

MEDISTEM INC.  
Form 10-12G/A  
December 12, 2013

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Amendment No. 3**

**to**

**FORM 10**

**GENERAL FORM FOR REGISTRATION OF SECURITIES PURSUANT TO SECTION 12(b) OR 12(g) OF  
THE SECURITIES EXCHANGE ACT OF 1934**

**Medistem Inc.**

State or other jurisdiction of incorporation or organization: **Nevada**

I.R.S. Employer Identification Number: **86-1047317**

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San Diego, CA 92121

Phone: 858-352-7071

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(Address and telephone number of principal executive offices)

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

None

(Title of each class)

N/A

(Name of each exchange on which to be registered)

Securities to be registered pursuant to Section 12(g) of the Act:

Common Stock, \$0.0001 par value

(Title of class)

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

Large accelerated filer   Accelerated filer  
Non-accelerated filer   Smaller reporting company

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*Except for the historical information presented, the matters discussed in this Report, including our product development and commercialization goals and expectations, our plans and anticipated timing and results of clinical development activities, potential market opportunities, revenue expectations and the potential advantages and applications of our products and product candidates under development, include forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed under the caption "Risk Factors." Unless the context requires otherwise, references to "we," "us," "our" and "Medistem" refer to Medistem Inc.*

## **ITEM 1. BUSINESS**

### Overview

Medistem Inc., a Nevada corporation (the "Company," "Medistem," "us", "our" or "we") was formed in 2001 under the name SGC Holdings, Inc., and has also formerly been known as Medistem Laboratories, Inc. Based in San Diego, California, we are a therapeutics company focused on the emerging field of regenerative medicine. Our business strategy is to develop and ultimately commercialize safe and efficacious adult stem cell therapies to address unmet medical needs. We anticipate that therapies generated using our product platform will be scalable and reimbursable.

We are developing the Endometrial Regenerative Cell (ERC), our universal donor adult stem cell product. ERCs were discovered by us in 2007, and preclinical tests have shown their likely ability to promote new blood vessel formation (angiogenesis), reduce inflammation, regulate immune system function, and augment tissue repair and healing. We believe ERCs have the potential to treat a range of diseases, including ischemic conditions, cardiovascular disease, certain neurological diseases, autoimmune diseases (such as Type 1 Diabetes), kidney failure, liver failure, pulmonary diseases and a range of orphan disease indications. Cook General BioTechnology, LLC, located in Indianapolis, Indiana, currently manufactures ERCs for us under cGMP. Our intellectual property protecting our ERC business consists of an issued patent and several patent applications, trade secrets, and proprietary manufacturing know-how that we believe provide us with a competitive advantage.

Our primary focus is to address the unmet medical needs in Critical Limb Ischemia (CLI), Congestive Heart Failure (CHF), and Type 1 Diabetes. We have been cleared by the U.S. Food and Drug Administration (FDA) to begin clinical studies of ERCs in the United States for CLI. In addition, we have initiated a Phase II clinical trial in CHF in Moscow, Russia in collaboration with a major cardiovascular center in Moscow. The Russian regulatory system does not use "Phase" nomenclature and the FDA has not approved or cleared any clinical trials of ERCs for CHF in the U.S. or any other country. The FDA has no jurisdiction over our Russian clinical trial in CHF; however, we have structured and are endeavoring to conduct this trial in conformity with FDA guidelines, and this trial has been approved by Russian authorities. Nonetheless, in this Form 10 registration statement we refer to our CHF clinical trial as a Phase II clinical trial, as it is a study to establish safety and efficacy. Investors and authorities in the United States

often consider that clinical trial results from trials not conducted in the United States or Western Europe are less reliable than those from trials conducted in the United States or Western Europe. Therefore it is possible the FDA may not honor some or all the data derived from this trial.

We are committed to the rapid commercialization of the ERC platform technology. Our ongoing strategy is to maximize shareholder value through rapid completion of existing clinical programs and to expand our market opportunities by initiating new programs based on the biological properties of our platform. We intend to partner with commercial and academic organizations as a key component of our ongoing strategy. We need to raise funds in order to finance our clinical and research activities further.

