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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2018

Commission File Number **001-33718**

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

Florida **65-0945967**
(State or other jurisdiction of incorporation
or organization) (IRS Employer Identification No.)

13794 NW 4th Street, Suite 212 **33325** **(954) 835-15000**
Sunrise, Florida (Address of principal executive office) (Zip Code) (Registrant's telephone number, Including area code)

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, \$0.001 par value per share**

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 (\S 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

As of June 30, 2018, the last day of registrant's second fiscal quarter, the aggregate market value of the registrant's common stock, \$0.001 par value, held by non-affiliates, computed by reference to the closing sale price of the common stock reported on the OTC Markets, Inc., OTCQB as of June 30, 2018, was approximately \$9,732,678. 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 13, 2019 was 386,675,905.

Documents Incorporated By Reference None

U.S. STEM CELL, INC.

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[CERTIFICATION PURSUANT TO SECTION 302 \(a\) OF THE SARBANES-OXLEY ACT OF 2002](#)

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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 clinical trials for product candidates in our development programs;
- our ability to build and maintain the management and human resources infrastructure necessary to support the growth of our business;
- our ability to operate our subsidiary businesses successfully and grow such subsidiary businesses as anticipated;
- the success and profitability of related clinics and our ability to directly, or in conjunction with third parties, open and manage new clinics
- 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;
- 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; and
- our ability to complete our planned clinical trials (or initiate other trials) in accordance with our estimated timelines due to delays associated with obtaining sufficient capital to complete such trials, enrolling patients due to the novelty of the treatment, the size of the patient population and the need of patients to meet the inclusion criteria of the trial or otherwise.

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.

Except as required by law, the Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future 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, stem cell banking, and the creation and management of stem cell clinics. 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 is Adipocell, a proprietary kit for the isolation of adipose derived stem cells.

Biotechnology Product Candidates

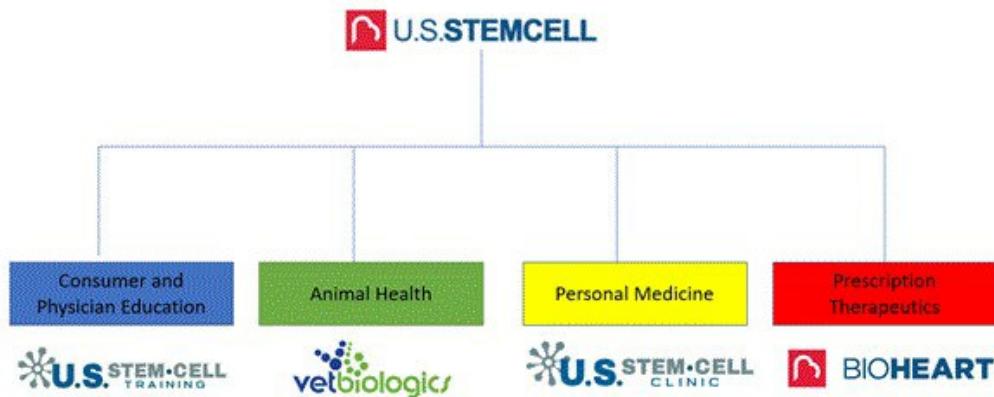
Our business includes the development of proprietary cell therapy products as well as revenue generating physician and patient based regenerative medicine / cell therapy training services, cell collection and cell storage services, the sale of cell collection and treatment kits for humans and animals, and the operation of a cell therapy clinic. Management maintains that revenues and their associated cash in-flows generated from our businesses will, over time, provide funds to support our clinical development activities as they do today for our general business operations. We believe the combination of our own therapeutics pipeline combined with our revenue generating capabilities provides the Company with a unique opportunity for growth and a pathway to profitability.

US Stem Cell Training, ("SCT"), an operating division of U.S. Stem Cell, Inc., 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.

Vetbiologics, ("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.

US Stem Cell Clinic, LLC, , and Regenerative Wellness Clinic, LLC, partially owned (33.3% as of December 31, 2018) investments by our company, is a physician run regenerative medicine/cell therapy clinic providing cellular treatments for patients afflicted with neurological, autoimmune, orthopedic and degenerative diseases. On January 29, 2019, through a reorganization of Member Interests of U.S. Stem Cell Clinic, LLC and Regenerative Wellness Clinic, LLC respectively, we increased our holdings to a 49.9 percent Member Interest ownership of U.S. Stem Cell Clinic, LLC and Regenerative Wellness Clinic, LLC respectively. The clinics are operating in compliance with the FDA 1271s which allow for same day medical procedures to be considered the practice of medicine. We isolate stem cells from bone marrow and adipose tissue and also utilize platelet rich plasma.

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 13794 NW 4th Street, Suite 212, Sunrise, Florida 33325 and our telephone number is (954) 835-1500. Information about us is available on our corporate websites at www.us-stemcell.com, www.usstemcelltraining.com, www.vetbiologics.com, www.regenerativewellnessclinic.com and www.usstemcellclinic.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 websites 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.

Various adult stem cell therapies are in clinical development for an array of human diseases, including autoimmune, oncologic, neurologic and orthopedic, among other indications. While no assurances can be given regarding future medical developments, we believe that the field of cell therapy holds the promise to better the human experience and minimize or ameliorate the pain and suffering from many common diseases and/or from the process of aging.

According to Robin R. Young's Stem Cell Summit Executive Summary-Analysis and Market Forecasts 2014-2024, the United States stem cell therapy market is estimated to grow from an estimated \$237 million in 2013 to more than \$5.7 billion in 2020.

With approved cell therapy products currently being sold in the United States and abroad, and an increasing number of Phase 2 and Phase 3 trials with cell therapies underway, we believe the "promise" of cell therapy is becoming clearer. We contend that cell therapies, if approved, should cut health care costs as they aim to facilitate functional restoration of damaged tissues and not just abate or moderate symptoms. Safe and efficacious cell therapies for chronic diseases could potentially capture an increasing portion of future healthcare spending in the United States, driven both by favorable demographics and meaningful pharma-coeconomic benefit.

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, 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.

Adipocell is a proprietary kit which also for isolation of patient-derived cell therapy that is currently being utilized in clinic treatments at the point of care. US Stem Cell clinic and other trained physicians utilize this therapy as a medical procedure for a variety of indications.

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.

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™ to date have been 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. The Company, to continue the efforts stemming from the progress observed from the last activity in 2010, is also presently seeking a joint development partner for its MyoCell™ SDF-1 product candidate.

Adipocell

U.S. Stem Cell has successfully completed various trials using adipose stem cells. We have completed the Phase 1 Angel Trial for Adipocell (kits to obtain adipose derived stem cells) in congestive heart failure patients. Five patients were enrolled and treated in the second quarter of 2013. At the twelve (12) month time point, patients demonstrated a statistically significant average improvement in ejection fraction (“EF”) by echocardiogram.

At the three (3) month time point, 100% of the patients demonstrated either improvement or stayed the same. After three (3) months, patients showed an average absolute improvement of 3 percentage points in EF. The patients continued to improve from 3 months to 6 months with a statistically significant average absolute improvement of 10 percentage points ($p=0.01$) and at the 12 month follow up patients showed this same level of improvement ($p=0.01$).

These trials were expanded to include a total of 28 patients. The patients underwent a local tumescent liposuction procedure to remove approximately 60 ml of fat tissue. The fat was separated to isolate the SVF and the cells were delivered into the akinetic myocardial scar region using a transendocardial delivery system (MyoCath®) in patients who had experienced a previous myocardial infarct. The subjects were then monitored for adverse events, ejection fraction via echocardiogram and 6-minute walk test (6MWT) over a period of 6 months.

The average EF was 29% at baseline and significantly increased to 35% at both 3 and 6 months. Patients walked an average of 349 meters at baseline and demonstrated a statistically significant improvement at 3 and 6 months’ post treatment of more than 80 meters. Overall, patients were pleased with the treatment results. More importantly, the procedure demonstrated a strong safety profile with no severe adverse events or complications linked to the therapy.

The adipose cells have also been utilized in a phase I trial in Europe for critical limb ischemia (n=20). Patients enrolled in the trial were already on the list for amputation. The cells were directly injected into the affected limbs in an effort to prevent the amputation. Seventy-five percent of the patients were able to avoid amputation and progressed to wound healing. No adverse events or complications were reported or linked to the cell therapy.

We have also initiated several Institutional Review Board studies in 2013 using adipose derived stem cells for various indications including dry macular degeneration, degenerative disc disease (DDD), erectile dysfunction (ED) and chronic obstructive pulmonary disease (COPD). At this time, we are not enrolling patients in any IRB studies. We have discontinued any studies or patient treatments with macular degeneration. We are continuing to see patients in the clinic for various indications including ED and COPD.

In the DDD trial, a total of 15 patients underwent a local tumescent liposuction procedure to remove approximately 60 ml of fat tissue. The fat was separated to isolate the SVF and the cells were delivered into the disc nucleus of patients with degenerative disc disease. The subjects were then monitored for adverse events, range of motion, visual analog scale (VAS), present pain intensity (PPI), Oswestry Disability Index (ODI), Beck Depression Inventory (BDI), Dallas Pain Questionnaire and Short Form (SF)-12 scores over a period of 6 months. Safety events were followed for 12 months.

No severe adverse events (SAEs) were reported during a 12 month follow up period with no incidences of infection. Patients demonstrated statistically significant improvements in several parameters including flexion, pain ratings, VAS, PPI, and short form questionnaires. In addition, both ODI and BDI data was trending positive and a majority of patients reported improvements in their Dallas Pain Questionnaire scores. Overall, we observed that patients were pleased with the treatment results. More importantly, the procedure demonstrated a strong safety profile with no severe adverse events or complications linked to the therapy.

We have published a variety of studies using adipose cells and these studies are available on PubMed. Studies include COPD, ischemia, salivary gland damage, safety analysis, and osteoarthritis. These studies are expressly not incorporated by reference to this report.

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 personalized cellular therapeutic treatments.

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 has developed a multifaceted portfolio of revenue generating products and services in its US Stem Cell Training, Vetbiologics, and US Stem Cell Clinic, 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 for venture financings – a modern biotechnology company development strategy.

Today, we contend that U.S. Stem Cell is a combination of opportunistic business enterprises. We estimate that the products and services we offer through US Stem Cell Training, Vetbiologics, and US Stem Cell Clinics has the potential, although we cannot provide assurances as to if and when it will be accomplished, to drive up to \$100 million dollars in cumulative peak annual revenues. What we are establishing is a foundation of value in the products and services we are selling and plan to sell from US Stem Cell Training, Vetbiologics, and US Stem Cell clinics. Our strategy is to expand the revenues generated from each of these operating divisions and to reinvest the profits we generate into our U.S. Stem Cell clinical development pipeline.

On January 29th, 2015 we announced an update and diversification of our clinical development pipeline. Our cardiovascular and vascular product candidates have been streamlined, putting our best opportunities at the forefront of our efforts. The MYOCELL™ and MYOCELL™ SDF-1 candidates will, in our opinion, advance forward in the treatment of chronic heart failure (CHF). We are in active prospective partnering discussion for the MYOCELL™ SDF-1 program. Partnering, we contend, will enhance our capabilities, reduce our development cost through cost sharing and potentially accelerate our time to approval and commercialization. We will continue to apply our ADIPOCELL technology to the treatment of patients in clinic at the point of care. We believe that updating and diversifying our clinical development programs increases the probability of our success, brings operational and fiscal clarity to our Company, and will ultimately enhance shareholder value.

We will continue to evaluate and act upon opportunities to increase our top line revenue position and that correspondingly increase cash inflows. 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) 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.

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.

US STEM CELL CLINIC, LLC, REGENERATIVE WELLNESS CLINIC, LLC and US STEM CELL OF THE VILLAGES, LLC

US Stem Cell Clinic LLC, Regenerative Wellness Clinic LLC and US Stem Cell of the Villages LLC, partly owned investments, are offering in-clinic regenerative medicine treatments to patients suffering from degenerative diseases. Adipose stem cells can be obtained from the patient easily, abundantly, and with minimal patient discomfort. Clinical applications for patients can be performed in an office setting using autologous adipose-derived stem cells. Current applications include orthopedic conditions (tendon/ligament injuries, osteoarthritis, etc.), degenerative conditions (COPD, diabetes), neurological (MS, Parkinson's, spinal cord injuries, autism, etc.) and auto-immune (RA, Crohn's, colitis, lupus). Pricing depends on application and ranges from \$5,000 to \$12,000. We will provide operating assistance as well as management services to US Stem Cell of the Villages LLC, the latter to be compensated at fee of five percent (5%) of the LLC gross revenues.

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 are required to return all leased equipment and along with any maintenance records, logs, etc. in our possession to the lessor with no right of repurchase.

American Stem Cell Centers of Excellence are clinics derived from the investment group behind the Asset Purchase and Leaseback Agreement. American Stem Cell Centers of Excellence provide comprehensive stem cell treatments using innovative technologies and the latest research with the intent that after treatment, the body's own healing potential naturally repairs and regenerates damaged tissue. With a new clinic in Miami, Florida and, as we intend, additional clinics opening soon around the country, management contends that American Stem Cell Centers of Excellence provides comprehensive stem cell treatments using the U.S. Stem Cell Inc. innovative technologies and the latest regenerative medicine research. U.S. Stem Cell's team of scientists have pioneered these in-clinic regenerative medicine protocols and, in our estimation, have helped thousands of patients through their partly-owned subsidiary U.S. Stem Cell Clinic. American Stem Cell Centers of Excellence would like to replicate this success and have partnered and, with the Board of Directors' approval and continued oversight that this will not diminish their responsibilities to our company, have retained the professional services of Mike Tomas as CEO to with scientific and successful operational deployment of their clinics. The board of directors contends that the successful deployment of American Stem Cell Centers of Excellence will lead to the financial value and revenue growth of US Stem Cell, Inc. through sales of our products and services at American Stem Cell Center of Excellence clinics.

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 carry balance as of December 31, 2018 and 2017 was \$68,500 and \$71,500, 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.

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.

Primary MyoCath Patent

The Primary MyoCath Patent includes device claims that we believe covers, among other things, the structure of MyoCath. The Primary MyoCath Patent expired in the United States in September 2017.

In January 2000, we entered into a license agreement with Comedicus Incorporated pursuant to which Comedicus granted us a royalty-free, fully paid-up, non-exclusive and irrevocable license to the Primary MyoCath Patent in exchange for a payment of \$50,000. This agreement was amended in August 2000 to provide us an exclusive license to the Primary MyoCath Patent in exchange for a payment of \$100,000 and our loan of \$250,000 to Comedicus. Pursuant to this amendment we also received the right, but not the obligation, with Comedicus' consent, which consent is not to be unreasonably withheld, to defend the Primary MyoCath Patent against third party infringers.

In June 2003, we entered into agreements with Advanced Cardiovascular Systems, Inc., or ACS, originally a subsidiary of Guidant Corporation and now d/b/a Abbott Vascular, a division of Abbott Laboratories, pursuant to which we assigned our rights under the license agreement with Comedicus, as amended, and committed to deliver 160 units of MyoCath and sold certain of our other catheter related intellectual property, or, collectively, with the Primary MyoCath Patent (the Catheter IP), for aggregate consideration of \$900,000. In connection with these agreements, ACS granted to us a co-exclusive, irrevocable, fully paid-up license to the Catheter IP for the life of the patents related to the Catheter IP.

ACS has the exclusive right, at its own expense, to file, prosecute, issue, maintain, license, and defend the Catheter IP, and the primary right to enforce the Catheter IP against third party infringers. If ACS fails to enforce the Catheter IP against a third party infringer within a specified period of time, we have the right to do so at our expense. The party enforcing the Catheter IP is entitled to retain any recoveries resulting from such enforcement. The asset purchase agreement only pertains to the Catheter IP developed or acquired by us prior to June 24, 2003.

Our subsequent catheter related developments and/or acquisitions, such as MyoCath II, were not sold or licensed to ACS.

MyoCell™ SDF-1 Patents

To develop our MyoCell™ SDF-1 product candidate, we rely primarily on patents. We had an agreement to license patents from Juventas. These patents relate to methods of repairing damaged heart tissue by transplanting myoblasts that express SDF-1 and other therapeutic proteins capable of recruiting other stem cells within a patient's own body to the cell transplant area. We believe we will also need to, among other things, license some additional intellectual property to commercialize MyoCell™ SDF-1 in the form we believe may prove to be the most safe and/or effective.

MyoCath II Patents

In April 2006, we entered into an agreement with Tricardia, LLC pursuant to which Tricardia granted us a sublicenseable license to certain patents and patent applications in the United States, Australia, Canada, Europe and Japan covering the modified injection needle we intend to use as part of MyoCath II, or the MyoCath II Patents, in exchange for a one-time payment of \$100,000. Our license covers and is exclusive with respect to products developed under the MyoCath II Patents for the delivery of therapeutic compositions to the heart. Unless earlier terminated by mutual consent of the parties, our agreement with Tricardia will terminate upon the expiration date of the last MyoCath II Patent. Tricardia has the obligation to take all actions necessary to file, prosecute and maintain the MyoCath II Patents. We are required to reimburse Tricardia, on a pro-rata basis with other licensees of Tricardia of the MyoCath II Patents, for all reasonable out-of-pocket costs and expenses incurred by Tricardia in prosecuting and maintaining the MyoCath II Patents. To the extent Tricardia determines not to initiate suit against any infringer, we have the right, but not the obligation, to commence litigation for such alleged infringement with respect to any jurisdiction or, in the alternative, the agreement will be automatically amended to exclude such jurisdiction.

GOVERNMENT REGULATION

The health care industry is one of the most highly regulated industries in the United States and abroad. Various governmental regulatory authorities, as well as private accreditation organizations, oversee and monitor the activities of individuals and businesses engaged in the development, manufacture and delivery of health care products and services. The following is a general description of certain current laws and regulations that are relevant to our business.

