UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

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

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

For the transition period from _____ to _____

U.S. STEM CELL, INC.
(Exact name of registrant as specified in its charter)

FLORIDA	**001-33718**	**65-0945967**
(State or other jurisdiction of incorporation or organization)	(Commission file number)	(I.R.S. Employer Identification No.)

1560 Sawgrass Corporate Pkwy
4th Floor, Sunrise, FL 33323
(Address of Principal Executive Offices)

(954) 835-1500
(Issuer's telephone number)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	USRM	OTC

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

(Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

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

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

The aggregate market value of the registrant's voting equity held by non-affiliates of the registrant, as of June 30, 2021, the last day of the registrant's most recently completed second fiscal quarter, was $2,376,858 (based on the closing sale price of the common stock reported on the OTC Markets, Inc. on June 30, 2021). For purposes of the above statement only, all directors, executive officers and 10% shareholders are assumed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares outstanding of the registrant's Common Stock, $0.001 par value, as of March 31, 2022 was 571,626,258.

Transitional Small Business Disclosure Format Yes ☐ No ☒

Documents Incorporated By Reference None

U.S. STEM CELL, INC.

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Fiscal Year Ended December 31, 2021

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K includes "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, as well as historical information. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements, or industry results, to be materially different from anticipated results, performance or achievements expressed or implied by such forward-looking statements. When used in this Annual Report on Form 10-K, statements that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "plan," "intend," "may," "will," "expect," "believe," "could," "anticipate," "estimate," or "continue" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements, although some forward-looking statements are expressed differently. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity or our achievements or industry results, to be materially different from any future results, performance levels of activity or our achievements or industry results expressed or implied by such forward-looking statements. Such forward looking statements appear in Item 1- "Business" and Item 7-"Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as elsewhere in this Annual Report. Factors that could cause our actual results to differ materially from anticipated results expressed or implied by forward-looking statements include, among others:

• our ability to manage our business despite operating losses and cash outflows;

• our ability to obtain sufficient capital or strategic business arrangements to fund our operations and expansion plans, including meeting our financial obligations under various licensing and other strategic arrangements and the funding of our development programs;

• our ability to build and maintain the management and human resources infrastructure necessary to support the growth of our business;

• whether a large global market is established for our cellular-based products and services and our ability to capture a meaningful share of this market;

• the effect of any U.S. Food and Drug Administration rulings, rules and regulations;

• scientific and medical developments beyond our control;

• our ability to obtain and maintain, as applicable, appropriate governmental licenses, accreditations or certifications or comply with healthcare laws and regulations or any other adverse effect, actions, or limitations caused by government regulation of our business;

• whether any of our current or future patent applications result in issued patents, the scope of those patents and our ability to obtain and maintain other rights to technology required or desirable for the conduct of our business;

• our ability to bring our filings with the Securities and Exchange Commission current and maintain current filings;

• the economic effects of the pandemic, the promptness of distribution of vaccines, domestically and internationally to limit the impact of COVID-19, the effect of new variants of COVID-19, and the short and long term economic impact of COVID-19 on the marketplace

The factors discussed herein, including those selected risks described in Item 1A. "Risk Factors" and elsewhere in this Annual Report on Form 10-K and in the Company's other periodic filings with the Securities and Exchange Commission (the "SEC") which are available for review at *www.sec.gov* under "Search for Company Filings" could cause actual results and developments to be materially different from those expressed or implied by such statements. All forward-looking statements attributable to us are expressly qualified in their entirety by these and other factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof.

Consequently, all the forward-looking statements made in this Form 10-K are qualified by these cautionary statements and there can be no assurance that the actual results anticipated by management will be realized or, even if substantially realized, that they will have the expected consequences to or effects on our business operations. Except as required by law, we undertake no obligation to update or revise these forward-looking statements, whether to reflect events or circumstances after the date initially filed or published, to reflect the occurrence of unanticipated events or otherwise.

Unless otherwise indicated or the context otherwise requires, all references in this Form 10-K to "we," "us," "our," "our company," "U.S. Stem Cell" or the "Company" refer to U.S. Stem Cell, Inc. and its subsidiaries.

PART I

Item 1. BUSINESS

OVERVIEW

We are a biotechnology company focused on the discovery, development and, subject to regulatory approval, commercialization of autologous cell therapies for the treatment of disease and injury. We are also a regenerative medicine company specializing in physician/veterinary training and certification and stem cell products. Our lead cardiac product candidate is MyoCell™, an innovative clinical therapy designed to populate regions of scar tissue within a patient's heart with autologous muscle cells, or cells from a patient's body, for the purpose of improving cardiac function in chronic heart failure patients. Our lead product for in clinic use was Adipocell, a proprietary kit for the isolation of adipose derived stem cells which, as of the date of this filing, is currently on hold.

Biotechnology Product Candidates

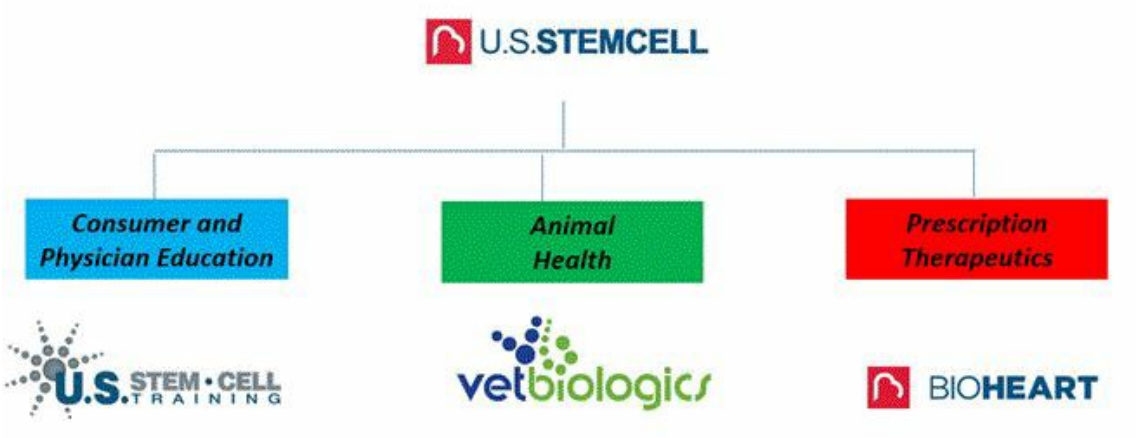
We are an enterprise in the regenerative medicine/cellular therapy industry. Our prior focus was on the discovery, development, and commercialization of cell based therapeutics. Our business included the development of proprietary cell therapy products, distribution of regenerative medicine products, as well as revenue generating physician and patient based regenerative medicine/cell therapy training services.

US Stem Cell Training, Inc. ("SCT"), an operating division of our company, is a content developer of regenerative medicine/cell therapy informational and training materials for physicians and patients. SCT also provides in-person and online training courses which are delivered through in-person presentations at SCT's state of the art facilities and globally at university, hospital and physician's office locations as well as through online webinars. Additionally, SCT provides hands-on clinical application training for physicians and health care professionals interested in providing regenerative medicine / cell therapy procedures.

Vet biologics, ("VBI"), an operating division of our company, is a veterinary regenerative medicine company committed to providing veterinarians with the ability to deliver the highest quality regenerative medicine therapies to dogs, cats and horses. VBI provides veterinarians with extensive regenerative medicine capabilities including the ability to isolate regenerative stem cells from a patient's own adipose (fat) tissue directly on-site within their own clinic or stall-side.

In early 2021, following the adjustments to our business plan, we divested ourselves of our Member Interests in US Stem Cell Clinic, LLC, ("SCC") and retained our 49% Member Interests in US Stem Cell Clinic of the Villages, LLC, which is currently dormant.

U.S. Stem Cell's comprehensive map of products and services:



U.S. Stem Cell, Inc. was incorporated in the State of Florida in August 1999 as Bioheart, Inc. In 2015, we changed our name to U.S. Stem Cell, Inc. Our principal executive offices are located at 1560 Sawgrass Corporate Parkway, 4th FL Sunrise FL 33323 and our telephone number is (954) 835-1500. Information about us is available on our corporate websites at www. us-stemcell.com. We include our website addresses in the Annual Report on Form 10-K only as an interactive textual reference and do not intend it to be an active link to our website. The information on our website is expressly not incorporated by reference in the Annual Report on Form 10-K.

The Annual Report includes the following trademarks, service marks and trade names owned by the Company: U.S. Stem Cell, Inc. ™, US Stem Cell Training, Vetbiologics, US Stem Cell Clinic, LLC., MyoCell ™ and Adipocell ™. These trademarks, service marks and trade names are the property of U.S. Stem Cell, Inc. and its affiliates.

REGENERATIVE MEDICINE / CELL THERAPY INDUSTRY

Regenerative medicine is defined as the process of replacing or regenerating human cells, tissues or organs to restore normal function. Among the categories of therapeutic technology platforms within this field are cell therapy; tissue engineering; tools, devices and diagnostics; and aesthetic medicine. U.S. Stem Cell's business model is focused on two of these areas. First, cell therapy, in which we introduce cells (adult, donor or patient, stem cell or differentiated) into the body to prevent and treat disease; and second, we are a provider of services and products to physicians and veterinaries who provide or seek to provide cellular therapies and direct patient care for individuals and animals who may benefit from cellular therapy.

All living complex organisms start as a single cell that replicates, differentiates (matures) and perpetuates in an adult organism through its lifetime. Cellular therapy is the process that uses cells to prevent, treat or cure disease, or regenerate damaged or aged tissue. To date, the most common type of cell therapy has been the replacement of mature, functioning cells such as through blood and platelet transfusions. Since the 1970s, first bone marrow and then blood and umbilical cord-derived stem cells have been used to restore bone marrow, as well as blood and immune system cells damaged by the chemotherapy and radiation that are used to treat many cancers. These types of cell therapies are standard practice world-wide and are typically reimbursed by insurance.

Within the field of cell therapy, research and development using stem cells to treat a host of diseases and conditions has greatly expanded. Stem cells (in either embryonic or adult forms) are primitive and undifferentiated cells that have the unique ability to transform into or otherwise affect many different cells, such as white blood cells, nerve cells or heart muscle cells. U.S. Stem Cell's cell therapy development efforts are focused on the use of adult stem cells; those cells which are found in the muscle, fat tissue and peripheral blood.

There are two general classes of cell therapies: Patient Specific Cell Therapies ("PSCTs") and Off-the-Shelf Cell Therapies ("OSCTs"). In PSCTs, cells collected from a person ("donor") are transplanted, with or without modification, to a patient ("recipient"). In cases where the donor and the recipient are the same individual, these procedures are referred to as "autologous". In cases in which the donor and the recipient are not the same individual, these procedures are referred to as "allogeneic." Autologous cells offer a low likelihood of rejection by the patient and we believe the long-term benefits of these PSCTs can best be achieved with an autologous product. In the case of OSCT, donor cells are expanded many fold in tissue culture, and large banks of cells are frozen in individual aliquots that may result in treatments, in our observation, for as many as 10,000 people from a single donor tissue. By definition, OSCTs are always allogeneic in nature.

CELLULAR THERAPY PRODUCT DEVELOPMENT PIPELINE

Specific to cellular therapy, we are focused on the discovery, development and commercialization of autologous cellular therapies for the treatment of chronic and acute heart damage as well as vascular and autoimmune diseases.

In our pipeline, subject to development based on future financing, and regulatory approval we have multiple product candidates for the treatment of heart damage, including MyoCell™ and Myocell SDF-1. MyoCell and MyoCell SDF-1 are autologous muscle-derived cellular therapies designed to populate regions of scar tissue within a patient's heart with new living cells for the purpose of improving cardiac function in chronic heart failure patients.

MyoCell SDF-1 is intended to be an improvement to MyoCell™. MyoCell SDF-1 is similar to MyoCell but the myoblast cells to be injected for use in MyoCell SDF-1 are modified prior to injection by an adenovirus vector or non-viral vector so that they will release extra quantities of the SDF-1 protein, which expresses angiogenic factors.

At present, our development pipeline is on hold and no assurances can be provided as to when they will restart.

STATUS OF CELLULAR THERAPY PRODUCT DEVELOPMENT CLINICAL TRIALS.

MyoCell/MyoCell SDF-1

MyoCell™ is a regenerative, cellular therapy intended to improve cardiac function for those with congestive heart failure and is designed to be utilized months or even years after a patient has suffered severe heart damage due to a heart attack or other cause. We believe that MyoCell has the potential to become a leading treatment for severe, chronic damage to the heart due to its perceived ability to satisfy, at least in part, what we believe to be an unmet demand for more effective and/or more affordable therapies for chronic heart damage. MyoCell™ uses myoblasts, cells that are precursors to muscle cells, from the patient's own body. The myoblasts are removed from a patient's thigh muscle, isolated, grown through our proprietary cell culturing process, and injected directly in the scar tissue of a patient's heart. A qualified physician performs this minimally invasive procedure using an endoventricular catheter. We entered into an agreement with Biosense Webster (a Johnson & Johnson company) to use its NOGA® Cardiac Navigation System along with its MyoStar™ injection catheter for the delivery of MyoCell™ in the MARVEL Trial (as defined below).

When injected into scar tissue within the heart wall, myoblasts have been shown to be capable of engrafting in the damaged tissue and differentiating into mature skeletal muscle cells. In a number of clinical and animal studies, the engrafted skeletal muscle cells have been shown to express various proteins that are important components of contractile function. By using myoblasts obtained from a patient's own body, we believe MyoCell™ is able to avoid certain challenges currently faced by other types of cell-based clinical therapies including tissue rejection and instances of the cells differentiating into cells other than muscle. Although a number of therapies have proven to improve the cardiac function of a damaged heart, no currently available competing treatment, to our knowledge, has demonstrated an ability to generate new muscle tissue within the scarred regions of a heart as MyoCell™ has demonstrated.

Our completed clinical trials of MyoCell™ were primarily targeted to patients with severe, chronic damage to the heart, who are in Class II or Class III heart failure according to the New York Heart Association, or NYHA, heart failure classification system. The NYHA system classifies patients in one of four categories based on how limited they are during physical activity. NYHA Class II heart failure patients have a mild limitation of activity and are generally comfortable at rest or with mild exertion while NYHA Class III heart failure patients suffer from a marked limitation of activity and are generally comfortable only at rest.

We believe the market for treating patients in NYHA Class II or NYHA Class III heart failure is significant. According to the American Heart Association ("AHA") Statistics and the European Society of Cardiology Task Force for the Treatment of Chronic Heart Failure, in the United States and Europe there are approximately 5.2 million and 9.6 million, respectively, patients with heart failure. The AHA Statistics further indicate that, after heart failure is diagnosed, the one-year mortality rate is high, with one in five dying and that 80% of men and 70% of women under age 65 who have heart failure will die within eight years.

We believe that approximately 60% of heart failure patients are in either NYHA Class II or NYHA Class III heart failure based upon a 1999 study entitled "Congestive Heart Failure Due to Diastolic or Systolic Dysfunction – Frequency and Patient Characteristics in an Ambulatory Setting" by Diller, PM, et. al.

MyoCell™ SDF-1 is intended to be an improvement to MyoCell™. MyoCell™ SDF-1 is similar to MyoCell™ except that the myoblast cells to be injected for use in MyoCell™ SDF-1 will be modified prior to injection by an adenovirus vector or non-viral vector so that they will release extra quantities of the SDF-1 protein, which expresses angiogenic factors. Adipocell is a patient-derived cell therapy proposed for the treatment of acute myocardial infarction, chronic heart ischemia, and lower limb ischemia. We hope to demonstrate that these product candidates are safe and effective complements to existing therapies for chronic and acute heart damage.

We have completed various clinical trials for MyoCell™ including the SEISMIC Trial, a 40-patient, randomized, multicenter, controlled, Phase II-a study conducted in Europe and the MYOHEART Trial, a 20-patient, multicenter, Phase I dose-escalation trial conducted in the United States. We were approved by the U.S. Food and Drug Administration, or the "FDA", to proceed with a 330-patient, multicenter Phase II/III trial of MyoCell™ in North America and Europe, or the "MARVEL Trial". We completed the MyoCell™ implantation procedure on the first patient in the MARVEL Trial on October 24, 2007. Thus far, 20 patients, including 6 control patients, have been treated. Initial results for the 20 patients were released at the Heart Failure Society of American meeting in September, 2009, showing a significant (35%) improvement in the 6 minute walk for those patients who were treated, and no improvement for those who received a placebo. On the basis of these results, we have applied for and received approval from the FDA to reduce the number of additional patients in the trial to 134, for a total of 154 patients. We are planning, on the basis of these results, to request the FDA to consider the MARVEL Trial a pivotal trial (pivotal from Phase II to Phase III) and to reduce the number of patients in the trial to 150. No assurances can be provided that this request will be approved. We have also initiated the MIRROR trial, which is a Phase III, double-blind placebo controlled study for centers outside the United States. The SEISMIC, MYOHEART, MARVEL and MIRROR Trials have been designed to test the safety and efficacy of MyoCell™ in treating patients with severe, chronic damage to the heart. We received approval from the FDA in July of 2009 to conduct a Phase I safety study on 15 patients of a combined therapy (MyoCell™ with SDF-1) called the REGEN trial, during the first quarter of 2010.

Advancement of the MyoCell™ and MyoCell™ SDF-1 clinical development programs is contingent, among many factors, upon the Company obtaining access to sufficient funding to execute the necessary clinical trials to achieve proof of efficacy and regulatory authorization to market such products. No assurances can be provided that such development programs will be realized. At present, these development programs are on hold and no assurances can be provided as to when they will restart.

Adipocell

Adipocell, a proprietary kit for the isolation of adipose derived stem cells which, as of the date of this filing, is currently on hold.

Business Strategy

U.S. Stem Cell's mission is to advance to market novel regenerative medicine and cellular therapy products that substantially benefit humankind. Our business strategy is, to the extent possible, finance our clinical development pipeline through revenue (cash in-flows) generated through the marketing and sales of unique educational and training services, animal health products and distribution of products in the industry.

A fundamental shift in venture capital investment strategies where, management believes, financial sponsorship is now directed toward commercial or near commercial enterprises has required U.S. Stem Cell to adapt its mission combining immediate revenue generating opportunities with longer-term development programs. Accordingly, U.S. Stem Cell developed a multifaceted portfolio of revenue generating products and services in its US Stem Cell Training and Vetbiologics, operating divisions that will, if successful, financially support its clinical development programs. Our goal is to maximize shareholder value through the generation of short-term profits that increase cash in-flows and decrease the need venture financings – a modern biotechnology company development strategy. On May 9, 2018, the U.S. Department of Justice filed an injunctive action, specifically United States of America v. U.S. Stem Clinic, LLC, U.S. Stem Cell, Inc., Kristin C. Comella, and Theodore Gradel. The Complaint was filed at the request of the U.S. Food and Drug Administration (FDA) and alleges that the respective defendants manufacture "stromal vascular fraction" (SVF) products from patient adipose (fat) tissue, which the companies then market as stem cell-based treatments without first obtaining what the government alleges are necessary FDA approvals. The Company retained counsel to defend in this action. On June 25, 2019, the federal court for the Southern District of Florida ruled in favor of the government, enjoining the Company and the other defendants from certain product sales and processes. The Company filed an appeal on August 23, 2019 and attended oral argument on January 13th, 2021. On June 2nd, 2021, the Eleventh Circuit Court ruled to affirm lower courts' judgement. The Company did not challenge the district court's judgment upon any other ground. The Company is not able to predict the duration, scope, results, or consequences of the U.S. Department of Justice actions and final rulings and management is assessing its options on a going forward basis.

We will continue to evaluate and act upon opportunities to increase our top line revenue position and that correspondingly increase cash in-flows. These opportunities include but are not limited to the development and marketing of new products and services, mergers and acquisitions, joint ventures, licensing deals and more.

Further, if the opportunity presents itself whereby the Company can raise additional capital at a reasonable fair market value, the Company will do so. Accordingly, we plan to continue in our efforts to restructure, equitize or eliminate legacy balance sheet issues that are obstacles to market capitalization appreciation and capital fund raising.

US STEM CELL TRAINING

US Stem Cell Training offers a variety of courses for physicians and other health care professionals. These courses include didactic lecture series and hands-on clinical techniques in the field of regenerative medicine. We are currently hosting these courses throughout the United States and in multiple countries. These courses are also available in an online format. Pricing currently ranges from $500-$7,500 depending on the location and modules.

U.S. STEM CELL, INC.

U.S. Stem Cell markets several products to physicians for in clinic regenerative medicine use. These products include equipment (centrifuges, heating block, laminar hood, autoclave) for laboratory use. We are also providing a variety of materials necessary to obtain bone marrow including, trocars, syringes and other supplies.

VETBIOLOGICS

Vetbiologics is focused on providing regenerative medicine therapies to veterinarians for use in both small and large animals. We provide a complete regenerative medicine package which includes training, equipment and supplies necessary for in clinic cell therapy. We sell kits for isolating stem cells from bone marrow and fat. We also provide kits for isolating platelet rich plasma. The kits include all of the disposables and reagents necessary. Vetbiologics is also working on several off the shelf type products including an allogeneic stem cell source.

GENERAL AMERICAN CAPITAL PARTNERS

On March 3, 2017, we entered into an asset sale and lease agreement (sale/leaseback transaction; "Asset Sale and Lease Agreement"), with GACP (General American Capital Partners) Stem Cell Bank LLC, a Florida limited liability company ("GACP) whereby we sold certain lab, medical and other equipment relating to the cell banking business for $400,000 and leased back the sold equipment over a three year term. The lease includes a base monthly rental payment of $20,000, due the first day of each calendar month. In addition, we are required to pay 2.3%, 22.5% and 31.6% of revenues collected on deposits arising from cell banking business for years 1, 2 and 3, respectively. At the expiration of the lease, we returned all leased equipment and along with any maintenance records, logs, etc. in our possession to the lessor with no right of repurchase. Further, as a consequence of the Court Order , the Company resolved to divest itself of certain equipment and other assets (the "Equipment Assets") used in connection with the Company's human tissue banking business, but consistent however with the requirements of the Court Order, and to adjust the business plan and operations to accommodate this potential divesture. The divestiture became effective October 10th, 2019.

Royalty Agreement/Middle East

On November 9, 2016, the Company entered into an Intellectual Property License Agreement whereby the Company granted High Rise Group Company the exclusive right to the Company's intellectual property (as defined) for the licensed use and development in Kuwait and other GCC/Middle East countries for 25 years in exchange for a payment of $75,000 and a 5% royalty generated under the agreement. The royalty payment is recorded as deferred revenue and amortized over the term of the agreement. The carrying balance as of December 31, 2021 and 2020 was $59,500 and $62,500 respectively.

The intent is for U.S. Stem Cell Middle East to offer regenerative treatment options to patients, based on U.S. Stem Cell, Inc. products and technologies like MyoCell™. To date, the first clinic in Kuwait City has been completed but has not begun operations as High Rising Group has not yet been able to secure regulatory approvals to operate. No assurances can be provided as to the ability to secure regulatory approvals to operate or the capacity for any significant revenues arising from such operation once commenced.

U.S. STEM CELL, INC.

U.S. Stem Cell markets several products to physicians for in clinic regenerative medicine use. These products include equipment (centrifuges, heating block, laminar hood, autoclave) necessary to separate and obtain cellular medicine therapies. We are also providing a variety of materials necessary to obtain fat and/or bone marrow including cannulas, trocars, syringes and other supplies. U.S. Stem Cell also supplies laboratory kits for processing adipose and bone marrow tissue to obtain a mixture of cells for use in clinic. These kits include disposables and reagents. U.S. Stem Cell also provides banking services to patients interested in storing their fat or bone marrow and the cells from this tissue. U.S. Stem Cell is a registered FDA tissue bank in good standing.

Patents and Proprietary Rights

We own or hold licenses or sublicenses to an intellectual property portfolio consisting of numerous patents and patent applications in the United States, and in foreign countries, for use in the field of heart muscle regeneration. References in this report to "our" patents and patent applications and other similar references include the patents and patent applications that are owned by us, and references to patents and patent applications that are "licensed" to us and other similar references refer to patents, patent applications and other intellectual property that are licensed or sublicensed to us.

Patent life determination depends on the date of filing of the application or the date of patent issuance and other factors as promulgated under the patent laws. Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, as amended, a patent which claims a product, use or method of manufacture covering drugs and certain other products, including biologic products, may be extended for up to five years to compensate the patent holder for a portion of the time required for research and FDA review of the product. Only one patent applicable to an approved drug or biologic product is eligible for a patent term extension. This law also establishes a period of time following approval of a drug or biologic product during which the FDA may not accept or approve applications for certain similar or identical drugs or biologic products from other sponsors unless those sponsors provide their own safety and efficacy data.

MyoCell™ is no longer protected by patents, which means that competitors will be free to sell products that incorporate the same or similar technologies that are used in MyoCell™ without infringing our patent rights. As a result, MyoCell, if approved for use, may be vulnerable to competition. In addition, many of the patent and patent applications that have been licensed to us that pertain to our other product candidates do not cover certain countries within Europe.

Our commercial success will depend to a significant degree on our ability to:

- defend and enforce our patents and/or compel the owners of the patents licensed to us to defend and enforce such patents, to the extent such patents may be applicable to our products and material to their commercialization;
- obtain additional patent and other proprietary protection for MyoCell™ and our other product candidates;
- obtain and/or maintain appropriate licenses to patents, patent applications or other proprietary rights held by others with respect to our technology, both in the United States and other countries; and
- preserve company trade secrets and other intellectual property rights relating to our product candidates; and operate without infringing the patents and proprietary rights of third parties.