From 2003 to 2008 we were active as a publicly reporting company. We “went dark” (ceased to be a publicly reporting company) in 2008 and sharply reduced all non-ERC activities. We will, upon the effectiveness of this Form 10 registration statement, become a publicly reporting company again in 2013.

#### Emerging Growth Company

We qualify as an “emerging growth company” (EGC) under the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). An EGC may take advantage of public reporting requirements that are in certain respects reduced from those otherwise applicable to public companies. The reduced reporting requirements include having to present only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations, and reduced disclosure obligations regarding executive compensation. Section 107(a) of the JOBS Act allows an EGC to elect to be treated as a non-EGC, thereby forgoing the special provisions of the JOBS Act and choosing to make disclosure and provide financial reporting required of non-EGC companies. We have elected, under Section 107(b), to be treated as an EGC for all purposes of the JOBS Act. We shall continue to be deemed an emerging growth company until the earliest of:

- a. the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective Securities Act registration statement;

b. the last day of our fiscal year in which we have total annual gross revenues of \$1,000,000,000 (as such amount is indexed for inflation every 5 years by the Securities and Exchange Commission to reflect the change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics) or more;

c. the date on which we have, during the previous 3-year period, issued more than \$1,000,000,000 in non-convertible debt; or

d. the date on which we are deemed to be a “large accelerated filer,” as defined in section 240.12b-2 of title 17, Code of Federal Regulations, or any successor thereto.

As an emerging growth company we are exempt from Section 404(b) of the Sarbanes-Oxley Act of 2002. Section 404(a) of the Sarbanes-Oxley Act requires issuers to publish information in their annual reports concerning the scope and adequacy of the internal control structure and procedures for financial reporting. This statement shall also assess the effectiveness of such internal controls and procedures. Section 404(b), from which EGCs are exempt, requires that the issuer’s independent registered public accounting firm shall, in the same report, attest to and report on the assessment on the effectiveness of the internal control structure and procedures for financial reporting.

As an emerging growth company we are also exempt from Section 14A (a) and (b) of the Securities Exchange Act of 1934 which deal with shareholder voting as to executive compensation and golden parachutes.

We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(2) of the JOBS Act, thereby allowing us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to those of companies that comply with public company effective dates.

It is possible that even after we lose EGC status we could still be able to qualify as a “smaller reporting company” as defined by Securities Exchange Act of 1934 regulations (for example, if we lose EGC status on the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective Securities Act registration statement). Under current law, “smaller reporting companies” are eligible for many of the same exemptions and reduced reporting requirements as EGCs are.

Regenerative Medicine Industry

Historically, efforts toward preventing and treating disease focused on the use of drugs, specifically chemicals identified to alter or slow the course of a disease by selectively affecting one or a handful of molecular targets. This approach has led to the development of drugs that can combat infection, suppress cancer progression, and alleviate symptoms in numerous diseases. Unfortunately, diseases are often multifactorial and require a broader approach for effective treatment. Drawbacks of drug approaches include a) lack of target specificity that leads to complications (e.g. side effects); b) the ability of diseases to acquire resistance to the drug and c) lack of efficacy.

Regenerative medicine is the process of replacing or regenerating human cells, tissues or organs to restore or establish normal function and has been described as the "next evolution of medical treatments" and "the vanguard of 21st century healthcare" by the U.S. Department of Health and Human Services. This new field of medicine is expected to revolutionize health care. Our business focus is the development of regenerative medicine therapies.

Cell therapies potentially offer a complete solution for complex pathological processes that are not addressed using traditional drug approaches. Cell therapies hold the potential to regenerate damaged tissues or to stimulate the body's own repair mechanisms. By altering the course of disease, cell therapies could make it possible to eliminate the need for daily treatments, reduce hospitalizations and avert expensive medical procedures, while enabling patients to lead healthier lives.