HCT/P Regulations

Manufacturing facilities that produce cellular therapies are subject to extensive regulation by the FDA. In particular, FDA regulations set forth requirements pertaining to establishments that manufacture human cells, tissues, and cellular and tissue-based products (“HCT/Ps”). Title 21, Code of Federal Regulations, Part 1271 provides for a unified registration and listing system, donor-eligibility, current Good Tissue Practices (“cGTP”), and other requirements that are intended to prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps. More specifically, key elements of Part 1271 include:

- Registration and listing requirements for establishments that manufacture HCT/Ps;
- Requirements for determining donor eligibility, including donor screening and testing;
- cGTP requirements, which include requirements pertaining to the manufacturer’s quality program, personnel, procedures, manufacturing facilities, environmental controls, equipment, supplies and reagents, recovery, processing and process controls, labeling, storage, record-keeping, tracking, complaint files, receipt, pre-distribution shipment, distribution, and donor eligibility determinations, donor screening, and donor testing;
- Adverse reaction reporting;
- Labeling of HCT/Ps; and
- FDA inspection, retention, recall, destruction, and cessation of manufacturing operations.

U.S. Stem Cell and its affiliated entities currently collects, processes, stores and manufactures HCT/Ps, including the manufacture of cellular therapy products. Therefore, U.S. Stem Cell must comply with cGTP and with the current Good Manufacturing Practices (“cGMP”) requirements that apply to biological products. Cell and tissue based products may also be subject to the same approval standards, including demonstration of safety and efficacy, as other biologic and drug products if they meet certain criteria such as if the cells or tissues are more than minimally manipulated or if they are intended for a non-homologous use.

Management believes that requirements pertaining to premarket approval do not currently apply to U.S. Stem Cell because those entities are not currently investigating, marketing or selling cellular therapy products. If U.S. Stem Cell changes its business operations in the future, the FDA requirements that apply to U.S. Stem Cell may also change.

Pharmaceutical and Biologic Products

Government authorities in the United States, at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising promotion, distribution, marketing, import and export of biological products such as MyoCell™. The process of obtaining required regulatory approvals and the subsequent compliance with appropriate statutes and regulations require the expenditure of substantial time and money, and there is no guarantee that we will successfully complete the steps needed to obtain regulatory approval of MyoCell™ or any future product candidates. In addition, these regulations may change and our product candidates may be subject to new legislation or regulations.

In the United States, pharmaceutical and biologic products, including cellular therapies, are subject to extensive pre- and post-market regulation by the U.S. FDA. The Federal Food, Drug, and Cosmetic Act (“FD&C Act”), and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Biological products are approved for marketing under provisions of the Public Health Service Act, or PHS Act. However, because most biological products also meet the definition of “drugs” under the FD&C Act, they are also subject to regulation under FD&C Act provisions. The PHS Act requires the submission of a biologics license application (“BLA”), rather than a New Drug Application (“NDA”), for market authorization. However, the application process and requirements for approval of BLAs are similar to those for NDAs, and biologics are associated with similar approval risks and costs as drugs.

Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs or BLAs, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of a notice of claimed investigational exemption or an investigational new drug application (“IND”), which must become effective before clinical testing can commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug or biologic for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Submission of an IND may not result in FDA authorization to initiate a clinical trial if FDA raises concerns or questions about the design of the clinical trial or the preclinical or manufacturing information supporting it, including concerns that human research subjects will be exposed to unreasonable health risks. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations; good clinical practice, or GCP, as set forth in FDA guidance, which is meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. Sponsors of clinical trials of FDA regulated products, including drugs and biologics, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial is not being conducted in accordance with FDA requirements, or presents an unacceptable risk to the clinical trial patients (See Item 3). The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions

Clinical trials to support NDAs or BLAs for marketing approval are typically conducted in four sequential phases, but the phases may overlap.

- *Phase 1:* Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients when the drug or biologic is too toxic to be ethically given to healthy individuals.
- *Phase 2:* Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3:* These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically-dispersed clinical trial sites. In most cases FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.
- *Phase 4:* In some cases, FDA may condition approval of an NDA or BLA for a product candidate on the sponsor's agreement to conduct additional clinical trials after NDA or BLA approval. In other cases, a sponsor may voluntarily carry out additional trials post approval to gain more information about the drug or biologic. Such post approval trials are typically referred to as Phase 4 studies.

After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the U.S. The NDA or BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA or BLA is substantial. Under federal law, the submission of most NDAs or BLAs is additionally subject to a substantial application user fee, currently exceeding \$2,169,000, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently exceeding \$104,000 per product and \$554,000 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. Most such applications for standard review drug or biologic products are reviewed within ten to twelve months; most applications for priority review drugs or biologics are reviewed in six to eight months. FDA can extend these reviews by three months. Priority review can be applied to drugs or biologics that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for products intended to treat a serious or life-threatening disease relative to the currently approved products.

The FDA may refer applications for novel drug or biologic products, or drug or biologic products which present difficult questions of safety or efficacy, to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP - a quality system regulating manufacturing - is satisfactory and the NDA or BLA contains data that provide substantial evidence that the drug or biologic is safe and effective in the indication studied.

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After the FDA evaluates the NDA and the manufacturing facilities, it issues an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in 2 or 6 months depending on the type of information included.

Additional Controls

The PHS Act also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the U.S. and between states.

Biosimilars

The Patient Protection and Affordable Care Act, or Affordable Care Act, signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, which created an abbreviated approval pathway for biological products shown to be highly similar to, or interchangeable with, an FDA-licensed reference biological product. The BPCI Act is susceptible to modification or elimination by the United States Congress and the executive branch of government as part of its current policy of dismantling or indirectly affecting The Patient Protection and Affordable Care Act. We cannot be certain how, or if, any adjustments would impact the Company. This is conceptually similar to the established process for generic drug approval in that it attempts to minimize duplicative testing. Biosimilarity, which requires that there be no differences in conditions of use, route of administration, dosage form, and strength and there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, must be shown through analytical studies, animal studies, and at least one clinical study, absent a waiver by the Secretary. Interchangeability requires that a product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. No biosimilar or interchangeable products have been approved under the BPCIA to date. Complexities associated with the larger and often more complex structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the same condition for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) eighteen months after the first interchangeable biosimilar is approved if there is no legal challenge, (iii) 18 months after the resolution in the first interchangeable applicant's favor of a lawsuit challenging the reference biologics' patents, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a lawsuit is ongoing within the 42 month period.

Post-Approval Regulation

Once an NDA or BLA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. As a condition of NDA or BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the product drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. The requirement for a REMS can materially affect the potential market and profitability of the product.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA or NDA supplement or BLA supplement before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements and BLA supplements as it does in reviewing NDAs or BLAs. The FDA has broad enforcement authority under the FDC Act, and failure to abide by these regulations can result in enforcement action, including the issuance of a Warning Letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and federal civil and criminal investigations, prosecutions and penalties. State enforcement actions relating to promotional violations are also becoming more common.

Adverse experiences associated with the use of the drug must be reported to the FDA and could result in the imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

Current Good Manufacturing Practices (cGMP) Standards

The FDA Act and FDA regulations govern the quality control, manufacture, packaging, and labeling procedures of products regulated as a drug or biological product, including cellular therapies comprised of HCT/Ps. These laws and regulations include requirements for cGMP. These requirements are designed to ensure that a facility's processes - and products resulting from those processes - meet defined safety requirements. The cGMP requirements, are federal regulations that govern the manufacture, processing, packaging and holding of drug and cell therapy products.

The objective of compliance with cGMP standards is to protect the public health and safety by ensuring that products (i) have the identity, strength, quality and purity that they purport or are represented to possess; (ii) meet their specifications; and (iii) are free of objectionable microorganisms and contamination.

A central focus of the cGMP requirements is to design and build quality into the manufacturing processes and the facilities in which products are produced and to ensure the consistency, product integrity, and reproducibility of results and product characteristics. This is done by implementing quality systems and processes including specifications and documentation.

In addition, drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Failure to comply with applicable FDA requirements can result in regulatory inspections and associated observations, warning letters, other requirements of remedial action, and, in the case of failures that are more serious, suspension of manufacturing operations, seizure, injunctions, product recalls, fines, and other penalties. We believe that our facilities are in material compliance with applicable existing FDA requirements.

Additionally, FDA, other regulatory agencies, or the United States Congress may be considering, and may enact laws or regulations regarding the use and marketing of stem cells, cell therapy products, or products derived from human cells or tissue. These laws and regulations can affect us directly or the business of some of U.S. Stem Cell's clients and therefore the amount of business U.S. Stem Cell receives from these clients.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers or deferrals for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity-patent or non-patent-for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition - generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Approval of Medical Devices

Medical devices are also subject to extensive regulation by the FDA. To be commercially distributed in the United States, medical devices must receive either 510(k) clearance or pre-market approval, or PMA, from the FDA prior to marketing. Devices deemed to pose relatively low risk are placed in either Class I or II, which requires the manufacturer to submit a pre-market notification requesting permission for commercial distribution, or 510(k) clearance. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, devices deemed not substantially equivalent to a previously 510(k) cleared device and certain other devices are placed in Class III which requires PMA. We anticipate that MyoCath will be classified as a Class III device.

To obtain 510(k) clearance, a manufacturer must submit a pre-market notification demonstrating that the proposed device is substantially equivalent in intended use and in safety and efficacy to a previously 510(k) cleared device, a device that has received PMA or a device that was in commercial distribution before May 28, 1976. The FDA's 510(k) clearance pathway usually takes from four to twelve months, but it can last longer.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require PMA. The FDA requires each manufacturer to make this determination, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA is obtained.

A product not eligible for 510(k) clearance must follow the PMA pathway, which requires proof of the safety and efficacy of the device to the FDA's satisfaction. The PMA pathway is much more costly, lengthy and uncertain than the 510(k) approval pathway. A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with quality system regulation requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. Upon acceptance by the FDA of what it considers a completed filing, the FDA commences an in-depth review of the PMA application, which typically takes from one to two years, but may last longer. The review time is often significantly extended as a result of the FDA asking for more information or clarification of information already provided.

If the FDA's evaluation of the PMA application is favorable, and the applicant satisfies any specific conditions (e.g., changes in labeling) and provides any specific additional information (e.g., submission of final labeling), the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and efficacy of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in an enforcement action, which could have material adverse consequences, including the loss or withdrawal of the approval.

Even after approval of a pre-market application, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process.

Post-Approval Requirements

Even if regulatory clearances or approvals for our product candidates are obtained, our products and the facilities manufacturing our products will be subject to continued review and periodic inspections by the FDA. For example, as a condition of approval of a new drug application, the FDA may require us to engage in post-marketing testing and surveillance and to monitor the safety and efficacy of our products. Holders of an approved new BLA, PMA or 510(k) clearance product are subject to several post-market requirements, including the reporting of certain adverse events involving their products to the FDA, provision of updated safety and efficacy information, and compliance with requirements concerning the advertising and promotion of their products.

In addition, manufacturing facilities are subject to periodic inspections by the FDA to confirm the facilities comply with cGMP requirements. In complying with cGMP, manufacturers must expend money, time and effort in the area of production and quality control to ensure full compliance. For example, manufacturers of biologic products must establish validated systems to ensure that products meet high standards of sterility, safety, purity, potency and identity. Manufacturers must report to the FDA any deviations from cGMP or any unexpected or unforeseeable event that may affect the safety, quality, or potency of a product. The regulations also require investigation and correction of any deviations from cGMP and impose documentation requirements.

In addition to regulations enforced by the FDA, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state and local regulations. Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials and radioactive compounds.

Other Health Care Regulations

Health Privacy Laws

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”), require health care plans, health care providers and health care clearinghouses, collectively defined under HIPAA as “Covered Entities,” to comply with standards for the use and disclosure of health information within such organizations and with third parties. These include standards for:

- Common health care transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures;
- Unique identifiers for providers, employers, health plans and individuals; and
- Security and privacy of health information.

Although the obligations of HIPAA only apply directly to Covered Entities, any Covered Entity that uses third parties (referred to in HIPAA as “Business Associates”) to perform functions on its behalf involving the creation or use of certain patient health information is required to have a contract with the Business Associate that limits the use and disclosure of such information by the Business Associate.

HIPAA does not preempt, or override, state privacy laws that provide even more protection for individuals’ health information. These laws’ requirements could further complicate U.S. Stem Cell’s ability to obtain necessary research data from its collaborators. In addition, certain state privacy and genetic testing laws may directly regulate our research activities, affecting the manner in which we use and disclose individuals’ health information, potentially increasing the cost of doing business, and exposing us to liability claims. In addition, patients and research collaborators may have contractual rights that further limit our ability to use and disclose individually identifiable health information. Claims that we violated individuals’ privacy rights or breached its contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm the business.

While we believe that the current business operations of U.S. Stem Cell would not cause either of them to be considered a Covered Entity, there is a risk that due to conflicting interpretations of the regulations, U.S. Stem Cell may be deemed to be a Covered Entity. If U.S. Stem Cell is a Covered Entity, there is a risk of liability that U.S. Stem Cell may not be complying fully with all HIPAA requirements. U.S. Stem Cell has signed Business Associate Agreements where requested by U.S. Stem Cell's customers who are Covered Entities, which would require compliance with certain privacy and security requirements relating to individually identifiable health information created or used in connection with such relationships. U.S. Stem Cell is in substantial compliance with such Business Associate Agreements. However, given the law's complexity and the possibility that the regulations may change and may be subject to changing and even conflicting interpretation, U.S. Stem Cell's ability to comply fully with all of the HIPAA requirements and requirements of its Business Associate Agreements is uncertain. Further, as a result of amendments the HITECH Act, U.S. Stem Cell's compliance burden has increased and they will be subject to audit and enforcement by the federal government and, in some cases, by state authorities. Further, they are obligated to publicly disclose wrongfull disclosures or losses of personal health information.

Fraud and Abuse Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal prosecution, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of States also have statutes or regulations similar to the federal anti-kickback statute and false claims laws, which apply to items and services, reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

Affordable Care Act

In late March 2010, the Federal government enacted the comprehensive health care reform package, the Affordable Care Act. Among other provisions, the Affordable Care Act imposes individual and employer health insurance requirements, provides certain insurance subsidies (e.g., premiums and cost sharing), mandates extensive insurance market reforms, creates new health insurance access points (e.g., State and federal-based health insurance exchanges), expands the Medicaid program, promotes research on comparative clinical effectiveness of different technologies and procedures, and makes a number of changes to how products and services will be reimbursed by the Medicare program.

Amendments to the Federal False Claims Act under the Affordable Care Act have made it easier for private parties to bring "qui tam" (whistleblower) lawsuits against companies, under which the whistleblower may be entitled to receive a percentage of any money paid to the government. The Affordable Care Act is susceptible to modification or elimination by the United States Congress and the executive branch of government as part of its current policy of dismantling or indirectly affecting The Patient Protection and Affordable Care Act. We cannot be certain how, or if, any adjustments would impact the Company.

There are a number of provisions in the Affordable Care Act that may directly impact our customers and, therefore, indirectly affect us. For example, the Affordable Care Act expands the number of individuals that will be covered by either private or public health insurance, which may, in turn, increase the pool of potential purchasers for our customers' products to the extent they are reimbursable by private or public health insurance. The Affordable Care Act also requires health insurance issuers in the individual and small group markets to cover certain "essential health benefits," which include prescription drugs and which may increase coverage for our customers' products. In addition, the Affordable Care Act reduces income and raises costs for our customers through, for instance, the imposition of drug price discounts for Medicare Part D enrollees in the "donut hole" and the imposition of an annual fee on prescription drug and biologic manufacturers. Such provisions may cause our customers to seek to restrain costs in other areas, including the services that we provide. The effective dates of the various provisions within the Affordable Care Act are staggered over the next several years, with some changes occurring immediately. Much of the interpretation of the Affordable Care Act will be subject to administrative rulemaking, the development of agency guidance, and court interpretation.

Other Applicable Laws

In addition to those described above, other federal and State laws and regulations that could directly or indirectly affect our ability to operate the business and/or financial performance include:

- State and local licensure, registration and regulation of laboratories, the processing and storage of human cells and tissue, and the development and manufacture of pharmaceuticals and biologics;
- other laws and regulations administered by the United States FDA, including the Federal Food, Drug, and Cosmetic Act and related laws and regulations and the Public Health Service Act and related laws and regulations;
- laws and regulations administered by the United States Department of Health and Human Services, including the Office for Human Research Protections;
- State laws and regulations governing human subject research;
- federal and state coverage and reimbursement laws and regulations, including laws and regulations administered by the Centers for Medicare & Medicaid Services and State Medicaid agencies;
- The federal Medicare and Medicaid Anti-Kickback Law and similar state laws and regulations;
- The federal physician self-referral prohibition commonly known as the Stark Law, and State equivalents of the Stark Law;
- Occupational Safety and Health Administration ("OSHA") requirements;
- State and local laws and regulations dealing with the handling and disposal of medical waste; and
- the Intermediate Sanctions rules of the IRS providing for potential financial sanctions with respect to "Excess Benefit Transactions" with HUMC or other tax-exempt organizations.

Other Regulations

We are also subject to various local, State and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our research and development activities. These laws include, but are not limited to, the Occupational Safety and Health Act, the Toxic Substances Control Act and the Resource Conservation and Recovery Act. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, there can be no assurances that accidental contamination or injury to employees and third parties from these materials will not occur. Our insurance program does not include environmental coverage.

Regulation in the European Union

In the European Union, or EU, medicinal products, including advanced therapy medicinal products, are subject to extensive pre- and post-market regulation by regulatory authorities at both the EU and national levels. Advanced therapy medicinal products comprise gene therapy products, somatic cell therapy products and tissue engineered products, which are cells or tissues that have undergone substantial manipulation and that are administered to human beings in order to regenerate, repair or replace a human tissue. We anticipate that our cell therapy products in development, including MyoCell™, would be regulated as advanced therapy medicinal products in the EU.

Clinical Trials

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on Good Clinical Practices, or GCP. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the EU, it must appoint an entity within the EU to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the competent authority, and a positive opinion from an independent ethics committee. The application for a clinical trial authorization must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. Currently, clinical trial authorization applications must be submitted to the competent authority in each EU member state in which the trial will be conducted. Under proposed new rules, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees.

The sponsor of a clinical trial must register the clinical trial in advance, and information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial will be made public as part of the registration. The results of the clinical trial must be submitted to the competent authorities and, with the exception of non-pediatric Phase 1 trials, will be made public at the latest within 12 months after the end of the trial.

During the development of a medicinal product, the European Medicines Agency, or EMA, and national medicines regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each scientific advice procedure.

Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned. To date, we have not initiated any scientific advice procedures or other discussions with the EMA or any national regulatory authorities in the EU.