In addition to patented intellectual property, we also rely on our own trade secrets and proprietary know-how to protect our technology and maintain our competitive position, since patent protection may not be available or applicable to our technology. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. The agreements generally provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of the individual's relationship with us except in limited circumstances. These agreements generally also provide that we shall own all inventions conceived by the individual in the course of rendering services to us. Moreover, some of our academic institution licensors, collaborators and scientific advisors have rights to publish data and information to which we have rights, which may impair our ability to protect our proprietary information or obtain patent protection in the future.

We work with others in our research and development activities and one of our strategies is to enter into collaborative agreements with third parties to develop our proposed products. Disputes may arise about inventorship and corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our licensors, collaborators, consultants and others. In addition, other parties may circumvent any proprietary protection we do have. As a result, we may not be able to maintain our proprietary position.

We are not currently a party to any litigation or other adverse proceeding challenging our patents, patent licenses or intellectual property rights. However, if we become involved in litigation or any other adverse intellectual property proceeding, for example, as a result of an alleged infringement, or a third party alleging an earlier date of invention, we may have to spend significant amounts of money and time and, in the event of an adverse ruling, we could be subject to liability for damages, including treble damages, invalidation of our intellectual property and injunctive relief that could prevent us from using technologies or developing products, any of which could have a significant adverse effect on our business, financial condition and results of operation.

In addition, any claims relating to the infringement of third party proprietary rights, or earlier date of invention, even if not meritorious, could result in costly litigation, lengthy governmental proceedings, divert management's attention and resources and require us to enter royalty or license agreements which are not advantageous, if available at all.

See Item 1A. "Risk Factors — Risks Related to Our Intellectual Property" for a discussion of additional risks we face with respect to our intellectual property rights.

Recent Developments

COVID-19

In December 2019, a novel strain of coronavirus, COVID-19, was reported in Wuhan, China. The World Health Organization determined that the outbreak constituted a "Public Health Emergency of International Concern" and declared a pandemic. The COVID-19 pandemic is disrupting businesses and affecting production, supply, and sales across a range of industries, as well as causing volatility in the financial markets. The extent of the impact of the COVID-19 pandemic on our customer demand, sales and financial performance will depend on certain developments, including, among other things, the duration and spread of the outbreak of the virus and the variants and the impact on our customers and employees, all of which are uncertain and cannot be predicted. See "Risk Factors" for information regarding certain risks associated with the pandemic.

The effects of the COVID-19 pandemic are rapidly evolving, and the ongoing impact and duration of the virus are unknown. Currently, the COVID-19 pandemic has not had a significant impact on our operations or financial performance; however, the ultimate extent of the impact of the COVID-19 pandemic on our operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, the corresponding variants, and its impact on our customers, supply chain problems, ability to raise capital as well impact of as industry events, all of which are uncertain and cannot be predicted.

For further information pertaining to the risk of Covid-19 upon our business, see risk factors.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the website at http://www.sec.gov. The public may also read and copy any document we file with the SEC at its Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, on official business days during the hours of 10:00 am to 3:00 pm. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

Item 1A. Risk Factors

The risk factors required pursuant to Regulation S-K, Item 503(c) are not required for smaller reporting companies. Accordingly, the Company has determined to provide particular risk factors at this time. The risks and uncertainties described below are not the only ones facing us. Other events that we do not currently anticipate or that we currently deem immaterial also may affect our results of operations and financial condition. If any events described in the risk factors actually occur, our business, operating results, prospects and financial condition could be materially harmed. In connection with the forward looking statements that appear elsewhere in this annual report, you should also carefully review the cautionary statement referred to under “Cautionary Note Regarding Forward Looking Statements.”

SHOULD ONE OR MORE OF THE FOREGOING RISKS OR UNCERTAINTIES MATERIALIZE, OR SHOULD THE UNDERLYING ASSUMPTIONS OF OUR BUSINESS PROVE INCORRECT, ACTUAL RESULTS MAY DIFFER SIGNIFICANTLY FROM THOSE ANTICIPATED, BELIEVED, ESTIMATED, EXPECTED, INTENDED OR PLANNED.

Risks Related to Our Financial Position and Need for Additional Financing

We will need to secure additional financing in 2021 in order to continue to finance our operations. If we are unable to secure additional financing on acceptable terms, or at all, we may be forced to curtail or cease our operations.

As of December 31, 2021, we had cash and cash equivalents of $39,393 and an accumulated capital deficit of $139,801,924. As such, our existing cash resources are insufficient to finance even our immediate operations. Accordingly, we will need to secure additional sources of capital to develop our business and product candidates as planned. We are seeking substantial additional financing through public and/or private financing, which may include equity and/or debt financings, research grants and through other arrangements, including collaborative arrangements.

As part of such efforts, we may seek loans from certain of our executive officers, directors and/or current shareholders. We may also seek to satisfy some of our obligations to the guarantors of our loan with Seaside National Bank & Trust, or the Guarantors, through the issuance of various forms of securities or debt on negotiated terms. On January 3, 2018, the Company renewed the loan with Seaside National Bank and Trust extends the maturity date to May 18, 2020, all other terms and conditions remain unchanged. On May 18, 2020, the Seaside loan was turned into a Demand Note with no fixed maturity date but with a re-documentation requirement every four years. The new re-documentation deadline is May 2022. However, financing and/or alternative arrangements with the Guarantors may not be available when we need it, or may not be available on acceptable terms.

If we are unable to secure additional financing in the near term, we may be forced to:

- curtail or abandon our existing business plans;
- reduce our headcount;
- default on our debt obligations;
- file for bankruptcy;
- seek to sell some or all of our assets; and/or
- Cease our operations.

If we are forced to take any of these steps, any investment in our common stock may be worthless.

If we raise additional capital and/or secure alternative arrangements, with the Guarantors or otherwise, by issuing equity, equity-related or convertible securities, the economic, voting and other rights of our existing shareholders may be diluted, and those newly issued securities may be issued at prices that are a significant discount to current and/or then prevailing market prices. In addition, any such newly issued securities may have rights superior to those of our common stock. If we obtain additional capital through collaborative arrangements, we may be required to relinquish greater rights to our technologies or product candidates than we might otherwise have or become subject to restrictive covenants that may affect our business.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm issued its report dated March 31, 2022 in connection with the audit of our financial statements as of December 31, 2021, which included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. In addition, the notes to our financial statements for the year ended December 31, 2021 included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern for a reasonable period of time. If we are not able to continue as a going concern, it is likely that holders of our common stock will lose all of their investment. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We are a development stage life sciences company with a limited operating history and a history of net losses and negative cash flows from operations. We may never be profitable, and if we incur operating losses and generate negative cash flows from operations for longer than expected, we may be unable to continue operations.

We are a development stage life sciences company and have a limited operating history, limited capital, limited sources of revenue, and have incurred losses since inception. Our operations to date have been limited to organizing our company, developing and engaging in clinical trials of our MyoCell™ product candidate, expanding our pipeline of complementary product candidates through internal development and third party licenses, expanding and strengthening our intellectual property position through internal programs and third party licenses and recruiting management, research and clinical personnel. Consequently, it may be difficult to predict our future success or viability due to our lack of operating history. As of December 31, 2021, we have accumulated a deficit of approximately $139.8 million. Our MyoCell™ product candidate has not received regulatory approval or generated any material revenues and is not expected to generate any material revenues until commercialization of MyoCell, if ever.

Our ability to continue generating revenues from any of our product candidates will depend on a number of factors, including our ability to successfully complete clinical trials, obtain necessary regulatory approvals and implement our commercialization strategy. In addition, even if we are successful in obtaining necessary regulatory approvals and bringing one or more product candidates to market, we will be subject to the risk that the marketplace will not accept those products. We may, and anticipate that we will need to, transition from a company with a research and development focus to a company capable of supporting commercial activities and we may not succeed in such a transition.

Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, we are unable to predict the extent of our future losses or when or if we will become profitable. Our failure to successfully commercialize our product candidates or to become and remain profitable could impair our ability to raise capital, expand our business, diversify our product offerings and continue our operations.

Risks Related to Product Development

All of our product candidates are in an early stage of development and we may never succeed in developing and/or commercializing them. We depended heavily on the success of our MyoCell™ product candidate. If we are unable to commercialize MyoCell™ or any of our other product candidates or experience significant delays in doing so, our business may fail.

- We have invested a significant portion of our efforts and financial resources in our MyoCell™ product candidate and depended heavily on its success. MyoCell™ was currently in the clinical testing stage of development, although we have suspended work under our clinical trials.

- We need to devote significant additional research and development, financial resources and personnel to develop commercially viable products, obtain regulatory approvals and establish a sales and marketing infrastructure.

- We are likely to encounter hurdles and unexpected issues as we proceed in the development of our other product candidates. There are many reasons that we may not succeed in our efforts to develop our product candidates, including the possibility that:

- our product candidates will be deemed ineffective, unsafe or will not receive regulatory approvals;
- our product candidates will be too expensive to manufacture or market or will not achieve broad market acceptance
- others will hold proprietary rights that will prevent us from marketing our product candidates; or
- our competitors will market products that are perceived as equivalent or superior.

Our approach of using cell-based therapy for the treatment of heart damage is risky and unproven and no products using this approach have received regulatory approval in the United States or Europe.

No company, to our knowledge, has yet been successful in its efforts to obtain regulatory approval in the United States or Europe of a cell-based therapy product for the treatment of heart damage. Cell-based therapy products, in general, may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy or other characteristics that may prevent or limit their approval by regulators or commercial use. Many companies in the industry have suffered significant setbacks in advanced clinical trials, despite promising results in earlier trials.

One of our competitors exploring the use of skeletal myoblasts ceased enrolling new patients in its European Phase II clinical trial based on the determination of its monitoring committee that there was a low likelihood that the trial would result in the hypothesized improvement in heart function. Although our clinical research to date suggests that MyoCell™ may improve the contractile function of the heart, we have not yet been able to demonstrate a mechanism of action and additional research is needed to precisely identify such mechanism.

U.S. Food and Drug Administration injunction has curtailed our business.

On May 9, 2018, the U.S. Department of Justice filed an injunctive action, specifically United States of America v. U.S. Stem Clinic, LLC, U.S. Stem Cell, Inc., Kristin C. Comella, and Theodore Gradel. The Complaint was filed at the request of the U.S. Food and Drug Administration (FDA) and alleges that the respective defendants manufacture “stromal vascular fraction” (SVF) products from patient adipose (fat) tissue, which the companies then market as stem cell-based treatments without first obtaining what the government alleges are necessary FDA approvals. The Company has retained counsel to defend in this action. . On June 25, 2019, the federal court for the Southern District of Florida ruled in favor of the government, enjoining the Company and the other defendants from certain product sales and processes. The Company filed an appeal on August 23, 2019 and attended oral argument on January 13, 2021. On June 2, 2021, the Eleventh Circuit Court ruled to affirm lower courts’ judgement. The Company did not challenge the district court’s judgment upon any other ground. The Company is not able to predict the duration, scope, results, or consequences of the U.S. Department of Justice actions and final rulings and management is assessing its options on a going forward basis.

Healthcare reform could substantially reduce our revenues, earnings and cash flows.

We cannot predict how employers, private payors or persons buying insurance might react to the changes brought on by broad U.S. healthcare reform legislation or what form many of these regulations will take before implementation. The healthcare reform legislation, enacted in 2010, introduced healthcare insurance exchanges which provide a marketplace for eligible individuals and small employers to purchase healthcare insurance. While patients have begun receiving insurance coverage through these exchanges, the business and regulatory environment for these exchanges continues to evolve as the exchanges mature. Additionally, there is uncertainty about how the applicable state and federal agencies will enforce regulations relating to the exchanges. There is also a considerable amount of uncertainty as to the prospective implementation of the federal healthcare reform legislation and what similar measures might be enacted at the state level. There have been multiple attempts through legislative action and legal challenges to repeal or amend the Patient Protection and Affordable Care Act of 2010, as modified by the Health Reform Acts, including the case that was recently heard by the U.S. Supreme Court, King v. Burwell. Although the Supreme Court upheld the provision by the federal government of subsidies to individuals in federally facilitated healthcare exchanges in *Burwell*, which ultimately did not disrupt significantly the implementation of the healthcare reform legislation, we cannot predict whether other current or future efforts to repeal or amend these laws will be successful, nor can we predict the impact that such a repeal or amendment would have on our business and operations, or on our revenues and earnings. In addition, in the last year, the executive branch and Congress have taken actions to weaken or modify the Affordable Care Act. The enacted reforms, future legislative changes, as well as current ongoing uncertainty in matters related to the Affordable Care Act, could have a material adverse effect on our results of operations.

Risks Related to Our Common Stock

Our common stock may be considered a "penny stock," and thereby be subject to additional sale and trading regulations that may make it more difficult to sell.

Our common stock is considered to be a "penny stock." It does not qualify for one of the exemptions from the definition of "penny stock" under Section 3a51-1 of the Exchange Act. Our common stock is a "penny stock" because it meets one or more of the following conditions (i) the stock trades at a price less than $5.00 per share; (ii) it is not traded on a "recognized" national exchange or (iii) it is not quoted on the NASDAQ Global Market, or has a price less than $5.00 per share. The principal result or effect of being designated a "penny stock" is that securities broker-dealers participating in sales of our common stock are subject to the "penny stock" regulations set forth in Rules 15-2 through 15g-9 promulgated under the Securities Exchange Act. For example, Rule 15g-2 requires broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document at least two business days before effecting any transaction in a penny stock for the investor's account. Moreover, Rule 15g-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult and time consuming for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

FINRA sales practice requirements may limit a shareholder's ability to buy and sell our common shares.

In addition to the "penny stock" rules described above, FINRA has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common shares, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares. In addition, there are a limited number of clearing houses that clear "penny stocks" and those that will clear such stocks may enforce internal time consuming administrative requirements and may arbitrarily determine to refuse to clear any stock.

Rule 144 sales in the future may have a depressive effect on the company's stock price as an increase in supply of shares for sale, with no corresponding increase in demand will cause prices to fall.

All of the outstanding shares of common stock held by the present officers, directors, and affiliate stockholders are "restricted securities" within the meaning of Rule 144 under the Securities Act of 1933, as amended. As restricted shares, these shares may be resold only pursuant to an effective registration statement or under the requirements of Rule 144 or other applicable exemptions from registration under the Securities Act of 1933 and as required under applicable state securities laws. Rule 144 provides in essence that a person who is an affiliate or officer or director who has held restricted securities for six months may, under certain conditions, sell every three months, in brokerage transactions, a number of shares that does not exceed the greater of 1.0% of a Company's issued and outstanding common stock. There is no limit on the amount of restricted securities that may be sold by a non-affiliate after the owner has held the restricted securities for a period of six months if the Company is a current reporting company under the Securities Exchange Act of 1934. The Company, as of the date of this report, not current in its filings but is making efforts to bring the filings current. A sale under Rule 144 or under any other exemption from the Securities Act of 1933, if available, or pursuant to subsequent registration of shares of common stock of present stockholders, may have a depressive effect upon the price of the common stock in any market that may develop. In addition, if we are deemed a shell company pursuant to Section 12(b)-2 of the Act, our "restricted securities", whether held by affiliates or non-affiliates, may not be re-sold for a period of 12 months following the filing of a Form 10 level disclosure or registration pursuant to the Securities Act of 1933. Currently, we are not current in our report and the exemption to registration required pursuant to Rule 144 is unavailable to our shareholders. While we intend to bring our filings current to permit the use of the exemption to registration required pursuant to Rule 144, there can be no assurances as to timing and subsequent continued filings.

Failure to achieve and maintain effective internal controls in accordance with section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and operating results.

It is time consuming, difficult and costly for us to develop and maintain the internal controls, processes and reporting procedures required by the Sarbanes-Oxley Act, and as our business develops, we may need to hire additional financial reporting, internal auditing and other finance staff in order to remain compliant. The cost of compliance will adversely affect our financial results, while, if we are unable to comply, we may not be able to obtain the independent accountant certifications that the Sarbanes-Oxley Act requires of publicly traded companies.

If we fail to comply in a timely manner with the requirements of Section 404 of the Sarbanes-Oxley Act regarding internal control over financial reporting or to remedy any material weaknesses in our internal controls that we may identify, such failure could result in material misstatements in our financial statements, cause investors to lose confidence in our reported financial information and have a negative effect on the trading price of our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act and current SEC regulations, we are required to prepare assessments regarding internal controls over financial reporting and furnish a report by our management on our internal control over financial reporting. Failure to achieve and maintain an effective internal control environment or complete our Section 404 certifications could have a material adverse effect on our stock price.

In addition, in connection with our on-going assessment of the effectiveness of our internal control over financial reporting, we may discover "material weaknesses" in our internal controls as defined in standards established by the Public Company Accounting Oversight Board, or the PCAOB. A material weakness is a significant deficiency, or combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. The PCAOB defines "significant deficiency" as a deficiency that results in more than a remote likelihood that a misstatement of the financial statements that is more than inconsequential will not be prevented or detected.

In the event that a material weakness is identified, upon receiving sufficient financing or generating sufficient revenues, we will employ qualified personnel and adopt and implement policies and procedures to address any such material weaknesses. However, the process of designing and implementing effective internal controls is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. We cannot assure you that the measures we will take will remediate any material weaknesses that we may identify or that we will implement and maintain adequate controls over our financial process and reporting in the future.

Any failure to complete our assessment of our internal control over financial reporting, to remediate any material weaknesses that we may identify or to implement new or improved controls, or difficulties encountered in their implementation, could harm our operating results, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Any such failure could also adversely affect the results of the periodic management evaluations of our internal controls and, in the case of a failure to remediate any material weaknesses that we may identify, would adversely affect the annual auditor attestation reports regarding the effectiveness of our internal control over financial reporting that are required under Section 404 of the Sarbanes-Oxley Act. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

The systems of internal controls and procedures that we have developed and implemented to date are adequate in a research and development business. The current transaction volume and limited transaction channels mean that operating management, financial management, board members and auditor can, and do, efficiently perform a very extensive and detailed transaction review to ensure compliance with the Company's established procedures and controls. If our business grows rapidly, we may not be able to keep up with recruiting and training personnel, and enhancing our systems of internal control in line with the growth in transaction volumes and compliance risks which could result in loss of assets, profit, and ability to manage the daily operations of our Company.

Public disclosure requirements and compliance with changing regulation of corporate governance pose challenges for our management team and result in additional expenses and costs which may reduce the focus of management and the profitability of our company.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Dodd-Frank Wall Street Reform and Consumer Protection Act and the rules and regulations promulgated thereunder, the Sarbanes-Oxley Act and SEC regulations, have created uncertainty for public companies and significantly increased the costs and risks associated with accessing the U.S. public markets. Our management team will need to devote significant time and financial resources to comply with both existing and evolving standards for public companies, which will lead to increased general and administrative expenses and a diversion of management time and attention from revenue generating activities to compliance activities.

COVID-19.

We cannot, at this point, determine the extent to which COVID-19 outbreak will impact business or the economy as both are highly uncertain and cannot be predicted.

THE OUTBREAK OF THE CORONAVIRUS MAY NEGATIVELY IMPACT SOURCING AND MANUFACTURING OF THE PRODUCTS THAT WE SELL AS WELL AS CONSUMER SPENDING, WHICH COULD ADVERSELY AFFECT OUR BUSINESS, RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China, which has and is continuing to spread throughout China and other parts of the world, including the United States. On January 30, 2020, the World Health Organization declared the outbreak of the coronavirus disease (COVID-19) a "Public Health Emergency of International Concern." On January 31, 2020, U.S. Health and Human Services Secretary Alex M. Azar II declared a public health emergency for the United States to aid the U.S. healthcare community in responding to COVID-19, and on March 11, 2020 the World Health Organization characterized the outbreak as a "pandemic". The significant outbreak of COVID-19 has resulted in a widespread health crisis that could adversely affect the economies and financial markets worldwide, and could adversely affect our business, results of operations and financial condition.

THE OUTBREAK OF THE COVID-19 MAY ADVERSELY AFFECT OUR MARKET.

Further, such risks as described above could also adversely affect our market, resulting in reduced spending in non-COVID-19 health care. Risks related to an epidemic, pandemic or other health crisis, such as COVID-19, could also lead to the complete or partial interruption of our operations. The ultimate extent of the impact of any epidemic, pandemic or other health crisis on our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of such epidemic, pandemic or other health crisis and actions taken to contain or prevent their further spread, among others. These and other potential impacts of an epidemic, pandemic or other health crisis, such as COVID-19, could therefore materially and adversely affect our business, financial condition and results of operations.

The global impact of COVID-19 and actions taken to reduce its spread continues to rapidly evolve and we will continue to monitor the situation and the effects on our business and operations closely. We do not yet know the full extent of potential impacts on our business or operations or on the global economy as a whole, particularly if the COVID-19 pandemic continues and persists for an extended period of time. The length of time it may take for global vaccine distribution and more normal economic and operating conditions to resume remains uncertain and the economic recovery period could continue for a prolonged period even after the health risks of the pandemic subside. Given the uncertainty, we cannot reasonably estimate the impact on our future results of operations, cash flows or financial condition. To the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section of this Annual Report. We will continue to evaluate the nature and extent of COVID-19's impact to our business, consolidated results of operations, financial condition and liquidity, and our results presented herein are not necessarily indicative of the results to be expected for future years.

THE OUTBREAK OF COVID-19 HAS RESULTED IN A WIDESPREAD HEALTH CRISIS THAT COULD ADVERSELY AFFECT THE ECONOMIES AND FINANCIAL MARKETS WORLDWIDE AND COULD EXPONENTIALLY INCREASE THE RISK FACTORS DESCRIBED HEREIN AND IN OUR PRIOR FILINGS.

SHOULD ONE OR MORE OF THE FOREGOING RISKS OR UNCERTAINTIES MATERIALIZE, OR SHOULD THE UNDERLYING ASSUMPTIONS PROVE INCORRECT, ACTUAL RESULTS MAY DIFFER SIGNIFICANTLY FROM THOSE ANTICIPATED, BELIEVED, ESTIMATED, EXPECTED, INTENDED OR PLANNED

Item 1B. Unresolved Staff Comments

This Item is not applicable to us as we are not an accelerated filer, a large accelerated filer, or a well-seasoned issuer.

Item 2. Properties

Our headquarters are located in Sunrise, Florida which we currently lease on a month-to-month basis at a monthly lease rate of $99.00 per month.

We believe the space available at our headquarters will be sufficient to meet the needs of our operations for the foreseeable future.

Item 3. Legal Proceedings

On December 12, 2017, a product liability lawsuit was filed in Broward County, specifically Jeannine Mallard v. U.S. Stem Cell, Inc., US Stem Cell Clinics LLC., Regenestem, LLC., Regenestem Network, LLC., and Kristin C. Comella. The Company will continue to defend it vigorously. On December 6, 2019, the Company was one of the parties to a Settlement Agreement and General Release (the "Agreement") related to certain medical procedures. Without admitting any liability, and as part of that Agreement, the Company agreed to provide a five-year non-interest bearing unsecured promissory note, dated December 6, 2019, in the principal amount of $250,000, payable in monthly increments of $750 per month, with a final balloon payment of $205,000 due on January 1, 2025.

On September 17, 2015, a product liability lawsuit was filed in Broward County, specifically Patsy Bade v. Bioheart, Inc. US Stem Cell Clinics LLC, Alejandro Perez, ARNP, and Shareen Greenbaum, M.D., and on November 30, 2015, a product liability lawsuit was filed in Broward County, specifically Elizabeth Noble v. Bioheart, Inc. US Stem Cell Clinics LLC, Alejandro Perez, ARNP, and Shareen Greenbaum, M.D. During the year ended December 31, 2016, both matters settled by the Company's insurance policy with no additional cost to the Company, excluding the Company payment of the $100,000 insurance company deductible of which $11,000 was paid in fiscal 2017. As a result of the final settlement and determination of insurance coverage, the Company recognized $100,000 of expense due to litigation for the year ended December 31, 2017. The remaining amount due under this settlement is $26,600 and $28,850 as of December 31, 2021 and 2020, respectively, and is included in accounts payable.

On June 3, 2019, the Company was one of the parties to a Settlement Agreement and General Release (the "Agreement") related to certain medical procedures. Without admitting any liability, and as part of that Agreement, the Company agreed to provide a five-year 5.25% Promissory Note, dated June 15, 2019, in the principal amount of Five Hundred Thousand Dollars ($500,000), payable in monthly increments of Five Thousand ($5,000) per month.

On July 27, 2020, Brenda Leonhardt filed a lawsuit against U.S. Stem Cell, Inc., Mike Tomas, Dr. William P. Murphy, Jr., Richard T. Spencer, III, Mark Borman, Dr. Samuel S. Ahn, Charles Hart, Sheldon T. Anderson, Greg Knutson, and Kristin Comella in Broward County Court, Case No. CACE-10-012095. The lawsuit alleges breach of a settlement agreement, breach of contract with respect to failure to make a balloon payment under a promissory note, and several tort theories such as misrepresentation and fraudulent transfer. The Company denies most of the allegations in the lawsuit and moved to dismiss almost all of the claims. The motions to dismiss was recently denied. U.S. Stem Cell, Inc. does note that it provided a promissory note to Ms. Leonhardt, which has not been fully satisfied.

The Company is subject at times to other legal proceedings and claims, which arise in the ordinary course of its business. Although occasional adverse decisions or settlements may occur, the Company believes that the final disposition of such matters should not have a material adverse effect on its financial position, results of operations or liquidity. There was no outstanding litigation as of December 31, 2021 or subsequent to December 31, 2020 other than that described above.