Regenerative medicine focuses on the use of stem cells as a cell therapy. Stem cells are non-specialized cells with a potential for both self-renewal and differentiation into cell types with a specialized function, such as blood vessels, heart tissue, and pancreatic cells. Stem cells have the ability to undergo asymmetric division such that one of the two daughter cells retains the properties of the stem cell, while the other begins to differentiate into a more specialized cell type. Stem cells are therefore central to normal human growth and development, and also are a potential source of new cells for the regeneration of diseased and damaged tissue. Stem cell therapy aims to restore diseased tissue function by the replacement and/or regeneration of healthy cells.

Currently, companies and researchers are exploring two principal approaches for stem cell therapy: (i) embryonic stem cells, isolated from the inner mass of a few days old embryo; and (ii) adult stem cells, sourced from bone marrow, cord blood and various organs. Although embryonic stem cells are the easiest to grow and differentiate, their use in human therapy is limited by safety concerns associated with their tendency to develop teratomas (a type of tumor) and their potential to elicit immune rejection. In addition, embryonic stem cells have generated significant political and ethical debate due to their origin from early human embryos. Some of the drawbacks of embryonic stem cells have been recently overcome by the introduction of inducible pluripotent stem cells. These cells are generated from adult tissue by the process of reprogramming. While these cells overcome ethical issues associated with embryonic stem cell production, clinical use has not occurred to date, in part due to potential safety issues.

Adult stem cell therapy does not share the same drawbacks. Because adult stem cells have a limited ability to multiply and are more differentiated, teratoma formation has not been observed in clinical studies to date. In fact, adult stem cells have been used for over 4 decades in over 200,000 patients in the context of bone marrow transplantation, which is the standard of care for numerous hematological conditions including leukemia, lymphoma and other cancers. Adult stem cells do not have the ethical and political issues associated with embryonic stem cells.

Generally, adult stem cells can be isolated from either the same patient, referred to as “autologous”, or from a donor, referred to as “allogeneic”. For many adult stem cell therapies, the use of allogeneic cells is not feasible due to the immune rejection that occurs following the injection of cells from an unrelated donor. However, our ERCs possess properties such that they typically do not trigger an immune response when injected into unrelated recipients, thus allowing for allogeneic use.

Our ERCs are characterized by low to absent expression of Human Leukocyte Antigen (HLA) 2 genes.<sup>1</sup> HLA-2 is responsible for stimulation of immune responses against transplanted tissues or cells. Given the low expression of this molecule in ERCs, the immune system of an unmatched recipient does not "recognize" ERC as foreign, and as a result immune responses are not mediated against ERCs that are derived from a different individual. Studies supporting this include the demonstration that ERCs do not stimulate, but actively inhibit, multiplication of non-matched immune cells in vitro<sup>2</sup>; in addition, in vivo studies show that human ERCs mediate therapeutic effects in immune competent animals without rejection.<sup>3</sup> Additionally, human studies involving multiple administrations of ERCs isolated from non-matched donors have not resulted in sensitization of the patient to ERC.<sup>4</sup>

Since patients with metabolic, cardiovascular or chronic disease have markedly suppressed stem cell activity, the procurement of cells from young healthy donors permits the selection of stem cells with optimal activity.

#### Endometrial Regenerative Cells

We are developing an allogeneic adult stem cell product, the ERC, which we believe has potential utility for treating a broad range of diseases and could have widespread application in the field of regenerative medicine. Our product is obtained by culturing cells isolated from the menstrual blood of healthy female volunteers. By this process we have identified a novel population of stem cells that originate from the endometrium (lining of the uterus). The endometrium is the only tissue in the body that undergoes approximately 500 cycles of highly vascularized growth and regression in the lifetime of the average female. These cells appear to coordinate the monthly production of new blood vessels that occurs as part of the menstrual cycle. In a 2007 publication by Thomas E. Ichim, Ph.D., our President and Chief Scientific Officer and others, describing the discovery of these cells, we named this cell population Endometrial Regenerative Cells (ERCs).<sup>4</sup>