Marketing Authorizations

After completion of the required clinical testing, we must obtain a marketing authorization before we may place a medicinal product on the market in the EU. There are various application procedures available, depending on the type of product involved. All application procedures require an application in the common technical document, or CTD, format, which includes the submission of detailed information about the manufacturing and quality of the product, and non-clinical and clinical trial information. There is an increasing trend in the EU towards greater transparency and, while the manufacturing or quality information is currently generally protected as confidential information, the EMA and national regulatory authorities are now liable to disclose much of the non-clinical and clinical information in marketing authorization dossiers, including the full clinical study reports, in response to freedom of information requests after the marketing authorization has been granted. The EMA is currently considering a procedure under which clinical study reports would be posted on the agency’s website following the grant, denial or withdrawal of a marketing authorization application, subject to procedures for limited redactions and protection against unfair commercial use. A similar requirement is contained in a draft new Regulation on Clinical Trials that is expected to become applicable in mid-2016 or later.

The centralized procedure gives rise to marketing authorizations that are valid throughout the EU and, by extension (after national implementing decisions), in Norway, Iceland and Liechtenstein, which, together with the EU member states, comprise the European Economic Area, or EEA. Applicants file marketing authorization applications with the EMA, where they are reviewed by a relevant scientific committee, in most cases the CHMP. The EMA forwards CHMP opinions to the European Commission, which uses them as the basis for deciding whether to grant a marketing authorization. The centralized procedure is compulsory for medicinal products that (1) are derived from biotechnology processes, (2) contain a new active substance (not yet approved) indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders, viral diseases or autoimmune diseases and other immune dysfunctions, (3) are orphan medicinal products or (4) are advanced therapy medicinal products, such as cell therapy medicines. For medicines that do not fall within these categories, an applicant may voluntarily submit an application for a centralized marketing authorization to the EMA, as long as the CHMP agrees that (i) the medicine concerned contains a new active substance (not yet approved), (ii) the medicine is a significant therapeutic, scientific, or technical innovation, or (iii) if its authorization under the centralized procedure would be in the interest of public health.

For those medicinal products for which the centralized procedure is not available, the applicant must submit marketing authorization applications to the national medicines regulators through one of three procedures: (1) a national procedure, which results in a marketing authorization in a single EU member state; (2) the decentralized procedure, in which applications are submitted simultaneously in two or more EU member states; and (3) the mutual recognition procedure, which must be used if the product has already been authorized in at least one other EU member state, and in which the EU member states are required to grant an authorization recognizing the existing authorization in the other EU member state, unless they identify a serious risk to public health. A national procedure is only possible for one member state; as soon as an application is submitted in a second member state the mutual recognition or decentralized procedure will be triggered.

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, defined by three cumulative criteria: the seriousness of the disease (e.g. heavy disabling or life-threatening diseases) to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days.

Data Exclusivity

Marketing authorization applications for generic medicinal products do not need to include the results of pre-clinical and clinical trials, but instead can refer to the data included in the marketing authorization of a reference product for which regulatory data exclusivity has expired. If a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate pre-clinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Orphan Medicinal Products

The EMA's Committee for Orphan Medicinal Products, or COMP, may recommend orphan medicinal product designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the product in the EU would be sufficient to justify the necessary investment in developing the medicinal product. The COMP may only recommend orphan medicinal product designation when the product in question offers a significant clinical benefit over existing approved products for the relevant indication. Following a positive opinion by the COMP, the European Commission adopts a decision granting orphan status. The COMP will reassess orphan status in parallel with EMA review of a marketing authorization application and orphan status may be withdrawn at that stage if it no longer fulfills the orphan criteria (for instance because in the meantime a new product was approved for the indication and no convincing data are available to demonstrate a significant benefit over that product). Orphan medicinal product designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following marketing authorization. During this period, the competent authorities may not accept or approve any similar medicinal product, unless it offers a significant clinical benefit. This period may be reduced to 6 years if the orphan medicinal product designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. The EMA is currently preparing guidance on assessing similarity of active ingredients for purposes of orphan exclusivity. It is possible that for biological products a narrow interpretation of similarity will be adopted.

Pediatric Development

In the EU, companies developing a new medicinal product must agree to a Pediatric Investigation Plan, or PIP, with the EMA and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies (e.g. because the relevant disease or condition occurs only in adults). The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Post-Approval Controls

The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, or QPPV, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new marketing authorization applications must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. Risk management plans and PSURs are routinely available to third parties requesting access, subject to limited redactions.

All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

Manufacturing

Medicinal products may only be manufactured in the EU, or imported into the EU from another country, by the holder of a manufacturing authorization from the competent national authority. The manufacturer or importer must have a qualified person, or QP, who is responsible for certifying that each batch of product has been manufactured in accordance with EU standards of good manufacturing practice, or GMP, before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Human Cells and Tissues

Human cells and tissues that are intended for human applications but that do not fall within the scope of rules governing medicinal products or medical devices are not subject to premarket review and approval, nor do they require extensive preclinical and clinical testing. However, there are EU rules governing the donation, procurement, testing and storage of human cells and tissues intended for human application, whether or not they are advanced therapy medicinal products. These rules also cover the processing, preservation and distribution of human cell and tissues that are not advanced therapy medicinal products. Establishments that conduct such activities must be licensed and are subject to inspection by regulatory authorities.

Such establishments must implement appropriate quality systems and maintain appropriate records to ensure that cells and tissues can be traced from the donor to the recipient and vice versa. There are also requirements to report serious adverse events and reactions linked to the quality and safety of cells and tissues. More detailed rules may exist at the national level.

Named Patient Sales

The EU medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a healthcare professional and for use by an individual patient under his direct personal responsibility. This may in certain countries also apply to products manufactured in a country outside the EU and imported to treat specific patients or small groups of patients. In addition, advanced therapy medicinal products do not need a marketing authorization if they are prepared on a non-routine basis and are used within the same EU member state in a hospital in accordance with a medical prescription for an individual patient.

These exemptions may allow us to make limited sales of our products before we obtain a marketing authorization in the EU. However, the exemptions could also allow our competitors to make sales without having obtained a marketing authorization and without undergoing the expense of clinical trials, especially if those competitors have cell processing facilities in the relevant EU member state. Similarly, certain hospitals may be able to compete with us on the basis of these rules.

Pricing and Reimbursement

Governments influence the price of medicinal products in the EU through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Regulation in Other Countries

We intend to seek to market our products in jurisdictions outside the United States and the EU. Most of these jurisdictions have product approval and post-approval regulatory processes that are similar in principle to those in the United States or EU. Any such considerations are in the early stages.

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 2019 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, 2018, we had cash and cash equivalents of \$1,357,146 and an accumulated capital deficit of \$129,788,678. 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. 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 13, 2019 in connection with the audit of our financial statements as of December 31, 2018, 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, our note to our financial statements for the year ended December 31, 2018 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, 2018, we have accumulated a deficit of approximately \$129.8 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.

To our knowledge, the partially owned clinics and the clinics that purchase our Adipocell kits are operating in compliance with the FDA 1271s which allow for same day medical procedures to be considered the practice of medicine. Should the FDA code of federal regulations change, this could affect our ability to generate revenues.

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 depend 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 depend heavily on its success. MyoCell™ is currently in the clinical testing stage of development, although we have suspended work under our clinical trials as we seek to raise sufficient funds to complete the 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 MyoCell™ and 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.

If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, we will not receive regulatory approval for or be able to commercialize our product candidates.

We cannot market any product candidate until regulatory agencies grant approval or licensure. In order to obtain regulatory approval for the sale of any product candidate, we must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to the satisfaction of regulatory authorities that our product candidates are safe and effective for each indication under the applicable standards relating to such product candidate. The preclinical studies and clinical trials of any product candidates must comply with the regulations of the FDA and other governmental authorities in the United States and similar agencies in other countries.

Even if we achieve positive interim results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not be indicative of success in later trials. For example, MyoCell™ has been studied in a limited number of patients to date. Even though our early data has been promising, we have not yet completed any large-scale pivotal trials to establish the safety and efficacy of MyoCell™. A number of participants in our clinical trials have experienced serious adverse events adjudicated or determined by trial investigators to be potentially attributable to MyoCell™. There is a risk that safety concerns relating to our product candidates or cell-based therapies in general will result in the suspension or termination of our clinical trials.

We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent regulatory approval and/or commercialization of our product candidates, including the following:

- the FDA or similar foreign regulatory authorities may find that our product candidates are not sufficiently safe or effective or may find our cell culturing processes or facilities unsatisfactory (see Item 3);
- officials at the FDA or similar foreign regulatory authorities may interpret data from preclinical studies and clinical trials differently than we do;
- our clinical trials may produce negative or inconclusive results or may not meet the level of statistical significance required by the FDA or other regulatory authorities, and we may decide, or regulators may require us, to conduct additional preclinical studies and/or clinical trials or to abandon one or more of our development programs;
- the FDA or similar foreign regulatory authorities may change their approval policies or adopt new regulations;
- there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities or obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites;
- we, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks or undesirable side effects;
- we may experience difficulties in managing multiple clinical sites;

- enrollment in our clinical trials for our product candidates may occur more slowly than we anticipate, or we may experience high drop-out rates of subjects in our clinical trials, resulting in significant delays;
- we may be unable to manufacture or obtain from third party manufacturers sufficient quantities of our product candidates for use in clinical trials; and
- our product candidates may be deemed unsafe or ineffective, or may be perceived as being unsafe or ineffective, by healthcare providers for a particular indication.

In the SEISMIC Trial, we experienced delays attributable to slower than anticipated enrollment of patients. We may continue to experience difficulties in enrolling patients in our clinical trials, which could increase the costs or affect the timing or outcome of these trials and could prevent us from completing these trials.

Failures or perceived failures in our clinical trials would delay and may prevent our product development and regulatory approval process, make it difficult for us to establish collaborations, negatively affect our reputation and competitive position and otherwise have a material adverse effect on our business.

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.

We depend on third parties to assist us in the conduct of our preclinical studies and clinical trials, and any failure of those parties to fulfill their obligations could result in costs and delays and prevent us from obtaining regulatory approval or successfully commercializing our product candidates on a timely basis, if at all.

We engage consultants and CROs to help design, and to assist us in conducting, our preclinical studies and clinical trials and to collect and analyze data from those studies and trials. The consultants and contract research organizations we engage interact with clinical investigators to enroll patients in our clinical trials. As a result, we depend on these consultants and CROs to perform the studies and trials in accordance with the investigational plan and protocol for each product candidate and in compliance with regulations and standards, commonly referred to as “good clinical practice”, for conducting, recording and reporting results of clinical trials to assure that the data and results are credible and accurate and the trial participants are adequately protected, as required by the FDA and foreign regulatory agencies. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. The risk of delays is heightened for our clinical trials conducted outside of the United States, where it may be more difficult for us to ensure that studies are conducted in compliance with foreign regulatory requirements.

Any third parties that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical trial protocols or for other reasons, our clinical trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful. If there are delays or failures in clinical trials or regulatory approvals as a result of the failure to perform by third parties, our development costs will increase, and we may not be able to obtain regulatory approval for our product candidates.

In addition, we may not be able to establish or maintain relationships with these third parties on favorable terms, if at all. If we need to enter into replacement arrangements because a third party is not performing in accordance with our expectations, we may not be able to do so without undue delays or considerable expenditures or at all.

Our cell-based product candidates are based on novel technologies and the FDA and regulatory agencies in other countries have limited experience reviewing product candidates using these technologies.

We are subject to the risks of failure inherent in the development of product candidates based on new technologies. The novel nature of our product candidates creates significant challenges in regards to product development and optimization, government regulation, third party reimbursement and market acceptance. These include:

- the scientific basis of our technology could be determined to be less sound than we believe;
- the time and effort required to solve novel technical problems could delay the development of our product candidates;
- the FDA and regulatory agencies in other countries have relatively limited experience with therapies based upon cellular medicine generally and, as a result, the pathway to regulatory approval for our cell-based product candidates may be more complex and lengthy

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. 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.

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.

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 and consists of 4,860 square feet of space, which we lease at a current rent of approximately \$82,620 per year. In September 2013, the Company amended its facility lease to extend the term until July 31, 2016. On February 4, 2016, the Company extended its facility lease to extend the term of the lease until August 31, 2019 at a monthly base rent of \$7,306 plus a pro rata share of landlord's operating expenses. In connection with the renewal, the Company was required to pay \$11,072 security deposit.

In addition to our corporate offices, at this location, we maintain:

- our MyoCell™ cell culturing facility for supply within the United States; and
- a fully equipped cell culturing laboratory where we perform experimental work in the areas of cell culturing, cell engraftment, and other advanced research projects related to our core business.

Approximate annual future minimum lease obligations under this non-cancelable facilities operating lease agreement as of December 31, 2018 are as follows:

Year ending December 31,	
2019	58,448

On November 17, 2017, the Company executed an Amendment to the Lease which required a payment of \$25,000 and monthly payments going forward of an additional \$4,500 for a period of ten months.

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 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, of which \$89,000 is included in accrued expenses at December 31, 2018 and December 31, 2017.

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, 2018 other than that described above.

SEC Investigation

On or about March 1, 2018, the U.S. Securities and Exchange Commission ("Commission"), Miami Regional Office ("Commission Staff"), served a subpoena upon U.S. Stem Cell, Inc., which seeks the production of certain documents and communications. The Commission Staff is conducting a formal non-public, fact-finding inquiry of U.S. Stem Cell, Inc ("Investigation"). The Investigation is neither an allegation of wrongdoing nor a finding that any violation of law has occurred. The Company is cooperating with, and has provided information and documents to, the Commission Staff.

As part of the Investigation, on or about May 14, 2018, the Commission Staff served subpoenas upon Kristin Comella and Mike Tomas, respectively, seeking the production of certain documents and communications. Ms. Comella and Mr. Tomas responded to the respective subpoenas and provided information and documents to the Commission Staff.

At this juncture, the Company is not able to predict the duration, scope, results, or consequences of the investigation. There can be no assurance that the Investigation will be resolved in a manner that is not adverse to the Company.

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. The Company is not able to predict the duration, scope, results, or consequences of the U.S. Department of Justice actions. There can be no assurance that this matter will be resolved in a manner that is not adverse to the Company.

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. (OTCQB) 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 2017	
	High	Low
First Quarter	\$ 0.179	\$ 0.0019
Second Quarter	\$ 0.1409	\$ 0.0276
Third Quarter	\$ 0.0537	\$ 0.0160
Fourth Quarter	\$ 0.0560	\$ 0.0210
Fiscal Year 2018		
	High	Low
First Quarter	\$ 0.0810	\$ 0.0274
Second Quarter	\$ 0.0800	\$ 0.0250
Third Quarter	\$ 0.0395	\$ 0.0300
Fourth Quarter	\$ 0.0353	\$ 0.0124

Holders

As of December 31, 2018, there were approximately 495 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, 2018:

	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)	112,970,693	0.033	75,068,070
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 2018, we sold an aggregate of 9,350,508 shares of our common stock for gross cash proceeds of \$367,700. 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 amended (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 subsequently registered under the Securities Act or transferred in a transaction exempt from registration under the Securities Act. We filed a Notice of Exempt Offering of Securities on Form D on May 4, 2018.

Issuer Purchases of Equity Securities

None.

Transfer Agent: Continental Stock Transfer & Trust Company, 17 Battery Place, 8th 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, 2017 or 2018.

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

The Company's management has evaluated whether there is substantial doubt about the Company's 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 Yearly Report on Form 10-K (the "Form 10-K"). This determination was based on the following factors: (i) during the twelve months ended December 31, 2018, the Company incurred net losses of \$2,160,427 and (ii) the Company has a working capital deficit (current liabilities in excess of current assets) of \$4,410,129. In the opinion of management, these factors, among others, raise substantial doubt about the ability of the Company to continue as a going concern for a reasonable period of time.

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.

Our most recent completed clinical trials of MyoCell™ are 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 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.

The SEISMIC, MYOHEART and MARVEL Trials have been designed to test the safety and efficacy of MyoCell™ in treating patients with severe, chronic damage to the heart. Upon regulatory approval of MyoCell, we intend to generate revenue in the United States from the sale of MyoCell™ cell-culturing services for treatment of patients by qualified physicians.

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), which we believe was the first approval of a study combining gene and cell therapies. We initially commenced work on this study, called the REGEN Trial, during the first quarter of 2010. We suspended activity on the trial in 2010 while seeking additional funding necessary to conduct the trial. We are seeking to secure sufficient funds to reinitiate enrollment in the MARVEL and REGEN trials. If we successfully secure such funds, we intend to re-engage a contract research organization, or CRO, investigators and certain suppliers to advance such trials. We have initiated and enrolled our first patient in the MIRROR trial in 2013. The trial is very similar to the MARVEL trial but focuses on sites outside the US. We will continue enrollment in the MIRROR trial once we have secured sufficient funds.

We have completed the Phase 1 Angel Trial for Adipocell (adipose derived stem cells). Five patients were enrolled and treated in the second quarter of 2013. At the twelve (12) month time point, patients demonstrated a statistically significant average improvement in ejection fraction (EF) by echocardiogram. This trial was extended to 28 patients and the data has been published in a peer reviewed journal.

We also initiated several Institutional Review Board studies in 2013 using adipose derived stem cells for various indications including dry macular degeneration, degenerative disc disease, erectile dysfunction and chronic obstructive pulmonary disease. We have published results of the degenerative disc trial. All other trials are not enrolling patients. We provide these therapies to patients through the clinic.

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. We are currently producing Myocath catheters with a contract manufacturer on an as needed basis.

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 are required to return all leased equipment and along with any maintenance records, logs, etc. in our possession to the lessor with no right of repurchase.

American Stem Cell Centers of Excellence are clinics derived from the investment group behind the Asset Purchase and Leaseback Agreement. American Stem Cell Centers of Excellence provide comprehensive stem cell treatments using innovative technologies and the latest research with the intent that after treatment, the body's own healing potential naturally repairs and regenerates damaged tissue. With a new clinic in Miami, Florida and, as we intend, additional clinics opening soon around the country, management contends that American Stem Cell Centers of Excellence provides comprehensive stem cell treatments using the U.S. Stem Cell Inc. innovative technologies and the latest regenerative medicine research. U.S. Stem Cell's team of scientists have pioneered these in-clinic regenerative medicine protocols and, in our estimation, have helped thousands of patients through their partly-owned subsidiary U.S. Stem Cell Clinic. American Stem Cell Centers of Excellence would like to replicate this success and have partnered and, with the Board of Directors' approval and continued oversight that this will not diminish their responsibilities to our company, has retained the professional services of Mike Tomas as CEO to assist with scientific and successful operational deployment of their clinics. The board of directors contends that the successful deployment of American stem cell centers of excellence will lead to the financial value and revenue growth of US Stem Cell, Inc. through sales of our products and services at American Stem Cell Center of Excellence clinics.