Government Claim

On May 9, 2018, the U.S. Department of Justice filed an injunctive action, specifically United States of America v. U.S. Stem Clinic, LLC, U.S. Stem Cell, Inc., Kristin C. Comella, and Theodore Gradel. The Complaint was filed at the request of the U.S. Food and Drug Administration (FDA) and alleges that the respective defendants manufacture "stromal vascular fraction" (SVF) products from patient adipose (fat) tissue, which the companies then market as stem cell-based treatments without first obtaining what the government alleges are necessary FDA approvals. The Company has retained counsel to defend in this action. . On June 25, 2019, the federal court for the Southern District of Florida ruled in favor of the government, enjoining the Company and the other defendants from certain product sales and processes. The Company filed an appeal on August 23, 2019 and attended oral argument on January 13, 2021. On June 2, 2021, the Eleventh Circuit Court ruled to affirm lower courts' judgement. . The Company did not challenge the district court's judgment upon any other ground. The Company is not able to predict the duration, scope, results, or consequences of the U.S. Department of Justice actions and final rulings and management is assessing its options on a going forward basis. The Company, in having divested certain equipment and other assets and assigning its lease, has and will continue to experience a decrease in revenues as the Company both maintains the remainder of the business and transitions into similar or unrelated business opportunities as determined by management. After the Court's issuance of the Order of Permanent Injunction, the Company has received demand letters for compensation from persons who store their SVF Product and/or other tissue product with the tissue bank (several of the persons have requested refunds of the monies paid to the tissue bank and one person has requested a full refund of monies paid to an altogether separate company due to her not receiving the full amount of treatments she requested; such requests for compensation, to date, have not been material) and requests that the Company preserve cells in the Company's possession. The Company sought guidance from the Court, which entered an order generally staying the requirement to destroy any SVF Product, pending a decision on the Company's appeal. However, that appeal has now been concluded and the stay order is no longer in place.

Item 4. Mine Safety Disclosures.

Not applicable

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is listed on the OTC Markets, Inc. (OTC) under the symbol "USRM". For the periods indicated, the following table sets forth the high and low bid prices per share of common stock, as reported by the OTC Markets. These prices represent inter-dealer quotations without retail markup, markdown, or commission and may not necessarily represent actual transactions.

	Fiscal Year 2020	
	High	Low
First Quarter	$ 0.0300	$ 0.0175
Second Quarter	$ 0.0255	$ 0.0089
Third Quarter	$ 0.0100	$ 0.0041
Fourth Quarter	$ 0.0064	$ 0.0036

	Fiscal Year 2021	
	High	Low
First Quarter	$ 0.0872	$ 0.0135
Second Quarter	$ 0.0639	$ 0.0120
Third Quarter	$ 0.0165	$ 0.0051
Fourth Quarter	$ 0.0135	$ 0.0055

Holders

As of December 31, 2021, there were approximately 459 shareholders of record of our common stock.

Dividends

We have never declared or paid any cash dividends on our common stock or other securities and do not currently anticipate paying any cash dividends in the foreseeable future. The declaration and payment of dividends by us are subject to the discretion of our Board of Directors and the restrictions specified in our articles of incorporation, any contractual limitations, and by applicable law. Any future determination to pay cash dividends will depend on our results of operations, financial condition, capital requirements, contractual restrictions and other factors deemed relevant by our Board of Directors.

Securities Authorized For Issuance Under Equity Compensation Plans

The following table provides certain information regarding our existing equity compensation plans as of December 31, 2021:

	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for issuance under equity compensation plans
Equity compensation plans approved by security holders (1)	112,969,663	0.033	75,069,100
Equity compensation plans not approved by security holders (2)	1,114,019	14.735	0

(1) Consists of our 1999 Officers and Employees Stock Option Plan, 1999 Directors and Consultants Stock Option Plan and Omnibus Equity Compensation Plan, 2013 Omnibus Equity Compensation Plan.

(2) Includes:

- 8,000 warrants in connection with a joint venture agreement dated March 10, 2014. The warrants are exercisable at $21.70 for four years vesting from June 8, 2014 through March 10, 2016.
- 4,000 warrants in connection with use of certain intellectual property. The warrants are exercisable at $48.10 for four years vesting from July 6, 2014 through April 6, 2017.
- 4,000 warrants in connection with the termination of a joint venture agreement. The warrants are exercisable at $15.70 for four years vesting May 27, 2015.
- Warrants issued in connection with our private placements in 2014 to purchase an aggregate of 41,592 shares of our common stock at prices from $11.00 to $23.25 per share expiring ten years from the date of issuance.
- Warrants issued in connection with our private placements in 2015 to purchase 1,444 shares of our common stock at $11.27 per share expiring ten years from date of issuance.
- Warrants issued in connection with settlement of debt to purchase 628 shares of our common stock at $40.00 per share expiring four years from date of issuance in 2014.
- 1,000,000 warrants issued for services at $0.2713 per share on August 27, 2018 expiring ten years from date of issuance.

Recent Sales of Unregistered Securities

In fiscal 2021, we issued an aggregate of 6,642,197 shares of our common stock, having a fair value of $231,742, in settlement of outstanding accounts payable, we issued 930,916 shares of our common stock, having a fair value of $19,800, in lieu of payment in cash of accrued and unpaid interest of $18,340 and we issued an aggregate of 4,000,000 shares of its common stock, having a fair value of $128,000, for services. We have issued 27,500,000 common shares under the Form 1-A for cash proceeds of $275,000. The issuance of such shares of our common stock was effected in reliance on the exemptions for sales of securities not involving a public offering, as set forth in Rule 506(b) promulgated under the Securities Act of 1933, as mended (the "Securities Act") and in Section 4(2) of the Securities Act, based on the following: the investors confirmed to us that they were "accredited investors," as defined in Rule 501 of Regulation D promulgated under the Securities Act and had such background, education and experience in financial and business matters as to be able to evaluate the merits and risks of an investment in the securities; (b) there was no public offering or general solicitation with respect to the offering; (c) the investors were provided with certain disclosure materials and all other information requested with respect to our company; (d) the investors acknowledged that all securities being purchased were "restricted securities" for purposes of the Securities Act, and agreed to transfer such securities only in a transaction registered under the Securities Act or exempt from registration under the Securities Act; and (e) a legend was placed on the certificates representing each such security stating that it was restricted and could only be transferred if subsequent registered under the Securities Act or transferred in a transaction exempt from registration under the Securities Act.

Issuer Purchases of Equity Securities

None.

Transfer Agent: Continental Stock Transfer & Trust Company, One State Street, 30th Floor, New York, NY 10004 acts as transfer agent for our common stock.

Item 6. Selected Financial Data

Not required under Regulation S-K for "smaller reporting companies."

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following is management's discussion and analysis ("MD&A") of certain significant factors that have affected our financial position and operating results during the periods included in the accompanying financial statements, as well as information relating to the plans of our current management. This report includes forward-looking statements. Generally, the words "believes," "anticipates," "may," "will," "should," "expect," "intend," "estimate," "continue," and similar expressions or the negative thereof or comparable terminology are intended to identify forward-looking statements. Such statements are subject to certain risks and uncertainties, including the matters set forth in this report or other reports or documents we file with the Securities and Exchange Commission from time to time, which could cause actual results or outcomes to differ materially from those projected. Undue reliance should not be placed on these forward-looking statements which speak only as of the date hereof. We undertake no obligation to update these forward-looking statements.

The following discussion and analysis should be read in conjunction with our financial statements and the related notes thereto and other financial information contained elsewhere in this Form 10-K

The Company's MD&A is comprised of significant accounting estimates made in the normal course of its operations, overview of the Company's business conditions, results of operations, liquidity and capital resources and contractual obligations. The Company did not have any off balance sheet arrangements as of December 31, 2021 or 2020.

The discussion and analysis of the Company's financial condition and results of operations is based upon its financial statements, which have been prepared in accordance with generally accepted accounting principles generally accepted in the United States (or "GAAP"). The preparation of those financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities at the date of its financial statements. Actual results may differ from these estimates under different assumptions or conditions.

Our Ability To Continue as a Going Concern

Our management has evaluated whether there is substantial doubt about our ability to continue as a going concern and has determined that substantial doubt existed as of the date of the end of the period covered by this Annual Report on Form 10-K (the "Form 10-K"). This determination was based on the following factors, as of December 31, 2021, the Company had cash on hand of $39,393 and a working capital deficit (current liabilities in excess of current assets) of $11,987,776. During the year ended December 31, 2021, the net loss was $3,287,416 and net cash used in operating activities was $1,057,939. The Company's existence is dependent upon management's ability to develop profitable operations and to obtain additional funding sources. There can be no assurance that ourfinancing efforts will result in profitable operations or the resolution of the Company's liquidity problems. The accompanying statements do not include any adjustments that might result should the Company be unable to continue as a going concern. Along with diversifying the portfolio of products distributed by the Company, including equipment and biologics, it is the intention of our management to both continue to adhere to the Court Order (see Note 12 of the Financial Statements) as well as re-establish its good standing with the Agency (FDA). These points are not mutually exclusive nor negotiable and management believes that there are still business and patient goodness opportunities while still abiding by all legal requirements As a result, management shall be continuing with the development of US Stem Cell Training, Inc., an operating division of the Company, that is a content developer of regenerative medicine/cell therapy informational and training materials for physicians and patients and complies with both requirements--as well as Vetbiologics, an operating division of the Company, that is a veterinary regenerative medicine company committed to providing veterinarians with the ability to deliver the highest quality regenerative medicine therapies to dogs, cats and horses.

Overview

We are a biotechnology company focused on the discovery, development and, subject to regulatory approval, commercialization of autologous cell therapies for the treatment of chronic and acute heart damage. Our lead product candidates are MyoCell™ and Adipocell. MyoCell™ is an innovative clinical therapy designed to populate regions of scar tissue within a patient's heart with autologous muscle cells, or cells from a patient's body, for the purpose of improving cardiac function in chronic heart failure patients. Adipocell is an innovative cell therapy kit with multiple possible treatment applications using autologous adipose cells. We are presently investigating the use of adipose cells in a variety of clinical applications.

Biotechnology Product Candidates

We are focused on the discovery, development and, subject to regulatory approval, commercialization of autologous cell therapies for the treatment of chronic and acute heart damage. In our pipeline, we have multiple product Candidates for the treatment of heart damage, including MyoCell, MyoCell™ SDF-1 and Adipocell. MyoCell™ and MyoCell™ SDF-1 are clinical muscle-derived cell therapies designed to populate regions of scar tissue within a patient's heart with new living cells for the purpose of improving cardiac function in chronic heart failure patients.

MyoCell™ SDF-1 is intended to be an improvement to MyoCell™. MyoCell™ SDF-1 is similar to MyoCell™ except that the myoblast cells to be injected for use in MyoCell™ SDF-1 will be modified prior to injection by an adenovirus vector or non-viral vector so that they will release extra quantities of the SDF-1 protein, which expresses angiogenic factors. Adipocell is a kit to obtain patient-derived cells proposed for various in clinic procedures. We hope to demonstrate that these product candidates are safe and effective complements to existing therapies for various indications.

MyoCath Product Candidate

The MyoCath is a deflecting tip needle injection catheter that has a larger (25 gauge) needle to allow for better flow rates and less leakage than systems that are 27 gauge. This larger needle allows for thicker compositions to be injected, which helps with cell retention in the heart. Also, the MyoCath needle has more fluoroscopic brightness than the normally used nitinol needle, enabling superior visualization during the procedure. Seeing the needle well during injections enables the physician who is operating the catheter to pinpoint targeted areas more precisely.

The MyoCath is used to inject cells into cardiac tissue in therapeutic procedures to treat chronic heart ischemia and congestive heart failure. Investigators in our MARVEL Trial may use either our MyoCath catheters or Biosense Webster's (a Johnson & Johnson company) NOGA® Cardiac Navigation System along with the MyoStar™ injection catheter for the delivery of MyoCell™ to patients enrolled in the trial. This trial has not been enrolling in 2021.

We conduct operations in one business segment. We may organize our business into more discrete business units when and if we generate significant revenue from the sale of our product candidates. Our revenue since inception has been generated inside and outside the United States, and the majority of our long-lived assets are located in the United States.

GENERAL AMERICAN CAPITAL PARTNERS

On March 3, 2017, we entered into an asset sale and lease agreement (sale/leaseback transaction; "Asset Sale and Lease Agreement"), with GACP (General American Capital Partners) Stem Cell Bank LLC, a Florida limited liability company ("GACP) whereby we sold certain lab, medical and other equipment relating to the cell banking business for $400,000 and leased back the sold equipment over a three year term. The lease includes a base monthly rental payment of $20,000, due the first day of each calendar month. In addition, we are required to pay 2.3%, 22.5% and 31.6% of revenues collected on deposits arising from cell banking business for years 1, 2 and 3, respectively. At the expiration of the lease, we returned all leased equipment and along with any maintenance records, logs, etc. in our possession to the lessor with no right of repurchase. Further, as a consequence of the Court Order , the Company resolved to divest itself of certain equipment and other assets (the "Equipment Assets") used in connection with the Company's human tissue banking business, but consistent however with the requirements of the Court Order, and to adjust the business plan and operations to accommodate this potential divesture. The divestiture became effective October 10th, 2019.

U.S. Stem Cell Clinic, LLC

On February 10, 2021, as part of a settlement agreement, the Company transferred its entire member interest in U.S. Stem Cell Clinic, LLC to Dr. Kristen Comella as settlement for $100,000 of accrued interest owed to Dr. Comella.

Results of Operations Overview
Comparison of Years Ended December 31, 2021 and December 31, 2020

Revenues

Our primary source of revenue is from the sale of test kits and equipment, training services, patient treatments and laboratory services, and cell banking. Our revenue may vary substantially from quarter to quarter and from year to year. We believe that period-to-period comparisons of our results of operations are not meaningful and should not be relied upon as indicative of our future performance. We do not expect to generate substantial revenues until we obtain regulatory approval for and commercialize our product candidates.

We recognized revenues of $200,749 in 2021 compared to revenues of $277,087 in 2020. Our revenue in 2021 was generated from the sale of test kits and equipment and training services. Our revenues for 2020 were generated from the sale, test kits and equipment, and training services. Decrease in revenue due to court case result.

As a consequence of the Court Order (see Note 12) the Company divested itself of certain equipment and other assets (the "Equipment Assets") used in connection with the Company's human tissue banking business, but consistent however with the requirements of the Court Order, and adjusted the business plan and operations to accommodate this divesture.

Cost of Sales

Cost of sales consists of the costs associated with the production of MyoCath and test kits, product costs, labor for production and training and lab and banking costs consistent with products and services provided.

Cost of sales was $52,030 in the year ended December 31, 2021 compared to $64,117 in the year ended December 31, 2020. The decrease is due to the decrease in revenues.

Research and Development

Our research and development expenses consist of costs incurred in identifying, developing and testing our product candidates. These expenses consist primarily of costs related to our clinical trials, the acquisition of intellectual property licenses and preclinical studies. We expense research and development costs as incurred.

Research and development expenses were $0 in 2021 remaining the same as $0 in 2020.

Selling, General and Administrative

Our selling, general and administrative expenses primarily consist of the costs associated with our general management and clinical marketing and trade programs, including, but not limited to, salaries and related expenses for executive, administrative and marketing personnel, rent, insurance, legal and accounting fees, consulting fees, travel and entertainment expenses, conference costs and other clinical marketing and trade program expenses.

Selling, general and administrative expenses were $2,284,577 in 2021, a decrease of $328,634 in selling, general and administrative expenses of $2,613,211 in 2020. The decrease is due to reduced operations due to the Court order.

Gain (loss) on settlement of debt

During the year ended December 31, 2021, we recognized a net loss of $151,410 primarily related to interest. In 2020, we recognized a gain of $182 primarily related to the settlement of accounts payable and accrued interest.

Gain on sale of equipment

In March 2017, we entered a sale/leaseback transaction whereby we sold our lab and other medical equipment and re-leased the equipment back for 36 months. In connection with the sale/leaseback, we realized a gain on sale of equipment of $0. During the year ended December 31, 2021, we recognized $0 in current period operations as compared to $21,474 for the previous year.

Income from equity investment

Our investment of a 49.9% member interest ownership of Regenerative Wellness Clinic as well as a 49% interest in U.S. Stem Cell Clinic of the Villages LLC are accounted for using the equity method of accounting. As such, we report our pro rata share of income (loss) from equity investments for the period. For the year ended December 31, 2021 and 2020 our pro rata share of income (loss) was $0 and $(23,539), respectively. We divested ourselves of our member interests in Regenerative Wellness Clinic, LLC in March 2021.

Interest Expense

Interest expense during the year ended December 31, 2021 was $1,000,148 compared to $488,369 for the year ended December 31, 2020. Interest expense primarily consists of interest incurred on the principal amount of the Northstar loan, the Seaside National Bank loan, the Capital Lease with GACP, accrued fees and interest payable to the Guarantors, imputed interest on non-interest bearing debt, the amortization of debt discounts and non-cash interest incurred relating to our issued convertible notes payable. There was nominal change in interest year over year.

On January 3, 2018, we renewed the loan with Seaside National Bank and Trust extend the maturity date to May 18, 2020 all other terms and conditions remain unchanged. On May 18, 2020, the Seaside loan was turned into a Demand Note with no fixed maturity date but with a re-documentation requirement every four years. The new re-documentation deadline is May 2022.

Stock-Based Compensation

Stock-based compensation which is included in the Selling, General and Administrative above, reflects our recognition as an expense of the value of stock options and other equity instruments issued to our employees and non-employees over the vesting period of the options and other equity instruments. We have granted to our employees options to purchase shares of common stock at exercise prices as determined by our Board of Directors, with input from management.

In valuing our common stock, our Board of Directors considered a number of factors, including, but not limited to:

- our financial position and historical financial performance;
- the illiquidity of our capital stock;
- arm's length sales of our common stock;
- the development status of our product candidates;
- the business risks we face;
- vesting restrictions imposed upon the equity awards;
- an evaluation and benchmark of our competitors; and
- the prospects of a liquidity event.

On April 1, 2013, our Board of Directors approved, subject to subsequently received shareholder approval, the establishment of the Bioheart 2013 Omnibus Equity Compensation Plan, or the "2013 Omnibus Plan" (replacing the 1999 Officers and Employees Stock Option Plan, or the Employee Plan, and the 1999 Directors and Consultants Stock Option Plan). The 2013 Omnibus Plan initially reserved up to fifty thousand (50,000) shares of common stock for issuance. On August 4, 2014, the Board of Directors approved to set the reserve to one hundred thousand (100,000) shares of common stock for issuance and to close the 1999 Officers and Employees Stock Option Plan. On February 2, 2015, at the annual meeting of shareholders, the majority of shareholders approved the 2013 Omnibus Equity Compensation Plan. On November 2, 2015, the Board of Directors approved the increase of the reserve under the 2013 Omnibus Plan to five hundred million (500,000,000) shares of common stock for issuance, effective September 16, 2016, approved an addition of twenty five million (25,000,000) shares of common stock to the reserve, effective April 21, 2017, approved an addition of twenty five million (25,000,000) shares of common stock to the reserve, effective August 7, 2017, approved an addition of thirty million (30,000,000) shares of common stock to the reserve and effective May 7, 2018, approved an addition of one hundred million (100,000,000) shares of common stock to reserve.

A summary of options at December 31, 2021 and activity during the year then ended is presented below:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)
Options outstanding at December 31, 2020	111,119,914	$ 0.0247	7.2
Granted	—		
Exercised	—		
Forfeited/Expired	(476,030)	$ 0.0298	
Options outstanding at December 31, 2021	110,643,884	$ 0.0247	6.3
Options exercisable at December 31, 2021	93,491,384	$ 0.0256	6.1
Available for grant at December 31, 2021	34,168,070		

The following information applies to stock options outstanding and exercisable at December 31, 2021:

Options Outstanding				Options Exercisable	
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Weighted Average Exercise price	Exercisable Number of Options	Weighted Average Exercise price
$0.004 to $0.010	41,800,000	7.0	$ 0.0051	30,150,000	$ 0.0050
$0.011 to $0.020	16,250,000	4.7	0.0196	16,250,000	0.0196
$0.021 to $0.030	9,510,000	6.9	0.0252	9,007,500	0.0252
$0.0363	22,635,000	5.6	0.0363	22,635,000	0.0363
$0.0536	20,000,000	6.4	0.0536	15,000,000	0.0536
$0.1540	448,884	3.8	0.1540	448,884	0.1540
Total	110,643,884	6.3	$ 0.0247	93,491,384	$ 0.0256

The aggregate intrinsic value of outstanding stock options was $36,686, based on options with an exercise price less than the Company's stock price of $0.0060 as of December 31, 2021, which would have been received by the option holders had those option holders exercised their options as of that date.

The fair value of all options that vested during the years ended December 31, 2021 and 2020 was $428,556 and $685,939, respectively. As of December 31, 2021, the Company had $157,289 of total unrecognized compensation cost related to non-vested awards granted under the 2013 Omnibus Plan, which the Company expects to recognize over a weighted average period of 0.55 years.

Warrants

A summary of warrant activity for the year ended December 31, 2021 is presented below:

	Number of Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Life in Years
Outstanding at December 31, 2020	1,110,468	$ 12.84	7.1
Issued	-		
Exercised	-		
Expired	(7,341)	$ 77.88	
Outstanding at December 31, 2021	1,103,127	$ 12.41	6.2
Exercisable at December 31, 2021	1,101,582	$ 1.64	6.2

The following information applies to warrants outstanding and exercisable at December 31, 2021:

Warrants Outstanding				Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life in Years	Weighted Average Exercise Price	Exercisable Number of Warrants	Weighted Average Exercise Price
$0.03 –20.00	1,081,036	6.3	$ 1.17	1,081,036	$ 1.17
$20.01 –30.00	19,543	2.2	$ 25.06	19,543	$ 25.06
$49.86	1,003	2.2	$ 49.86	1,003	$ 49.86
$7,690.00	$ 1,545	5.0	$ 7,690.00	-	$ -
	1,103,127	6.2	$ 12.41	$ 1,101,582	$ 1.64

Interest Expense

Interest expense during the year ended December 31, 2021 was $1,000,148 compared to $488,369 for the year ended December 31, 2020. Interest expense primarily consists of interest incurred on the principal amount of the Northstar loan, the Seaside National Bank loan, the Capital Lease with GACP, accrued fees and interest payable to the Guarantors, imputed interest on non-interest bearing debt, the amortization of debt discounts and non-cash interest incurred relating to our issued convertible notes payable. There was nominal change in interest year over year.

On January 3, 2018, we renewed the loan with Seaside National Bank and Trust extend the maturity date to May 18, 2020 all other terms and conditions remain unchanged. On May 18, 2020, the Seaside loan was turned into a Demand Note with no fixed maturity date but with a re-documentation requirement every four years. The new re-documentation deadline is May 2022.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. While our critical accounting policies are described in Note 1 to our financial statements appearing elsewhere in this report, we believe the following policies are important to understanding and evaluating our reported financial results:

Revenue Recognition

Effective January 1, 2018, we recognize revenue in accordance with Accounting Standards Codification 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific revenue recognition guidance throughout the Industry Topics of the Accounting Standards Codification. The updated guidance states that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance also provides for additional disclosures with respect to revenues and cash flows arising from contracts with customers.

At the time of each transaction, management assesses whether the fee associated with the transaction is fixed or determinable and whether or not collection is reasonably assured. The assessment of whether the fee is fixed or determinable is based upon the payment terms of the transaction. Collectability is assessed based on a number of factors, including past transaction history with the client and the creditworthiness of the client.

Our primary sources of revenue are from the sale of test kits and equipment, training services, patient treatments, laboratory services and cell banking.

Revenues for kits and equipment sold are not recorded until kits and equipment are received by the customer. Revenues from in-person trainings are recognized when the training occurs and revenues from on demand online trainings are recognized when the customer purchases the rights to the training course. Any cash received as a deposit for trainings are recorded by the Company as a liability.

Patient treatments and laboratory services revenue are recognized when those services have been completed or satisfied.

Revenues for cell banking sales are accounted for as multiple performance obligations as described in 606 and addresses accounting for arrangements that may involve the delivery or performance of multiple products, services and/or rights to use assets. Because the Company sells its services separately, on more than a limited basis and at a price within a narrow range, our company was able to allocate revenue based on stand-alone pricing. The multiple performance obligations include stem cell banking, dose retrieval and yearly storage fees. Revenues for stem cell banking and dose retrieval is recognized at the point of service and revenues for the yearly storage fees is recognized over the term of the banking contract, which is typically one year with annual renewals.

Stock-based compensation

We measure the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. The fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period. Stock-based compensation expense is recorded by our company in the same expense classifications in the statements of operations, as if such amounts were paid in cash.

Income taxes

Income taxes are accounted for under the asset and liability method. 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 carry forwards that are available to be carried forward to future years for tax purposes. 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. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. When it is not considered to be more likely than not that a deferred tax asset will be realized, a valuation allowance is provided for the excess. Although we have significant loss carry forwards available to reduce future income for tax purposes, no amount has been reflected on the balance sheet for deferred income taxes as any deferred tax asset has been fully offset by a valuation allowance.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include stock-based compensation, debt discounts and the valuation allowance related to deferred tax assets. Actual results may differ from these estimates.

Research and Development Costs

We account for research and development costs in accordance with Accounting Standards Codification subtopic 730-10, Research and Development (“ASC 730-10”). Under ASC 730-10, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred. Third-party research and development costs are expensed when the contracted work has been performed or as milestone results have been achieved as defined under the applicable agreement. Company-sponsored research and development costs related to both present and future products are expensed in the period incurred.

Depreciation

Depreciation is computed using the straight-line method over the assets' expected useful lives or the term of the lease, for assets under capital leases.

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand, deposits in banks with maturities of three months or less, and all highly liquid investments which are unrestricted as to withdrawal or use, and which have original maturities of three months or less.

Options and warrants issued

We allocate the proceeds received from equity financing and the attached options and warrants issued, based on their relative fair values, at the time of issuance. The amount allocated to the options and warrants is recorded as additional paid in capital.

Related Parties

For the purposes of these financial statements, parties are considered to be related if one party has the ability, directly or indirectly, to control the party or exercise significant influence over the party in making financial and operating decisions, or vice versa, or where our company and the party are subject to common control or common significant influence. Related parties may be individuals or other entities.