Preclinical studies by others and us indicate that ERCs can alter the immune system in a manner that is beneficial for autoimmunity. Specifically, ERCs can augment expression of immune suppressive cytokines and several immune regulatory enzymes.<sup>4,5</sup> In addition, in vitro and in vivo studies have shown that ERCs induce the generation of T regulatory cells.<sup>3</sup>

We believe that ERCs are Superior to Other Adult Stem Cells

- *Non-invasive Method of Collection.* Unlike the painful and highly invasive process of collecting bone marrow cells, our collection processes involves extraction of a small amount of menstrual blood from young healthy donors. Even other types of stem cell therapy require tissue sources that are more difficult to procure than ERCs are, for example, placental, cord blood, and adipose tissue.

*ERCs are Universal Donor Stem Cells.* Unlike traditional bone marrow or hematopoietic stem cell transplants that require extensive genetic matching between donor and recipient or reinsertion of a patient's own autologous cells, ERCs are administered without tissue matching or the requirement for immune suppressive drugs. ERCs are delivered to the point-of-care as a cryogenically preserved allogeneic product that is ready to use, without need for end user manipulation, in any and all patients. This feature could make it practical for clinicians to efficiently deliver stem cell therapy to large numbers of patients. Additionally, we believe commercialized ERCs will be able to provide an off-the-shelf therapy with a validated one-year storage life, comparable to the shelf life of many prescription drugs.

*ERCs are Safe.* Safety of ERCs has been demonstrated in pilot and preclinical studies. Animal studies in immune competent and immune deficient models have shown safety after both acute and chronic administration. Published pilot clinical trials provide evidence for human safety when ERCs are administered via intramuscular, intravenous, intracoronary, and intrathecal routes.<sup>4,5,6</sup> No infusion reactions or allo-sensitization has been observed in a total of 17 patients treated under our cardiac protocol as well as 4 multiple sclerosis patients, 1 Duchenne muscular dystrophy patient, and 1 heart failure patient.<sup>7,8</sup> We plan to conduct additional clinical trials, which we believe will further establish ERCs' safety.

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1 Meng et al. Journal of Translational Medicine. 2007 Nov 15;5:57.

2 Wang et al. Journal of Translational Medicine, 2012 Oct 5;10:207.

3 Murphy et al. Journal Translational Medicine, 2008 Aug 19;6:45.

4 Meng et al. Journal of Translational Medicine. 2007 Nov 15;5:57.

5 Peron et al. Stem Cell Review, 2012 Sep;8(3):940-52.

*ERCs Should Have Superior Therapeutic Properties Compared to Other Adult Stem Cells.* Preclinical studies conducted by us, and subsequently independently confirmed, support the belief that ERCs are superior to competitor stem cell types at stimulating new blood vessel formation, self-renewing, and immune modulating. A recent study by the National Institutes of Health demonstrated that ERCs possess 40-fold higher expression of the stem cell potency gene aldehyde dehydrogenase compared to bone marrow mesenchymal stem cells (MSCs).<sup>6</sup> An animal study from the University of Keio, Japan, demonstrated ERCs were more effective than bone marrow MSCs at regenerating heart muscle and reducing fibrosis after experimental myocardial infarction.<sup>9</sup> We plan to conduct additional clinical trials, which we believe will further establish ERCs' therapeutic properties.

*ERCs Can Readily Be Collected and Cultured.* After culturing, one ERC donor procedure can provide 20,000 doses (100 million cells per dose) in a well validated and reproducible manner. Since the ERCs express high levels of regenerative genes (OCT4 and hTERT), they can be expanded in significantly higher numbers compared to some other kind of adult stem cells. Additionally, the rapid doubling time of ERCs compared to some other kinds of adult stem cells allows for less reagent use in production, thus providing a modest manufacturing advantage.