Subsequent events

In January and February 2019, the Company issued an aggregate of 8,598,928 shares of common stock for services rendered.

On January 29, 2019, through a reorganization of Member Interests of U.S. Stem Cell Clinic, LLC and Regenerative Wellness Clinic, LLC respectively, we increased our holdings, without additional consideration, to a 49.9 percent Member Interest ownership of U.S. Stem Cell Clinic, LLC and Regenerative Wellness Clinic, LLC respectively.

Results of Operations Overview

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, which we do not expect to occur before 2020.

We recognized revenues of \$6,700,888 in 2018 compared to revenues of \$5,520,537 in 2017. Our revenue in 2018 was generated from the sale of test kits and equipment, training services, patient treatments and laboratory services, and cell banking. Our revenues for 2017 were generated from the sale, test kits and equipment, training services, patient treatments and laboratory services, and cell banking. Our significant overall increase in 2018 as compared to 2017 was generated by a 48% increase in our banking revenue.

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 \$2,110,532 in the year ended December 31, 2018 compared to \$1,885,371 in the year ended December 31, 2017. The increase is primarily due higher revenue volume. The margins are higher in 2018 compared to 2017 due to increases in prices.

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.

Marketing, General and Administrative

Our marketing, 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.

Stock-Based Compensation

Stock-based compensation which is included in the Marketing, 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, 2018 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, 2017	71,630,763	\$ 0.0280	9.2
Granted	41,340,000	\$ 0.0458	10.0
Exercised	—	—	—
Forfeited/Expired	(70)	\$ 2,625.080	—
Options outstanding at December 31, 2018	112,970,693	\$ 0.03294	8.7
Options exercisable at December 31, 2018	43,089,443	\$ 0.02776	8.4
Available for grant at December 31, 2018	75,068,070	—	—

The following information applies to options outstanding and exercisable at December 31, 2018:

Exercise Price	Number Outstanding	Option Outstanding		Weighted Average Exercise price	Number Exercisable	Options Exercisable			
		Options Average				Remaining Contractual Life (years)	Weighted Average Exercise price		
		Remaining Contractual Life (years)	Options Average						
\$ 0.0043	16,200,000	8.11	\$ 0.0043		4,050,000	\$ 0.0043			
0.0196	22,850,000	7.72	0.0196		15,350,000	0.0196			
0.02511	9,000,000	9.93	0.02511		9,000,000	0.02511			
0.02576	2,340,000	9.61	0.02576		-	0.02576			
0.03626	31,865,000	8.61	0.03626		14,060,000	0.03626			
0.03680	10,000	8.61	0.03680		2,500	0.03680			
0.0536	30,000,000	9.36	0.0536		-	0.0536			
0.15402	705,363	6.75	0.15402		626,613	0.15402			
19.32	150	5.85	19.32		150	19.32			
70.00	100	2.66	70.00		100	70.00			
210.00	40	2.62	210.00		40	210.00			
680.00	40	1.11	680.00		40	680.00			
Total	112,970,693	8.67	\$ 0.03294		43,089,443	\$ 0.02776			

On May 7, 2018, we granted an aggregate 30,000,000 options to purchase the Company's common stock at \$0.0536 per share to key employees, vesting over 4 years, at grant date anniversary and exercisable over 10 years. The aggregate fair value of \$1,438,473, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 261.13% and Risk free rate: 2.90%.

On August 8, 2018, we granted an aggregate 2,340,000 options to purchase our company's common stock at \$0.02576 per share to key employees, vesting over 4 years, at grant date anniversary and exercisable over 10 years. The aggregate fair value of \$91,988, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 217.72% and Risk free rate: 2.83%.

On December 3, 2018, we granted an aggregate 9,000,000 options to purchase our company's common stock at \$0.02511 per share to board members, vesting immediately exercisable over 10 years. The aggregate fair value of \$195,722, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 215.29% and Risk free rate: 2.83%.

On February 6, 2017, we granted an aggregate 16,200,000 options to purchase our company's common stock at \$0.0043 per share to key employees, vesting over 4 years, at grant date anniversary and exercisable over 10 years. The aggregate fair value of \$53,271, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 235.22% and Risk free rate: 1.86%.

On August 7, 2017, we granted an aggregate 23,750,000 options to purchase our company's common stock from \$0.03626 to \$0.0368 per share to key employees, vesting over 4 years, at grant date anniversary and exercisable over 10 years. The aggregate fair value of \$860,211, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 259.16% and Risk free rate: 1.81%.

On August 7, 2017, we granted an aggregate 8,125,000 options to purchase our company's common stock at \$0.03626 per share to members of the Board of Directors, vesting immediately and exercisable over 10 years. The aggregate fair value of \$293,545, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 259.16% and Risk free rate: 1.81%.

The fair value of all options vesting during the years ended December 31, 2018 and 2017 of \$753,007 and \$645,483, respectively, was charged to current period operations.

As of December 31, 2018, we had approximately \$1,973,194 of total unrecognized compensation cost related to non-vested awards granted under the 2013 Omnibus Plan, which we expect to recognize over a weighted average period of 1.64 years.

Warrants

A summary of common stock purchase warrants at December 31, 2018 and activity during the year ended December 31, 2018 is presented below:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)
Outstanding at December 31, 2017	133,591	\$ 126.26	4.7
Issued	1,000,000	\$ 0.02713	10.0
Exercised	-		
Expired	(19,572)	\$ 24.46	
Outstanding at December 31, 2018	1,114,019	\$ 14.735	9.1
Exercisable at December 31, 2018	112,474	\$ 40.07	4.3

The following information applies to common stock purchase warrants outstanding and exercisable at December 31, 2018:

Warrants Outstanding			Warrants Exercisable			
Exercise Price	Shares	Weighted-Average Remaining Contractual Term	Exercise Price	Shares	Weighted-Average Exercise Price	
\$ 0.01 – 20.00	1,086,536	9.2	\$ 1.267	86,536	\$ 15.59	
\$ 20.01 – 30.00	19,543	5.2	\$ 25.06	19,543	\$ 25.06	
\$ 40.01 - 50.00	2,253	3.8	\$ 48.83	2,253	\$ 48.83	
\$ 50.01 – 60.00	543	2.6	\$ 60.00	543	\$ 60.00	
> \$60.00	<u>\$ 5,144</u>	2.8	\$ 2,800.69	<u>3,599</u>	\$ 701.78	
	<u>1,114,019</u>	<u>9.1</u>	<u>\$ 14.74</u>	<u>\$ 112,474</u>	<u>\$ 40.070</u>	

On August 27, 2018, we issued 1,000,000 warrants to purchase our company's common stock at \$0.02713 per share for services rendered, vesting 6 months from issuance and exercisable over 10 years. The aggregate fair value of \$24,986, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 217.01% and Risk free rate: 2.85%.

Interest Expense

Interest expense during the year ended December 31, 2018 was \$1,444,807 compared to \$642,102 for the year ended December 31, 2017. 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.

The debt discounts amortization and non-cash interest incurred during the year ended December 31, 2018 and 2017 was \$195,967 and \$126,457, respectively. Our increase in interest expense in 2018 as compared to 2017 was primarily due to our Capital Lease with GACP with contractually escalating payments.

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.

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.

Derivative instrument liability

We account for derivative instruments in accordance with ASC 815, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value, regardless of hedging relationship designation. Accounting for changes in fair value of the derivative instruments depends on whether the derivatives qualify as hedge relationships and the types of relationships designated are based on the exposures hedged. At December 31, 2018 and 2017, we did not have any derivative instruments that were designated as hedges.

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.

Comparison of Years Ended December 31, 2018 and December 31, 2017

Revenues

We recognized revenues of \$6,700,888 in 2018, revenues generated from the sale of, kits and equipment, services, and laboratory services. In 2017, we recognized revenues of \$5,520,537, revenues generated from the sales of kits and laboratory services. Our significant overall increase in 2018 as compared to 2017 was generated by a 48% increase in our banking revenue.

Cost of Sales

Cost of sales was \$2,110,532 in 2018 and \$1,885,371 in 2017. The increase is primarily due higher revenues in 2016 as compared to 2017. The margins increased by approximately 3% due to stronger mix of banking revenue as compared to kit sales in 2018.

Research and Development

Research and development expenses were \$5,439 in 2018, a decrease of \$1,205 from research and development expenses of \$6,644 in 2017. The decrease was primarily attributable to a decrease in the amount of available funds.

The timing and amount of our planned research and development expenditures is dependent on our ability to obtain additional financing.

Marketing, General and Administrative

Marketing, general and administrative expenses were \$5,682,296 in 2018, an increase of \$1,255,644 from marketing, general and administrative expenses of \$4,426,632 in 2017. The increase in marketing, general and administrative expenses is attributable, in part, to increases in stock based compensation, salaries and insurance and advertising expenses.

Gain (loss) on settlement of debt

During the year ended December 31, 2018, we incurred a net gain of \$5,625 primarily related to the settlement of accounts payable and debt restructured during the current period. In 2017, we incurred a loss of \$126,457 primarily due to the settlement of accounts payable, net with refinancing of debt during the current period.

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 \$386,536 which we will recognize to operations over the term of the lease (36 months). During the year ended December 31, 2018, we recognized \$128,845 in current period operations as compared to \$107,371 for the previous year.

Loss on change in fair value of derivative liabilities.

During the year ended December 31, 2016, we issued convertible notes and common stock purchase warrants with anti-dilutive provisions that had the possibility of exceeding our common shares authorized when considering the number of possible shares that may be issuable to satisfy settlement provisions of these agreements after consideration of all existing instruments that could be settled in shares. As such, we are required to determine the fair value of this derivative and mark to market each reporting period. For the year ended December 31, 2017, we incurred a \$(1,891,205) loss on change in fair value of our derivative liabilities. We did not have notes payable with anti-dilutive provisions in the 2018 year.

Income from equity investment

Our investment of 33% member interest ownerships of U.S. Stem Cell Clinic, LLC and Regenerative Wellness Clinic, LLC (subsequently increased after December 31, 2018) and well as our 49% member interest ownership in U.S. Stem Cell of the Villages LLC are accounted for using the equity method of accounting. As such, we report our pro rata share of its income or loss for the period. For the year ended December 31, 2018 and 2017, our pro rata share of its income was \$247,813 and \$192,383, respectively.

Loss on litigation settlement

On March 1, 2017, we settled outstanding litigation with Northstar Biotech Group, LLC whereby we issued 10,000,000 and issued an additional 1,000,000 (for an aggregate of 11,000,000) shares of our common stock at a fair value of \$316,800. Accordingly, we recorded in operations a loss on litigation settlement of \$316,800 for the year ended December 31, 2017.

Interest Expense

Interest expense was \$1,444,807 in 2018 compared to interest expense of \$642,102 in 2017. Non cash interest comprised of amortization of debt discounts and non-cash interest totaled \$195,967 in 2018 as compared to \$126,457 in 2017. Our increase in interest expense in 2018 as compared to 2017 was primarily due to our Capital Lease with GACP with contractually escalating payments.

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 2018, we continued to finance our operational cash needs with cash generated from financing activities.

Operating Activities

Net cash provided by operating activities was \$602,467 in 2018 as compared to \$1,231,393 of cash provided in 2017. Our source of cash for operations in 2018 reflected a net loss generated during the period of \$2,160,427, adjusted for non-cash items such as stock-based compensation of \$1,227,924, amortization of debt discounts associated with our convertible and other notes of \$195,967, related party notes payable issued for services rendered of \$800,000, bad debt expense of \$62,207, common stock issued in settlement of related party expenses of \$14,522 and depreciation expense of \$207,132, net with gain on sale of equipment of \$128,846, \$5,625 gain on settlement of debt and income from equity investments of \$247,813. A net increase in operating assets of \$95,134 and a net increase in operating liabilities of \$732,560 contributed to our source of operating cash in 2018.

Investing Activities

Net cash provided by investing activities was \$311,700 for the year ended December 31, 2018 represented proceeds from our equity investments as compared to cash provided by investing activities of \$225,000 from our equity investments, \$400,000 from sale and leaseback of equipment and proceeds from deposits of \$100,000, net with purchase of equipment of \$1,162 for the same period last year.

Financing Activities

Net cash used in financing activities was an aggregate of \$543,820 in the year ended December 31, 2018 as compared to cash used of \$1,239,152 in the year ended December 31, 2017. In the year ended December 31, 2018, we received \$367,700 from the sale of our common stock, \$130,000 from related party advances, \$103,159 equity contribution from related party and proceeds from issuance of notes payable of \$220,211, net with repayments of notes and capital leases payable of \$656,468 and \$708,422 related party notes.

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, 2018, we had cash and cash equivalents totaling \$1,357,146; our working capital deficit as of such date was \$4,410,129. Our independent registered public accounting firm has issued its report dated March 13, 2019 in connection with the audit of our financial statements as of December 31, 2018 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, 2018, we had \$5,224,942 in outstanding debt.

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 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.

As of December 31, 2018, management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the criteria in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992) (“COSO”) and have concluded our controls are effective.

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, 2018, 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	53	Director, President and Chief Executive Officer, Chief Financial Officer
William P. Murphy, Jr., M.D.	95	Director, Chairman of the Board
Mark P. Borman	64	Director
Kristin Comella	42	Director, Chief Scientific Officer
Sheldon T. Anderson	68	Director
Greg Knutson	67	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 seven 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 is currently a board member with public and private technology companies and serves 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, a Certified Public Accountant and Chartered Financial Analyst. Mr. Borman is a Board Leadership Fellow and member of the National Association of Corporate Directors.

Kristin Comella, Ph.D. Dr. Comella, USRM's Chief Science Officer, has an extensive background in the study and implementation of stem cell therapy. As a student focusing on the mechanics and systems of the body in order to achieve optimal health, her more than 20+ years' experience has given her notable training with experts in the stem cell arena. Her graduate studies and PhD course work at Ohio State University provided her the opportunity to work with Dr. Jeffery Chalmers to focus on the use of nano-particles magnets to isolate and separate cells. She then delved more deeply into biomedical engineering at the Cleveland Clinic and Osiris Therapeutics — a small start-up in Maryland founded by the 'father of Mesenchymal Stem Cells,' Dr. Arnie Caplan. Her work at Osiris led to one of the first IND approvals of stem cells in orthopedics from the FDA in 2002, and was the beginning of her zeroing in on stem cells and their application for healing.

Following her work at Osiris, Dr. Comella was offered the opportunity to work at Tulane University with Dr. Darwin Prockop, the Grandfather of cellular therapy research on mesenchymal progenitor. Her responsibilities included managing the FDA GMP facility (good manufacturing practices) at Tulane's Center of Gene Therapy, where she designed, implemented and administered the application of stem cell therapy for spinal cord injuries.

Her dedication to the advancement of stem cell therapy and regenerative medicine led her to what is now U.S. Stem Cell in 2004.

Dr. Comella was named number 24 on Terrapin's list of the Top 50 Global Stem Cell Influencers and number 1 on the Academy of Regenerative Practices list of Top 10 Stem Cell Innovators. Dr. Comella holds a PhD in Biomedical Engineering from Florida International University, an M.S. in Chemical Engineering from Ohio State University and a B.S. in Chemical Engineering from the University of South Florida.

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 Form 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, 2018 and 2017, 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, 2018 , 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, CFO and Director	2018	\$ 1,305,837	\$ 500,000 (1)	\$ —	\$ 991,602 (2)(3)				\$ 2,797,439
	2017	1,493,194	500,000 (4)	—	\$ 630,359 (5)(6)(7)	—	—	—	\$ 2,623,553
Kristin Comella Chief Science Officer and Director	2018	452,588	300,000 (1)	—	\$ 512,111 (2)(3)				\$ 1,264,699
	2017	585,179	300,000 (4)	—	\$ 342,276 (5)(6)(7)				\$ 1,277,455

- (1) On May 7, 2018, Mr. Tomas and Ms. Comella received \$500,000 and \$300,000, respectively, promissory notes for bonuses awarded. The promissory notes bear 5% interest per annum, unsecured and were due on demand
 - (2) On May 7, 2018, Mr. Tomas and Ms. Comella were granted 20,000,000 and 10,000,000, respectively, options to purchase the Company's common stock at \$0.0536 per share for ten years, vesting over four years at each anniversary.
 - (3) On December 3, 2018, Mr. Tomas and Ms. Comella were granted 1,500,000 options (each) to purchase the Company's common stock at \$0.02511 per share for ten years, vesting immediately.
 - (4) On August 7, 2017, Mr. Tomas and Ms. Comella received \$500,000 and \$300,000, respectively, promissory notes for bonuses awarded. The promissory notes bear 5% interest per annum, unsecured and were due on demand
 - (5) On February 6, 2017, Mr. Tomas and Ms. Comella were granted 10,000,000 and 5,000,000, respectively, options to purchase the Company's common stock at \$0.0043 per share for ten years, vesting over four years at each anniversary.
 - (6) On August 7, 2017, Mr. Tomas and Ms. Comella were granted 15,000,000 and 7,500,000, respectively, options to purchase the Company's common stock at \$0.03626 per share for ten years, vesting over four years at each anniversary.
 - (7) On August 7, 2017, Mr. Tomas and Ms. Comella were granted 1,500,000 options (each) to purchase the Company's common stock at \$0.03626 per share for ten years, vesting immediately.