Results of Operations

We are a research and development stage company and our MyoCell™ product candidate has not received regulatory approval or generated any material revenues and is not expected to until late 2019, if ever. We have generated substantial net losses and negative cash flow from operations since inception and anticipate incurring significant net losses and negative cash flows from operations for the foreseeable future as we continue clinical trials, undertake new clinical trials, apply for regulatory approvals, make capital expenditures, add information systems and personnel, make payments pursuant to our license agreements upon our achievement of certain milestones, continue development of additional product candidates using our technology, establish sales and marketing capabilities and incur the additional cost of operating as a public company.

Selling, General and Administrative

Selling, general and administrative expenses were $2,284,577 in 2021, a decrease of $328,634 in selling, general and administrative expenses of $2,613,211 in 2020. The decrease is due to reduced operations due to the Court order.

Inflation

Our opinion is that inflation has not had, and is not expected to have, a material effect on our operations.

Climate Change

Our opinion is that neither climate change, nor governmental regulations related to climate change, have had, or are expected to have, any material effect on our operations.

Liquidity and Capital Resources

In 2021, we continued to finance our operational cash needs with cash generated from financing activities.

Economic Injury Disaster Loan (EIDL)

On June 20, 2020, the Company executed the standard loan documents for an EIDL from the U.S. Small Business Administration in light of the impact of the COVID-19 pandemic on our business. Pursuant to that certain Loan Authorization and Agreement (the "SBA Loan Agreement"), the principal amount of the EIDL received was $150,000, with proceeds to be used for working capital purposes. Interest accrues at the rate of 3.75% per annum. Installment payments, including principal and interest, are due monthly beginning June 20, 2021 (twelve months from the date of the SBA Loan Agreement) in the amount of $731. On March 15, 2021, the initial payment date was extended 12 months to June 20, 2022. The balance of principal and interest is payable thirty years from the date of the SBA Loan Agreement. As of December 31, 2021 and 2020, the remaining carrying value of the note was $150,000. At December 31, 2021 and 2020, accrued interest on the note was $8,615 and $2,990, respectively, and is included in accrued expenses on the accompanying balance sheet.

Operating Activities

Net cash used in operating activities was $1,057,939 in 2021 as compared to $478,886 of net cash used in operations in 2020. Our net cash used in operations in 2021 resulted primarily from a net loss of $3,287,416, partially offset by non-cash items including interest and amortization of debt discount of $977,386, stock-based compensation of $556,556, related party notes payable issued for services rendered of $422,722, loss on settlement of accounts payable and accrued interest of $151,410 and bad debts of $93,241, as well as an increase in accounts payable of $73,195.

Investing Activities

Net cash provided by investing activities was $0 for the year ended December 31, 2021.

Financing Activities

Net cash provided by financing activities was $1,078,762 in the year ended December 31, 2021 as compared to net cash provided of $497,456 in the year ended December 31, 2020. Our net cash provided by financing activities in 2021 resulted from proceeds of received from the issuance of convertible notes payable of $766,000, proceeds from the sale of common shares of $275,000 and proceeds received from related party advances of $90,000, partially offset by repayments of notes payable of 52,238.

Existing Capital Resources and Future Capital Requirements

Our MyoCell™ product candidate has not received regulatory approval or generated any material revenues. We do not expect to generate any material revenues or cash from sales of our MyoCell™ product candidate until commercialization of MyoCell, if ever. We have generated substantial net losses and negative cash flow from operations since inception and anticipate incurring significant net losses and negative cash flows from operations for the foreseeable future. Historically, we have relied on proceeds from the sale of our common stock and our incurrence of debt to provide the funds necessary to conduct our research and development activities and to meet our other cash needs.

At December 31, 2021, we had cash and cash equivalents totaling $39,393; our working capital deficit as of such date was $11,987,776. Our independent registered public accounting firm has issued its report dated March 31, 2022 in connection with the audit of our financial statements as of December 31, 2021 that included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern.

As of December 31, 2021, we had $8,016,314 in outstanding debt, net of debt discount of $273,216.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

Recent Accounting Pronouncements

Refer to Note 1. *Organization and Summary of Significant Accounting Policies* in the notes to our financial statements for a discussion of recent accounting pronouncements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data

Our Financial Statements begin on page F-1 of this Annual Report on Form 10-K and are incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

(a) *Evaluation of disclosure controls and procedures.* Our management, with the participation of our Chief Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15 under the Securities Exchange Act of 1934 (the "Exchange Act")) as of the end of the period covered by this Annual Report on Form 10-K. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our Chief Executive Officer and Principal Financial Officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were not effective.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined In Exchange Act Rule 13a-15(f). The term "internal control over financial reporting" is defined as a process designed by, or under the supervision of, the registrant's principal executive and principal financial officers, or persons performing similar functions, and effected by the registrant's board of directors, management and other personnel,

- to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:
- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the registrant;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the registrant are being made only in accordance with authorizations of management and directors of the registrant; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the registrant's assets that could have a material effect on the financial statements.

Our internal control system is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. In addition, because of changes in conditions, the effectiveness of internal control may vary over time.

We carried out an evaluation, with the participation of our management, including our Chief Executive Officer ("CEO") who also acts as our Chief Financial Officer (CFO) of the effectiveness our disclosure controls and procedures (as defined under Rule 13a-15(e) under the Exchange Act) as of December 31, 2021. Based upon that evaluation, our CEO/ CFO concluded that our disclosure controls and procedures are not effective at the reasonable assurance level due to the following material weaknesses:

We do not have sufficient segregation of duties within accounting functions, which is a basic internal control. Due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible. However, to the extent possible, the initiation of transactions, the custody of assets and the recording of transactions should be performed by separate individuals. Management evaluated the impact of our failure to have segregation of duties on our assessment of our disclosure controls and procedures and has concluded that the control deficiency that resulted represented a material weakness.

To address these material weaknesses, management performed additional analyses and other procedures to ensure that the financial statements included herein fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.

Remediation of Material Weaknesses

We intend to remediate the material weaknesses in our disclosure controls and procedures identified above by hiring a full-time CFO with SEC reporting experience in the future and expanding accounting staff when working capital permits and by working with our independent registered public accounting firm to refine our internal procedures. We currently address the limitations through a separately-designated standing Audit Committee established in accordance with Section 3(a) (58) (A) of the Exchange Act. The members of our Audit Committee are Mr. Borman, who serves as Chairperson of the Audit Committee, Dr. Murphy, and Mr. Anderson. Our Board of Directors has determined that Mr. Borman qualifies as a "financial expert" as that term is defined in the rules of the SEC implementing requirements of the Sarbanes-Oxley Act of 2002.

The Company is a smaller reporting company and is not subject to Section 404(b) of the Sarbanes Oxley Act. Accordingly, this Annual Report does not contain an attestation report of our independent registered public accounting firm regarding internal control over financial reporting, since the rules for smaller reporting companies provide for this exemption.

(b) *Changes in internal control over financial reporting.* There have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2021, that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Executive Officers and Directors

Set forth below is information regarding our current executive officers and directors

Mike Tomas	57	Director, President and Chief Executive Officer, Chief Financial Officer
William P. Murphy, Jr., M.D.	98	Director, Chairman Emeritus
Mark P. Borman	67	Director, Chairman of the Board
Sheldon T. Anderson	71	Director
Greg Knutson	70	Director

Our Bylaws provide that we shall have that number of directors determined by the majority vote of the board of directors. Currently we have six directors. Each director will serve until our next annual shareholder meeting. Directors are elected for one-year terms. Our Board of Directors elects our officers at the regular annual meeting of the Board of Directors following the annual meeting of shareholders. Vacancies may be filled by a majority vote of the remaining directors then in office. Our directors and executive officers are as follows:

Executive Officers and Directors

Mike Tomas. Mike Tomas, President & CEO of U.S. Stem Cell Inc, is considered by many in the industry as one of the most experienced marketers and operating executives for IT/Communications and Biotech/Life Sciences private equity and venture groups portfolio companies. The son of a serial entrepreneur, he spent nearly 20 years driving the evolution of telecommunications technology in the U.S. and Mexico in leadership roles ranging from sales, marketing, customer service, telemarketing, engineering, and operations. Upon retiring as Chief Marketing Officer of Avantel, MCI/Worldcom's Global Ventures $1B investment with Banamex (at the time, the largest bank in Latin America), Mr. Tomás joined other former-MCI executives (including MCI CEO Jerry Taylor) and helped form an integrated customer communications software solution that was named on Red Herring magazine's "Top Ten to Watch" list.

Upon the successful sale of that company in 2001, Mr. Tomas helped launch The ASTRI Group, an early-stage private equity investment company providing capital, business development and strategic marketing support to emerging private companies. Mr. Tomas sits on the board of U.S. Stem Cell Inc. (adult stem cell development and applications) and has sat on the boards of The IDEA Center (Miami Dade College's entrepreneurial institute), Career Source Florida (appointed by Florida Governor Rick Scott to his statewide workforce investment board) and is the past chairman of Florida International University's Global Entrepreneurship Center. Mr. Tomas is an inductee into the Miami-Dade College and WACE Halls of Fame for business, an FIU Torch Award winner--and winner of top communications, medical innovations, education and entrepreneurial awards. An avid athlete, Mr. Tomas was also a Miami-Dade County Sports Commissioner.

William P. Murphy, Jr., M.D. Dr. Murphy has served as a member of our Board of Directors since June 2003. Dr. Murphy founded Small Parts, Inc., a supplier of high quality mechanical components for design engineers, in 1964 and served as its Chairman until his retirement in April 2005. Small Parts, Inc. was acquired by Amazon.com, Inc. in March 2005. From October 1999 until October 2004, Dr. Murphy served as the Chairman and Chief Executive Officer of Hyperion, Inc., a medical diagnosis company which had an involuntary bankruptcy filed against it in December 2003. Dr. Murphy is the founder of Cordis Corporation (now Cordis Johnson & Johnson) which he led as President, Chairman and Chief Executive Officer at various times during his 28 years at Cordis until his retirement in October 1985. Cordis Johnson & Johnson is a leading firm in cardiovascular instrumentation.

Dr. Murphy received an M.D. in 1947 from the University of Illinois and a B.S. in pre-medicine from Harvard College in 1946. He also studied physiologic instrumentation at Massachusetts Institute of Technology, or MIT. After a two year rotating internship at St. Francis Hospital in Honolulu, he became a Research Fellow in Medicine at the Peter Bent Brigham Hospital in Boston where he was the dialysis engineer on the first clinical dialysis team in the United States. He continued as an Instructor in Medicine and then a research associate in Medicine at Harvard Medical School. Dr. Murphy is the author of numerous papers and owns 17 patents.

He is the recipient of a number of honors, including the prestigious Lemelson-MIT Lifetime Achievement Award, the MIT Corporate Leadership Award, the Distinguished Service Award from North American Society of Pacing and Electrophysiology, and the Jay Malina Award from the Beacon Council of Miami, Florida. He is also a member of the Inventors Hall of Fame.

Mark P. Borman. Mr. Borman has served as a member of the Company's Board of Directors since May 2009. He is a seasoned financial officer with more than 30 years of broad-based financial and investor relations experience. Mr. Borman brings small-company entrepreneurial passion and larger-company disciplines. In addition to the valuable experience he gained working with entrepreneurs and their startups from 2009 to present, Mr. Borman has experience with global, NASDAQ- and NYSE-listed companies in various executive and financial roles. He serves and has served as a board member with public and private companies, and on advisory and non-profit boards. During his career, Mr. Borman has held positions with ADC Telecommunications, General Instrument Corporation, First Chicago Corporation, FMC Corporation, Price Waterhouse, and KPMG. Mr. Borman received his B.A. in Accounting from Michigan State University and his M.B.A. in Finance from the University of Chicago Booth School of Business. He is an Audit Committee Financial Expert under SEC rules and was a Certified Public Accountant and Chartered Financial Analyst.

Sheldon T. Anderson. Mr. Anderson is Chairman of the Florida Advisory Board of Northern Trust Corporation. From 1992 through December 31, 2012, Mr. Anderson served in a variety of executive capacities with Northern Trust Corporation, including his most recent position as Chairman and Chief executive Officer Southeast Region of Northern Trust Corporation. Mr. Anderson is the Chair-elect of the Beacon Council, Miami-Dade County's economic development agency. He is a Board member of the Miami-Dade College Foundation, Inc.; Museum of Contemporary Art (MOCA); the New World Symphony; Baptist Health Systems Governing Board and Carrollton School of the Sacred Heart. He is Past Chair and a member of the Advisory Council of the United Way of Miami-Dade County. Anderson is President of the Board of Cleveland Orchestra Miami / Miami Music Association and also serves on the Advisory Board of the University of Miami School of Law for Ethics& Public Service. He is a member of the Orange Bowl Committee and the President's Council of Florida International University. A Miami native, Sheldon holds a degree in International Studies from Ohio State University.

Greg Knutson. Mr. Knutson founded Concrete Specialists, Inc. in 1985 and continues to serve as its President. Mr. Knutson founded Sunwood Properties in 2009 and continues to serve as its President. Mr. Knutson founded G&G Land Development, LLC and continues to serve as its Managing Partner. Mr. Knutson, a holder of Member Interests in Northstar, was appointed as a Manager of Northstar Biotech Group, LLC in late 2014.

Family Relationships

There are no family relationships among our executive officers and directors.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent (10%) of our outstanding Common Stock, or the Reporting Persons, to file with the SEC initial reports of ownership on Form 3 and reports of changes in ownership of Common Stock on Forms 4 or 5. Such persons are required by SEC regulation to furnish us with copies of all such reports they file. Based solely on a review of Forms 3 and 4 furnished to us by the Reporting Persons or prepared on behalf of the Reporting Persons by the Company and on written representations from certain Reporting Persons that no Forms 5 was required, the Company believes that the Reporting Persons have complied with reporting requirements applicable to them.

Conflicts of Interest

Members of our management are associated with other firms involved in a range of business activities. Consequently, there are potential inherent conflicts of interest in their acting as officers and directors of our company. Although the officers and directors are engaged in other business activities, we anticipate they will devote an important amount of time to our affairs.

Our officers and directors are now and may in the future become shareholders, officers or directors of other companies, which may be formed for the purpose of engaging in business activities similar to ours. Accordingly, additional direct conflicts of interest may arise in the future with respect to such individuals acting on behalf of us or other entities. Moreover, additional conflicts of interest may arise with respect to opportunities which come to the attention of such individuals in the performance of their duties or otherwise. Currently, we do not have a right of first refusal pertaining to opportunities that come to their attention and may relate to our business operations.

Our officers and directors are, so long as they are our officers or directors, subject to the restriction that all opportunities contemplated by our plan of operation which come to their attention, either in the performance of their duties or in any other manner, will be considered opportunities of, and be made available to us and the companies that they are affiliated with on an equal basis. A breach of this requirement will be a breach of the fiduciary duties of the officer or director. If we or the companies with which the officers and directors are affiliated both desire to take advantage of an opportunity, then said officers and directors would abstain from negotiating and voting upon the opportunity. However, all directors may still individually take advantage of opportunities if we should decline to do so. Except as set forth above, we have not adopted any other conflict of interest policy with respect to such transactions.

Involvement in Certain Legal Proceedings

None of the following events have occurred during the past ten years and are material to an evaluation of the ability or integrity of any director or officer of the Company:

1. A petition under the Federal bankruptcy laws or any state insolvency law was filed by or against, or a receiver, fiscal agent or similar officer was 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;
2. Such person was convicted in a criminal proceeding or is a named subject of a pending criminal proceeding (excluding traffic violations and other minor offenses);
3. Such person 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 from, or otherwise limiting, the following activities:

a. 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;

b. Engaging in any type of business practice; or

c. 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;

4. Such person 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 paragraph (f)(3)(i) of this section, or to be associated with persons engaged in any such activity;
5. Such person was found by a court of competent jurisdiction in a civil action or by the Commission to have violated any Federal or State securities law, and the judgment in such civil action or finding by the Commission has not been subsequently reversed, suspended, or vacated;
6. Such person 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;
7. Such person 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:

a. Any Federal or State securities or commodities law or regulation; or

b. 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

c. Any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

8. Such person was the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act (15 U.S.C. 78c(a)(26))), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act (7 U.S.C. 1(a)(29)), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Code of Ethics

As part of our system of corporate governance, our Board of Directors has adopted a code of ethics that is specifically applicable to our Chief Executive Officer and senior financial officers. This Code of Ethics for Senior Financial Officers, as well as our Code of Business Conduct and Ethics, applicable to all directors, officers and employees. If we make substantive amendments to the Code of Ethics for Senior Financial Officers or the Code of Business Conduct and Ethics or grant any waiver, including any implicit waiver, we will disclose the nature of such amendment or waiver on our website or in a report on Form 8-K within four days of such amendment or waiver.

Shareholder Recommendations for Board Nominees

There have been no material changes to the procedures by which security holders may recommend nominees to the Company's Board of Directors.

Audit Committee

The Board of Directors has a separately-designated standing Audit Committee established in accordance with Section 3(a) (58) (A) of the Exchange Act. The members of our Audit Committee are Mr. Borman, who serves as Chairperson of the Audit Committee, Dr. Murphy, and Mr. Anderson. Our Board of Directors has determined that Mr. Borman qualifies as a "financial expert" as that term is defined in the rules of the SEC implementing requirements of the Sarbanes-Oxley Act of 2002.

Item 11. Executive Compensation.

Summary Compensation Table

The following table sets forth, for the fiscal years ended December 31, 2021 and 2020, the aggregate compensation awarded to/earned by or paid to our Chief Executive Officer and our two most highly compensated officers (other than the Chief Executive Officer), who were serving as executive officers as of December 31, 2021, or the Named Executive Officers.

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Mike Tomas									
CEO, President,	2021	$ 327,279	$ 0	$ —	$ 0				$ 327,279
CFO and Director	2020	$ 130,385	$ 500,000(1)	$ —	$ 0				$ 630,385

(1) On July 1, 2020, Mr. Tomas received a $500,000 promissory note for a bonus awarded. The promissory note bears 5% interest per annum, is unsecured and is due on demand.

Our Stock Option Plans

On April 1, 2013, the Board of Directors approved, subject to subsequently received shareholder approval, the establishment of the Bioheart 2013 Omnibus Equity Compensation Plan, or the "2013 Omnibus Plan" (replacing the 1999 Officers and Employees Stock Option Plan, or the Employee Plan, and the 1999 Directors and Consultants Stock Option Plan).. The 2013 Omnibus Plan initially reserved up to fifty thousand (50,000) shares of common stock for issuance. On August 4, 2014, the Board of Directors approved to set the reserve to one hundred thousand (100,000) shares of common stock for issuance and to close the 1999 Officers and Employees Stock Option Plan. On February 2, 2015, at the annual meeting of shareholders, the majority of shareholders approved the 2013 Omnibus Equity Compensation Plan. On November 2, 2015, the Board of Directors approved the increase of the reserve under the 2013 Omnibus Plan to five hundred million (500,000,000) shares of common stock for issuance, effective September 16, 2016, approved an addition of twenty five million (25,000,000) shares of common stock to the reserve, effective April 21, 2017, approved an addition of twenty five million (25,000,000) shares of common stock to the reserve, effective August 7, 2017, approved an addition of thirty million (30,000,000) shares of common stock to the reserve and effective May 7, 2018, approved an addition of one hundred million (100,000,000) shares of common stock to reserve.

Employment Agreements

Employment Agreements

On July 1, 2019, the Company's Board of Directors approved the 2019/2020 salary for Mike Tomas, Chief Executive Officer, for $750,000 per year, beginning July 1, 2019 with an incentive bonus ranging from $150,000 to $500,000. In addition, the Board of Directors approved a bonus of $500,000 and options to acquire 20,000,000 shares of the Company's common stock for ten years with four-year vesting and a cashless exercise provision. The cash bonus may be paid in the form a six-month promissory note bearing interest at 5% per annum. On May 7, 2018, the Company's Board of Directors approved the 2018/2019 salary for Mike Tomas, Chief Executive Officer, for $750,000 per year, beginning July 1, 2018 with an incentive bonus ranging from $150,000 to $500,000. In addition, the Board of Directors approved a bonus of $500,000 and options to acquire 20,000,000 shares of the Company's common stock for ten years with four-year vesting and a cashless exercise provision. The cash bonus may be paid in the form a six-month promissory note bearing interest at 5% per annum. There were no increases in salary or cash bonuses in 2021.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth outstanding equity awards held by our Named Executive Officers as of December 31, 2021

	Number of Securities Underlying Unexercised Options and Warrants		Option Exercise Price	Option Expiration
Name	**Total (#)**	**Unexercisable (#)**	**($/per share)**	**Date**
Mike Tomas	500	-	0.15402	1/16/2022
	2,000	-	0.15402	8/6/2022
	10,000	-	0.15402	8/1/2023
	400	-	0.15402	9/1/2023
	10,800	-	0.15402	2/24/2024
	4,299	-	0.15402	5/12/2024
	10,000	-	0.15402	8/1/2024
	400	-	0.15402	11/3/2024
	291,885	-	0.15402	11/2/2025
	10,000	-	0.15402	11/2/2025
	11,500,000	-	0.01960	9/19/2026
	10,000,000	-	0.00430	2/6/2027
	16,500,000	-	0.03626	8/7/2027
	20,000,000	5,000,000	0.05360	5/7/2028
	1,500,000	-	0.02511	12/3/2028
	20,000,000	10,000,000	0.00557	9/1//2029
	1,500,000	-	0.00495	11/18/2029

Options Exercises and Stocks Vested

Options exercised and stocks vested as at December 31, 2021 are as follows:

	Option awards		Stock awards	
Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($)	Number of Shares Acquired on Vesting (#)	Value Realized on Investing ($)
Mike Tomas, CEO	0	0	0	0

Grants of Plan-Based Awards

Grants of plan-based awards as at December 31, 2021 are as follows:

		Estimated future payouts under non-equity incentive plan awards			Estimated future payouts under equity incentive plan awards			All other stock awards: Number of shares of stock or units	All other option awards: Number of securities underlying options	Exercise or base price of option awards	Grant date fair value of stock and option awards
Name	Grant date	Threshold ($)	Target ($)	Maximum ($)	Threshold ($)	Target ($)	Maximum ($)	(#)	(#)	($/Sh)	
Mike Tomas, CEO	n/a	0	0	0	0	0	0	0	0	0	0

Reference – Grant Date - n/a = not applicable.

Non-Qualified Deferred Compensation

As at December 31, 2021 the Company had no formalized deferred compensation plan.

Name	Executive contributions in last FY ($)	Registrant contributions in last FY ($)	Aggregate earnings in last FY ($)	Aggregate withdrawals/ distributions ($)	Aggregate balance at last FYE ($)
Mike Tomas, CEO	0	0	0	0	0

Golden Parachute Compensation

As at December 31, 2021, the Company had no arrangements in place relating to the termination of employees.

Name	Cash ($)	Equity ($)	Pension/NQDC ($)	Perquisites/benefits ($)	Tax reimbursement ($)	Other ($)	Total ($)
Mike Tomas, CEO	0	0	0	0	0	0	0

Compensation of Directors

The following table sets forth summary information concerning the total compensation paid to our non-employee directors during the fiscal year ended December 31, 2021 for services to our company.

Name	Fees Earned or Paid in Cash ($)	Equity Awards ($)	Total ($)
William P Murphy, Jr.	$ -	$ -	$ -
Sheldon T. Andersen	$ -	$ -	$ -
Mark Borman	$ -	$ -	$ -
Gregory Knutson	$ -	$ -	$ -
Total:	$ -	$ -	$ -

Pension Benefits

As of December 31, 2021, the Company had no pension or retirement plans.

Name	Plan name	Number of years credited service (#)	Present value of accumulated benefit ($)	Payments during last fiscal year ($)
Mike Tomas,CEO	not applicable	0	0	0

Equity Compensation Plan Information

The following table sets forth information as of December 31, 2021 for all compensation plans under the Company's Stock Option Plan:

Name	No. of Shares of Common Stock Underlying Unexercised Common Stock Purchase Options Exercisable (#)	Date of Grant	Additional Consideration to be Received Upon Exercise or Material Conditions Required to Exercise	Option Exercise Price ($)	Value Realized if Exercised ($)	Option Expiration Date
Mike Tomas, CEO	500	1/16/2012	—	0.15402	—	1/16/2022
	2,000	8/6/2012	—	0.15402	—	8/6/2022
	10,000	8/01/2013	—	0.15402	—	8/1/2023
	400	9/1/2013	—	0.15402	—	9/1/2023
	10,000	2/24/2014	—	0.15402	—	2/24/2024
	800	2/24/2014	—	0.15402	—	2/24/2024
	3,225	5/12/2014	—	0.15402	—	5/12/2014
	10,000	8/01/2014	—	0.15402	—	8/1/2024
	400	11/3/2014	—	0.15402	—	11/3/2024
	291,885	11/2/2015	—	0.15402	—	11/2/2025
	5,000	11/2/2015	—	0.15402	—	11/2/2025
	1,500,000	9/19/2016	—	0.01960	—	9/19/2026
	2,500,000	9/19/2016	—	0.01960	—	9/19/2026
	1,500,000	8/7/2017	—	0.03626	—	8/7/2027
	20,000,000	5/7/2018	—	0.05360	—	5/7/2028
	1,500,000	12/3/2018	—	0.02511	—	12/3/2028
	20,000,000	9/1/2019	—	0.00557	—	09/01/2029
	1,500,000	11/18/2019	—	0.00495	—	11/18/2029

Director Compensation

As of December 31, 2021, we had five directors that qualified for compensation. Our non-employee directors do not receive cash compensation for their services as directors. However, it is generally our policy to annually grant each non-employee director options to purchase shares of our common stock provided that he or she has served as a member of our Board of Directors for at least six months and one day of the twelve month period immediately preceding the date of grant. In addition, we reimburse non-employee directors for actual out-of-pocket expenses incurred.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth the beneficial ownership (1) of our common stock as of March 25th, 2022 based on an aggregate of 566,550,051 common shares issued, for each of our greater than 5% shareholders, directors, named executive officers that continue to serve as executive officers of U.S. Stem Cell and by all of our directors and named executive officers as a group as of December 31, 2021. Unless otherwise indicated, the address of each of the individuals and entities named below is: c/o U.S. Stem Cell, Inc., 1560 Sawgrass Corporate Parkway, 4th FL Sunrise FL 33323. Except as noted below, to our knowledge, each person named in the table has sole voting and investment power with respect to all shares of our common stock beneficially owned by them.

