the annual usage limitations. The Company is delinquent in filing its federal tax returns for several of the previous year periods since inception. Therefore, all tax years since the Company’s inception remain open for examination. Management expects to retain a tax professional to assist in bringing these filings current.

The Company’s NOL and tax credit carryovers may be significantly limited under the Internal Revenue Code (“IRC”). NOL and tax credit carryovers are limited under Section 382 when there is a significant “ownership change” as defined in the IRC. During the year ended December 31, 2020 and in prior years, the Company may have experienced such ownership changes, which could impose such limitations.

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

NOTE 13 – COMMITMENTS AND CONTINGENCIES

The employment agreements for the Company’s new 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 12 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 12 months.

The Company’s General Counsel’s employment agreement contains a 12 month severance payment in the instance of a termination without cause, as defined therein.

The QSAM License Agreement requires multiple milestone-based payments including: $60,000 and other expense reimbursements within 60 days of signing, which have been paid, up to $150,000 as the Technology advances through multiple stages of clinical trials, and $1.5 million upon commercialization. IGL will also receive equity in the form of a warrant in QSAM equal to 5% of the company to be issued within 60 days of signing, which has not yet been issued. Upon commercialization, IGL will receive an on-going royalty equal to 4.5% of Net Sales, as defined in the License Agreement, and up to 50% of any Sublicense Consideration received by QSAM, as defined in the License Agreement. QSAM will also pay for ongoing patent filing and maintenance fees, and has certain requirements to defend the patents against infringement claims. As of December 31, 2020, the Company has paid $60,000 under the QSAM License Agreement representing the full upfront license fee, as well $60,000 in expense reimbursements required under that agreement. Total costs of $120,000 paid under and in connection with this license, as well as an additional $86,943 in drug development costs paid to service providers, have been reflected as research and development expenses on the unaudited condensed consolidated statements of operations.

Pursuant to a services agreement signed in 2018, an additional 6,000 warrants with a five-year term and exercisable at 1.00 per share are issuable to the provider but have not formally been issued as of December 31, 2020 and are not considered outstanding.

NOTE 14 - SUBSEQUENT EVENTS

On January 8, 2021, the Company approved a modification of the Series B convertible preferred stock offering (the “Series B Offering”) to provide investors in that offering (other than the lead investor) non-registered warrants to purchase an aggregate of up to 6.27 million shares of common stock at $0.35 per share, expiring on July 8, 2021 (six months). This was fully authorized by the Company’s Board on February 1, 2021. In addition, the lead investor earned and received in January 2021 a warrant for 475,000 shares priced at $0.45 per share exercisable until January 15, 2022, for the full performance of its obligations in the offering. The shares of Series B convertible preferred stock and the warrants issued under this private placement were not registered under the Securities Act, 1933, as amended, but were issued in reliance on an exemption from registration set forth in Section 4(a)(2) of the Securities Act and/or Regulation D thereunder.

On January 27, 2021, the Company closed 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 Company also issued the warrants described above. The offering was led by Checkmate Capital Group, LLC, a California based investment firm that previously held a significant portion of the Company’s Bridge Notes which were converted into common shares as of December 31, 2020. In connection with the closing, two of the Company’s officers and directors converted a total of $23,000 of short-term notes payable into 23 shares of Series B preferred stock and received a total of 143,750 warrants.

On January 27, 2021, one institutional investor converted its remaining portion of the Debenture in the amount of $72,500 into 329,545 shares of common stock at a rate of $0.22 per share, and as a result that Debenture has been retired. On February 9, 2021, the other institutional investor converted $30,000 of its Debenture into 187,541 shares of common stock at a rate of $0.16 per share.

On February 1, 2021, the Board of Directors increased the number of stock options and other incentive shares allowed to be issued under the Company's 2016 Omnibus Equity Incentive Plan, as amended, from 400,000 to 1 million shares.

On February 1, 2021, the Company entered into a financial services consulting agreement providing for payment by the Company of cash compensation of $21,000 per month for eight months and warrants to purchase 750,000 shares of common stock at $0.22 prior to August 1, 2021. On March 1, 2021, this agreement was amended to provide an additional 250,000 shares of common stock, which was earned immediately upon issuance.

On February 8 and 16, 2021, one institutional investor converted a total of $120,000 of its Series A Preferred stock into 750,000 shares of common stock.

On February 15, 2021, the Company appointed Charles J. Link Jr., M.D. to the Company's Board of Directors. Dr. Link also agreed to serve the Company in a part-time, non-executive role as Medical Director. For his services, Dr. Link received 850 shares of Series E-1 Incentive Preferred Stock, which vest in two equal instalments 12 months and 24 months after issuance. Concurrently with the appointment, the Company accepted the resignation of Scott W. Whitney, a Board member since 2016.

Between January 1, 2021 and March 22, 2021, the holders of the Company's Bridge Notes converted the remaining $1,447,312 in principal and interest under their notes into 6,578,702 shares of common stock. As of the end of the first quarter of 2021, no Bridge Notes remained outstanding.

On March 23, 2021, the Company sold its common subordinated equity interests in EPH, its equity method investee, to an unaffiliated party for $100,000.

Exhibit 21.1

Subsidiaries

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

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, 2020;

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: April 15, 2021

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, Thomas Knight, certify that:

1. I have reviewed this annual report on Form 10-K of QSAM Biosciences Inc. for the year ending December 31, 2020;

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: April 15, 2021

By: */s/ Thomas Knight*
Thomas Knight
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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Douglas Baum, Chief Executive Officer and Thomas Knight, 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.

April 15, 2021

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

By: */s/ Thomas Knight*
Thomas Knight
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.