## Our Clinical Programs

### *Critical Limb Ischemia (CLI)*

CLI is a debilitating condition caused by occlusion of the arteries supplying blood to the legs and feet, and is often associated with other serious conditions including hypertension, cardiovascular disease, dyslipidemia, diabetes, obesity and stroke. CLI is the most serious and advanced stage of peripheral arterial disease resulting from chronic inflammation and lipid accumulation. In addition to chronic pain, patients experience ulcers, gangrene, and high mortality. Approximately 20-45% of patients require amputation. For these patients, the 1-year mortality rate is estimated to be as high as 45%. According to the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II), treatment for CLI should be focused on revascularization using surgical or percutaneous means. Unfortunately, because of disease severity, less than half of the patients are eligible to undergo these procedures. For the patients that are eligible, efficacy is limited due to high levels of restenosis and the need for further surgery. Non-surgical options for CLI are limited to drug therapy, which offers minimal or no benefit. Many CLI patients are considered "unsuitable for revascularization" (also known as "no option") as they have exhausted all other reasonable treatment options and will likely require amputation. According to the SAGE Group (2010) there are an estimated 1.1-2.0 million CLI patients that are currently ineligible for revascularization. In addition, the SAGE Group estimates the annual amputation rate due to CLI is approximately 150,000 in the US per year.

Angiogenesis, the process of making new blood vessels in tissues lacking oxygen, is an attempt by the body to correct inadequate circulation in the legs of patients with CLI. Patients who have higher propensity for angiogenesis have better outcomes and fewer amputations compared to those with lower angiogenic ability. Attempts have been made at augmenting this natural process through gene therapy by administration of HGF-1 or FGF-4 genes. Unfortunately these approaches have yielded poor results that appear to be related to the fact that the process of angiogenesis requires a coordinated "symphony of cytokines." Evidence suggests that administration of stem cells, which naturally

produce these cytokines in a coordinated manner, should elicit a markedly superior therapeutic effect.

Although difficult to scale up and implement, autologous bone marrow stem cell therapy has provided clinical signals that stem cell based approaches are effective in the treatment of CLI. In 2002 Tateishi-Yuyama et al treated 45 CLI patients with autologous bone marrow cells harvested from the hip and injected the cells into the gastrocnemius muscle of the ischemic leg. A statistically significant increase in ankle brachial index, transcutaneous oxygen pressure, pain free walking time, and amelioration of rest pain was observed at 4 and 24-week follow-up. Importantly, the new blood vessels that were generated in response to bone marrow cell administration were stable at 24 weeks. Additionally, clinical improvement was persistent for the length of the study follow-up, which was more than one year. Further studies have confirmed the therapeutic benefit of bone marrow administration for treatment of CLI. For example, Nizankowski et al treated 10 CLI patients with autologous bone marrow and observed improvement in circulation, walking distance and decrease in pain severity. Furthermore, Durdu et al performed intramuscular injection of autologous bone marrow mononuclear cells in 28 CLI patients. Of the 28 patients, only 1 required amputation in the one-year follow-up period. Statistically significant increases in rest pain scores, walking time, and quality of life were noted. Angiographic evidence of collateral vessel formation was observed in 22 of the patients at 6 months.

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6 Zhong et al. Journal of Translational Medicine, 2009 Feb 20;7:15.

7 Ichim et al. International Archives of Medicine, 2010 Apr 14;3(1):5.

8 Bockeria et al. Journal of Translational Medicine, 2013 Mar 5;11:56.

9 Wang et al. Journal of Translational Medicine 2012, 10:207.

Thus, autologous bone marrow therapy for CLI appears to be a promising solution to the current lack of treatments. However, the invasiveness of the bone marrow extraction procedure precludes many patients from therapy because of the co-morbidities of this patient population. Specifically, many vascular surgeons refuse to allow their patients to undergo the highly invasive procedure of bone marrow harvest. Additionally, it is widely accepted that bone marrow from patients with CLI have markedly impaired angiogenic properties. An "off-the-shelf" product, such as our ERC product, may overcome the current drawbacks of autologous bone marrow therapy. Specifically, our ERC therapy does not require bone marrow extraction, does not even need to be autologous, and possesses highly angiogenic properties.