(1) The number and percentage of shares beneficially owned is determined in accordance with Rule 13d-3 under the Exchange Act, and the information is not necessarily indicative of beneficial ownership for any other purpose. The Company believes that each individual or entity named has sole investment and voting power with respect to the securities indicated as beneficially owned by them, subject to community property laws, where applicable, except where otherwise noted. The "Amount of Beneficial Ownership" in calculated based on total shares held plus warrants held (plus stock options entitled to exercise). The aggregate of these items will be used as the denominator each for the percentage calculation below.

Name and Address of Beneficial Owner	Amount of Beneficial Ownership		Percent of Class
Mike Tomas, President, CEO, CFO, and Director	38,596,563	(1)	6.3
William P. Murphy, Chairman Emeritus**	6,066,121	(2)	1.0
Mark P. Borman, Chairman of the Board of Directors	6,529,562	(3)	1.1
Sheldon T. Anderson, Director	6,005,282	(4)	1.0
Greg Knutson**	41,125,000	(5)	6.7
All officers and directors as a group (6 persons)	92,322,528	(6)	14.8
Northstar Biotechnology Group, LLC	38,005,331	(7)	6.2

* less than 1%

** Excludes Northstar Biotechnology Group, LLC ("Northstar"), owned partly by certain directors and existing shareholders of the Company, including Dr. William P. Murphy Jr. and controlled by Gregory Knutson, a member of the Board of Directors appointed on March 5, 2017.

(1) Includes shares are held by The Astri Group over which Mr. Tomas has shared voting and investment power and includes (i) includes 8,279 shares of common stock and (ii) 28,588,284 shares of common stock issuable upon exercise of presently exercisable stock options .
(2) Includes (i) 63,481 shares of common stock and (ii) 6,002,640 shares of common stock issuable upon exercise of presently exercisable stock options. Shares are directly owned by trusts controlled by Dr. Murphy and his spouse.
(3) Includes (i) 526,942 shares of common stock and (ii) 6,002,620 shares of common stock issuable upon exercise of presently exercisable stock options
(4) Includes (i) 1,941 shares of common stock and (ii) 6,003,341 shares of common stock issuable upon exercise of presently exercisable options and warrants.
(5) Includes (i) 26,675,000shares of common stock and (ii) 44,750,000 shares of common stock issuable upon exercise of presently exercisable options and warrants.
(6) Includes an aggregate of (i) 27,275,643shares of common stock and (ii) 65,609,975 shares of common stock issuable upon exercise of presently exercisable stock options and warrants.
(7) Includes 38,005,331shares of common stock and (ii) 20,000 shares of common stock issuable upon exercise of warrants.

DESCRIPTION OF SECURITIES

The following statements relating to the capital stock set forth the material terms of our securities; however, reference is made to the more detailed provisions of, and such statements are qualified in their entirety by reference to, the Certificate of Incorporation, amendment to the Certificate of Incorporation and the By-laws, copies of which are filed as exhibits to this registration statement.

COMMON STOCK

The holders of our Common Stock are entitled to one vote per share on all matters to be voted on by our stockholders, including the election of directors. Our stockholders are not entitled to cumulative voting rights, and, accordingly, the holders of a majority of the shares voting for the election of directors can elect the entire board of directors if they choose to do so and, in that event, the holders of the remaining shares will not be able to elect any person to our board of directors.

On February 4, 2013, effective with the filing of the amendment to the Company's Articles of Incorporation with the Florida Secretary of State (confirmed as filed on February 11, 2013), the Company amended its Articles of Incorporation to increase the authorized shares of capital stock of the Company to nine hundred and seventy million (970,000,000) shares of capital stock consisting of nine hundred and fifty million (950,000,000) shares of common stock and twenty million (20,000,000) shares of preferred stock, both $.001 par value respectively.

Effective May 22, 2014, the Company amended its articles of incorporation to increase the authorized shares of capital stock of the Company from nine hundred and fifty million (950,000,000) shares of common stock and twenty million (20,000,000) shares of preferred stock, both $.001 par value respectively, to two billion (2,000,000,000) shares of shares of common stock and twenty million (20,000,000) shares of preferred stock, both $.001 par value respectively.

On October 12, 2015, the Company filed an amendment to its Articles of Incorporation and affected a 1-for-1,000 reverse stock split of its issued and outstanding shares of common stock, $0.001 par value, and effective November 19, 2015. The Financial Industry Regulatory Authority ("FINRA") declared the ex-dividend date for the dividend date as November 4, 2015 (the "2015 Reverse Split").

The holders of the Company's Common Stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the board of directors, in its discretion, from funds legally available there for and subject to prior dividend rights of holders of any shares of our Preferred Stock which may be outstanding and any contractual limitations. Upon the Company's liquidation, dissolution or winding up, subject to prior liquidation rights of the holders of our Preferred Stock, if any, the holders of our Common Stock are entitled to receive on a pro rata basis our remaining assets available for distribution. Holders of the Company's Common Stock have no preemptive or other subscription rights, and there are no conversion rights or redemption or sinking fund provisions with respect to such shares. All outstanding shares of the Company's Common Stock are, fully paid and not liable to further calls or assessment by the Company.

Preferred Stock

The Company is authorized to issue 20,000,000 shares of preferred stock, par value $0.001. The designations, rights, and preferences of such preferred stock are to be determined by the Board of Directors. Subsequently and prior to the 2015 "Reverse Split", 20,000,000 shares were designated as Series A Preferred Stock.

The Series A Preferred Stock collectively has voting rights equal to 25 votes on all matters presented to be voted by the holders of common stock per share of preferred stock and the right to convert to one share of common stock for each share of preferred stock. Northstar Biotechnology Group, LLC was issued, prior to the 2015 "Reverse Split" , an aggregate of 20,000,000 shares of Series A Preferred Stock which were converted to common stock pursuant to a Settlement Agreement dated March 1, 2017. As of the date of this report, no shares of preferred stock are issued and outstanding.

DIVIDENDS

Dividends, if any, will be contingent upon our revenues and earnings, if any, capital requirements and financial conditions. The payment of dividends, if any, will be within the discretion of our Board of Directors. We presently intend to retain all earnings, if any, for use in its business operations and accordingly, the Board of Directors does not anticipate declaring any dividends prior to a business combination.

INDEMNIFICATION OF DIRECTORS AND OFFICERS.

We are incorporated under the laws of the State of Florida. Our articles of incorporation require us to indemnify and limit the liability of directors to the fullest extent permitted by the Florida Business Corporation Act, or the "FBCA", as it currently exists or as it may be amended in the future.

Pursuant to the FBCA, a Florida corporation may indemnify any person who may be a party to any third party proceeding 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 entity, against liability incurred in connection with such proceeding (including any appeal thereof) if he or she acted in good faith and in a manner he or she 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 his or her conduct was unlawful.

In addition, in accordance with the FBCA, a Florida corporation is permitted to indemnify any person who may be a party to a derivative action if such person acted in any of the capacities set forth in the preceding paragraph, against expenses and amounts paid in settlement not exceeding, in the judgment of the board of directors, the estimated expenses of litigating the proceeding to conclusion, actually and reasonably incurred in connection with the defense or settlement of such proceeding (including appeals), provided that the person acted under the standards set forth in the preceding paragraph. However, no indemnification shall be made for any claim, issue, or matter for which such person is found to be liable unless, and only to the extent that, the court determines that, despite the adjudication of liability, but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnification for such expenses which the court deems proper.

Any indemnification made under the above provisions, unless pursuant to a court's determination, may be made only after a determination that the person to be indemnified has met the standard of conduct described above. This determination is to be made by a majority vote of a quorum consisting of the disinterested directors of the board of directors, by duly selected independent legal counsel, or by a majority vote of the disinterested shareholders. The board of directors also may designate a special committee of disinterested directors to make this determination. Notwithstanding the foregoing, a Florida corporation must indemnify any director, officer, employee or agent of a corporation who has been successful in the defense of any proceeding referred to above.

Generally, pursuant to the FBCA, a director of a Florida corporation is not personally liable for monetary damages to our company or any other person for any statement, vote, decision, or failure to act, regarding corporate management or policy, unless: (a) the director breached or failed to perform his duties as a director; and (b) the director's breach of, or failure to perform, those duties constitutes (i) a violation of criminal law, unless the director had reasonable cause to believe his conduct was lawful or had no reasonable cause to believe his conduct was unlawful, (ii) a transaction from which the director derived an improper personal benefit, either directly or indirectly, (iii) an approval of an unlawful distribution, (iv) with respect to a proceeding by or in the right of the company to procure a judgment in its favor or by or in the right of a shareholder, conscious disregard for the best interest of the company, or willful misconduct, or (v) with respect to a proceeding by or in the right of someone other than the company or a shareholder, recklessness or an act or omission which was committed in bad faith or with malicious purpose or in a manner exhibiting wanton and willful disregard of human rights, safety, or property. The term "recklessness," as used above, means the action, or omission to act, in conscious disregard of a risk: (a) known, or so obvious that it should have been known, to the directors; and (b) known to the director, or so obvious that it should have been known, to be so great as to make it highly probable that harm would follow from such action or omission.

Furthermore, under the FBCA, a Florida corporation is authorized to make any other further indemnification or advancement of expenses of any of its directors, officers, employees or agents under any bylaw, agreement, vote of shareholders or disinterested directors, or otherwise, both for actions taken in an official capacity and for actions taken in other capacities while holding such office. However, a corporation cannot indemnify or advance expenses if a judgment or other final adjudication establishes that the actions of the director, officer, employee, or agent were material to the adjudicated cause of action and the director, officer, employee, or agent (a) violated criminal law, unless the director, officer, employee, or agent had reasonable cause to believe his or her conduct was unlawful, (b) derived an improper personal benefit from a transaction, (c) was or is a director in a circumstance where the liability for unlawful distributions applies, or (d) engaged in willful misconduct or conscious disregard for the best interests of the corporation in a proceeding by or in right of the corporation to procure a judgment in its favor.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

We maintain a liability insurance policy, pursuant to which our directors and officers may be insured against liability they incur for serving in their capacities as directors and officers of our company, including liabilities arising under the Securities Act or otherwise.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed hereby in the Securities Act and we will be governed by the final adjudication of such issue.

Amendment of our Bylaws

Our bylaws may be adopted, amended or repealed by the affirmative vote of a majority of our outstanding shares. Subject to applicable law, our bylaws also may be adopted, amended or repealed by our Board of Directors.

Item 13. Certain Relationships and Related Transactions and Director Independence.

Certain Relationships and Related Party Transactions

Advances

As of December 31, 2021 and 2020, our officers and directors have provided net advances in the aggregate of $90,000 and $349,688, for working capital purposes, respectively. The advances are unsecured, due on demand and non-interest bearing.

Northstar Biotechnology Group, LLC-Preferred stock

On March 1, 2017, the Series A Preferred share were converted to common stock pursuant to a Settlement Agreement dated March 1, 2017. In addition, and separate and apart from the conversion, Northstar will receive Ten Million (10,000,000) shares of common stock. Northstar will receive ten percent (10%) of all Company international sales (based on a gross sales basis). Furthermore, a Northstar designee, Greg Knutson, was appointed to the Board of Directors of the Company (see Item 5.02The parties agreed to a mutual release and Northstar agreed to terminate any UCC lien on the Company assets previously filed for the benefit of Northstar.

Notes payable-related party

Northstar Biotechnology Group, LLC

On February 29, 2012, a promissory note issued to BlueCrest Master Fund Limited was assigned to Northstar Biotechnology Group, LLC (“Northstar”), owned partly by certain directors and existing shareholders of the Company at the time, including Dr. William P. Murphy Jr., Dr. Samuel Ahn and Charles Hart. At the date of the assignment, the principal amount of the BlueCrest note was $544,267 the (“Note”).

On March 30, 2012, the Company and Northstar agreed to extend until May 1, 2012 the initial payment date for any and all required monthly under the Note, such that the first of the four monthly payments required under the Note will be due and payable on May, 2012 and all subsequent payments will be due on a monthly basis thereafter commencing on June 1, 2012, and to waive any and all defaults and/or events of default under the Note with respect to such payments. The Company did not make the required payment, and as a result, was in default of the revised agreement. The Company renegotiated the terms of the Note and Northstar agreed to suspend the requirement of principal payments by the Company and allow payment of interest-only in common stock.

On September 21, 2012, the Company issued 5,000 common stock purchase warrants to Northstar that was treated as additional interest expense upon issuance.

On October 1, 2012, the Company and Northstar entered into a limited waiver and forbearance agreement providing a recapitalized new note balance comprised of all sums due Northstar with a maturity date extended perpetually. The Company agreed to issue 5,000,000 shares of Series A Convertible Preferred Stock and 10,000 shares of common stock in exchange for $210,000 as payment towards outstanding debt, default interest, penalties, professional fees outstanding and due Northstar. In addition, the Company executed a security agreement granting Northstar a lien on all patents, patent applications, trademarks, service marks, copyrights and intellectual property rights of any nature, as well as the results of all clinical trials, know-how for preparing Myoblasts, old and new clinical data, existing approved trials, all right and title to Myoblasts, clinical trial protocols and other property rights.

In addition, the Company granted Northstar a perpetual license on products as described for resale, relicensing, and commercialization outside the United States. In connection with the granted license, Northstar shall pay the Company a royalty of up to 8% on revenues generated.

Effective October 1, 2012, the effective interest rate was 12.85% per annum. The parties agreed, as of February 28, 2013, to reduce the interest rate to 7% per annum.

In connection with the consideration paid, Northstar waived, from the effective date through the earlier of termination or expiration of the agreement, satisfaction of the obligations as described in the forbearance agreement.

In 2012, 5,000,000 shares of Series A Convertible Preferred Stock were approved to be issued, which was subsequently increased to 20,000,000 shares of preferred stock as Series A Convertible Preferred Stock. In addition, the Company was obligated to issue additional preferred stock equal in lieu of payment of cash of accrued and unpaid interest on each six month anniversary of the effective date (October 1, 2012). In lieu of the initial two payments in preferred stock, the parties agreed to modify the voting rights of the subsequently cancelled Series A Convertible Preferred Stock from 20 votes per share on matters to be voted on by the common stock holders to 25 votes per share on matters to be voted on by the common stock holders and all prior and subsequent payments of interest will be in common stock. The Company is required to issue additional shares of its common stock (as amended), in lieu of cash, each six month anniversary of the effective date for any accrued and unpaid interest.

On March 1, 2017, Northstar and the Company entered into a settlement agreement ("Settlement Agreement") related to then pending litigation (See Note 10). Pursuant to the terms and conditions of the Settlement Agreement, Northstar converted its outstanding Series A Convertible preferred stock, into twenty million (20,000,000) shares of common stock according to the original conversion terms. In addition, and separate and apart from the conversion, Northstar received Eleven Million (11,000,000) shares of the Company's common stock. Northstar will receive ten percent (10%) of all Company international sales (based on a gross sales basis). There was no effect of the 10% obligation as there were no international sales in 2017 or, to date, in 2018 Furthermore, a Northstar designee, Greg Knutson, was appointed as a member of the Board of Directors of the Company and two Company directors, Michael Tomas and Kristin Comella, each exercised their prior Northstar options to each receive a Five percent (5%) Member Interest in Northstar. The parties agreed to a mutual release and Northstar agreed to terminate any UCC lien on the Company assets previously filed for the benefit of Northstar. On March 9, 2017 and April 1, 2017, the Company issued 30,000,000 and 1,000,000 shares of its common stock, respectively, as described above. In connection with the settlement, the Company recorded a loss on litigation settlement of $316,800.

On September 30, 2013, the Company issued 8,772 shares of its common stock as payment of $100,000 towards cash advances.

On December 24, 2013, the Company issued 3,916 shares of its common stock as payment of accrued interest through June 30, 2013 of $85,447.

On April 2, 2014, the Company issued 275 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,635 due April 1, 2014 per the forbearance agreement.

On September 17, 2014, the limited waiver and forbearance agreement entered into on October 1, 2012 to provide that the perpetual license on products as described for resale, relicensing and commercialization outside the United States was amended as such on the condition that Northstar provide certain financing, which financing the Company, in its sole discretion, could decline and retain the license.

On October 3, 2014, the Company issued 515 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,705 due October 1, 2014 per the forbearance agreement.

On April 3, 2015, the Company issued 1,363 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,635 due April 1, 2015 per the forbearance agreement.

On October 2, 2015, the Company issued 4,156 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,705 due October 1, 2015 per the forbearance agreement.

On October 7, 2015, the Company issued 34,522 shares of its common stock in settlement of $100,000 principal payment towards the outstanding debt.

On April 7, 2016, the Company issued 57,778 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,705 due April 1, 2016 per the forbearance agreement.

On October 6, 2016, the Company issued 848,490 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,705 due October 1, 2016 per the forbearance agreement.

On April 1, 2017, the Company issued 286,315 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,703 due October 1, 2016 per the forbearance agreement.

On October 2, 2017, the Company issued 559,187 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,705 due October 1, 2016 per the forbearance agreement.

On October 19, 2018, the Company issued 164,523 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $9,195 due October 1, 2016 per the forbearance agreement.

On April 1, 2019, the Company issued 379,141 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $9,145.

On October 2, 2019, the Company issued 1,692,353 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $9,195.

On April 1, 2020, the Company issued 1,445,647 shares of its common stock, having a fair value of $11,565, in lieu of payment in cash of accrued and unpaid interest of $9,145, resulting in a loss on settlement of $2,420.

On October 1, 2020, the Company issued 2,035,820 shares of its common stock, having a fair value of $10,179, in lieu of payment in cash of accrued and unpaid interest of $9,195, resulting in a loss on settlement of $984.

As of December 31, 2021 and 2020, the remaining carrying value of the note was $262,000. At December 31, 2021 and 2020, accrued interest on the note was $8,751 and $8,751, respectively, and is included in accrued expenses on the accompanying balance sheet.

Officer and Director Notes

	2021	2020
Note payable, Mr. Tomas	161,786	161,786
Note payable, Mr. Tomas	500,000	500,000
Note payable, Mr. Tomas	500,000	500,000
Note payable, Mr. Tomas	178,077	178,077
Note payable, Mr. Tomas	187,500	187,500
Note payable, Mr. Tomas	187,500	187,500
Note payable, Mr. Tomas	500,000	500,000
Note payable, Mr. Tomas	100,962	100,962
Note payable, Mr. Tomas	143,653	143,654
Note payable, Mr. Tomas	90,990	
Note payable, Mr. Tomas	43,270	
Note payable, Mr. Tomas	187,500	
Note payable, Mr. Tomas	100,931	
Total	$ 3,144,201	$ 2,459,479

* Kristin Comella ceased to be a member of the Board of Director or an officer as of September 1, 2019.

Notes payable, Mr. Tomas

On August 7, 2017, the Company issued a $500,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due one year from date of issuance. During the year ended December 31, 2021 and 2020, the Company paid principal of $0 and $0, respectively, of this note. As of December 31, 2021 and 2020, the remaining carrying value of the note was $161,786.

On May 7, 2018, the Company issued a $500,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due six months from date of issuance. As of December 31, 2021 and 2020, the remaining carrying value of the note was $500,000.

On July 1, 2019, the Company issued a $500,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due November 7, 2019. As of December 31, 2021 and 2020, the remaining carrying value of the note was $500,000.

On December 31, 2019, the Company issued a $178,077 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021 and 2020, the remaining carrying value of the note was $178,077.

On March 31, 2020, the Company issued a $187,500 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021, the remaining carrying value of the note was $187,500.

On June 30, 2020, the Company issued a $187,500 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021, the remaining carrying value of the note was $187,500.

On July 1, 2020, the Company issued a $500,000 promissory note as payment of an annual bonus awarded. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021, the remaining carrying value of the note was $500,000.

On September 30, 2020, the Company issued a $100,962 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021, the remaining carrying value of the note was $100,962.

On December 31, 2020, the Company issued a $143,654 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021, the remaining carrying value of the note was $143,654.

On March 31, 2021 the Company issued a $90,991 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021, the remaining carrying value of the note was $90,991.

On June 30 2021 the Company issued a $43,270 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021, the remaining carrying value of the note was $43,270.

On September 30 2021 the Company issued a $187,500 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021, the remaining carrying value of the note was $187,500.

At December 31, 2021 and 2020, accrued interest on the notes was $612,323 and $482,468, respectively, and is included in accrued expenses on the accompanying balance sheet.

Item 14. Principal Accounting Fees and Services. Independent Registered Public Accounting Firm Fees

Aggregate fees billed to us for the fiscal years ended December 31, 2021 and 2020 by our independent registered public accounting firms are as follows:

Types of Fees	2021	2020
Audit Fees (1)	$ 80,000	$ 130,000
Audit Related Fees	$ —	$ —
Tax Fees		$ 0
All Other Fees	—	—

(1) This category also includes advice on audit and accounting matters that arose during, or as a result of, the audit of the annual financial statements or the reviews of the interim financial statements.

Audit Committee Pre-Approval Policy

Consistent with policies of the SEC regarding auditor independence, the Audit Committee has responsibility for the appointment, compensation and oversight of the work of the independent auditor. As part of this responsibility, the Audit Committee has adopted, and our Board has ratified, an Audit and Non-Audit Services Pre-Approval Policy pursuant to which the Audit Committee is required to pre-approve the audit and non-audit services performed by our independent registered public accounting firm in order to assure that these services do not impair the auditor's independence from us.

Prior to engagement of the independent auditor for the next year's audit, the independent auditor and the Audit Committee will review a list of services and related fees expected to be rendered during that year within each of four categories of services to the Audit Committee for approval:

(i) Audit Services: Audit services include the annual financial statement audit (including required quarterly reviews), equity investment audits and other procedures required to be performed by the independent auditor to be able to form an opinion on our financial statements. Audit Services also include information systems and procedural reviews and testing performed in order to understand and place reliance on the systems of internal control, and consultations relating to the audit or quarterly review as well as the attestation engagement for the independent auditor's report on management's report on internal controls for financial reporting.

(ii) Audit-Related Services: Audit-related services are assurance and related services that are reasonably related to the performance of the audit or review of our financial statements, including due diligence related to potential business acquisitions/dispositions, accounting consultations related to accounting, financial reporting or disclosure matters not classified as "Audit Services," assistance with understanding and implementing new accounting and financial reporting guidance from rulemaking authorities, financial audits of employee benefit plans, agreed-upon or expanded audit procedures related to accounting and/or billing records required to respond to or comply with financial, accounting or regulatory reporting matters and assistance with internal control reporting requirements.

(iii) Tax Services: Tax services include services such as tax compliance, tax planning and tax advice; however, the Audit Committee will not permit the retention of the independent registered public accounting firm in connection with a transaction initially recommended by the independent registered public accounting firm, the sole business purpose of which may be tax avoidance and treatment which may not be supported in the Internal Revenue Code and related regulations.

(iv) All Other Services: All other services are those permissible non-audit services that the Audit Committee believes are routine and recurring and would not impair the independence of the auditor and are consistent with the SEC's rules on auditor independence.

Prior to engagement, the Audit Committee pre-approves the services and fees of the independent auditor within each of the above categories. During the year, it may become necessary to engage the independent auditor for additional services not previously contemplated as part of the engagement. In those instances, the Audit and Non-Audit Services Pre-Approval Policy requires that the Audit Committee specifically approve the services prior to the independent auditor's commencement of those additional services. Under the Audit and Non-Audit Services Pre-Approval Policy, the Audit Committee may delegate the ability to pre-approve audit and non-audit services to one or more of its members provided the delegate reports any pre-approval decision to the Audit Committee at its next scheduled meeting. As of the date hereof, the Audit Committee has not delegated its ability to pre-approve audit.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

See Item 8. "Financial Statements and Supplementary Data" for Financial Statements included with this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules

All schedules have been omitted because the required information is not applicable or the information is included in the financial statements or the notes thereto.