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

See page F-27

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, 2018:

Name	Number of Securities Underlying Unexercised Options and Warrants		Option Exercise Price (\$/per share)	Option Expiration Date
	Total (#)	Unexercisable (#)		
Mike Tomas	500	-	0.15402	6/18/2020
	500	-	0.15402	8/12/2021
	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
	10,000	-	0.15402	2/24/2024
	800	-	0.15402	2/24/2024
	4,299	-	0.15402	5/24/2024
	10,000	-	0.15402	8/1/2024
	400	-	0.15402	11/3/2024
	291,885	-	0.15402	11/2/2025
	10,000	2,500	0.15402	11/2/2025
	1,500,000	-	0.01960	9/19/2026
	10,000,000	5,000,000	0.01960	9/19/2026
	10,000,000	7,500,000	0.00430	2/6/2027
	15,000,000	11,250,000	0.03626	8/7/2027
	1,500,000	-	0.03626	8/7/2027
	20,000,000	20,000,000	0.05360	5/7/2028
	1,500,000	-	0.02511	12/3/2028
Kristin Comella	20	—	0.15402	1/19/2019
	3	—	0.15402	3/13/2019
	30	—	0.15402	5/28/2019
	250	—	0.15402	8/12/2021
	500	-	0.15402	8/6/2022
	5,000	-	0.15402	8/1/2023
	5,000	-	0.15402	2/24/2024
	400	-	0.15402	2/24/2024
	5,000	-	0.15402	8/1/2024
	400	-	0.15402	11/3/2024
	1,000	-	0.15402	2/2/2025
	175,131	-	0.15402	11/2/2025
	5,000	1,250	0.15402	11/2/2025
	1,500,000	-	0.01960	9/19/2026
	5,000,000	2,500,000	0.01960	9/19/2026
	5,000,000	3,750,000	0.00430	2/6/2027
	7,500,000	5,625,000	0.03626	8/7/2027
	1,500,000	-	0.03626	8/7/2027
	10,000,000	10,000,000	0.05360	5/7/2028
	1,500,000	-	0.02511	12/3/2028

Options Exercises and Stocks Vested

Options exercised and stocks vested as at December 31, 2018 are as follows:

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

Grants of Plan-Based Awards

Grants of plan-based awards as at December 31, 2018 are as follows:

Name	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 (\$/Sh)	Grant date fair value of stock and option awards
	Grant date	Threshold (\$)	Target (\$)	Maximum (\$)	Threshold (\$)	Target (\$)	Maximum (\$)	(#)	(#)	(\$/Sh)		
Mike Tomas, NEO	n/a	0	0	0	0	0	0	0	0	0	0	0
Kristin Comella, NEO	n/a	0	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, 2018 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, NEO	0	0	0	0	0
Kristin Comella, NEO	0	0	0	0	0

Golden Parachute Compensation

As at December 31, 2018, 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, NEO	0	0	0	0	0	0	0
Kristin Comella, NEO	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, 2018 for services to our company.

Name	Fees Earned or Paid in Cash (\$)	Equity Awards (\$)	Total (\$)
William P Murphy, Jr.	\$ -	\$ 32,620(1)	\$ 62,620
Sheldon T. Andersen	\$ -	\$ 32,620(1)	\$ 32,620
Mark Borman	\$ -	\$ 32,620(1)	\$ 32,620
Gregory Knutson	\$ -	\$ 32,620(1)	\$ 32,620
Total:	\$ -	\$ 130,480	\$ 130,480

- (1) Represents (i) a stock option granted December 3, 2018 for the purchase of 1,500,000 shares of common stock, vesting immediately, at an exercise price of \$0.02511 per share and termination date of December 3, 2028

Pension Benefits

As of December 31, 2018, 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, NEO	not applicable	0	0	0	0
Kristin Comella, NEO	not applicable	0	0	0	0

Equity Compensation Plan Information

The following table sets forth information as of December 31, 2018 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, NEO	500	6/18/2010	\$ —	\$ 0.15402	\$ —	6/18/2020
	500	8/12/2011	—	0.15402	—	8/12/2021
	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
Kristin Comella, NEO	20	1/9/2009	—	0.15402	—	1/9/2019
	3	3/13/2009	—	0.15402	—	3/13/2019
	30	5/29/2009	—	0.15402	—	5/28/2019
	250	8/12/2011	—	0.15402	—	8/12/2021
	500	8/06/2012	—	0.15402	—	8/06/2022
	5,000	8/01/2013	—	0.15402	—	8/1/2023
	5,000	2/24/2014	—	0.15402	—	2/24/2024
	400	2/24/2014	—	0.15402	—	2/24/2024
	5,000	8/01/2014	—	0.15402	—	8/1/2024
	400	11/3/2014	—	0.15402	—	11/3/2024
	1,000	2/2/2015	—	0.15402	—	2/2/2025
	175,131	11/2/2015	—	0.15402	—	11/2/2025
	2,500	11/2/2015	—	0.15402	—	11/2/2025
	1,500,000	9/19/2016	—	0.01960	—	9/19/2026
	1,250,000	9/19/2016	-	0.01960	-	9/19/2026
	1,500,000	8/7/2017	-	0.03626	-	8/7/2027
	10,000,000	5/7/2018	-	0.05360	-	5/7/2028
	1,500,000	12/3/2018	-	0.02511	-	12/3/2028

Director Compensation

As of December 31, 2018, 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. Our two employee directors, Mike Tomas and Kristin Comella, also are granted director options to purchase shares of our common stock. 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 13, 2019, based on an aggregate of 378,076,976 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, 2018. Unless otherwise indicated, the address of each of the individuals and entities named below is: c/o U.S. Stem Cell, Inc., 13794 NW 4th Street, Suite 212, Sunrise, Florida 33325. 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” is 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	22,097,063 (1)	5.5
Kristin Comella, Chief Scientific Officer and Director	14,071,484 (2)	3.6
William P. Murphy, Director**	4,566,461 (3)	1.2
Mark P. Borman, Director	5,029,752 (4)	1.2
Sheldon T. Anderson, Director	4,505,282 (5)	1.2
Greg Knutson**	2,125,000 (6)	*
All officers and directors as a group (6 persons)	51,866,183 (7)	12.1
Northstar Biotechnology Group, LLC	31,805,502 (8)	8.4

* 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) 22,088,784 shares of common stock issuable upon exercise of presently exercisable stock options .
- (2) Includes 14,071,484 shares of common stock issuable upon exercise of presently exercisable stock options.
- (3) Includes (i) 63,481 shares of common stock and (ii) 4,502,980 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.
- (4) Includes (i) 526,942 shares of common stock and (ii) 4,502,810 shares of common stock issuable upon exercise of presently exercisable stock options

- (5) Includes (i) 1,941 shares of common stock and (ii) 4,503,341 shares of common stock issuable upon exercise of presently exercisable options and warrants.
- (6) Includes 2,125,000 shares of common stock issuable upon exercise of presently exercisable stock options.
- (7) Includes an aggregate of (i) 73,725 shares of common stock and (ii) 51,794,399 shares of common stock issuable upon exercise of presently exercisable stock options and warrants.
- (7) Includes 31,785,502 shares 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, 2018 and 2017, our officers and directors have provided advances in the aggregate of \$234,901 and \$104,901, 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 5.02) and two Company directors, Michael Tomas and Kristin Comella, will each exercise 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.

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 11). 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.

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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.

As of December 31, 2018 and 2017, the principal of this note was \$262,000.

Officer and Director Notes

	2018	2017
Note payable, Mr. Tomas	\$ -	\$ 101,729
Note payable, Mr. Tomas	-	500,000
Note payable, Mr. Tomas	483,293	500,000
Note payable, Mr. Tomas	500,000	-
Note payable, Dr. Comella	147,711	237,797
Note payable, Dr. Comella	300,000	300,000
Note payable, Dr. Comella	300,000	-
Total	<u><u>\$ 1,731,004</u></u>	<u><u>\$ 1,639,526</u></u>

Notes payable, Mr. Tomas

On July 1, 2014, the Company issued a \$500,000 promissory note in settlement of compensation earned. The promissory note bears interest of 5% per annum and was due on January 1, 2015. During the year ended December 31, 2018 and 2017, the Company paid off \$101,729 and \$398,271 the outstanding promissory note. The principal outstanding balance of this note as of December 31, 2018 and 2017 is \$0 and \$101,729, respectively.

On September 6, 2016, 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 upon demand. During the year ended December 31, 2018, the Company paid off \$500,000 of the outstanding promissory note. The principal outstanding balance of this note as of December 31, 2018 and 2017 is \$0 and \$500,000, respectively.

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, 2018, the Company paid off \$16,707 of the outstanding promissory note. The principal outstanding balance of this note as of December 31, 2018 and 2017 is \$483,293 and \$500,000, respectively.

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. The principal outstanding balance of this note as of December 31, 2018 is \$500,000.

At December 31, 2018 and 2017, the Company has recorded accrued interest on the outstanding and past notes to Mr. Tomas in the amount of \$340,009 and \$282,701, respectively, which is included in the accrued expenses on the balance sheet.

Notes payable, Dr. Comella

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 was due upon demand. During the year ended December 31, 2018 and 2017, the Company paid off \$90,086 and \$62,203 of the outstanding promissory note, respectively. The principal outstanding balance of this note as of December 31, 2018 and 2017 is \$147,711 and \$237,797, respectively.

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. The principal outstanding balance of this note as of December 31, 2018 and 2017 is \$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. The principal outstanding balance of this note as of December 31, 2018 is \$300,000.

At December 31, 2018 and 2017, the Company has recorded accrued interest on the outstanding notes to Dr. Comella in the amount of \$102,974 and \$67,884, respectively, which is included in the accrued expenses on the balance sheet.

Transactions with Pavillion

On May 1, 2016, the Company entered into a consulting agreement with Pavillion, Inc., whose owner is related to an officer of the Company. The agreement is for 12 months and renewable for 6 month periods. Compensation is at \$250 per hour or, at the Company's discretion, in shares of the Company's common stock. For the year ended December 31, 2018 and 2017, the Company has incurred \$120,000 and \$120,000 of expense under the agreement, respectively. As of December 31, 2018 and 2017, the Company had \$64,909 and \$187,409, respectively, in accounts payable owed to Pavillion. On June 1, 2018, effective June 30, 2018, the Company terminated the agreement in accordance with its terms and no further compensation was derived by Pavillion.

Transactions with GACP

On March 3, 2017, the Company entered into an asset sale and lease agreement (sale/leaseback transaction, the "Asset Sale and Lease Agreement") with GACP, whereby the Company 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 (See "*Lab and Medical Equipment Capitalized Lease*" below). The Company determined that the transaction was a capitalized lease and accordingly recorded the leased assets and liability based on the estimated present value of the minimum lease payments (see Notes 4 and 6).

In connection with the asset sale and lease agreement, the Company is obligated to accrue 10% of banking revenue as for marketing, offset by any incurred costs of the Company. At December 31, 2018 and 2017, the outstanding accrued marketing obligation is \$179,352 and \$141,560, respectively (see Note 5).

On March 3, 2017, the Company also entered into a customer purchase agreement with GACP, whereby the Company agreed to sell, for \$50,000, the first 5,000 customers of the cell banking business after the effective date of the equipment sale/leaseback agreement with rights to purchase additional customers at a price of \$20 per customer. There is no reduction in the selling price should the new customers be fewer than 5,000. The effective date of the sale is upon the expiry or early termination of the related equipment lease transaction.

On March 3, 2017, the Company also entered into an asset purchase agreement of intellectual property with GACP whereby the Company agreed to sell all of the Company's worldwide rights, title or interest in certain intellectual and other property (as defined) associated with the cell banking business for \$50,000. The effective date of the sale is upon the expiry or early termination of the related equipment lease transaction.

In connection with the March 3, 2017 asset purchase agreement, the CEO of U.S. Stem Cell, Inc. has been retained as CEO of American Stem Cell Centers of Excellence, which is owned by General American Capital Partners (GACP), to help with scientific and successful operational deployment of clinics.

On April 3, 2017, U.S. Stem Cell received a commitment to invest up to \$5,000,000 from GACP with the intent for GACP to receive up to 63,873,275 shares of common stock. To date, GACP has invested, pursuant to this commitment, \$250,000 in return for 858,281 shares. Subsequent to this investment, GACP has informed the Company that they will make no further investments pursuant to this agreement and has entered into a new agreement to invest \$3,000,000 to open their own clinics (branded American Stem Cell) using the US Stem Cell Inc. protocols, procedures, products and technologies. As of September 30, 2018 (effective May 9, 2018), pursuant to an Amendment to Asset Sale and Lease Agreement, dated June 18, 2018, GACP has suspended their obligation to open additional clinics (tolling such obligation to a mutually agreeable date in the future) and has suspended the monthly aggregate number of stem cell kits set forth for purchase in a given month arising from such clinics. All other terms and conditions of the agreements between U.S. Stem Cell, Inc. and GACP remain in full force and effect. As of December 31, 2018 and 2017, GACP owns 4,021,945 shares of the Company's common stock.

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

We engaged RBSM LLP ("RBSM") as our independent registered public accounting firm for the audit of our financial statements for the year ended December 31, 2018 commencing April 23, 2018. Prior to the engagement of RBSM, Fiondella, Milone, LaSaracina LLP (FML) served as our independent registered public accounting firm.

Aggregate fees billed to us for the fiscal years ended December 31, 2018 and 2017 by our independent registered public accounting firms are as follows:

Types of Fees	2018	2017
Audit Fees (1)	\$ 95,500	\$ 135,500
Audit Related Fees	\$ —	\$ —
Tax Fees	\$ 5,300	\$ 5,300
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
31.01*	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.
32.01*	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	XBRL Instance Document
101 SCH	XBRL Taxonomy Extension Schema Document
101 CAL	XBRL Taxonomy Calculation Linkbase Document
101 DEF	XBRL Taxonomy Extension Definition Linkbase Document
101 LAB	XBRL Taxonomy Labels Linkbase Document
101 PRE	XBRL Taxonomy Presentation Linkbase Document

* 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 13, 2019

By: /s/ Mike Tomas

Mike Tomas
Chief Financial Officer (Principal Accounting Officer)

March 13, 2019

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
<u>/s/ William P. Murphy, Jr., M.D.</u> William P. Murphy, Jr., M.D.	Chairman of the Board	March 13, 2019
<u>/s/ Mike Tomas</u> Mike Tomas	Chief Executive Officer, Chief Financial Officer, & Director	March 13, 2019
<u>/s/ Mark P. Borman</u> Mark Borman	Director	March 13, 2019
<u>/s/ Kristin Comella</u> Kristin Comella	Director	March 13, 2019
<u>/s/ Sheldon Anderson</u> Sheldon Anderson	Director	March 13, 2019
<u>/s/ Greg Knutson</u> Greg Knutson	Director	March 13, 2019

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FORM 10-K—ITEM 8

U.S. STEM CELL, INC.

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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 sheet of U.S Stem Cell, Inc. (the Company) as of December 31, 2018, and the related statements of operations, stockholders' equity, and cash flow for the year ended December 31, 2018, 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, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America. The balance sheet as of December 31, 2017, and the related statement of operations, changes in stockholders' deficit and cash flow for the year ended December 31, 2017 and the related notes were audited by another accounting firm.

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, 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 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 audit. 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 audit 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 audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit 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 audit 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 audit provide a reasonable basis for our opinion.

/s/ RBSM LLP

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

New York, NY
March 13, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheet of US Stem Cell, Inc. (the Company) as of December 31, 2017, and the related statements of operations, stockholders' deficit, and cash flows for the years in the year ended December 31, 2017, 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, 2017, and the results of its operations and its cash flows for each of the year ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

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 audit. 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.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred losses from operations and has an accumulated deficit, which raises substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Fiondella, Milone & LaSaracina LLP

We had served as the Company's auditor since 2012.

Glastonbury, CT
April 16, 2018

U.S. STEM CELL, INC.
BALANCE SHEETS
DECEMBER 31, 2018 AND 2017

	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,357,146	\$ 986,799
Accounts receivable, net	18,035	42,959
Inventory	93,215	70,364
Prepaid and other	38,128	3,128
Total current assets	1,506,524	1,103,250
Property and equipment, net	242,615	449,747
Other assets		
Investments	57,790	34,926
Deposits	10,160	10,160
Total assets	\$ 1,817,089	\$ 1,598,083
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable, including \$75,714 and \$201,973 to related parties, respectively	\$ 1,182,730	\$ 1,378,124
Accrued expenses	1,155,792	929,119
Advances, related party	234,901	104,901
Deferred revenue	293,665	211,042
Deferred gain on sale of equipment	128,845	128,845
Deposits	465,286	465,286
Notes payable, related party	1,993,104	1,901,526
Notes and capital leases payable, net of debt discount of \$62,240 and \$61,729, respectively	462,330	1,344,594
Total current liabilities	5,916,653	6,463,437
Long term debt:		
Deferred revenue	65,500	68,500
Deferred gain on sale of equipment	21,474	150,320
Long term deposits	100,000	100,000
Promissory note, long term portion, net of debt discount of \$99,183 and \$169,072, respectively	1,298,579	1,228,690
Notes and capital lease payable, long term portion, net of debt discount of \$12,413 and \$33,138, respectively	1,297,093	687,453
Total long term debt	2,782,646	2,234,963
Total liabilities	8,699,299	8,698,400
Commitments and contingencies	-	-
Stockholders' deficit:		
Preferred stock, par value \$0.001; 20,000,000 shares authorized, -0- issued and outstanding as of December 31, 2018 and 2017	-	-
Common stock, par value \$0.001; 2,000,000,000 shares authorized, 378,076,976 and 342,113,098 shares issued and outstanding as of December 31, 2018 and 2017, respectively	378,077	342,113
Additional paid in capital	122,528,391	120,185,821
Accumulated deficit	(129,788,678)	(127,628,251)
Total stockholders' deficit	(6,882,210)	(7,100,317)
Total liabilities and stockholders' deficit	\$ 1,817,089	\$ 1,598,083

See the accompanying notes to these financial statements

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

	Year ended December 31,	
	2018	2017
Revenue:		
Products	\$ 1,664,016	\$ 2,126,436
Services	5,036,872	3,394,101
Total revenue	<u>6,700,888</u>	<u>5,520,537</u>
Cost of sales	<u>2,110,532</u>	<u>1,885,371</u>
Gross profit	4,590,356	3,635,166
Cost and operating expenses:		
Research and development	5,439	6,644
Marketing, general and administrative	5,682,296	4,426,632
Depreciation and amortization	524	6,571
Total operating expenses	<u>5,688,259</u>	<u>4,439,847</u>
Loss from operations	(1,097,903)	(804,681)
Other income (expenses):		
Gain (loss) on settlement of debt	5,625	(126,457)
Gain on sale of equipment	128,845	107,371
Loss on change of fair value of derivative liability	-	(1,891,205)
Income from equity investment	247,813	192,383
Loss on litigation settlement	-	(316,800)
Interest expense	(1,444,807)	(642,102)
Total other income (expenses)	<u>(1,062,524)</u>	<u>(2,676,810)</u>
Net loss before income taxes	(2,160,427)	(3,481,491)
Income taxes (benefit)	-	-
NET LOSS	<u>\$ (2,160,427)</u>	<u>\$ (3,481,491)</u>
Net loss per common share, basic and diluted	<u>\$ (0.01)</u>	<u>\$ (0.01)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>365,636,453</u>	<u>309,009,904</u>