### *Our Critical Limb Ischemia Program*

Since 2008 we have developed preclinical data to support the utilization of ERCs in patients with CLI. In 2008 our President and Chief Scientific Officer, Thomas E. Ichim, Ph.D., published with Michael P. Murphy, M.D., a vascular surgeon and associate professor of surgery at Indiana University School of Medicine, who is considered an opinion leader in the CLI space, animal efficacy data demonstrating that administering ERCs in a mouse model of CLI was effective at preventing limb loss associated with experimentally induced ischemia.<sup>3</sup> Based on this data, we applied for an Investigational New Drug (IND) application to treat 15 "no option" CLI patients by intramuscular administration of ERCs. The clinical protocol was cleared by the FDA in September of 2011 and granted IND #13898. As designed, the Phase I clinical trial will assess safety of 3 escalating doses of ERCs injected into 3 cohorts of 5 patients each. We anticipate starting our U.S. Phase I CLI trial during the second half of 2013. The trial will run through the fourth quarter of 2015 and we expect to dose 15 subjects.

The purpose of the trial will be to determine safety of intramuscularly delivered ERCs in patients with critical limb ischemia ineligible for revascularization. Safety will be defined as freedom from treatment associated adverse events.

In order to reduce risks associated with implementation of our FDA clinical trial, we provided our ERCs to Shanghai Jia Fu Medical Apparatus Inc., a Chinese conglomerate, to conduct a three no-option patient pilot CLI clinical study in China. The pilot CLI clinical study mirrors the Phase I CLI clinical trial we anticipate initiating in the U.S. The ERCs were shipped from Cook General BioTechnology in Bloomington, Indiana, to Shanghai, China, in a cryogenic shipping container. On arrival in Shanghai, China, and before administration to the patients, the ERCs were thawed and exceeded our viability criteria of a minimum of 70%. A total of three no-option CLI patients were injected intramuscularly (into the gastrocnemius muscle in the calf of the leg) and showed no adverse effects over the initial period of evaluation of 30 days. Patients will remain under evaluation through January 2014.

The pilot CLI clinical study was not conducted under a formal agreement with Shanghai Jia Fu Medical Apparatus Inc. and no payments were made or will be made for this study.

Under the protocol for the pilot CLI clinical study in China and also our FDA-cleared Phase I clinical trial, patients received/will receive 25, 50, or 100 million ERCs in ten injections of 2.5, 5, or 10 million ERCs suspended in a volume of 1 milliliter per injection. Injections were/will be spaced at least 2 centimeters apart from each other in the gastrocnemius muscle above the failed vascular perfusion area.

#### *Critical Limb Ischemia Market*

According to the SAGE Group, endovascular procedures for revascularization of CLI patients represent a market of approximately \$2.9 billion annually. Despite these procedures, approximately 150,000 amputations occur each year in the U.S. due to this condition. Additionally, medical treatments for CLI, which have not demonstrated meaningful limb salvage but merely provide amelioration of symptoms, such as Alprostadil (PGE1) and Iloprost (PGI2 analogue), represent hundreds of millions of dollars in yearly drug sales for this condition alone.

#### *Congestive Heart Failure (CHF)*

Congestive Heart Failure (CHF) has emerged as a major chronic disease in the United States. The initial stages of heart failure are managed with medical therapy and end-stage heart failure is managed with surgical procedures in addition to medical therapy. These patients have severely compromised perfusion of the myocardium leading to angina, which significantly limits their daily activities and interferes with their rest at night. Some of the proven surgical procedures include myocardial revascularization, ventricular assist devices, and heart transplantation. Although surgical and catheter based revascularization of ischemic myocardium can treat angina, reduce the risk of myocardial infarction, and improve function of viable myocardium, these treatments cannot restore the viability of severely ischemic and/or necrotic myocardium. Many patients with reversible ischemia in regions of the myocardium are not amenable to Coronary Artery Bypass Graft (CABG) or Percutaneous Transluminal Coronary Angioplasty (PTCA).