(a)(3) Exhibits

Exhibit No.	Exhibit Description
2.1(20)	Asset Sale and Lease Agreement between U.S. Stem Cell, Inc. and GACP Stem Cell Bank LLC., dated March 3, 2017.
2.2(20)	Asset Purchase Agreement between U.S. Stem Cell, Inc. and GACP Stem Cell Bank LLC., dated March 3, 2017.
2.3(20)	Customer Purchase Agreement between U.S. Stem Cell, Inc. and GACP Stem Cell Bank LLC., dated March 3, 2017.
3.1 (1)	Articles of Incorporation
3.2(5)	Amended and Restated Articles of Incorporation
3.3(8)	Articles of Amendment to the Articles of Incorporation
3.4(17)	Articles of Amendment to the Articles of Incorporation
3.5 (7)	Amended and Restated Bylaws
3.6(19)	Amendment to Bylaws
4.1(4)	Loan and Security Agreement, dated as of May 31, 2007 by and between BlueCrest Capital Finance, L.P. and the Registrant
4.2(9)	Amendment to Loan and Security Agreement, between the Company and BlueCrest Venture Finance Master Fund Limited, dated as of April 2, 2009
4.3(9)	Grant of Security Interest (Patents), between the Company and BlueCrest Venture Finance Master Fund Limited, dated as of April 2, 2009
4.4(9)	Security Agreement (Intellectual Property), between the Company and BlueCrest Venture Finance Master Fund Limited, dated as of April 2, 2009
4.5(9)	Subordination Agreement, by Hunton & Williams, LLP in favor of BlueCrest Venture Finance Master Fund Limited, entered into and effective April 2, 2009
4.6(9)	Amended and Restated Promissory Note, dated April 2, 2009, by the Company to BlueCrest Venture Finance Master Fund Limited
4.7(9)	Warrant to purchase shares of the Registrant's common stock, dated April 2, 2009, issued to BlueCrest Venture Finance Master Fund Limited
4.8(10)	Warrant to purchase shares of the Registrant's common stock, dated April 2, 2009, issued to Rogers Telecommunications Limited
4.9(10)	Warrant to purchase shares of the Registrant's common stock, dated April 2, 2009, issued to Hunton & Williams, LLP
4.10 (15)	Series A Convertible Preferred Stock
10.1(1)	Lease Agreement between the Registrant and Sawgrass Business Plaza, LLC, as amended, dated November 14, 2006.
10.2(3)	Loan Guarantee, Payment and Security Agreement, dated as of June 1, 2007, by and between the Registrant, Howard J. Leonhardt and Brenda Leonhardt
10.3(3)	Loan Guarantee, Payment and Security Agreement, dated as of June 1, 2007, by and between the Registrant and William P. Murphy Jr., M.D.
10.4(3)	Loan Agreement, dated as of June 1, 2007, by and between the Registrant and Bank of America, N.A.
10.5(5)	Loan Guarantee, Payment and Security Agreement, dated as of September 12, 2007, by and between the Registrant and Samuel S. Ahn, M.D.
10.6(5)	Loan Guarantee, Payment and Security Agreement, dated as of September 12, 2007, by and between the Registrant and Dan Marino
10.7(5)	Loan Guarantee, Payment and Security Agreement, dated as of September 19, 2007, by and between the Registrant and Jason Taylor
10.8(6)	Loan Guarantee, Payment and Security Agreement, dated as of October 10, 2007, by and between the Registrant and Howard and Brenda Leonhardt
10.9(6)	Second Amendment to Loan Guarantee, Payment and Security Agreement, dated as of October 10, 2007, by and between the Registrant and Howard and Brenda Leonhardt

10.10(6)	Second Amendment to Loan Guarantee, Payment and Security Agreement, dated as of October 10, 2007, by and between the Registrant and William P. Murphy, Jr., M.D.
10.11(11)	Loan Agreement with Seaside National Bank and Trust, dated October 25, 2010.
10.12(11)	Promissory Note with Seaside National Bank and Trust, dated October 25, 2010.
10.13(11)	Amended and Restated Loan and Security Agreement with BlueCrest Venture Finance Master Fund Limited, dated October 25, 2010.
10.14(12)	Unsecured Convertible Promissory Note for $25,000, with Magna Group, LLC, dated January 3, 2011.
10.15(12)	Promissory Note for $139,728.82 with Magna Group, LLC, dated January 3, 2011.
10.16(13)	Unsecured Convertible Promissory Note for $34,750, with Magna Group, LLC, dated May 16, 2011.
10.17(13)	Promissory Note for $139,728.82 with Magna Group, LLC, dated May 16, 2011.
10.18**(14)	2013 U.S. Stem Cell, Inc. Omnibus Equity Compensation Plan
10.19(16)	Senior Convertible Note with Magna Equities II, LLC, dated October 1, 2015
10.20(16)	Securities Purchase Agreement, dated as of October 1, 2015, by and between Magna Equities II, LLC and U.S. Stem Cell, Inc.
10.21(16)	Registration Rights Agreement, dated as of October 1, 2015, by and between Magna Holdings I, LLC and U.S. Stem Cell, Inc.
10.22(18)	Senior Convertible Note Magna Equities II, LLC, dated December 3, 2015
10.23(18)	Amended and Restated Senior Convertible Note, dated December 3, 2015.
10.24(18)	Securities Purchase Agreement, dated as of December 3, 2015, by and between Magna Equities II, LLC and U.S. Stem Cell, Inc.
10.25(18)	Registration Rights Agreement, dated as of December 3, 2015, by and between Magna Holdings I, LLC and U.S. Stem Cell, Inc.
10.26(20)	Non-Competition and Non-Solicitation Agreement between U.S. Stem Cell, Inc. and GACP Stem Cell Bank LLC., dated March 3, 2017.
10.27(21)	First Amendment to Lease Agreement between the Registrant and Sawgrass Business Plaza, LLC, as amended, dated November 17, 2017
14.1(2)	Code of Business Conduct and Ethics
21.0*	Subsidiary List
31.1*	Certification of Chief Executive Officer and Chief Financial Officer (Principal Accounting Officer) pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer (Principal Accounting Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101 INS	Inline XBRL Instance Document
101 SCH	Inline XBRL Taxonomy Extension Schema Document
101 CAL	Inline XBRL Taxonomy Calculation Linkbase Document
101 DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101 LAB	Inline XBRL Taxonomy Labels Linkbase Document
101 PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

*	Filed herewith
**	Indicates management contract or compensatory plan.
(1)	Incorporated by reference to the Company's Form S-1 filed with the Securities and Exchange Commission (the "SEC") on February 13, 2007.
(2)	Incorporated by reference to Amendment No. 1 to the Company's Form S-1 filed with the SEC on June 5, 2007.
(3)	Incorporated by reference to Amendment No. 3 to the Company's Form S-1 filed with the SEC on August 9, 2007.
(4)	Incorporated by reference to Amendment No. 4 to the Company's Form S-1 filed with the SEC on September 6, 2007.
(5)	Incorporated by reference to Amendment No. 5 to the Company's Form S-1 filed with the SEC on October 1, 2007.
(6)	Incorporated by reference to Post-effective Amendment No. 1 to the Company's Form S-1 filed with the SEC on October 11, 2007.
(7)	Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on July 3, 2008.
(8)	Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on August 8, 2008.
(9)	Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on April 8, 2009.
(10)	Incorporated by reference to the Company's Annual Report on Form 10-K filed with the SEC on April 15, 2009.
(11)	Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on October 29, 2010.
(12)	Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on January 12, 2011.
(13)	Incorporated by reference to the Company Current Report on Form 8-K filed with the SEC on May 25, 2011.
(14)	Incorporated by reference to the Company Quarterly Report on Form 10-Q filed with the SEC on May 9, 2013.
(15)	Incorporated by reference to the Company's Definitive Proxy Statement on Schedule 14A filed with the SEC on April 28, 2014.
(16)	Incorporated by reference to the Company Current Report on Form 8-K filed with the SEC on October 2, 2015.
(17)	Incorporated by reference to the Company Current Report on Form 8-K filed with the SEC on November 4, 2015.
(18)	Incorporated by reference to the Company Current Report on Form 8-K filed with the SEC on December 4, 2015.
(19)	Incorporated by reference to the text of the Company Current Report on Form 8-K filed with the SEC on August 3, 2016.
(20)	Incorporated by reference to the Company Current Report on Form 8-K filed with the SEC on March 8, 2017.
(21)	Incorporated by reference to the Company Annual Report on Form 10-K filed with the SEC on April 16, 2018.

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.

U.S. STEM CELL, INC.

By: /s/ Mike Tomas
Mike Tomas
Chief Executive Officer & President

March 31, 2022

By: /s/ Mike Tomas
Mike Tomas
Chief Financial Officer (Principal Accounting Officer)

March 31, 2022

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.

Each person whose signature appears below, hereby authorizes Mike Tomas, as attorney in fact to sign on his or her behalf, individually, in each capacity stated below, and to file all amendments or supplements to this annual report on Form 10-K.

SIGNATURE	TITLE	DATE
/s/ Mark P. Borman Mark P. Borman	Director, Chairman of the Board	March 31, 2022
/s/ William P. Murphy Jr., MD William P. Murphy Jr., MD	Director, Chairman Emeritus	March 31, 2022
/s/ Mike Tomas Mike Tomas	Chief Executive Officer, Chief Financial Officer, & Director	March 31, 2022
/s/ Sheldon Anderson Sheldon Anderson	Director	March 31, 2022
/s/ Greg Knutson Greg Knutson	Director	March 31, 2022

FORM 10-K—ITEM 8

U.S. STEM CELL, INC.

TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of U.S Stem Cell, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of U.S Stem Cell, Inc. (the Company) as of December 31, 2021 and 2020, and the related statements of operations, stockholders' deficit, and cash flow for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations, generated negative cash flows from operating activities, will require additional capital to fund its current operating plan, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there were no critical audit matters.

/s/ RBSM LLP

We have served as the Company's auditor since 2018.

PCAOB ID 587
New York, NY
March 31, 2022

U.S. STEM CELL, INC.
BALANCE SHEETS

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,393	$ 18,570
Accounts receivable, net of allowance of $75,000 and $13,203, respectively	1,213	54,164
Inventories	393	5,418
Prepaid expenses and other current assets	10,000	10,000
Total current assets	50,999	88,152
Total assets	$ 50,999	$ 88,152
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,373,413	$ 1,282,010
Accrued expenses	1,951,390	1,511,281
Advances - related parties	951,432	861,432
Deferred revenue, current portion	3,000	3,000
Deposits	465,286	465,286
Notes payable - related parties	3,144,200	2,721,478
Notes payable, current portion, net of debt discount of $10,052 and $9,610, respectively	2,557,881	2,562,149
Promissory note payable	1,397,762	1,397,762
Convertible notes payable, net of debt discount of $241,589 and $1,874, respectively	194,411	43,126
Total current liabilities	12,038,775	10,847,524
Long-term liabilities:		
Deferred revenue	56,500	59,500
Notes payable, net of debt discount of $21,575 and $31,627, respectively	722,060	760,420
Total long-term liabilities	778,560	819,920
Total liabilities	12,817,335	11,667,444
Commitments and contingencies (See Note 12)		
Stockholders' deficit:		
Preferred stock, par value $0.001; 20,000,000 shares authorized, -0- issued and outstanding	-	-
Common stock, par value $0.001; 2,000,000,000 shares authorized, 503,525,051 and 435,560,794 shares issued and outstanding, respectively	503,525	435,561
Additional paid-in capital	126,532,063	124,499,655
Accumulated deficit	(139,801,924)	(136,514,508)
Total stockholders' deficit	(12,766,336)	(11,579,292)
Total liabilities and stockholders' deficit	$ 50,999	$ 88,152

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

U.S. STEM CELL, INC.
STATEMENTS OF OPERATIONS

	For the Year Ended December 31, 2021	2020
Revenue:		
Products	$ 180,894	$ 209,696
Services	19,855	67,391
Total revenue	200,749	277,087
Cost of sales	52,030	64,117
Gross profit	148,719	212,970
Operating expenses:		
Selling, general and administrative	2,284,577	2,613,211
Total operating expenses	2,284,577	2,613,211
Loss from operations	(2,135,858)	(2,400,241)
Other income (expense):		
Gain (loss) on settlement of accounts payable and accrued interest, net	(151,410)	182
Gain on sale of equipment	-	21,474
Income (loss) from equity investments	-	(23,539)
Interest expense	(1,000,148)	(488,369)
Total other income (expense)	(1,151,558)	(490,252)
Net loss before income taxes	(3,287,416)	(2,890,493)
Income taxes (benefit)	-	-
NET LOSS	$ (3,287,416)	$ (2,890,493)
Net loss per common share, basic and diluted	$ (0.01)	$ (0.01)
Weighted average number of common shares outstanding, basic and diluted	460,794,491	429,291,011

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

U.S. STEM CELL, INC.
STATEMENT OF STOCKHOLDERS' DEFICIT
FOR THE TWO YEARS ENDED DECEMBER 31, 2021

	Preferred Stock		Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance, December 31, 2019	-	$ -	417,724,767	$ 417,725	$ 123,726,894	$ (133,624,015)	$ (9,479,396)
Common stock issued in settlement of accounts payable	-	-	10,354,560	10,355	41,559	-	51,914
Common stock issued in lieu of interest	-	-	3,481,467	3,481	18,263	-	21,744
Common stock issued for services	-	-	4,000,000	4,000	12,000	-	16,000
Beneficial conversion feature recognized on convertible note	-	-	-	-	15,000	-	15,000
Stock-based compensation	-	-	-	-	685,939	-	685,939
Net loss	-	-	-	-	-	(2,890,493)	(2,890,493)
Balance, December 31, 2020	-	-	435,560,794	435,561	124,499,655	(136,514,508)	(11,579,292)
Common stock issued in settlement of accounts payable	-	-	6,642,197	6,642	225,100	-	231,742
Common stock issued in lieu of interest	-	-	930,916	931	18,869	-	19,800
Common stock issued for services	-	-	4,000,000	4,000	124,000	-	128,000
Beneficial conversion feature recognized on convertible notes	-	-	-	-	641,688	-	641,688
Common stock issued for cash	-	-	27,500,000	27,500	247,500	-	275,000
Common shares issued upon conversion of convertible notes and accrued interest	-	-	28,891,144	28,891	346,695	-	375,586
Stock-based compensation	-	-	-	-	428,556	-	428,556
Net loss	-	-	-	-	-	(3,287,416)	(3,287,416)
Balance, December 31, 2021	-	$ -	503,525,051	$ 503,525	$ 126,532,063	$ (139,801,924)	$ (12,766,336)

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

U.S. STEM CELL, INC.
STATEMENTS OF CASH FLOWS

	For the Year Ended December 31, 2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,287,416)	$ (2,890,493)
Adjustments to reconcile net loss to net cash used in operating activities:		
Bad debt (recoveries)	93,241	-
Interest and amortization of debt discount	977,386	447,380
Loss (gain) on settlement of accounts payable and accrued interest	151,410	(182)
Gain on sale of equipment	-	(21,474)
Related party notes payable issued for services rendered	422,722	1,119,615
Loss on equity investments	-	23,539
Stock-based compensation	556,556	701,939
Changes in operating assets and liabilities:		
Accounts receivable	(40,290)	(5,956)
Inventories	5,025	2,678
Accounts payable	73,195	149,521
Accrued expenses	(6,768)	18,347
Deferred revenue	(3,000)	(23,800)
Net cash used in operating activities	(1,057,939)	(478,886)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from (repayments to) overdraft protection	-	(1,520)
Proceeds from sale of common shares	275,000	-
Proceeds from related party advances	90,000	349,688
Proceeds from notes payable	-	150,000
Repayments of notes payable	(52,238)	(45,712)
Proceeds from convertible note payable	766,000	45,000
Net cash provided by financing activities	1,078,762	497,456
Net increase in cash and cash equivalents	20,823	18,570
Cash and cash equivalents, beginning of period	18,570	-
Cash and cash equivalents, end of period	$ 39,393	$ 18,570
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	$ 22,762	$ 40,989
Income taxes paid	$ -	$ -
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Common shares issued in settlement of accounts payable	$ 231,742	$ 51,914
Common shares issued in lieu of interest	$ 19,800	$ 21,744
Beneficial conversion feature recognized on convertible note	$ 641,688	$ 15,000
Common shares issued upon conversion of convertible notes and accrued interest	$ 375,586	$ -

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

U.S. STEM CELL, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2021 AND 2020

NOTE 1 — NATURE OF OPERATIONS

U.S. Stem Cell, Inc. was incorporated under the laws of the State of Florida in August 1999. The Company is in the cardiovascular sector of the cell technology industry delivering cell therapies and biologics that help address congestive heart failure, lower limb ischemia, chronic heart ischemia, acute myocardial infarctions and other issues. The business includes the development of proprietary cell therapy products as well as revenue generating physician and patient-based regenerative medicine/cell therapy training services, cell collection and cell storage services, the sale of cell collection and treatment kits for humans and animals, and the operation of cell therapy clinics. To date, the Company has not generated significant revenues in that they remain less than their total operating expenses, has incurred expenses, and has sustained losses. Consequently, its operations are subject to all the risks inherent in the establishment of a research and development business enterprise.

NOTE 2 – GOING CONCERN AND MANAGEMENT'S LIQUIDITY PLANS

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

As shown in the accompanying financial statements, as of December 31, 2021, the Company had cash on hand of $39,393 and a working capital deficit (current liabilities in excess of current assets) of $11,987,776. During the year ended December 31, 2021, the net loss was $3,287,416 and net cash used in operating activities was $1,057,939. These conditions raise substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the financial statements.

The Company's primary source of operating funds has been from revenue generated from sales with additional cash proceeds from the sale of common stock and the issuances of promissory notes and other debt. The Company has experienced net losses from operations since inception, but it expects these conditions to improve in the future as it develops its business model. The Company had a stockholders' deficit at December 31, 2021 and requires additional financing to fund future operations.

The Company's existence is dependent upon management's ability to develop profitable operations and to obtain additional funding sources. There can be no assurance that the Company's financing efforts will result in profitable operations or the resolution of the Company's liquidity problems. The accompanying statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

NOTE 3 – SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include stock-based compensation, debt discounts and the valuation allowance related to deferred tax assets. Actual results may differ from these estimates.

Fair Value

Accounting Standards Codification subtopic 825-10, Financial Instruments ("ASC 825-10") requires disclosure of the fair value of certain financial instruments. The carrying value of cash and cash equivalents, accounts payable, accrued liabilities, and short-term borrowings, as reflected in the balance sheets, approximate fair value because of the short-term maturity of these instruments. All other significant financial assets, financial liabilities and equity instruments of the Company are either recognized or disclosed in the financial statements together with other information relevant for making a reasonable assessment of future cash flows, interest rate risk and credit risk. Where practicable the fair values of financial assets and financial liabilities have been determined and disclosed; otherwise only available information pertinent to fair value has been disclosed.

The Company follows Accounting Standards Codification subtopic 820-10, Fair Value Measurements and Disclosures ("ASC 820-10") and Accounting Standards Codification subtopic 825-10, Financial Instruments ("ASC 825-10"), which permits entities to choose to measure many financial instruments and certain other items at fair value.

U.S. STEM CELL, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2021 AND 2020

Cash

The Company considers cash to consist of cash on hand and temporary investments having an original maturity of 90 days or less that are readily convertible into cash.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are non-interest bearing and are stated at gross invoice amounts less an allowance for doubtful accounts. Credit is extended to customers based on an evaluation of their financial condition, industry reputation, and other judgmental factors considered by the Company's management. The Company generally does not require collateral or other security interest to support accounts receivable. Based on trends and specific factors, the customer's credit terms may be modified, including required payment upon delivery.

The Company performs regular on-going credit evaluations of its customers as deemed relevant. As events, trends, and circumstance warrant, the Company's management estimates the amounts that are more likely than not to be uncollectible. These amounts are recognized as bad debt expense and are reflected within selling, general, administrative and other expenses on the Company's accompanying statements of operations.

Any charges to the allowance for doubtful accounts on accounts receivable are charged to operations in amounts sufficient to maintain the allowance for uncollectible accounts at a level management believes is adequate to cover any probable losses. Management determines the adequacy of the allowance based on historical write-off percentages and the current status of accounts receivable. Accounts receivable are charged off against the allowance when collectability is determined to be permanently impaired. As of December 31, 2021 and 2020, the allowance for doubtful accounts was $75,000 and $13,203, respectively.

Inventories

Inventories are stated at the lower of cost or market with cost being determined on a first-in, first-out (FIFO) basis. The Company writes down its inventory for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. During the periods presented, there were no inventory write-downs.

Investments

The Company follows Accounting Standards Codification subtopic 323-10, Investments-Equity Methods and Joint Ventures ("ASC 323-10") which requires the accounting for investments where the Company can exert significant influence, but not control of a joint venture or equity investment. The Company accounted for its 49.9% member interest ownership of U.S. Stem Cell Clinic, LLC and its 49% member interest ownership of U.S. Stem Cell Clinic of the Villages utilizing the equity method of accounting (See Note 5).

Property and Equipment

Property and equipment are stated at cost. When retired or otherwise disposed, the related carrying value and accumulated depreciation are removed from the respective accounts and the net difference less any amount realized from disposition, is reflected in earnings. For financial statement purposes, property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives of 3 to 15 years.

Long-Lived Assets

The Company follows FASB ASC 360-10-15-3, "Impairment or Disposal of Long-lived Assets." Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. Long-lived assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell. The Company determined that there was no impairment on its long-lived assets during the period presented.

U.S. STEM CELL, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2021 AND 2020

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification Topic 606 "Revenue from Contracts with Customers" ("ASC 606"). ASC 606 is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.
The Company's primary sources of revenue are from the sale of test kits and equipment, training services, patient treatments, laboratory services and cell banking.

Revenues for kits and equipment sold are not recorded until kits and equipment are received by the customer. Revenues from in-person trainings are recognized when the training occurs and revenues from on demand online trainings are recognized when the customer purchases the rights to the training course. Any cash received as a deposit for trainings are recorded by the Company as a liability.

Patient treatments and laboratory services revenue are recognized when those services have been completed or satisfied.

Revenues for cell banking are accounted for as multiple performance obligations as described in ASC 606 and addresses accounting for arrangements that may involve the delivery or performance of multiple products, services and/or rights to use assets. Because the Company sells its services separately, on more than a limited basis and at a price within a narrow range, the Company was able to allocate revenue based on stand-alone pricing. The multiple performance obligations include stem cell banking, dose retrieval and yearly storage fees. Revenues for stem cell banking and dose retrieval is recognized at the point of service and revenues for the yearly storage fees is recognized over the term of the banking contract, which is typically one year with annual renewals.

At December 31, 2021 and 2020, the Company had deferred revenues of $59,500 and $62,500, respectively, all of which relates to the Intellectual Property Licensing Agreement.

Research and Development

The Company accounts for research and development costs in accordance with Accounting Standards Codification subtopic 730-10, Research and Development ("ASC 730-10"). Under ASC 730-10, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred. Third-party research and development costs are expensed when the contracted work has been performed or as milestone results have been achieved as defined under the applicable agreement. Company-sponsored research and development costs related to both present and future products are expensed in the period incurred. The Company incurred research and development expenses of $0 for the year ended December 31, 2021 and 2020.

Stock-Based Compensation

Stock-based compensation expense is measured at the grant date fair value of the award and is expensed over the requisite service period. For stock-based awards to employees, non-employees and directors, the Company calculates the fair value of the award on the date of grant using the Black-Scholes option pricing model. Determining the fair value of stock-based awards at the grant date under this model requires judgment, including estimating volatility, employee stock option exercise behaviors and forfeiture rates. The assumptions used in calculating the fair value of stock-based awards represent the Company's best estimates, but these estimates involve inherent uncertainties and the application of management's judgment.

Income Taxes

The Company follows Accounting Standards Codification subtopic 740-10, Income Taxes ("ASC 740-10") for recording the provision for income taxes. Deferred tax assets and liabilities are computed based upon the difference between the financial statement and income tax basis of assets and liabilities using the enacted marginal tax rate applicable when the related asset or liability is expected to be realized or settled. Deferred income tax expenses or benefits are based on the changes in the asset or liability during each period. If available evidence suggests that it is more likely than not that some portion or all of the deferred tax assets will not be realized, a valuation allowance is required to reduce the deferred tax assets to the amount that is more likely than not to be realized. Future changes in such valuation allowance are included in the provision for deferred income taxes in the period of change. Deferred income taxes may arise from temporary differences resulting from income and expense items reported for financial accounting and tax purposes in different periods.

Deferred taxes are classified as current or non-current, depending on the classification of assets and liabilities to which they relate. Deferred taxes arising from temporary differences that are not related to an asset or liability are classified as current or non-current depending on the periods in which the temporary differences are expected to reverse and are considered immaterial.

Net Loss per Common Share

The Company computes earnings (loss) per share under Accounting Standards Codification subtopic 260-10, Earnings Per Share ("ASC 260-10"). Net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the year. Diluted earnings per share, if presented, would include the dilution that would occur upon the exercise or conversion of all potentially dilutive securities into common stock using the "treasury stock" and/or "if converted" methods as applicable.

The computation of basic and diluted income (loss) per share as of December 31, 2021 and 2020 excludes potentially dilutive securities when their inclusion would be anti-dilutive, or if their exercise prices were greater than the average market price of the common stock during the period.

Potentially dilutive securities excluded from the computation of basic and diluted net loss per share are as follows:

	December 31,	
	2021	**2020**
Options	110,643,884	111,119,914
Warrants	1,103,127	1,110,468
Convertible notes	17,876,880	7,309,676
Total potentially dilutive shares	129,623,891	119,540,058

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, which simplifies the guidance on accounting for convertible debt instruments by removing the separation models for: (1) convertible debt with a cash conversion feature; and (2) convertible instruments with a beneficial conversion feature. As a result, the Company will not separately present in equity an embedded conversion feature in such debt. Instead, we will account for a convertible debt instrument wholly as debt, unless certain other conditions are met. We expect the elimination of these models will reduce reported interest expense and increase reported net income for the Company's convertible instruments falling under the scope of those models before the adoption of ASU 2020-06. Also, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share and the treasury stock method will be no longer available. The provisions of ASU 2020-06 are applicable for fiscal years beginning after December 15, 2021, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact of ASU 2020-06 on its financial statements.

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments", which significantly changes how entities will measure credit losses for most financial assets, including accounts receivable. ASU No. 2016-13 will replace today's "incurred loss" approach with an "expected loss" model, under which companies will recognize allowances based on expected rather than incurred losses. On November 15, 2019, the FASB delayed the effective date of Topic 326 for certain small public companies and other private companies until fiscal years beginning after December 15, 2022 for SEC filers that are eligible to be smaller reporting companies under the SEC's definition, as well as private companies and not-for-profit entities. The Company does not expect the new guidance will have a material impact on its financial statements.

There are various other updates recently issued, most of which represented technical corrections to the accounting literature or application to specific industries and are not expected to a have a material impact on the Company's financial position, results of operations or cash flows.