See the accompanying notes to these financial statements

U.S. STEM CELL, INC.
STATEMENT OF STOCKHOLDERS' DEFICIT
TWO YEARS ENDED DECEMBER 31, 2018

	Preferred stock		Common stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance, January 1, 2017	20,000,000	\$ 20,000	127,012,740	\$ 127,013	\$ 115,981,103	\$ (124,146,760)	\$ (8,018,644)
Common stock issued in settlement of accounts payable and accrued interest	-	-	14,058,588	14,058	659,087	-	673,145
Common stock issued in connection with settlement of other debt	-	-	164,270,878	164,271	2,081,013	-	2,245,284
Common stock issued in settlement of note payable, related party	-	-	1,748,947	1,749	56,852	-	58,601
Common stock issued upon conversion of preferred stock	(20,000,000)	(20,000)	20,000,000	20,000	-	-	-
Common stock issued in settlement of litigation	-	-	11,000,000	11,000	305,800	-	316,800
Proceeds from issuance of common stock	-	-	4,021,945	4,022	270,978	-	275,000
Reclassify derivative liability to equity upon payoff of notes payable	-	-	-	-	185,505	-	185,505
Stock based compensation	-	-	-	-	645,483	-	645,483
Net loss	-	-	-	-	-	(3,481,491)	(3,481,491)
Balance, December 31, 2017	-	\$ -	342,113,098	\$ 342,113	\$ 120,185,821	\$ (127,628,251)	\$ (7,100,317)

See the accompanying notes to these financial statements

U.S. STEM CELL, INC.
STATEMENT OF STOCKHOLDERS' DEFICIT
TWO YEARS ENDED DECEMBER 31, 2018

	Preferred stock		Common stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance, December 31, 2017	-	\$ -	342,113,098	\$ 342,113	\$ 120,185,821	\$ (127,628,251)	\$ (7,100,317)
Common stock issued in settlement of accounts payable and accrued interest	-	\$ -	15,220,378	\$ 15,220	\$ 563,259	-	\$ 578,479
Common stock issued for services	-	\$ -	10,866,274	\$ 10,866	\$ 439,065	-	\$ 449,931
Common stock issued for expenses incurred, related party	-	\$ -	526,918	\$ 527	\$ 13,995	-	\$ 14,522
Fair value of warrants issued for compensation	-	\$ -	-	\$ -	\$ 24,986	-	\$ 24,986
Proceeds from issuance of common stock	-	\$ -	9,350,508	\$ 9,351	\$ 358,349	-	\$ 367,700
Related party contribution to equity investment	-	\$ -	-	\$ -	\$ 189,909	-	\$ 189,909
Stock based compensation	-	\$ -	-	\$ -	\$ 753,007	-	\$ 753,007
Net loss	-	\$ -	-	\$ -	\$ -	\$ (2,160,427)	\$ (2,160,427)
Balance, December 31, 2018	<hr/>	\$ <hr/>	378,077,176	\$ 378,077	\$ 122,528,391	\$ (129,788,678)	\$ (6,882,210)

See the accompanying notes to these financial statements

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

	Year ended December 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (2,160,427)	\$ (3,481,491)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	207,132	178,745
Bad debt (recoveries)	62,207	16,740
Amortization of discount on debt	195,967	126,436
Change in fair value of derivative liability	-	1,891,205
(Gain) loss on settlement of debt	(5,625)	126,457
Gain on sale of equipment	(128,845)	(107,371)
Common stock issued as payment of expenses, related party	14,522	-
Common stock issued in settlement of litigation	-	316,800
Income on equity investments	(247,813)	(192,383)
Related party notes payable issued for services rendered	800,000	800,000
Stock based compensation	1,227,924	645,483
Changes in operating assets and liabilities:		
Receivables	(37,283)	(43,674)
Inventory	(22,851)	(28,146)
Prepaid and other current assets	(35,000)	(3,128)
Accounts payable	426,263	469,220
Accrued expenses	226,673	435,390
Deferred revenue	79,623	81,110
Net cash provided by operating activities	<u>602,467</u>	<u>1,231,393</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from (payments to) equity investments	311,700	225,000
Proceeds from sale of property and equipment	-	400,000
Proceeds from long term deposits	-	100,000
Acquisition of property and equipment	-	(1,162)
Net cash provided by investing activities	<u>311,700</u>	<u>723,838</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from notes payable	220,211	154,785
Proceeds from sale of common stock	367,700	275,000
Proceeds from related party advance	130,000	-
Equity contribution by related party	103,159	-
Repayments of related party notes	(708,422)	(1,138,759)
Repayments of notes payable	(656,468)	(530,178)
Net cash used in financing activities	<u>(543,820)</u>	<u>(1,239,152)</u>
Net increase in cash and cash equivalents	370,347	716,079
Cash and cash equivalents, beginning of period	986,799	270,720
Cash and cash equivalents, end of period	<u>\$ 1,357,146</u>	<u>\$ 986,799</u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Interest paid	\$ 1,114,693	\$ 255,874
Income taxes paid	<u>\$ -</u>	<u>\$ -</u>
Non cash financing activities:		
Common stock issued in settlement of notes payable	\$ -	\$ 111,972
Common stock issued in settlement of accounts payable	<u>\$ 578,479</u>	<u>\$ 673,145</u>
Common stock issued in settlement of note, related party	<u>\$ -</u>	<u>\$ 58,601</u>
Common stock issued or issuable in settlement of litigation	<u>\$ -</u>	<u>\$ 316,800</u>
Sale and leaseback of equipment	<u>\$ -</u>	<u>\$ 619,825</u>
Reclassify derivative liability to equity	<u>\$ -</u>	<u>\$ 185,505</u>
Equity contributed to investment by related party	<u>\$ 189,909</u>	<u>\$ -</u>

See the accompanying notes to these financial statements

U.S. STEM CELL, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2018 AND 2017

NOTE 1—SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies applied in the presentation of the accompanying financial statements follows:

Basis and business presentation

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 sales 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.

Revenue Recognition

In 2017 and prior, the Company recognized revenue in accordance with Accounting Standards Codification subtopic 605-10, Revenue Recognition (“ASC 605-10”) which requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred; (3) the selling price is fixed and determinable; and (4) collectability is reasonably assured. Determination of criteria (3) and (4) are based on management’s judgments regarding the fixed nature of the selling prices of the products delivered and the collectability of those amounts. Provisions for discounts and rebates to customers, estimated returns and allowances, and other adjustments are provided for in the same period the related sales are recorded.

Effective January 1, 2018, the Company recognizes 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.

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 sales 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.

U.S. STEM CELL, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2018 AND 2017

At December 31, 2018 and 2017, the Company had deferred revenues of \$359,165 and \$279,542, respectively, which includes \$68,500 and \$71,500, respectively, to the Intellectual Property Licensing Agreement.

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.

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

Trade receivables are carried at their estimated collectible amounts. Trade credit is generally extended on a short-term basis; thus trade receivables do not bear interest. Trade accounts receivable are periodically evaluated for collectability based on past credit history with customers and their current financial condition.

Allowance for Doubtful Accounts

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, 2018 and 2017, allowance for doubtful accounts was \$30,808 and \$12,298, 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 33 percent member interest ownerships of U.S. Stem Cell Clinic, LLC and Regenerative Wellness Clinic, LLC respectively and its 49 percent member interest ownership of U.S. Stem Cell Clinic of the Villages utilizing the equity method of accounting (See Note 3).

Comprehensive Income

The Company does not have any items of comprehensive income in any of the periods presented.

**U.S. STEM CELL, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2018 AND 2017**

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 2018 and 2017.

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. Equipment under capital leases are recorded at the estimated present value of the minimum lease payments. Equipment under capital leases are amortized over the term of the lease, which is three years.

Stock Based Compensation

The Company measures 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 the Company in the same expense classifications in the statements of operations, as if such amounts were paid in cash.

Net Loss per Common Share, basic and diluted

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, 2018 and 2017 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:

	2018	2017
Options to purchase common stock	112,970,693	71,630,763
Warrants to purchase common stock	1,114,019	133,591
Totals	114,084,712	71,764,354

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.

U.S. STEM CELL, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2018 AND 2017

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.

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.

As of December 31, 2018, four customers represented 41%, 10%, 16% and 10%, respectively, representing an aggregate of 77% of the Company's accounts receivable. As of December 31, 2017, three customers represented 27% 15% and 13% respectively, representing an aggregate of 55% of the Company's accounts receivable.

For the year ended December 31, 2018, the Company's revenues earned from the sale of products and services to one customer, a related party, were \$734,966, which represented 11% of the Company's revenues. For the year ended December 31, 2017, the Company's revenues earned from sale of products and services did not include any customers representing 10% or more of the Company's total revenues.

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 \$5,439 and \$6,644 for the year ended December 31, 2018 and 2017, respectively.

Reliance on Key Personnel and Consultants

The Company has ten full-time employees and one part-time employee. The Company is heavily dependent on the continued active participation of its two current executive officers, one employee and key consultants. The loss of any of the senior management or key consultants could significantly and negatively impact the business until adequate replacements can be identified and put in place.

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 and 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.

Derivative Instrument Liability

The Company accounts for derivative instruments in accordance with ASC 815, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value, regardless of hedging relationship designation. Accounting for changes in fair value of the derivative instruments depends on whether the derivatives qualify as hedge relationships and the types of relationships designated are based on the exposures hedged. At December 31, 2018 and 2017, the Company did not have any derivative instruments that were designated as hedges.

U.S. STEM CELL, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2018 AND 2017

At March 8, 2017 and prior, the Company had outstanding convertible notes and warrants that contained embedded derivatives. These embedded derivatives include certain conversion features and reset provisions. At December 31, 2018 and 2017, all notes and warrants that contained derivative instruments were converted, settled or paid off and thus there were no outstanding convertible notes or warrants with these features (See Note 6 and Note 8).

Long Term Deposits

Long term deposits are comprised of the following:

On March 3, 2017, the Company entered into a customer purchase agreement with General American Capital Partners (GACP), whereby the Company agreed to sell, for \$50,000, the first 5,000 customers of the cell banking business after the effective date of the equipment sale/leaseback agreement with rights to purchase additional customers at a price of \$20 per customer. There is no reduction in the selling price should the new customers be fewer than 5,000. The effective date of the sale is upon the expiry or early termination of the related equipment lease transaction (See Notes 4 and 6).

On March 3, 2017, the Company entered into an asset purchase agreement of intellectual property with GACP whereby the Company agreed to sell all of the Company's worldwide rights, title or interest in certain intellectual and other property (as defined) associated with the cell banking business for \$50,000. The effective date of the sale is upon the expiry or early termination of the related equipment lease transaction (See Notes 4, 6, and 7).

Recent Accounting Pronouncements

In February 2016, the FASB established ASC Topic 842, Leases (Topic 842), by issuing ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations. The Company adopted the new standard on January 1, 2019.

The new standard provides a number of optional practical expedients in transition. The Company has elected the 'package of practical expedients', which permit it not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company does not expect to elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter is not applicable to the Company.

The new standard will have a material effect on the Company's financial statements. The most significant effects of adoption relate to (1) the recognition of new ROU assets and lease liabilities on its balance sheet for real estate operating leases; and (2) providing significant new disclosures about its leasing activities.

Upon adoption, the Company will recognize additional operating lease liabilities, net of deferred rent, of approximately \$56,734 based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. The Company expects to recognize corresponding ROU assets of approximately \$56,734.

The new standard also provides practical expedients for an entity's ongoing accounting. The Company will elect the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. Beginning in 2019, the Company expects changes to its disclosed lease recognition policies and practices, as well as to other related financial statement disclosures due to the adoption of this standard. These revised disclosures will be made in the Company's first quarterly report in 2019.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815). The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments.

U.S. STEM CELL, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2018 AND 2017

As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value because of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt—Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). The amendments in Part II of this Update recharacterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception.

Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The Company is currently reviewing the impact of adoption of ASU 2017-11 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 have a material impact on the Company's financial position, results of operations or cash flows.

Subsequent Events

The Company evaluates events that have occurred after the balance sheet date but before the financial statements are issued. Based upon the evaluation, the Company did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the condensed consolidated financial statements, except as disclosed.

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 during year ended December 31, 2018, the Company incurred net losses of \$2,160,427 and as of December 31, 2018 has a working capital deficit (current assets less current liabilities) of \$4,410,129. These factors among others raise substantial doubts about the Company's ability to continue as a going concern for a reasonable period of time.

The Company's primary source of operating funds in 2018 and 2017 has been from revenue generated from sales with additional cash proceeds from the sale of common stock and the issuance of convertible and other debt. The Company has experienced net losses from operations since inception, but expects these conditions to improve in 2019 and beyond as it develops its business model. The Company has stockholders' deficiencies at December 31, 2018 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 — INVESTMENTS

U.S. Stem Cell Clinic, LLC

The investment in U.S. Stem Cell Clinic, LLC is comprised of a 33% member interest ownership and is accounted for using the equity method of accounting. The Company's 33% income earned by U.S. Stem Cell Clinic, LLC member interests was \$172,995 and \$192,383 for the year ended December 31, 2018 and 2017, respectively (inception to date income of \$548,206) which was recorded as other income/expense in the Company's Statement of Operations in the appropriate periods. In addition, during the year ended December 31, 2018 and 2017, the Company received distributions totaling \$199,000 and \$225,000 from U.S. Stem Cell Clinic, LLC, respectively (inception to date of \$599,000). The carrying value of the investment at December 31, 2018 and 2017 is \$8,921 and \$34,926, respectively.

U.S. STEM CELL, INC.
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At December 31, 2018 and 2017, accounts receivable for sales of product and services to U.S. Stem Cell Clinic, LLC was \$0 and \$8,449 respectively; revenues earned from sales to U.S. Stem Clinic, LLC for the year ended December 31, 2018 and 2017 were \$734,966 and \$540,023, respectively.

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

Regenerative Wellness Clinic, LLC

The investment in Regenerative Wellness Clinic, LLC is comprised of a 33% member interest ownership and is accounted for using the equity method of accounting. The Company has provided technical expertise, but no cash investment with Regenerative Wellness Clinic, LLC's startup in 2017. The Company's 33% loss incurred by Regenerative Wellness Clinic, LLC member interests was \$(12,765) for year ended December 31, 2017. However the recorded other income/expense in the Company's Statement of Operations was limited to \$0.

The carrying value was \$0 at December 31, 2017. For the year ended December 31, 2018, the Company's 33% income earned by Regenerative Wellness Clinic, LLC member interests was \$70,787 reported, after effects of 2017 loss, of \$9,695. In addition, during the year ended December 31, 2018, the Company received distributions totaling \$49,000 from Regenerative Wellness Clinic, LLC. The carrying value of the investment at December 31, 2018 and 2017 is \$21,787 and \$0, respectively.

At December 31, 2018 and 2017, accounts receivable for sales of products and services to Regenerative Wellness Clinic, LLC was \$0 and \$15,115, respectively; revenues earned from sales to Regenerative Wellness Clinic, LLC for the year ended December 31, 2018 and 2017 was \$198,294 and \$22,771, respectively.

An affiliate of one of the Company's officers is an investor in the Regenerative Wellness Clinic, LLC.

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 "LLC") 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 LLC. Currently, Knutson holds a 51% member interest in the LLC 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 LLC gross revenues.

As of December 31, 2018, upon completion of U.S. Stem Cell of the Villages LLC, the Company was credited with investment equity of \$86,750 from Greg Knutson, the holder of the 51% member interest. The Company then recorded the investment equity as contributed capital by the Company. The Company's 49% income (loss) incurred by U.S. Stem Cell of the Villages LLC member interests was \$4,031 for year ended December 31, 2018. In addition, during the year ended December 31, 2018, the Company received distributions totaling \$63,700 from U.S. Stem Cell of the Villages LLC. The carrying value was \$27,081 at December 31, 2018.

At December 31, 2018, accounts receivable for sales of products and services to U.S. Stem Cell of the Villages LLC was \$0; revenues earned from sales to U.S. Stem Cell of the Villages LLC for the year ended December 31, 2018 was \$197,716.

NOTE 4—PROPERTY AND EQUIPMENT

Property and equipment are recorded on the basis of cost. For financial statement purposes, property, plant and equipment are depreciated using the straight-line method over their estimated useful lives.

Expenditures for repair and maintenance which do not materially extend the useful lives of property and equipment are charged to operations. When property or equipment is sold or otherwise disposed of, the cost and related accumulated depreciation are removed from the respective accounts with the resulting gain or loss reflected in operations. Management periodically reviews the carrying value of its property and equipment for impairment in accordance with the guidance for impairment of long lived assets.

U.S. STEM CELL, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2018 AND 2017

Property and equipment as of December 31, 2018 and 2017 is summarized as follows:

	2018	2017
Laboratory and medical equipment	\$ 5,590	\$ 5,590
Furniture, fixtures and equipment	125,633	125,633
Computer equipment	49,951	49,951
Equipment under capital lease	624,602	624,602
Leasehold improvements	<u>362,046</u>	<u>362,046</u>
	1,167,822	1,167,822
Less accumulated depreciation and amortization	<u>(925,207)</u>	<u>(718,075)</u>
	<u>\$ 242,615</u>	<u>\$ 449,747</u>

On March 3, 2017, the Company entered into an asset sale and lease agreement (sale/leaseback transaction, the “Asset Sale and Lease Agreement”) with GACP, whereby the Company 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 Company determined that the transaction was a capitalized lease and accordingly recorded the leased assets and liability based on the estimated present value of the minimum lease payments.

Included in net property are assets under capital leases of \$624,602, less accumulated depreciation of \$383,559 as of December 31, 2018 and \$624,602, less accumulated depreciation of \$174,120 December 31, 2017, respectively.