A major advance in the treatment of CHF would be to reverse this condition of ischemia and to restore perfusion within the affected area of the myocardium. Thus, the aim of stem cell based therapies is to repopulate the myocardium with cells that may restore blood supply, improve cardiac function and thereby enhance the patient's quality of life.

*Our Congestive Heart Failure (CHF) Program*

In January 2012, we announced the initiation of our RECOVER-ERC (Non-Revascularizable IschEmic Cardiomyopathy treated with Retrograde COronary Sinus Venous DELivery of Cell TheRapy) Phase II clinical trial. Although we refer to this CHF clinical trial as a Phase II clinical trial (as it is a study to establish safety and efficacy), the FDA has not approved or cleared any clinical trials of ERCs for CHF in the U.S. or any other country. The FDA has no jurisdiction over our Russian clinical trial in CHF; however, we have structured and are endeavoring to conduct this trial in conformity with FDA guidelines, and this trial has been approved by Russian authorities.

This trial is being conducted at the Bakulev Scientific Center for Cardiovascular Surgery, Moscow, Russia, in collaboration with ERCCell LLC, our majority owned Moscow-based ERC Russia/ Commonwealth of Independent States commercialization subsidiary. The trial is a 60 patient double blind placebo controlled study evaluating safety and efficacy of ERCs in end stage CHF patients. Patients will be randomized into 3 groups of 20 patients each, with 15 patients receiving ERCs and 5 patients receiving placebo per group. Group 1 will receive 50 million ERCs, Group 2 will receive 100 million ERCs, and Group 3 will receive 200 million ERCs. Cells are administered via our patent-pending catheter-based retrograde administration technique into the coronary sinus. Intra-coronary sinus administration is a minimally invasive 30-minute procedure. Efficacy endpoints include ECHO and MRI analysis, conducted at 6 months after treatment with additional assessments at 12 months. To date 18 patients have entered the trial.

The process of retrograde administration into the coronary sinus involves temporary occlusion of afferent coronary circulation by means of a balloon catheter followed by administration against the outflowing blood. This results in the solution entering the myocardium via post capillary venules. In contrast to arterioles or capillaries, post-capillary venules have the smallest vessel diameter and conceptually would allow for greatest transfer of material into the heart muscle. Given that MSC, hematopoietic stem cell, and various tissue specific progenitors migrate into tissue using similar mechanisms/molecules of extravasation as activated leukocytes, it is reasonable to directly deliver cells to “exit ports” within the coronary microcirculation as compared to intra-arterially. The procedure used in the clinical trial takes approximately 30 minutes to complete and involves administration of 40 ml volume of cells in retrograde against a balloon that is inflated for 10 minutes.<sup>10</sup>

The Principal Investigator of the RECOVER-ERC trial is Leo Bockeria, M.D., Chairman of the Bakulev Center and Academician of the Russian Academy of Science. The Bakulev Center is Russia's premier institute for cardiovascular surgery and cardiology. Every year the Bakulev Center performs approximately 30,000 procedures including 7,000 open heart surgeries and more than 12,000 angioplasties. The International Principal Investigator for the trial is Amit Patel, M.D., Director of Clinical Regenerative Medicine at University of Utah, who is the first physician to administer stem cells into the human heart and is currently running 17 FDA clinical trials in regenerative medicine. Safety oversight for the trial is performed by the independent Data Safety Monitoring Board, which is chaired by Warren Sherman, M.D., Director of Cardiac Cell-Based Endovascular Therapies at Columbia University Medical Center. We anticipate completion of this clinical trial by the first quarter of 2015.