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NOTE 4 — PROPERTY AND EQUIPMENT

Property and equipment as of December 31, 2021 and 2020 is summarized as follows:

	December 31,	
	2021	2020
Furniture, fixtures and equipment	$ 5,598	$ 5,598
Computer equipment	1,809	1,809
Property and equipment, cost	7,407	7,407
Less: accumulated depreciation and amortization	(7,407)	(7,407)
Property and equipment, net	$ -	$ -

As a consequence of the Court Order (see Note 12 "Government Claim"), the Company resolved to divest itself of certain equipment and other assets (the "Equipment Assets") used in connection with the Company's human tissue banking business, but consistent however with the requirements of the Court Order, and to adjust the business plan and operations to accommodate this potential divesture. To facilitate the above, the Company entered into a Termination and Release Agreement and a Letter Agreement intended to divest itself of certain equipment and other assets underlying the related equipment lease transaction. In addition, on October 24, 2019, the Company entered into an Assignment and Assumption of Lease by and between the Company, American Cell Technology, LLC, and Sawgrass Business Plaza, LLC. Subsequently, the Company relocated to a new location within the same city and entered into a month-to-month lease. As part of the termination of the operating lease, the Company left certain property and equipment (all of which had been fully depreciated) at the old location.

In connection with the sale of the lab, medical and other equipment, the Company realized a gain on sale of equipment of $386,535. The gain is recognized ratably over the term of the lease to operations. During the year ended December 31, 2021 and 2020, the Company recognized $0 and $21,474, as the gain on sale of equipment, respectively. As of December 31, 2021 and 2020, deferred gain on sale of equipment was $0.

Depreciation expense was $0 for the year ended December 31, 2021 and 2020.

NOTE 5 — INVESTMENTS

During March 2021, we divested ourselves of our Member Interest in U.S. Stem Cell Clinic, LLC, while US Stem Cell Clinic of the Villages, LLC is currently dormant.

U.S. Stem Cell Clinic, LLC

The investment in U.S. Stem Cell Clinic, LLC was comprised of a 49.9% (increased from 33.3% on January 29, 2019) member interest ownership and is accounted for using the equity method of accounting. The Company's income (loss) earned by U.S. Stem Cell Clinic, LLC member interest was $0 and ($23,539) for the year ended December 31, 2021 and 2020, respectively (inception to date income of $599,721) and is included in other income (expense) in the accompanying statements of operations. In addition, during the year ended December 31, 2021 and 2020, the Company received distributions totaling $0 from U.S. Stem Cell Clinic, LLC (inception to date of $663,870). In March 2021, the Company divested its entire interest in U.S. Stem Cell Clinic, LLC (See Note 6, 7 and 12). The carrying value of the investment at December 31, 2021 and 2020 is $0.

At December 31, 2021 and 2020, accounts receivable for sales of product and services to U.S. Stem Cell Clinic, LLC was $28,763. Revenues earned from sales to U.S. Stem Clinic, LLC for the year ended December 31, 2021 and 2020 were $2,531 and $2,182, respectively.

An affiliate of one of the Company's officers is a minority investor in the U.S. Stem Cell Clinic, LLC.

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U.S. Stem Cell of the Villages LLC

On January 30, 2018, Greg Knutson, a director of the Company ("Knutson") and the Company agreed to open and operate a regenerative medicine/cell therapy clinic providing cellular treatments for patients afflicted with neurological, autoimmune, orthopedic and degenerative diseases in Florida. To that end, U.S. Stem Cell Clinic of The Villages LLC (the "Villages") was formed January 30, 2018. Knutson provided the Company with the sum of Three Hundred Thousand Dollars ($300,000) (the "Investment") to be utilized for the formation and initial operation of the Villages. Currently, Knutson holds a 51% member interest in the Villages and the Company holds a 49% member interest. The Company will provide operating assistance as well as management services, the latter to be compensated at fee of five percent (5%) of the Villages gross revenues.

As of December 31, 2018, upon completion of U.S. Stem Cell of the Villages LLC, the Company received $189,909 from Greg Knutson, the holder of the 51% member interest. Accordingly, this was recognized as additional paid-in capital. Subsequently, the Company contributed $86,750 as its initial investment in the Villages. The Company's 49% income (loss) earned by the Villages member interest was $0 for the year ended December 31, 2021 and 2020, respectively (inception to date loss of $23,050) and is included in other income (expense) in the accompanying statements of operations. In addition, during the year ended December 31, 2021 and 2020, the Company received distributions totaling $0 from the Villages. The carrying value of the investment at December 31, 2021 and 2020 is $0.

At December 31, 2021 and 2020, accounts receivable for sales of products and services to the Villages was $0. Revenues earned from sales to the Villages for the year ended December 31, 2021 and 2020 was $0.

During the year ended December 31, 2021 and 2020, the Company received $0 in management fees from the Villages.

As of the date of this filing, U.S. Stem Cell Clinic of the Villages, LLC is currently dormant.

NOTE 6 — ACCRUED EXPENSES

Accrued expenses consisted of the following as of December 31, 2021 and 2020:

	December 31,	
	2021	**2020**
Interest and fees payable to the Guarantors of the Company's loan agreement with Seaside Bank	$ 644,670	$ 549,628
Accrued interest payable	1,227,588	882,515
Vendor accruals and other	79,132	79,138
Total Accrued expenses	$ 1,951,390	$ 1,511,281

On February 10, 2021, as part of a settlement agreement, the Company transferred its entire member interest in U.S. Stem Cell, LLC to Dr. Kristen Comella as settlement for $100,000 of accrued interest owed to Dr. Comella, resulting in a gain on settlement of $100,000 (See Note 5, Note 7 and Note 12 "Litigation").

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NOTE 7 — NOTES PAYABLE

Notes and capital leases payable were comprised of the following as of December 31, 2021 and 2020:

	December 31,	
	2021	2020
Seaside Bank note payable	$ 980,000	$ 980,000
Dr. Comella note payable*	255,579	255,579
Dr. Comella note payable*	300,000	300,000
Dr. Comella note payable*	300,000	300,000
Dr. Comella note payable*	300,000	300,000
Hunton & Williams note payable	380,000	386,000
Weider note payable	413,239	450,477
Mallard note payable	232,750	241,750
EIDL note payable	150,000	150,000
Total notes payable	3,311,568	3,363,806
Less unamortized debt discount	(31,627)	(41,237)
Total notes payable net of unamortized debt discount	3,279,941	3,322,569
Less current portion	(2,557,881)	(2,562,149)
Long-term portion	$ 722,060	$ 760,420

* Dr. Comella is a former member of the Board of Directors and resigned on December 1, 2019.
This note was previously included in notes payable - related parties.

Seaside Bank

On October 25, 2010, the Company entered into a Loan Agreement with Seaside National Bank and Trust for a $980,000 loan at 4.25% per annum interest that was used to refinance the Company's loan with Bank of America. The obligation is guaranteed by certain stockholders of the Company. The Company renewed the loan with Seaside National Bank and Trust during the first quarter of 2018 to extend the maturity date to May 18, 2020. The Company renewed the loan with Seaside National Bank and Trust during the first quarter of 2020 to extend the maturity date to May 18, 2022.

Dr. Comella, former Chief Science Officer

On September 6, 2016, the Company issued a $300,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due upon demand. As of December 31, 2021 and 2020, the remaining carrying value of the note was $255,579.

On August 7, 2017, the Company issued a $300,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due one year from date of issuance. As of December 31, 2021 and 2020, the remaining carrying value of the note was $300,000.

On May 7, 2018, the Company issued a $300,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due six months from date of issuance. As of December 31, 2021 and 2020, the remaining carrying value of the note was $300,000.

On July 1, 2019, the Company issued a $300,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due November 7, 2019. As of December 31, 2021 and 2020, the remaining carrying value of the note was $300,000.

On February 10, 2021, as part of a settlement agreement, the Company transferred its entire member interest in U.S. Stem Cell, LLC to Dr. Kristen Comella as settlement for $100,000 of accrued interest owed to Dr. Comella, resulting in a gain on settlement of $100,000 (See Note 5, Note 6 and Note 12 “Litigation”). At December 31, 2021 and 2020, accrued interest on the notes was $166,424 and $208,645, respectively, and is included in accrued expenses on the accompanying balance sheet.

Dr. Comella has not served as member of the Board of Directors since September 1, 2019.

Hunton & Williams

At December 31, 2016, the Company has two outstanding notes payable with interest at 8% per annum due at maturity. The two notes, $61,150 and $323,822, are payable in one balloon payment upon the date the Noteholder provides written demand, however the Company is not obligated to make payments until the Northstar Biotech Group, LLC (or successor) Loan is paid off.

On August 31, 2017, the Company and the noteholder entered into a Note Forbearance, Modification and Repayment Agreement (“Agreement”). The two notes, $61,150 and $323,822, were payable in one balloon payment upon the date of a written demand and upon certain triggering events occurring. The sum of unpaid principal and accumulated interest for both notes as of August 31, 2017 of $747,680 and an accounts payable of $40,596 result in an aggregate balance due of $788,276.

The noteholder agreed to accept full payment of their obligation over a four (4) year period in 48 monthly installments on an adjusted debt obligation in aggregate of $624,000 (reducing the outstanding balance), with such payments staggered in amounts such that the Company will pay $10,000 monthly the first year, $12,000 monthly the second year, $14,000 monthly the third year, and $16,000 monthly the final year. In addition, the noteholder agreed to suspend accrual interest on the notes commencing September 1, 2017.

The Agreement remains in full force and effect provided the Company continues to make the monthly payments, there is no event of default as defined in the notes and an agreement to a subordination agreement by Northstar Biotech Group, LLC, which has been provided. In May 2019, the Company did not make the required scheduled payment. In September 2019, the noteholder agreed to waive their default rights under the agreement provided a minimum of $5,000 was paid by the end of 2019 and to reduce the required monthly payment to $500 per month commencing in January 2020. The Company satisfied the $5,000 payment requirement by the end of 2019 and commenced making the required $500 monthly payments in January 2020. The Company last made a $500 payment in March 2021 and thereby became delinquent until making three $1,500 payments during the fourth quarter of 2021 (a total of $6,000 in payments were made during 2021) thereby becoming current as of December 31, 2021.

The Company imputed an interest rate of 5% and discounted the note accordingly. The imputed debt discount of $69,700 was amortized to interest expense using the effective interest method. In September 2019, the Company was in default and was negotiating a revised payment structure. Thus, the remaining unamortized debt discount was charged to interest expense at September 30, 2019. As of December 31, 2021 and 2020, the remaining carrying value of the note was $380,000 and $386,000, respectively.

Weider

The Company, as one of the parties entered into a Settlement Agreement and General Release (the "Agreement") dated June 3, 2019 related to certain medical procedures. Without admitting any liability, and as part of that Agreement, the Company agreed to provide a five-year 5.25% unsecured promissory note, dated June 15, 2019, in the principal amount of $500,000, payable in monthly increments of $5,000 per month, with a final balloon payment due on June 15, 2024. Accordingly, the Company recognized Pre-litigation expense of $500,000. As of December 31, 2021 and 2020, the remaining carrying value of the note was $413,239 and $450,477, respectively.

Mallard

The Company, as one of the parties entered into a Settlement Agreement and General Release (the "Agreement") dated December 6, 2019 related to certain medical procedures. Without admitting any liability, and as part of that Agreement, the Company agreed to provide a five-year non-interest bearing unsecured promissory note, dated December 6, 2019, in the principal amount of $250,000, payable in monthly increments of $750 per month, with a final balloon payment of $205,000 due on January 1, 2025. The Company imputed an interest rate of 5% and discounted the note accordingly. The imputed debt discount of $51,063 is being amortized to interest expense using the effective interest method. Accordingly, the Company recognized Pre-litigation expense of $198,937. For the year ended December 31, 2021 and 2020, the Company amortized $9,610 and $9,211, respectively, of debt discount to interest expense. As of December 31, 2021 and 2020, the remaining carrying value of the note was $201,123 and $208,763, net of debt discount of $31,627 and $41,237, respectively.

Economic Injury Disaster Loan (EIDL)

On June 20, 2020, the Company executed the standard loan documents for an EIDL from the U.S. Small Business Administration in light of the impact of the COVID-19 pandemic on our business. Pursuant to that certain Loan Authorization and Agreement (the "SBA Loan Agreement"), the principal amount of the EIDL received was $150,000, with proceeds to be used for working capital purposes. Interest accrues at the rate of 3.75% per annum. Installment payments, including principal and interest, are due monthly beginning June 20, 2021 (twelve months from the date of the SBA Loan Agreement) in the amount of $731. On March 15, 2021, the initial payment date was extended 12 months to June 20, 2022. The balance of principal and interest is payable thirty years from the date of the SBA Loan Agreement. As of December 31, 2021 and 2020, the remaining carrying value of the note was $150,000. At December 31, 2021 and 2020, accrued interest on the note was $8,615 and $2,990, respectively, and is included in accrued expenses on the accompanying balance sheet.

NOTE 8 — PROMISSORY NOTE PAYABLE

On June 1, 2015, the Company issued an amended and restated promissory note of $1,697,762 in settlement of the $1,500,000 outstanding subordinated debt, related accrued interest of $373,469 and accumulated and unpaid guarantor fees of $624,737.

The note is unsecured and non-interest bearing and requires four semi-annual payments of $75,000 beginning on December 31, 2015 with the remaining unpaid balance due June 1, 2020. On June 1, 2020, the Company defaulted on the promissory note. Upon default, the note became due in full and the Company began accruing interest at the default interest rate of 18%.

The Company imputed an interest rate of 5% and discounted the promissory note accordingly. The imputed debt discount of $368,615 was amortized to interest expense using the effective interest method. For the year ended December 31, 2021 and 2020, the Company amortized $0 and $29,295, respectively of debt discount to interest expense. As of December 31, 2021 and 2020, the remaining carrying value of the note was $1,397,762.

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NOTE 9 — CONVERTIBLE NOTES PAYABLE

On February 5, 2020, the Company issued an unsecured convertible promissory note in the principal amount of $35,000 that matured on February 5, 2021 and accrued interest at a rate of 5% per annum. The investor had the right to convert the outstanding balance of the note at any time into shares of common stock of the Company at a conversion price equal to a thirty percent (30%) discount of the average closing price of the Company's common stock on the OTC Markets electronic exchange for the prior thirty (30) trading days prior to conversion, subject to adjustment. Upon the occurrence of an event of default, the investor may have accelerated the note pursuant to which the outstanding balance would become, at the noteholder's election, immediately due and payable. As a result of the beneficial conversion feature of the note, debt discount of $15,000 was recognized with a corresponding increase in additional paid-in capital. The debt discount was amortized to interest expense using the effective interest method. As of February 5, 2021, the maturity date, the note was in default. On July 30, 2021, the investor converted the full value of the note into 3,804,348 shares of the Company's common stock. The agreement contains a provision that in the event the conversion right is exercised, then the Holder waives all outstanding interest. Accordingly, all outstanding accrued interest at the time of conversion was reversed. For the year ended December 31, 2021 and 2020, the Company amortized $1,874 and $13,126, respectively, of debt discount to interest expense. As of December 31, 2021 and 2020, the remaining carrying value of the note was $0 and $33,126, net of debt discount of $0 and $1,874, respectively. At December 31, 2021 and 2020, accrued interest on the note was $0 and $1,582, respectively, and is included in accrued expenses on the accompanying balance sheet.

On September 8, 2020, the Company issued an unsecured convertible promissory note in the principal amount of $10,000 that was due on demand and accrued interest at a rate of 5% per annum. The investor had the right to convert the outstanding balance of the note at any time into shares of common stock of the Company at a conversion price of $0.0467. Upon the occurrence of an event of default, the remaining principal and accrued interest become immediately due and payable, with interest accruing at 18% per annum on any unpaid amounts. On November 9, 2021, the investor converted the entire principal balance of $10,000 and accrued interest of $588 into 226,713 shares of the Company's common stock. As the conversion was at a fixed conversion price, no gain or loss was recognized on conversion. As of December 31, 2021 and 2020, the remaining carrying value of the note was $0 and $10,000, respectively. As of December 31, 2021 and 2020, accrued interest on the note was $0 and $156, respectively, and is included in accrued expenses on the accompanying balance sheet.

From February 17, 2021 through February 26, 2021, the Company issued unsecured convertible promissory notes in the aggregate principal amount of $619,000 that matured 12 months after the respective issuance date. The notes are non-interest bearing and the investor has the right to convert the outstanding balance of the note at any time into shares of common stock of the Company at a conversion price of $0.0266. The agreements contain a provision that in the event the conversion right is exercised, then the Holder waives all outstanding interest. Upon the occurrence of an event of default, the remaining principal and accrued interest become immediately due and payable. As a result of the beneficial conversion feature of the notes, an aggregate of $521,850 of debt discount was recognized with a corresponding increase in additional paid-in capital. The debt discount is being amortized to interest expense using the effective interest method. On March 23, 2021, one of the holders, a related party, converted a convertible note with a face value of $200,000, dated February 26, 2021, into 7,518,797 shares of the Company's common stock. Upon conversion, the remaining unamortized debt discount was expensed immediately. In addition, all outstanding accrued interest at the time of conversion was reversed. As the conversion was at a fixed conversion price, no gain or loss was recognized on conversion (See Note 10 and 13). For the year ended December 31, 2021, the Company amortized $286,699 of debt discount to interest expense. As of December 31, 2021, the remaining carrying value of the notes was $183,850, net of debt discount of $235,150.

On March 24, 2021, the Company issued an unsecured convertible promissory note in the principal amount of $110,000 that matured 12 months after the issuance date. The note was non-interest bearing and the investor had the right to convert the outstanding balance of the note at any time into shares of common stock of the Company at a conversion price of $0.0070. The agreement contains a provision that in the event the conversion right is exercised, then the Holder waives all outstanding interest. Upon the occurrence of an event of default, the remaining principal and accrued interest become immediately due and payable. As a result of the beneficial conversion feature of the note, $110,000 of debt discount was recognized with a corresponding increase in additional paid-in capital. The debt discount was being amortized to interest expense using the effective interest method. On November 9, 2021, the holder converted the full value of the note into 15,741,286 shares of the Company's common stock. Upon conversion, the remaining unamortized debt discount was expensed immediately. In addition, all outstanding accrued interest at the time of conversion was reversed. As the conversion was at a fixed conversion price, no gain or loss was recognized on conversion (See Note 13). For the year ended December 31, 2021, the Company amortized $110,000 of debt discount to interest expense. As of December 31, 2021, the remaining carrying value of the note was $0.

On June 20, 2021, the Company issued an unsecured convertible promissory note in the principal amount of $20,000 that matured 12 months after the issuance date. The note was non-interest bearing and the investor had the right to convert the outstanding balance of the note at any time into shares of common stock of the Company at a conversion price of $0.0125. The agreement contains a provision that in the event the conversion right is exercised, then the Holder waives all outstanding interest. Upon the occurrence of an event of default, the remaining principal and accrued interest become immediately due and payable. As a result of the beneficial conversion feature of the note, $2,400 of debt discount was recognized with a corresponding increase in additional paid-in capital. The debt discount was being amortized to interest expense using the effective interest method. On November 9, 2021, the holder converted the full value of the note into 1,600,000 shares of the Company's common stock. Upon conversion, the remaining unamortized debt discount was expensed immediately. In addition, all outstanding accrued interest at the time of conversion was reversed. As the conversion was at a fixed conversion price, no gain or loss was recognized on conversion (See Note 13). For the year ended December 31, 2021, the Company amortized $2,400 of debt discount to interest expense. As of December 31, 2021, the remaining carrying value of the note was $0.

On October 29, 2021, the Company issued an unsecured convertible promissory note in the principal amount of $17,000 that matures 12 months after the issuance date. The note is non-interest bearing and the investor has the right to convert the outstanding balance of the note at any time into shares of common stock of the Company at a conversion price of $0.008. Upon the occurrence of an event of default, the remaining principal and accrued interest become immediately due and payable. As a result of the beneficial conversion feature of the note, $7,438 of debt discount was recognized with a corresponding increase in additional paid-in capital. The debt discount is being amortized to interest expense using the effective interest method. For the year ended December 31, 2021, the Company amortized $998 of debt discount to interest expense. As of December 31, 2021, the remaining carrying value of the note was $10,561, net of debt discount of $6,439.

NOTE 10 — RELATED PARTY TRANSACTIONS

Advances – Related Parties

As of December 31, 2020 and 2019, the Company's officers and directors have provided advances that are unsecured, non-interest bearing and due on demand. During the year ended December 31, 2021 and 2020, the Company received aggregate proceeds from advances of $90,000 and $349,688, respectively. As of December 31, 2021 and 2020, the Company owed $951,432 and $861,432, respectively, for related party advances.

Convertible Notes Payable – Related Parties

On March 23, 2021, one of the holders, a related party, converted a convertible note with a face value of $200,000, dated February 26, 2021, into 7,518,797 shares of the Company's common stock. (See Note 9).

Notes Payable – Related Parties

Northstar Biotechnology Group, LLC

On February 29, 2012, a promissory note issued to BlueCrest Master Fund Limited ("BlueCrest") was assigned to Northstar Biotechnology Group, LLC ("Northstar"), owned partly by certain directors and existing shareholders of the Company at the time, including Dr. William P. Murphy Jr., Dr. Samuel Ahn and Charles Hart. At the date of the assignment, the principal amount of the BlueCrest note was $544,267 (the "Note").

On March 30, 2012, the Company and Northstar agreed to extend until May 1, 2012 the initial payment date for any and all required monthly under the Note, such that the first of the four monthly payments required under the Note will be due and payable on May 1, 2012 and all subsequent payments will be due on a monthly basis thereafter commencing on June 1, 2012, and to waive any and all defaults and/or events of default under the Note with respect to such payments. The Company did not make the required payment, and as a result, was in default of the revised agreement. The Company renegotiated the terms of the Note and Northstar agreed to suspend the requirement of principal payments by the Company and allow payment of interest-only in common stock.

On September 21, 2012, the Company issued 5,000 common stock purchase warrants to Northstar that was treated as additional interest expense upon issuance.

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On October 1, 2012, the Company and Northstar entered into a limited waiver and forbearance agreement providing a recapitalized new note balance comprised of all sums due Northstar with a maturity date extended perpetually. The Company agreed to issue 5,000,000 shares of Series A Convertible Preferred Stock and 10,000 shares of common stock in exchange for $210,000 as payment towards outstanding debt, default interest, penalties, professional fees outstanding and due Northstar. In addition, the Company executed a security agreement granting Northstar a lien on all patents, patent applications, trademarks, service marks, copyrights and intellectual property rights of any nature, as well as the results of all clinical trials, know-how for preparing Myoblasts, old and new clinical data, existing approved trials, all right and title to Myoblasts, clinical trial protocols and other property rights.

In addition, the Company granted Northstar a perpetual license on products as described for resale, relicensing, and commercialization outside the United States. In connection with the granted license, Northstar shall pay the Company a royalty of up to 8% on revenues generated.

Effective October 1, 2012, the interest rate was 12.85% per annum. The parties agreed, as of February 28, 2013, to reduce the interest rate to 7% per annum.

In connection with the consideration paid, Northstar waived, from the effective date through the earlier of termination or expiration of the agreement, satisfaction of the obligations as described in the forbearance agreement.

In 2012, 5,000,000 shares of Series A Convertible Preferred Stock were approved to be issued, which was subsequently increased to 20,000,000 shares of preferred stock as Series A Convertible Preferred Stock. In addition, the Company was obligated to issue additional preferred stock equal in lieu of payment of cash of accrued and unpaid interest on each six-month anniversary of the effective date (October 1, 2012). In lieu of the initial two payments in preferred stock, the parties agreed to modify the voting rights of the subsequently cancelled Series A Convertible Preferred Stock from 20 votes per share on matters to be voted on by the common stockholders to 25 votes per share on matters to be voted on by the common stockholders and all prior and subsequent payments of interest will be in common stock. The Company is required to issue additional shares of its common stock (as amended), in lieu of cash, each six-month anniversary of the effective date for any accrued and unpaid interest.

On September 30, 2013, the Company issued 8,772 shares of its common stock as payment of $100,000 towards principal.

On December 24, 2013, the Company issued 3,916 shares of its common stock as payment of accrued interest through June 30, 2013 of $85,447.

On April 2, 2014, the Company issued 275 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,635 due April 1, 2014 per the forbearance agreement.

On September 17, 2014, the limited waiver and forbearance agreement entered into on October 1, 2012 to provide that the perpetual license on products as described for resale, relicensing and commercialization outside the United States was amended as such on the condition that Northstar provide certain financing, which financing the Company, in its sole discretion, could decline and retain the license.

On October 3, 2014, the Company issued 515 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,705 due October 1, 2014 per the forbearance agreement.

On April 3, 2015, the Company issued 1,363 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,635 due April 1, 2015 per the forbearance agreement.

On October 2, 2015, the Company issued 4,156 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,705 due October 1, 2015 per the forbearance agreement.

On October 7, 2015, the Company issued 34,522 shares of its common stock in settlement of $100,000 principal payment towards the outstanding debt.

On April 7, 2016, the Company issued 57,778 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,705 due April 1, 2016 per the forbearance agreement.

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On October 6, 2016, the Company issued 848,490 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,705 due October 1, 2016 per the forbearance agreement.

On March 1, 2017, Northstar and the Company entered into a settlement agreement ("Settlement Agreement ") related to then pending litigation. Pursuant to the terms and conditions of the Settlement Agreement, Northstar converted its outstanding Series A Convertible preferred stock, into twenty million (20,000,000) shares of common stock according to the original conversion terms. In addition, and separate and apart from the conversion, Northstar received eleven million (11,000,000) shares of the Company's common stock. Northstar will receive ten percent (10%) of all Company international sales (based on a gross sales basis). There was no effect of the 10% obligation as there were no international sales in 2017 or through 2019. Furthermore, a Northstar designee, Greg Knutson, was appointed as a member of the Board of Directors of the Company and two Company directors, Michael Tomas and Kristin Comella, each exercised their prior Northstar options to each receive a five percent (5%) member interest in Northstar. The parties agreed to a mutual release and Northstar agreed to terminate any UCC lien on the Company assets previously filed for the benefit of Northstar. On March 9, 2017 and April 1, 2017, the Company issued 30,000,000 and 1,000,000 shares of its common stock, respectively, as described above. In connection with the settlement, the Company recorded a loss on litigation settlement of $316,800.