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, 2018 and 2017, the Company recognized \$128,845 and \$107,371, as the gain on sale of equipment, respectively. As of December 31, 2018 and 2017, deferred gain on sale of equipment was \$150,319 and \$279,165, respectively.

Property and equipment are recorded on the basis of cost. For financial statement purposes, property, plant and equipment are depreciated using the straight-line method over their estimated useful lives.

Depreciation expense was \$207,132 and \$178,745 of which \$206,608 and \$172,174 were included in cost of sales for the year ended December 31, 2018 and 2017, respectively.

NOTE 5—ACCRUED EXPENSES

Accrued expenses consisted of the following as of December 31, 2018 and 2017:

	2018	2017
Interest and fees payable to the Guarantors of the Company’s loan agreement with Seaside Bank	\$ 347,235	\$ 248,746
Interest payable on notes payable-related party (See Note 7)	482,784	381,667
Vendor accruals and other	146,420	146,421
Marketing obligation	179,353	141,560
Employee commissions, compensation, etc.	<u>-</u>	<u>10,725</u>
	<u>\$ 1,155,792</u>	<u>\$ 929,119</u>

During the year ended December 31, 2018, the Company issued an aggregate of 15,220,378 shares of its common stock in settlement of outstanding accounts payable and accrued expenses. In connection with the issuance, the Company incurred a \$43,180 net gain in settlement of debt.

During the year ended December 31, 2017, the Company issued an aggregate of 14,058,588 shares of its common stock in settlement of outstanding accounts payable and accrued expenses. In connection with the issuance, the Company incurred a \$359,326 net loss in settlement of debt. Additionally the Company wrote off certain old payables and recorded a gain of settlement of accounts payable in the amount of \$37,674.

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NOTE 6—NOTES AND CAPITAL LEASE PAYABLE

Notes and capital lease payable were comprised of the following as of December 31, 2018 and 2017:

	2018	2017
Seaside Bank note payable.	\$ 980,000	\$ 980,000
Hunton & Williams note(s) payable	444,000	584,000
Power Up Lending Group notes payable	145,486	94,448
Lab and medical equipment capitalized leases	264,590	468,465
Total notes payable	1,834,076	2,126,913
Less unamortized debt discount	(74,653)	(94,866)
Total notes payable net of unamortized debt discount	1,759,423	2,032,047
Less current portion	(462,330)	(1,344,594)
Long term portion	<u><u>\$ 1,297,093</u></u>	<u><u>\$ 687,453</u></u>

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 shareholders 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.

Hunton & Williams Notes

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 note holder 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 total of unpaid principal and accumulated interest for both notes as of August 31, 2017 was \$747,680 and an accounts payable of \$40,596, for an aggregate total of \$788,276.

The note holder agreed to accept full payment of their obligation of 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 note holder 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.

The Company imputed an interest rate of 5% and discounted the note accordingly. The imputed debt discount of \$69,700 is amortized to interest expense using the effective interest method. For years ended December 31, 2018 and 2017, the Company amortized \$28,322 and \$10,176 of debt discounts to current period operations as interest expense. The unamortized debt discount at December 31, 2018 is \$31,201.

PowerUp Lending Group, Ltd

On February 22, 2017, the Company entered into a revenue based factoring agreement and received an aggregate of \$165,000 (less origination fees of \$3,300) in exchange for \$221,100 of future receipts relating to monies collected from customers or other third party payors. Under the terms of the factoring agreement, the Company is required to make daily payments equal to \$1,316 for 168 business days. The Company received net proceeds of \$51,700 along with cancellation of the previous revenue based factoring agreement issued in 2016. In connection with the cancellation of the August 2016 revenue based factoring agreement, the Company incurred a loss in settlement of debt of \$41,516.

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On September 12, 2017, the Company entered into a revenue based factoring agreement and received an aggregate of \$137,200 (less origination fees of \$2,800) in exchange for \$187,600 of future receipts relating to monies collected from customers or other third party payors. Under the terms of the factoring agreement, the Company is required to make daily payments equal to \$1,276 for 147 business days. The Company received net proceeds of \$103,085 along with cancellation of the previous revenue based factoring agreement issued in February 2017. In connection with the cancellation of the February 2017 revenue based factoring agreement, the Company incurred a gain in settlement of debt of \$2,734 in 2017.

The remaining principle balance of the PowerUp Lending Group promissory note payable at December 31, 2017 is \$94,447, net of unamortized discount of \$35,342.

On January 2, 2018, the Company entered into a revenue based factoring agreement and received an aggregate of \$137,200 (less origination fees of \$2,800) in exchange for \$187,600 of future receipts relating to monies collected from customers or other third party payors. Under the terms of the factoring agreement, the Company is required to make daily payments equal to \$1,276 for 147 business days. The Company received net proceeds of \$47,907 along with cancellation of the previous revenue based factoring agreement issued in September 2017. In connection with the cancellation of the September 2017 revenue based factoring agreement, the Company incurred a gain in settlement of debt of \$5,154 in 2018.

On May 29, 2018, the Company entered into a revenue based factoring agreement and received an aggregate of \$137,200 (less origination fees of \$2,800) in exchange for \$187,600 of future receipts relating to monies collected from customers or other third party payors. Under the terms of the factoring agreement, the Company is required to make daily payments equal to \$1,276 for 147 business days. The Company received net proceeds of \$78,495 along with cancellation of the previous revenue based factoring agreement issued in January 2018. In connection with the cancellation of the January 2018 revenue based factoring agreement, the Company incurred a loss in settlement of debt of \$5,105 in 2018.

On November 8, 2018, the Company entered into a revenue based factoring agreement and received an aggregate of \$137,200 (less origination fees of \$2,800) in exchange for \$187,600 of future receipts relating to monies collected from customers or other third party payors. Under the terms of the factoring agreement, the Company is required to make daily payments equal to \$1,276 for 147 business days. The Company received net proceeds of \$93,809 along with cancellation of the previous revenue based factoring agreement issued in May 2018. In connection with the cancellation of the January 2018 revenue based factoring agreement, the Company incurred a loss in settlement of debt of \$37,604 in 2018.

The remaining principle balance of the PowerUp Lending Group promissory note payable at December 31, 2018 is \$145,486, net of unamortized discount of \$43,452.

Lab and Medical Equipment Capitalized Lease

On March 3, 2017, the Company entered into an asset sale and lease agreement (sale/leaseback transaction; “Asset Sale and Lease Agreement”) with GACP, whereby the Company 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 Company recognized the arrangement as a capital lease. The Company initially recorded the equipment and the capitalized lease liability at the estimated present value of the minimum lease payments of \$619,825.

The lease includes a base monthly rental payment of \$20,000, due the first day of each calendar month plus contingent rent equal to 2.3%, 22.5%, and 31.6% of revenues collected on deposits arising from cell banking business for years 1, 2 and 3, respectively. The contingent rent is recognized as a period expense and as interest expense at the time of collection. At the expiration of the lease, the Company is required to return all leased equipment and along with any maintenance records, logs, etc. in the Company’s possession to the lessor with no right of repurchase.

The Company determined that the present value of the minimum lease payments exceeded 90% of the estimated fair value of the equipment and therefore classified the equipment sale/lease as a capitalized lease. The effective interest rate of the capitalized lease is estimated at 10.00% based on the Company estimated incremental borrowing rate.

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The following summarizes the assets under capital leases:

	2018	2017
Classes of property		
Lab, medical and other equipment	\$ 619,825	\$ 619,825
Office equipment	4,777	4,777
Less: accumulated depreciation	(383,559)	(174,120)
	<hr/>	<hr/>
	\$ 241,043	\$ 450,482

The following summarizes the current and long-term portion of capital leases:

	2018	2017
Current leases payable	\$ 225,084	\$ 203,875
Long-term leases payable	39,506	264,590
Total	<hr/>	<hr/>
	\$ 264,590	\$ 468,465

The following summarizes total future minimum lease payments at December 31, 2018:

Period ending December 31,	
2019	241,396
2020	60,000
Total minimum lease payments	301,396
Amount representing interest	(36,806)
Present value of minimum lease payments	264,590
Current portion of capital lease obligations	225,084
Capital lease obligation, less current portion	<hr/> \$ 39,506

Promissory note

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 with four semi-annual payments of \$75,000 beginning on December 31, 2015 with the remaining unpaid balance due June 1, 2020.

The Company imputed an interest rate of 5% and discounted the promissory note accordingly. The imputed debt discount of \$368,615 is amortized to interest expense using the effective interest method. For the years ended December 31, 2018 and 2017, the Company amortized \$69,889 and \$71,450 of debt discounts to current period operations as interest expense, respectively. The unamortized debt discount at December 31, 2018 is \$99,184.

As of December 31, 2018, the remaining principle due was \$1,397,762.

NOTE 7—RELATED PARTY TRANSACTIONS

Advances

As of December 31, 2018 and 2017, the Company's officers and directors have provided advances in the aggregate of \$234,901 and \$104,901 respectively, for working capital purposes. The advances are unsecured, due on demand, and non-interest bearing.

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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.

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On March 1, 2017, Northstar and the Company entered into a settlement agreement (“Settlement Agreement”) related to then pending litigation (See Note 11). 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.

As of December 31, 2018 and 2017, the principal of this note was \$262,000.

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Officer and Director Notes

	2018	2017
Note payable, Mr. Tomas	\$ -	\$ 101,729
Note payable, Mr. Tomas	-	500,000
Note payable, Mr. Tomas	483,293	500,000
Note payable, Mr. Tomas	500,000	-
Note payable, Dr. Comella	147,711	237,797
Note payable, Dr. Comella	300,000	300,000
Note payable, Dr. Comella	300,000	-
Total	\$ 1,731,004	\$ 1,639,526

Note payable, Ms. Murphy

At December 31, 2016, the Company has outstanding promissory note payable of \$50,000 due to Beverly Murphy with interest at 7% per annum due at maturity at October 15, 2015.

On March 29, 2017, the Company issued 1,748,947 shares of common stock in settlement of \$50,000 of outstanding notes payable and \$8,601 of accrued interest to Ms. Murphy.

Notes payable, Mr. Tomas

On July 1, 2014, the Company issued a \$500,000 promissory note in settlement of compensation earned. The promissory note bears interest of 5% per annum and was due on January 1, 2015. During the year ended December 31, 2018 and 2017, the Company paid off \$101,729 and \$398,271 the outstanding promissory note. The principal outstanding balance of this note as of December 31, 2018 and 2017 is \$0 and \$101,729, respectively.

On September 6, 2016, 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 upon demand. During the year ended December 31, 2018, the Company paid off \$500,000 of the outstanding promissory note. The principal outstanding balance of this note as of December 31, 2018 and 2017 is \$0 and \$500,000, respectively.

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, 2018, the Company paid off \$16,707 of the outstanding promissory note. The principal outstanding balance of this note as of December 31, 2018 and 2017 is \$483,293 and \$500,000, respectively.

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. The principal outstanding balance of this note as of December 31, 2018 is \$500,000.

At December 31, 2018 and 2017, the Company has recorded accrued interest on the outstanding and past notes to Mr. Tomas in the amount of \$340,009 and \$282,701, respectively, which is included in the accrued expenses on the balance sheet.

Notes payable, Dr. Comella

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 was due upon demand. During the year ended December 31, 2018 and 2017, the Company paid off \$90,086 and \$62,203 of the outstanding promissory note, respectively. The principal outstanding balance of this note as of December 31, 2018 and 2017 is \$147,711 and \$237,797, respectively.

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. The principal outstanding balance of this note as of December 31, 2018 and 2017 is \$300,000.

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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. The principal outstanding balance of this note as of December 31, 2018 is \$300,000.

At December 31, 2018 and 2017, the Company has recorded accrued interest on the outstanding notes to Dr. Comella in the amount of \$102,974 and \$67,884, respectively, which is included in the accrued expenses on the balance sheet.

Transactions with Pavillion

On May 1, 2016, the Company entered into a consulting agreement with Pavillion, Inc., whose owner is related to an officer of the Company. The agreement is for 12 months and renewable for 6 month periods. Compensation is at \$250 per hour or, at the Company's discretion, in shares of the Company's common stock. For the year ended December 31, 2018 and 2017, the Company has incurred \$120,000 and \$120,000 of expense under the agreement, respectively. As of December 31, 2018 and 2017, the Company had \$64,909 and \$187,409, respectively, in accounts payable owed to Pavillion. On June 1, 2018, effective June 30, 2018, the Company terminated the agreement in accordance with its terms and no further compensation was derived by Pavillion.

Transactions with GACP

On March 3, 2017, the Company entered into an asset sale and lease agreement (sale/leaseback transaction, the "Asset Sale and Lease Agreement") with GACP, whereby the Company 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 (See "*Lab and Medical Equipment Capitalized Lease*" below). The Company determined that the transaction was a capitalized lease and accordingly recorded the leased assets and liability based on the estimated present value of the minimum lease payments (see Notes 4 and 6).

In connection with the asset sale and lease agreement, the Company is obligated to accrue 10% of banking revenue as for marketing, offset by any incurred costs of the Company. At December 31, 2018 and 2017, the outstanding accrued marketing obligation is \$179,353 and \$141,560, respectively (see Note 5).

On March 3, 2017, the Company also entered into a customer purchase agreement with GACP, whereby the Company agreed to sell, for \$50,000, the first 5,000 customers of the cell banking business after the effective date of the equipment sale/leaseback agreement with rights to purchase additional customers at a price of \$20 per customer. There is no reduction in the selling price should the new customers be fewer than 5,000. The effective date of the sale is upon the expiry or early termination of the related equipment lease transaction.

On March 3, 2017, the Company also entered into an asset purchase agreement of intellectual property with GACP whereby the Company agreed to sell all of the Company's worldwide rights, title or interest in certain intellectual and other property (as defined) associated with the cell banking business for \$50,000. The effective date of the sale is upon the expiry or early termination of the related equipment lease transaction.

In connection with the March 3, 2017 asset purchase agreement, the CEO and CSO of U.S. Stem Cell, Inc. were also retained as CEO and CSO of American Stem Cell Centers of Excellence, which is owned by General American Capital Partners (GACP), to help with scientific and successful operational deployment of clinics. Subsequently, the CSO of U.S. Stem Cell, Inc. has vacated her position but retained her positions with U.S. Stem Cell, Inc. and subsidiaries.

On April 3, 2017, U.S. Stem Cell received a commitment to invest up to \$5,000,000 from GACP with the intent for GACP to receive up to 63,873,275 shares of common stock. To date, GACP has invested, pursuant to this commitment, \$250,000 in return for 858,281 shares. Subsequent to this investment, GACP has informed the Company that they will make no further investments pursuant to this agreement and has entered into a new agreement to invest \$3,000,000 to open their own clinics (branded American Stem Cell) using the US Stem Cell Inc. protocols, procedures, products and technologies. As of September 30, 2018 (effective May 9, 2018), pursuant to an Amendment to Asset Sale and Lease Agreement, dated June 18, 2018, GACP has suspended their obligation to open additional clinics (tolling such obligation to a mutually agreeable date in the future) and has suspended the monthly aggregate number of stem cell kits set forth for purchase in a given month arising from such clinics. All other terms and conditions of the agreements between U.S. Stem Cell, Inc. and GACP remain in full force and effect. As of December 31, 2018 and 2017, GACP owns 4,021,945 shares of the Company's common stock.

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NOTE 8—DERIVATIVE LIABILITIES

Reset warrants

On October 1, 2012, in connection with the forbearance agreement with Northstar as discussed in Note 7, the Company issued an aggregate of 15,000 common stock purchase warrants to purchase the Company's common stock with an exercise price of \$14.00 per share for ten years with anti-dilutive (reset) provisions.

The Company has identified embedded derivatives related to the issued warrants. These embedded derivatives included certain and anti-dilutive (reset) provisions. The accounting treatment of derivative financial instruments requires that the Company record fair value of the derivatives as of the inception date and to fair value as of each subsequent reporting date.

During the year ended December 31, 2017, the fair value of the reset provision was reduced to \$-0-.

The Company recorded a gain on change in derivative liabilities of \$24 during the year ended December 31, 2017.

Convertible notes

In fiscal 2016 and prior, the Company issued convertible promissory notes.

These promissory notes were convertible into common stock, at holders' option, at a discount to the market price of the Company's common stock. The Company has identified the embedded derivatives related to these promissory notes relating to certain anti-dilutive (reset) provisions. These embedded derivatives included certain conversion features. The accounting treatment of derivative financial instruments requires that the Company record fair value of the derivatives as of the inception date of these notes and to fair value as of each subsequent reporting date.

During the year ended December 31, 2017, the remaining promissory notes were converted or paid off in full settlement.

The fair value of the embedded derivative at note payoff, in the amount of \$185,505, was determined using the Binomial Option Pricing Model based on the following assumptions: (1) dividend yield of 0%; (2) expected volatility of 247.25%, (3) weighted average risk-free interest rate of 0.87%, (4) expected life of 0.54 years, and (5) estimated fair value of the Company's common stock of \$0.0271 per share. The Company reclassified the determined fair value from liability to equity at the time of the payoff.

The Company recorded a loss on change in derivative liabilities of \$1,891,229 during the year ended December 31, 2017. The remaining outstanding derivative liability at December 31, 2017 is \$-0-

Based upon ASC 840-15-25 (EITF Issue 00-19, paragraph 11) the Company had adopted a sequencing approach regarding the application of ASC 815-40 to its outstanding convertible promissory notes. Pursuant to the sequencing approach, the Company evaluates its contracts based upon earliest issuance date.

NOTE 9—STOCKHOLDERS' EQUITY

Preferred stock

On August 17, 2012, the Board of Directors designated 5,000,000 shares of preferred stock as Series A Convertible Preferred Stock which was increased to 20,000,000 shares of preferred stock as Series A Convertible Preferred Stock (currently held by Northstar Biotechnology Group, LLC). Each share of preferred stock is convertible into equal number of common shares at the option of the holder; entitled to 20 votes on all matters presented to be voted by the holders of common stock; upon event of liquidation, entitled to amount equal to stated value plus any accrued and unpaid dividends or other fees before distribution to junior securities. In lieu of the initial two payments due to Northstar on April 1, 2013 and October 1, 2013, the parties have determined to modify the voting rights of the 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 (see Note 7).

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During the year ended December 31, 2013, the Company issued an aggregate of 20,000,000 shares of Series A Convertible Preferred Stock for principle payment and settlement of forbearance (See Note 7).