On April 1, 2017, the Company issued 286,315 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,703.

On October 2, 2017, the Company issued 559,187 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $12,705.

On October 19, 2018, the Company issued 164,523 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $9,195.

On April 19, 2019, the Company issued 379,141 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $9,145.

On October 1, 2019, the Company issued 1,692,353 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of $9,195.

On April 1, 2020, the Company issued 1,445,647 shares of its common stock, having a fair value of $11,565, in lieu of payment in cash of accrued and unpaid interest of $9,145, resulting in a loss on settlement of $2,420.

On October 1, 2020, the Company issued 2,035,820 shares of its common stock, having a fair value of $10,179, in lieu of payment in cash of accrued and unpaid interest of $9,195, resulting in a loss on settlement of $984.

On April 1, 2021, the Company issued 187,575 shares of its common stock, having a fair value of $10,879, in lieu of payment in cash of accrued and unpaid interest of $9,145, resulting in a loss on settlement of $1,734.

On October 1, 2021, the Company issued 743,341 shares of its common stock, having a fair value of $8,921, in lieu of payment in cash of accrued and unpaid interest of $9,195, resulting in a gain on settlement of $274.

As of December 31, 2021 and 2020, the remaining carrying value of the note was $262,000. At December 31, 2021 and 2020, accrued interest on the note was $8,751 and is included in accrued expenses on the accompanying balance sheet.

Notes Payable - Mr. Tomas, President and Chief Executive Officer

On August 7, 2017, the Company issued a $500,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due one year from date of issuance. As of December 31, 2021 and 2020, the remaining carrying value of the note was $161,786.

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On May 7, 2018, the Company issued a $500,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due six months from date of issuance. As of December 31, 2021 and 2020, the remaining carrying value of the note was $500,000.

On July 1, 2019, the Company issued a $500,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due November 7, 2019. As of December 31, 2021 and 2020, the remaining carrying value of the note was $500,000.

On December 31, 2019, the Company issued a $178,077 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021 and 2020, the remaining carrying value of the note was $178,077.

On March 31, 2020, the Company issued a $187,500 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021 and 2020, the remaining carrying value of the note was $187,500.

On June 30, 2020, the Company issued a $187,500 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021 and 2020, the remaining carrying value of the note was $187,500.

On July 1, 2020, the Company issued a $500,000 promissory note as payment of an annual bonus awarded. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021 and 2020, the remaining carrying value of the note was $500,000.

On September 30, 2020, the Company issued a $100,962 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021 and 2020, the remaining carrying value of the note was $100,962.

On December 31, 2020, the Company issued a $143,654 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021 and 2020, the remaining carrying value of the note was $143,654.

On March 31, 2021, the Company issued a $90,990 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021, the remaining carrying value of the note was $90,990.

On June 30, 2021, the Company issued a $43,269 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021, the remaining carrying value of the note was $43,269.

On September 30, 2021, the Company issued a $187,500 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021, the remaining carrying value of the note was $187,500.

On December 31, 2021, the Company issued a $100,962 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of December 31, 2021, the remaining carrying value of the note was $100,962.

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At December 31, 2021 and 2020, accrued interest on the notes was $612,323 and $482,468, respectively, and is included in accrued expenses on the accompanying balance sheet.

	December 31,	
	2021	2020
Northstar	$ 262,000	$ 262,000
Note payable, Mr. Tomas	161,786	161,786
Note payable, Mr. Tomas	500,000	500,000
Note payable, Mr. Tomas	500,000	500,000
Note payable, Mr. Tomas	178,077	178,077
Note payable, Mr. Tomas	187,500	187,500
Note payable, Mr. Tomas	187,500	187,500
Note payable, Mr. Tomas	500,000	500,000
Note payable, Mr. Tomas	100,962	100,962
Note payable, Mr. Tomas	143,654	143,653
Note payable, Mr. Tomas	90,990	-
Note payable, Mr. Tomas	43,269	-
Note payable, Mr. Tomas	187,500	-
Note payable, Mr. Tomas	100,962	-
Total notes payable - related parties	$ 3,144,200	$ 2,721,478

NOTE 11 — FAIR VALUE MEASUREMENT

The Company adopted the provisions of ASC 825-10. ASC 825-10 defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required or permitted to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of non-performance. ASC 825-10 establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 825-10 establishes three levels of inputs that may be used to measure fair value:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets with insufficient volume or infrequent transactions (less active markets); or model-derived valuations in which all significant inputs are observable or can be derived principally from or corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs to the valuation methodology that are significant to the measurement of fair value of assets or liabilities.

All items required to be recorded or measured on a recurring basis are based upon Level 3 inputs.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is disclosed and is determined based on the lowest level input that is significant to the fair value measurement.

As of December 31, 2021 and 2020, the Company did not have any items that would be classified as level 1, 2 or 3 disclosures.

As of December 31, 2021 and 2020, the Company did not have any derivative instruments that were designated as hedges.

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NOTE 12 — COMMITMENTS AND CONTINGENCIES

Leases

In October 2019, the Company relocated to a new location within the same city and entered into a month-to-month lease. During the year ended December 31, 2021 and 2020, lease expense was comprised of the following:

	For the Year Ended December 31,	
	2021	2020
Operating lease expense	$ 4,711	$ 5,582
Total lease expense	$ 4,711	$ 5,582

Employment Agreements

On July 1, 2019, the Company's Board of Directors approved the 2019/2020 salary for Mike Tomas, Chief Executive Officer, for $750,000 per year, beginning July 1, 2019 with an incentive bonus ranging from $150,000 to $500,000. In 2020, the Board of Directors approved a bonus of $500,000 and options to acquire 20,000,000 shares of the Company's common stock for ten years with four-year vesting and a cashless exercise provision. The cash bonus may be paid in the form a six-month promissory note bearing interest at 5% per annum. There were no salary increases or bonuses issued in 2021.

Royalty Agreement / Middle East

On November 9, 2016, the Company entered into an Intellectual Property License Agreement whereby the Company granted High Rise Group Company the exclusive right to the Company's intellectual property (as defined) for the licensed use and development in Kuwait and other GCC/Middle East countries for 25 years in exchange for a payment of $75,000 and a 5% royalty generated under the agreement. The licensing agreement is recorded as deferred revenue and amortized over the term of the agreement. The carrying balance as of December 31, 2021 and 2020 was $59,500 and $62,500, respectively.

The intent is for U.S. Stem Cell Middle East to offer regenerative treatment options to patients, based on U.S. Stem Cell, Inc. products and technologies like MyoCell™. To date, the first clinic in Kuwait City has been completed but has not begun operations as High Rising Group has not yet been able to secure regulatory approvals to operate.

Litigation

On September 17, 2015, a product liability lawsuit was filed in Broward County, specifically Patsy Bade v. Bioheart, Inc. US Stem Cell Clinics LLC, Alejandro Perez, ARNP, and Shareen Greenbaum, M.D., and on November 30, 2015, a product liability lawsuit was filed in Broward County, specifically Elizabeth Noble v. Bioheart, Inc. US Stem Cell Clinics LLC, Alejandro Perez, ARNP, and Shareen Greenbaum, M.D. During the year ended December 31, 2016, both matters settled by the Company's insurance policy with no additional cost to the Company, except for the obligation to pay the insurance company deductible of $100,000, of which $11,000 was paid in fiscal 2017. The remaining amount due under this settlement is $26,600 and $28,850 as of December 31, 2021 and 2020, respectively, and is included in accounts payable.

On July 27, 2020, Brenda Leonhardt filed a lawsuit against U.S. Stem Cell, Inc., Mike Tomas, Dr. William P. Murphy, Jr., Richard T. Spencer, III, Mark Borman, Dr. Samuel S. Ahn, Charles Hart, Sheldon T. Anderson, Greg Knutson, and Kristin Comella in Broward County Court, Case No. CACE-10-012095. The lawsuit alleges breach of a settlement agreement, breach of contract with respect to failure to make a balloon payment under a promissory note, and several tort theories such as misrepresentation and fraudulent transfer. The Company denies most of the allegations in the lawsuit and moved to dismiss almost all of the claims. The motions to dismiss was recently denied. U.S. Stem Cell, Inc. does note that it provided a promissory note to Ms. Leonhardt, which has not been fully satisfied.

The Company, as one of the parties entered into a Settlement Agreement and General Release (the "Agreement") dated June 3, 2019 related to certain medical procedures. Without admitting any liability, and as part of that Agreement, the Company agreed to provide a five-year 5.25% unsecured promissory note, dated June 15, 2019, in the principal amount of $500,000, payable in monthly increments of $5,000 per month, with a final balloon payment due on June 15, 2024. Accordingly, the Company recognized Pre-litigation expense of $500,000. As of December 31, 2021 and 2020, the remaining carrying value of the note was $413,239 and $450,477, respectively. At present, the Company is delinquent one payment and, if not cured, would be considered in default of the promissory note underlying the Agreement.

On February 10, 2021, as part of a settlement agreement, the Company transferred its entire member interest in U.S. Stem Cell Clinic, LLC to Dr. Kristin Comella as settlement for $100,000 of accrued interest owed to Dr. Comella (See Note 5, 6 and 7).

The Company is subject at times to other legal proceedings and claims, which arise in the ordinary course of its business. Although occasional adverse decisions or settlements may occur, the Company believes that the final disposition of such matters should not have a material adverse effect on its financial position, results of operations or liquidity. There was no outstanding litigation as of December 31, 2021 other than that described above.

Government Claim

On May 9, 2018, the U.S. Department of Justice filed an injunctive action, specifically United States of America v. U.S. Stem Clinic, LLC, U.S. Stem Cell, Inc., Kristin C. Comella, and Theodore Gradel. The Complaint alleges, among other matters that the defendants manufacture "stromal vascular fraction" (SVF) products from patient adipose (fat) tissue, which the companies then market as stem cell-based treatments, and which U.S. Stem Cell Clinic, LLC administers to patients, without first obtaining what the government alleges are necessary FDA approvals. Although Theodore Gradel was initially listed as a defendant, he subsequently entered into a consent agreement and is no longer party to this case.

The U.S. and the defendants filed cross motions for summary judgment, each asking for a ruling in its favor. On June 3, 2019, the Court entered an order granting Summary Judgment for the government and denying the defendants' motion for summary judgment. The order focused on the defendants' actions in providing and marketing SVF therapy. In an order dated June 4, 2019, the Court granted the defendants' request to allow it the opportunity to work out the language of the form of injunction with the government, and if unsuccessful, to provide a status report to the Court by June 14, 2019, outlining areas of disagreement. The Court further ordered that the defendants (U.S. Stem Clinic, LLC, U.S. Stem Cell, Inc., and Kristin C. Comella) 'not sell, provide or otherwise engage in any SVF therapy or any other activities to be regulated by the FDA as explained in the Court's Order on the Parties' Motions for Summary Judgment." On June 25, 2019, the Court entered an Order of Permanent Injunction, generally enjoining the defendants with respect to the SVF Product and requiring other actions. The Company filed an appeal on August 23, 2019 and attended oral argument on January 13, 2021. On June 2, 2021, the Eleventh Circuit Court ruled to affirm lower courts' judgement. The Company is not able to predict the duration, scope, results, or consequences of the U.S. Department of Justice actions and final rulings and management is assessing its options on a going forward basis. The Company, in having divested certain equipment and other assets and assigning its lease, has and will continue to experience a decrease in revenues as the Company both maintains the remainder of the business and transitions into similar or unrelated business opportunities as determined by management. However, management is not able to predict the duration, scope, results, or consequences of the summary judgment and any transition of the business plan.

After the Court's issuance of the Order of Permanent Injunction, the Company has received demand letters for compensation from persons who store their SVF Product and/or other tissue product with the tissue bank (several of the persons have requested refunds of the monies paid to the tissue bank and one person has requested a full refund of monies paid to an altogether separate company due to her not receiving the full amount of treatments she requested; such requests for compensation, to date, have not been material) and requests that the Company preserve cells in the Company's possession. The Company sought guidance from the Court, which entered an order generally staying the requirement to destroy any SVF Product, pending a decision on the Company's appeal. However, that appeal has now been concluded and the stay order is no longer in place.

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NOTE 13 — STOCKHOLDERS' DEFICIT

Common Stock

During the year ended December 31, 2020, the Company issued an aggregate of 10,354,560 shares of its common stock, having a fair value of $51,914, in settlement of outstanding accounts payable. In connection with the issuances, the Company incurred a $3,586 net gain on settlement.

During the year ended December 31, 2020, the Company issued 3,481,467 shares of its common stock, having a fair value of $21,744, in lieu of payment in cash of accrued and unpaid interest of $18,340, resulting in a loss on settlement of $3,404.

During the year ended December 31, 2020, the Company issued an aggregate of 4,000,000 shares of its common stock, having a fair value of $16,000, for services.

During the year ended December 31, 2021, the Company issued an aggregate of 6,642,197 shares of its common stock, having a fair value of $231,742, in settlement of outstanding accounts payable. In connection with the issuances, the Company incurred a $151,742 net loss on settlement.

During the year ended December 31, 2021, the Company issued 930,916 shares of its common stock, having a fair value of $19,800, in lieu of payment in cash of accrued and unpaid interest of $18,340, resulting in a net loss on settlement of $1,459.

During the year ended December 31, 2021, the Company issued an aggregate of 4,000,000 shares of its common stock, having a fair value of $128,000, for services rendered.

During the year ended December 31, 2021, convertible notes with an aggregate face value of $375,000 and accrued interest of $586 were converted into an aggregate of 28,891,144 shares of the Company's common stock (See Note 9 and 10).

On September 10, 2021, the Company filing of an Offering Circular on Form 1-A, pursuant to Regulation A (File Number: 024-11617) was qualified by the Securities and Exchange Commission. The Company registered 250,000,000 shares of common stock for maximum proceeds of $2,500,000 (before deducting the maximum broker discount and costs of the offering). During the year ended December 31, 2021, the Company issued 27,500,000 shares of common stock to investors for cash proceeds of $275,000, net of fees and commission, pursuant to the Offering Circular.

Stock Options

On April 1, 2013, the Board of Directors approved, subject to subsequently received stockholder approval, the establishment of the Bioheart 2013 Omnibus Equity Compensation Plan, or the "2013 Omnibus Plan" (replacing the 1999 Officers and Employees Stock Option Plan, or the Employee Plan, and the 1999 Directors and Consultants Stock Option Plan). The 2013 Omnibus Plan initially reserved up to fifty thousand (50,000) shares of common stock for issuance. On August 4, 2014, the Board of Directors approved to set the reserve to one hundred thousand (100,000) shares of common stock for issuance and to close the 1999 Officers and Employees Stock Option Plan. On February 2, 2015, at the annual meeting of stockholders, the 2013 Omnibus Equity Compensation Plan was approved.

On November 2, 2015, the Company increased the shares reserved under the 2013 Omnibus Plan to five hundred million (500,000,000) shares of common stock for issuance. Effective September 16, 2016, the Company approved an additional twenty five million (25,000,000) shares of common stock to the reserve; effective April 21, 2017, the Company approved an additional twenty five million (25,000,000) shares of common stock to the reserve; effective August 7, 2017, the Company approved an additional thirty million (30,000,000) shares of common stock to the reserve; and effective May 7, 2018, the Company approved an additional one hundred million (100,000,000) shares of common stock to reserve.

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A summary of the stock option activity for the year ended December 31, 2021 and 2020 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, December 31, 2019	111,120,474	$ 0.0247	8.3	$ -
Granted	-			
Exercised	-			
Forfeited/Expired	(560)	$ 0.1540		
Outstanding, December 31, 2020	111,119,914	$ 0.0247	7.2	$ 296,636
Granted	-			
Exercised	-			
Forfeited/Expired	(476,030)	$ 0.0298		
Outstanding, December 31, 2021	110,643,884	$ 0.0247	6.3	$ 36,686
Exercisable, December 31, 2021	93,491,384	$ 0.0256	6.1	$ 31,642

	Options Outstanding			Options Exercisable	
Exercise Price	Outstanding Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Exercisable Number of Options	Weighted Average Exercise Price
$0.004 to $0.010	41,800,000	$ 0.0051	7.0	30,150,000	$ 0.0050
$0.011 to $0.020	16,250,000	$ 0.0196	4.7	16,250,000	$ 0.0196
$0.021 to $0.030	9,510,000	$ 0.0252	6.9	9,007,500	$ 0.0252
$0.0363	22,635,000	$ 0.0363	5.6	22,635,000	$ 0.0363
$0.0536	20,000,000	$ 0.0536	6.4	15,000,000	$ 0.0536
$0.1540	448,884	$ 0.1540	3.8	448,884	$ 0.1540
	110,643,884	$ 0.0247	6.3	93,491,384	$ 0.0256

The aggregate intrinsic value of outstanding stock options was $36,686, based on options with an exercise price less than the Company's stock price of $0.0060 as of December 31, 2021, which would have been received by the option holders had those option holders exercised their options as of that date.

The fair value of all options that vested during the years ended December 31, 2021 and 2020 was $428,556 and $685,939, respectively. As of December 31, 2021, the Company had $157,289 of total unrecognized compensation cost related to non-vested awards granted under the 2013 Omnibus Plan, which the Company expects to recognize over a weighted average period of 0.55 years.

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Warrants

A summary of the warrant activity for the year ended December 31, 2021 and 2020 is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, December 31, 2019	1,110,468	$ 12.84	7.1	$ -
Granted	-			
Exercised	-			
Expired	-			
Outstanding, December 31, 2020	1,110,468	$ 12.84	7.1	$ -
Granted	-			
Exercised	-			
Expired	(7,341)	$ 77.88		
Outstanding, December 31, 2021	1,103,127	$ 12.41	6.2	$ -
Exercisable, December 31, 2021	1,101,582	$ 1.64	6.2	$ -

	Warrants Outstanding			Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Exercisable Number of Warrants	Weighted Average Exercise Price
$0.03 to $20.00	1,081,036	$ 1.17	6.3	1,081,036	$ 1.17
$20.01 to $30.00	19,543	$ 25.06	2.2	19,543	$ 25.06
$49.86	1,003	$ 49.86	2.2	1,003	$ 49.86
$7,690.00	1,545	$ 7,690.00	5.0	-	$ 7,690.00
	1,103,127	$ 12.41	6.2	1,101,582	$ 1.64

The aggregate intrinsic value of the issued and exercisable warrants of $-0- represents the total pretax intrinsic value, based on warrants with an exercise price less than the Company's stock price of $0.0060 as of December 31, 2021, which would have been received by the warrant holders had those warrants holders exercised their warrants as of that date.

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NOTE 14 — INCOME TAXES

The Company's provision (benefit) for income taxes consists of the following United States federal and state components:

	For the Year Ended December 31,	
	2021	2020
Current:		
Federal	$ -	$ -
State	-	-
Deferred:		
Federal	843,633	962,911
State	174,551	199,230
	1,018,184	1,162,141
Change in valuation allowance	(1,018,184)	(1,162,141)
Income tax provision (benefit)	$ -	$ -

The deferred tax expense (benefit) is the change in the deferred tax assets and liabilities representing the tax consequences of changes in the amounts of temporary differences, net operating loss carryforwards and changes in tax rates during the year. The Company's deferred tax assets and liabilities are comprised of the following:

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating losses	$ 22,139,733	$ 23,317,369
Share-based compensation	4,371,729	4,263,112
Deferred compensation	1,023,375	916,236
Pre-litigation settlement notes payable	155,710	164,993
Other	274,703	260,494
Total deferred tax assets	27,965,250	28,922,204
Deferred tax liabilities:		
OID on convertible debt beneficial conversion feature	(61,231)	-
Total deferred tax liabilities	(61,231)	-
Valuation allowance	(27,904,019)	(28,922,204)
Total deferred tax assets (liabilities)	$ -	$ -

As of December 31, 2021 and 2020, the Company had U.S. federal net operating loss carryforwards of approximately $87.4 million and $92.0 million, respectively, of which $5.0 million do not expire, but are instead limited to 80% of taxable income in the year utilized. The remaining loss carryforwards expire at various dates from 2022 through 2037. These net operating loss carryforwards may be used to offset future taxable income and thereby reduce the Company's U.S. federal income taxes. Section 382 of the Internal Revenue Code of 1986 (the "Code") imposes an annual limit on the ability of a corporation that undergoes a greater than 50% ownership change to use its net operating loss carry forwards to reduce its tax liability. If in the future the Company issues common stock or additional equity instruments convertible in common shares which result in an ownership change exceeding the 50% limitation threshold imposed by Section 382 of the Code, the Company's net operating loss carryforwards may be significantly limited as to the amount of use in a particular year. In addition, all or a portion of the Company's net operating loss carryforwards may expire unutilized. As of December 31, 2021 and 2020, the Company had net operating loss carryforwards for state income tax purposes of approximately $87.4 million and $92.0 million, respectively, of which $5.0 million do not expire, but are instead limited to 80% of taxable income in the year utilized. The remaining loss carryforwards expire at various dates from 2022 through 2037.

For U.S. purposes, the Company has not completed its evaluation of NOL utilization limitations under Internal Revenue Code, as amended (the "Code") Section 382/383, change of ownership rules. If the Company has had a change in ownership, the NOL's would be limited as to the amount that could be utilized each year, based on the Code or might be eliminated.

The Company has provided a full valuation allowance against its net deferred tax assets, since in the opinion of management based upon the earnings history of the Company; it is more likely than not that the benefits of these assets will not be realized.

The Company complies with the provisions of FASB ASC 740-10 in accounting for its uncertain tax positions. ASC 740-10 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely that not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. Management has determined that the Company has no significant uncertain tax positions requiring recognition under ASC 740-10.

The Company is subject to income tax in the U.S., and certain state jurisdictions. The Company has not been audited by the U.S. Internal Revenue Service, or any states in connection with income taxes. The Company's tax years generally remain open to examination for all federal and state tax matters until its net operating loss carryforwards are utilized and the applicable statutes of limitation have expired. The federal and state tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

The Company recognizes interest and penalties related to unrecognized tax benefits, if incurred, as a component of income tax expense.

The significant elements contributing to the difference between the United States federal statutory tax rate and the Company's effective tax rate are as follows:

	For the Year Ended December 31,	
	2021	2020
US federal statutory rate	$ (690,357)	$ (607,004)
State tax rate, net of federal benefit	(137,277)	(124,658)
Effect of debt discount for beneficial conversion feature	166,437	-
Other	26,880	4,514
Effect of expiration of net operating loss carryforwards	1,652,501	1,889,289
Change in valuation allowance	(1,018,184)	(1,162,141)
Income tax provision (benefit)	$ -	$ -

NOTE 15 — CONCENTRATIONS

Concentrations of Credit Risk

The Company's financial instruments that are exposed to a concentration of credit risk are cash and accounts receivable. Generally, the Company's cash and cash equivalents in interest-bearing accounts does not exceed FDIC insurance limits. The financial stability of these institutions is periodically reviewed by senior management.

Concentrations of Revenues

For the year ended December 31, 2021 and 2020, the following customers accounted for more than 10% of the Company's net revenues:

	For the Year Ended December 31,	
	2021	2020
Customer 1	20%	22%
Customer 2	17%	-
Totals	37%	22%

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Concentrations of Accounts Receivable

As of December 31, 2021 and 2020, the following customers represented more than 10% of the Company's accounts receivable:

	December 31,	
	2021	**2020**
Customer 1	98%	44%
Customer 2	-	50%
Totals	98%	94%

Customer 2 is U.S. Stem Cell Clinic, LLC, a related party, a partly owned investment in which the Company held a 49.9% member interest through February 10, 2021 (See Note 5).

NOTE 16 — SUBSEQUENT EVENTS

In January 2022, the Company issued 1,951,207 common shares in exchange for services rendered.

In February, 2022 the company issued 3,125,000 common shares for a subscription agreement.

In February 2022, the Company issued 20,000,000 common shares in exchange for services rendered.

From February 17, 2022 through February 26, 2022, the Company defaulted on convertible notes payable with an aggregate face value of $419,000. The Company extended the maturity date of $234,000 of these convertible notes with an incentive stock issuance of 56,525,000 common shares and 12,500,000 warrant issued. The Company fully converted $25,000 into 3,125,000 common stock. The Company defaulted on $205,000 of convertible notes to which 12% interest was added commencing at the respective maturity date.

Exhibit 21

US Stem Cell Training

Vetbiologics

U.S. Stem Cell Clinic, LLC	0% Member Interest
Regenerative Wellness Clinic, LLC	0% Member Interest
U.S. Stem Cell Clinic of The Villages LLC	49.9% Member Interest

Exhibit 31.1

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

I, Mike Tomas, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2020, of U.S. Stem Cell, Inc.;

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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 subsidiaries, is made known to us by others within those entities, particularly during the period in which this 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; and

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 (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting.

5. 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 functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control 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 control over financial reporting.

/s/ Mike Tomas
Mike Tomas
Chief Executive Officer and President and Principal Financial and Accounting Officer

Date: March 31, 2022

Exhibit 32.1

CERTIFICATION 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 of U.S. Stem Cell, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mike Tomas, Chief Executive Officer and President And Principal Financial and Accounting Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 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.

A signed original of this written statement required by Section 906 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. The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. section 1350 and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

/s/ Mike Tomas

Mike Tomas
Chief Executive Officer and President
And Principal Financial and Accounting Officer
March 31, 2022