On March 6, 2017, the Company issued 20,000,000 shares of its common stock upon conversion of the outstanding 20,000,000 shares of Series A Convertible Preferred stock (see Note 7).

Common stock

During the year ended December 31, 2018, the Company issued an aggregate of 15,055,855 shares of its common stock in settlement of outstanding accounts payable and accrued expenses. In connection with the issuance, the Company incurred a \$43,180 net gain in settlement of debt.

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.

During the year ended December 31, 2018, the Company issued an aggregate of 10,866,274 shares of its common stock for services.

During the year ended December 31, 2018, the Company issued an aggregate of 9,350,508 shares of its common stock for \$367,700.

During the year ended December 31, 2018, the Company issued 526,818 shares of its common stock as reimbursement for expenses incurred by a member of the Company's board of directors.

During the year ended December 31, 2017, the Company issued an aggregate of 164,270,878 shares of its common stock for the conversion of \$242,427 of promissory notes payable and related accrued interest. Upon conversion of the promissory notes, the Company recorded an adjustment to the derivative liability in the amount of \$2,002,857 (see Note 6).

On April 7, 2017, the Company entered into an investment agreement whereby the Company agreed to sell an aggregate of 63,873,275 shares of its common stock for a net purchase price of \$5,000,000 (\$0.07828 per share). At the execution of the agreement, the Company sold 3,193,664 shares for a purchase price of \$250,000 with the remaining sale to be completed within 30 days. The investor has the right to terminate the agreement upon written notice and not complete the purchase. Upon completion of the investment, the investor, or his designee, shall fill one vacancy on the Company's Board of Directors. On May 18, 2017 the Company received notice from the investor terminating the agreement and, as such, no other shares were sold.

On March 1, 2017, the Company issued 11,000,000 shares of common stock in settlement of pending litigation (see note 7).

On March 29, 2017, the Company issued 1,748,947 of common stock in settlement of \$50,000 outstanding notes payable and \$8,601 of accrued interest.

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, 2015 per the forbearance agreement on Northstar note (See Note 7).

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, 2015 per the forbearance agreement on Northstar note (See Note 7).

On November 11, 2017, the Company issued 828,281 shares of common stock in exchange for \$25,000.

During the year ended December 31, 2017, the Company issued an aggregate of 14,058,588 shares of its common stock in settlement of outstanding accounts payable and accrued expenses. In connection with the issuance, the Company incurred \$359,326 net loss in settlement of debt.

U.S. STEM CELL, INC.
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Stock Options

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.

A summary of options at December 31, 2018 and activity during the two years then ended is presented below:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Weighted-Average Remaining Contractual Term (in years)
Options outstanding at January 1, 2017	23,555,777	\$ 0.03	9.7	9.7
Granted	48,075,000	\$ 0.025	—	10.0
Exercised	—	—	—	—
Forfeited/Expired	(14)	\$ 0.15	—	—
Options outstanding at December 31, 2017	71,630,763	\$ 0.0280	9.2	9.2
Granted	41,340,000	\$ 0.0458	—	10.0
Exercised	—	—	—	—
Forfeited/Expired	(70)	\$ 2,625.080	—	—
Options outstanding at December 31, 2018	112,970,693	\$ 0.03294	8.7	8.7
Options exercisable at December 31, 2018	43,089,443	\$ 0.02776	8.4	8.4
Available for grant at December 31, 2018	<u>75,068,070</u>			

The following information applies to options outstanding and exercisable at December 31, 2018:

Exercise Price	Number Outstanding	Option Outstanding			Number Exercisable	Options Exercisable Weighted Average Exercise price		
		Options Average		Weighted Average Exercise price				
		Remaining Contractual Life (years)	Exercise price					
\$ 0.0043	16,200,000	8.11	\$ 0.0043	4,050,000	\$ 0.0043	\$ 0.0043		
0.0196	22,850,000	7.72	0.0196	15,350,000	—	0.0196		
0.02511	9,000,000	9.93	0.02511	9,000,000	—	0.02511		
0.02576	2,340,000	9.61	0.02576	—	—	0.02576		
0.03626	31,865,000	8.61	0.03626	14,060,000	—	0.03626		
0.03680	10,000	8.61	0.03680	2,500	—	0.03680		
0.0536	30,000,000	9.36	0.0536	—	—	0.0536		
0.15402	705,363	6.75	0.15402	626,613	—	0.15402		
19.32	150	5.85	19.32	150	—	19.32		
70.00	100	2.66	70.00	100	—	70.00		
210.00	40	2.62	210.00	40	—	210.00		
680.00	40	1.11	680.00	40	—	680.00		
Total	<u>112,970,693</u>	8.67	\$ 0.03294	<u>43,089,443</u>	\$ 0.02776	\$ 0.02776		

U.S. STEM CELL, INC.
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The aggregate intrinsic value of the issued and exercisable options of \$189,540 and \$47,385, respectively, represents the total pretax intrinsic value, based on options with an exercise price less than the Company's stock price of \$0.016 as of December 31, 2018, which would have been received by the option holders had those option holders exercised their options as of that date.

On May 7, 2018, the Company granted an aggregate 30,000,000 options to purchase the Company's common stock at \$0.0536 per share to key employees, vesting over 4 years, at grant date anniversary and exercisable over 10 years. The aggregate fair value of \$1,438,473, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 261.13% and Risk free rate: 2.90%.

On August 8, 2018, the Company granted an aggregate 2,340,000 options to purchase the Company's common stock at \$0.02576 per share to key employees, vesting over 4 years, at grant date anniversary and exercisable over 10 years. The aggregate fair value of \$91,988, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 217.72% and Risk free rate: 2.83%.

On December 3, 2018, the Company granted an aggregate 9,000,000 options to purchase the Company's common stock at \$0.02511 per share to board members, vesting immediately exercisable over 10 years. The aggregate fair value of \$195,722, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 215.29% and Risk free rate: 2.83%.

On February 6, 2017, the Company granted an aggregate 16,200,000 options to purchase the Company's common stock at \$0.0043 per share to key employees, vesting over 4 years, at grant date anniversary and exercisable over 10 years. The aggregate fair value of \$53,271, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 235.22% and Risk free rate: 1.86%.

On August 7, 2017, the Company granted an aggregate 23,750,000 options to purchase the Company's common stock from \$0.03626 to \$0.0368 per share to key employees, vesting over 4 years, at grant date anniversary and exercisable over 10 years. The aggregate fair value of \$860,211, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 259.16% and Risk free rate: 1.81%.

On August 7, 2017, the Company granted an aggregate 8,125,000 options to purchase the Company's common stock at \$0.03626 per share to members of the Board of Directors, vesting immediately and exercisable over 10 years. The aggregate fair value of \$293,545, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 259.16% and Risk free rate: 1.81%.

The fair value of all options vesting during the years ended December 31, 2018 and 2017 of \$753,007 and \$645,483, respectively, was charged to current period operations.

As of December 31, 2018, the Company had approximately \$1,973,194 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 1.64 years.

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Warrants

A summary of common stock purchase warrants at December 31, 2018 and activity during the two years ended December 31, 2018 is presented below:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)
Outstanding at January 1, 2017	139,145	\$ 173.03	5.5
Issued	-	\$ -	
Exercised	-	\$ -	
Expired	(5,554)	\$ 1,297.98	
Outstanding at December 31, 2017	133,591	\$ 126.26	4.7
Issued	1,000,000	\$ 0.02713	10.0
Exercised	-	\$ -	
Expired	(19,572)	\$ 24.46	
Outstanding at December 31, 2018	1,114,019	\$ 14.735	9.1
Exercisable at December 31, 2018	112,474	\$ 40.07	4.3

The following information applies to common stock purchase warrants outstanding and exercisable at December 31, 2018:

Warrants Outstanding			Warrants Exercisable		
Exercise Price	Shares	Weighted-Average Remaining Contractual Term	Exercise Price	Shares	Weighted-Average Exercise Price
\$ 0.01 – 20.00	1,086,536	9.2	\$ 1.267	86,536	\$ 15.59
\$ 20.01 – 30.00	19,543	5.2	\$ 25.06	19,543	\$ 25.06
\$ 40.01 - 50.00	2,253	3.8	\$ 48.83	2,253	\$ 48.83
\$ 50.01 – 60.00	543	2.6	\$ 60.00	543	\$ 60.00
> \$60.00	\$ 5,144	2.8	\$ 2,800.69	3,599	\$ 701.78
	<u>1,114,019</u>	<u>9.1</u>	<u>\$ 14.74</u>	<u>112,474</u>	<u>\$ 40.070</u>

On August 27, 2018, the Company issued 1,000,000 warrants to purchase the Company's common stock at \$0.02713 per share for services rendered, vesting 6 months from issuance and exercisable over 10 years. The aggregate fair value of \$24,986, determined using the Black Scholes option pricing model with the following assumptions: Dividend yield: 0%; Volatility: 217.01% and Risk free rate: 2.85%.

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 \$0.016 as of December 31, 2018, which would have been received by the warrant holders had those warrants holders exercised their warrants as of that date.

**U.S. STEM CELL, INC.
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NOTE 10—COMMITMENTS AND CONTINGENCIES

Operating Leases

On February 4, 2016, the Company amended its facility lease to extend the term of the lease until August 31, 2019. Approximate annual future minimum lease obligations under non-cancelable operating lease agreements as of December 31, 2018 are as follows:

Period ending December 31,	
	2019
	58,448

Employment agreements

On May 7, 2018, the Company's Board of Directors approved the 2018/2019 salary for Mike Tomas, Chief Executive Officer, from \$625,000 to \$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 at an exercise price equal to the five day average closing price of the Company's common stock as of May 7, 2018. The cash bonus may be paid in the form a six month promissory note bearing interest at 5% per annum. On August 7, 2017, the Company's Board of Directors approved the 2017/2018 salary for Mike Tomas, Chief Executive Officer, from \$500,000 to \$625,000 per year beginning July 1, 2017 and a cash bonus of \$500,000 that will accrue interest at 5% per annum until paid. In addition, the Company granted Mr. Tomas 15,000,000 options to acquire the Company's stock with an exercise price of \$0.03626, vesting over four years on the anniversary and expiring ten years from the date of issuance.

On May 7, 2018, the Company's Board of Directors approved the 2018/2019 salary for Kristin Comella, Chief Scientific Officer, from \$325,000 to \$400,000 per year, beginning July 1, 2018 with an incentive bonus ranging from \$100,000 to \$300,000. In addition, the Board of Directors approved a bonus of \$300,000 and options to acquire 10,000,000 shares of the Company's common stock for ten years with four year vesting and a cashless exercise provision at an exercise price equal to the five day average closing price of the Company's common stock as of May 7, 2018. The cash bonus may be paid in the form a six month promissory note. On August 7, 2017, the Company's Board of Directors approved the 2017/2018 salary for Kristin Comella, Chief Scientific Officer, from \$250,000 to \$325,000 per year and a cash bonus of \$300,000 that will accrue interest at 5% per annum until paid. In addition, the Company granted Ms. Comella 7,500,000 options to acquire the Company's stock with an exercise price of \$0.03626, vesting over four years on the anniversary and expiring ten years from the date of issuance.

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, 2018 and 2017 was \$68,500 and \$71,500, 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 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 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, of which \$89,000 is included in accrued expenses at December 31, 2018 and 2017.

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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 September 30, 2018 other than that described above.

SEC Investigation

On or about March 1, 2018, the U.S. Securities and Exchange Commission (“Commission”), Miami Regional Office (“Commission Staff”), served a subpoena upon U.S. Stem Cell, Inc., which seeks the production of certain documents and communications. The Commission Staff is conducting a formal non-public, fact-finding inquiry of U.S. Stem Cell, Inc (“Investigation”). The Investigation is neither an allegation of wrongdoing nor a finding that any violation of law has occurred. The Company is cooperating with, and has provided information and documents to, the Commission Staff.

As part of the Investigation, on or about May 14, 2018, the Commission Staff served subpoenas upon Kristin Comella and Mike Tomas, respectively, seeking the production of certain documents and communications. Ms. Comella and Mr. Tomas responded to the respective subpoenas and provided information and documents to the Commission Staff.

At this juncture, the Company is not able to predict the duration, scope, results, or consequences of the investigation. There can be no assurance that the Investigation will be resolved in a manner that is not adverse to the Company.

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. The Company is not able to predict the duration, scope, results, or consequences of the U.S. Department of Justice actions. There can be no assurance that this matter will be resolved in a manner that is not adverse to the Company.

NOTE 11 — FAIR VALUE MEASUREMENT

The Company adopted the provisions of Accounting Standards Codification subtopic 825-10, Financial Instruments (“ASC 825-10”) on January 1, 2008. 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 nonperformance. 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.

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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.

Upon adoption of ASC 825-10, there was no cumulative effect adjustment to beginning retained earnings and no impact on the financial statements.

The carrying value of the Company's cash and cash equivalents, accounts receivable, accounts payable, short-term borrowings (including convertible notes payable), and other current assets and liabilities approximate fair value because of their short-term maturity.

As of December 31, 2018 and 2017, the Company did not have any items that would be classified as level 1 or 2 disclosures.

The Company recognizes its derivative liabilities as level 3 and values its derivatives using the methods discussed in note 8. While the Company believes that its valuation methods are appropriate and consistent with other market participants, it recognizes that the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date. The primary assumptions that would significantly affect the fair values using the methods discussed in Notes 6 and 8 are that of volatility and market price of the underlying common stock of the Company.

As of December 31, 2018 and 2017, the Company did not have any derivative instruments that were designated as hedges.

The following table provides a summary of changes in fair value of the Company's Level 3 financial liabilities as of December 31, 2018:

	Warrant Liability	Debt Derivative
Balance, January 1, 2017	\$ 24	\$ 297,132
Total (gains) losses		
Transfers out of Level 3 upon conversion or payoff of notes payable	—	(2,188,361)
Mark-to-market at December 31, 2017:	(24)	1,891,229
Balance, December 31, 2017	-	-
Total (gains) losses		
Transfers out of Level 3 upon conversion or payoff of notes payable	-	-
Mark-to-market at December 31, 2018:	-	-
Balance, December 31, 2018	\$ -	\$ -
Net gain (loss) for the period included in earnings relating to the liabilities held at December 31, 2018	\$ -	\$ -

Fluctuations in the Company's stock price are a primary driver for the changes in the derivative valuations during each reporting period. The Company's stock increased approximately 942% from December 31, 2016 to March 8, 2017 (final conversion of convertible notes). As the stock price increases for each of the related derivative instruments, the value to the holder of the instrument generally increases. Stock price is one of the significant unobservable inputs used in the fair value measurement of each of the Company's derivative instruments.

The estimated fair value of these liabilities is sensitive to changes in the Company's expected volatility. Increases in expected volatility would generally result in a higher fair value measurement.

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NOTE 12 — INCOME TAXES

The Company follows Accounting Standards Codification subtopic 740, Income Taxes (“ASC 740”) which requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under such 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 using enacted tax rates in effect for the year in which the differences are expected to reverse.

The difference between income tax expense computed by applying the federal statutory corporate tax rate and actual income tax expense is as follows:

	2018	2017
Income taxes using U.S. federal statutory rate	\$ (453,690)	\$ (1,183,707)
State income taxes, net of federal benefit	(22,280)	(748,740)
Return to Provision adjustments	-	-
Nontaxable Gain/Loss on Derivative Instrument	-	643,010
Change in Valuation Allowance	1,151,307	(13,387,737)
Other	(675,337)	2,185
Federal rate change – Tax Cuts and Jobs Act	-	14,674,989
	\$ -	\$ -

At December 31, 2018, the significant components of the deferred tax assets (liabilities) are summarized below:

	2018	2017
Deferred tax assets:		
Stock Based Compensation	\$ 3,902,930	\$ 3,701,469
Deferred Compensation	415,469	415,469
Net Operating Losses	25,419,811	24,502,969
Other	262,662	229,730
Total deferred tax assets	30,000,872	28,849,637
Deferred tax liabilities:		
Total deferred tax liabilities	-	-
Valuation allowance	30,000,872	28,849,637
Net deferred tax assets	\$ -	\$ -

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (the “Act”). The Act, which is also commonly referred to as “U.S. tax reform”, significantly changes U.S. corporate income tax laws by, among other provisions, reducing the maximum U.S. corporate income tax rate from 35% to 21% starting in 2018. During the year ending December 31, 2017, the Company reduced deferred tax assets by \$14.7 million, offset by a corresponding reduction to its valuation allowance, as a result of the re-measurement of deferred tax assets and liabilities from its 34% effective rate under existing law to the new lower statutory rate of 21%.

On December, 22, 2017, SAB 118 was issued due to the complexities involved in accounting for the recently enacted Tax Act. SAB 118 requires the company to include in its financial statements a reasonable estimate of the impact of the Tax Act on earnings to the extent such estimate has been determined. Accordingly, the U.S. provision for income tax for 2017 is based on the reasonable estimate guidance provided by SAB 118. The company is continuing to assess the impact from the Tax Act and will record adjustments in 2018 if necessary.

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As of December 31, 2018 and December 31, 2017, the Company had U.S. federal net operating loss carryforwards of approximately \$98.2 million and \$96.7 million, respectively, which expire at various dates from 2019 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 years. In addition, all or a portion of the Company's net operating loss carryforwards may expire unutilized. As of December 31, 2018 and December 31, 2017, the Company had net operating loss carryforwards for state income tax purposes of approximately \$98.2 million and \$96.7 million, respectively, which expire at various dates from 2019 through 2038.

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 than 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.

NOTE 13 — SUBSEQUENT EVENTS

In January and February 2019, the Company issued an aggregate of 8,598,928 shares of common stock for services rendered

On January 29, 2019, through a reorganization of Member Interests of U.S. Stem Cell Clinic, LLC and Regenerative Wellness Clinic, LLC respectively, we increased our holdings, without additional consideration, to a 49.9 percent Member Interest ownership of U.S. Stem Cell Clinic, LLC and Regenerative Wellness Clinic, LLC respectively.

Exhibit 21

US Stem Cell Training

Vetbiologics

U.S. Stem Cell Clinic, LLC
Regenerative Wellness Clinic, LLC
U.S. Stem Cell Clinic of The Villages LLC

49.9% Member Interest
49.9% Member Interest
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, 2018, 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 13, 2019

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, 2018 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 13, 2019