As noted above, the Russian regulatory system does not use "Phase" nomenclature and the FDA has not approved or cleared any clinical trials of ERCs for CHF in the U.S. or any other country. The FDA has no jurisdiction over our Russian clinical trial in CHF; however, we have structured and are endeavoring to conduct this trial in conformity with FDA guidelines, and this trial has been approved by Russian authorities. Nonetheless, we refer to the CHF clinical trial being conducted at the Bakulev Scientific Center for Cardiovascular Surgery as a Phase II clinical trial, as it is a study to establish safety and efficacy. Investors and authorities in the United States often consider that clinical trial results from trials not conducted in the United States or Western Europe are less reliable than those from trials conducted in the United States or Western Europe. Therefore it is possible the FDA may not honor some or all the data derived from this trial.

We are providing sponsorship and funding through ERCCell, LLC, our majority owned Moscow-based subsidiary, for the RECOVER-ERC trial. ERCCell, LLC is utilizing Cromos Pharma, LLC as the contract research organization (CRO) for the RECOVER-ERC trial. Cromos Pharma, LLC is an entity controlled by Vladimir Bogin, our Chairman of the Board of Directors, however, Dr. Bogin has recused himself from the conduct of the study.

#### *Congestive Heart Failure Market*

We believe CHF represents a large and expanding market opportunity for our products. Heart failure is believed to affect at least 5.7 million adult Americans or 2.4% of the adult population and costs the US healthcare system approximately \$35 billion per year in direct medical expenses. Heart failure patients account for approximately 10 million office visits per year. Heart failure incidence exceeds 700,000 new cases per year in the US. Given the aging population this incidence is expected to rise. In 2007, there were 277,000 deaths documented in the US as a direct result of heart failure. Sales of palliative medications for heart failure in the US exceed \$3 billion per year.

#### *Type 1 Diabetes*

Type 1 Diabetes, commonly known as juvenile diabetes or insulin-dependent diabetes, is an autoimmune disorder that attacks and destroys insulin producing islet cells in the pancreas causing glucose accumulation. As a result, those suffering from Type 1 Diabetes must take insulin injections over the course of their lifetime to regulate blood sugar levels. Over time, poorly controlled diabetes can lead to serious health conditions, including heart disease, stroke, blindness, amputations, kidney disease and nerve damage.

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10 Bockeria et al. Journal of Translational Medicine 2013 Mar 5;11:56.

### *Type 1 Diabetes Program*

We have discovered that ERCs are capable of suppressing pathological immune responses that are associated with Type 1 Diabetes. In 2008, our President and Chief Scientific Officer, Thomas E. Ichim, published results of preclinical research indicating that ERCs can inhibit production of interferon gamma, a cytokine associated with diabetes progression, and augment production of interleukin 4, a cytokine that protects animals from diabetes. Subsequently we generated data demonstrating that administration of ERCs can protect mice from immunological-mediated diabetes in the Non Obese Diabetes model.

On March 2, 2012, we licensed from Yale University U.S. patent application number 61/510,812 (and all foreign equivalents thereof) covering the use of ERCs as a source of insulin producing cells. Under the license agreement we received an exclusive worldwide license to develop and commercialize the licensed products. The license agreement called for a \$5,000 payment on execution of the agreement and annual minimum-royalty license maintenance payments of \$5,000, \$6,000, \$7,500 and \$9,000 on the first four anniversaries of the date of the agreement and \$12,000 on each anniversary thereafter. In addition, the agreement calls for us to pay a milestone payment of \$100,000 when we initiate a Phase I clinical trial of a licensed product and a milestone payment of \$1,000,000 when we obtain a biologics license application approval from the FDA. Yale is also entitled to a 2% royalty payment on net sales of licensed products. We are responsible for all past, present and future patent and patent application filing, prosecution and maintenance costs. Yale can terminate the license if we have not initiated a Phase I clinical trial of a licensed product by the fifth anniversary of the date of the agreement. The term of this license will automatically expire, on a country-by-country basis, on the date on which the last of the claims of the patent expires, lapses or is declared to be invalid by a non-appealable decision of a court or other authority of competent jurisdiction through no fault or cause by us.

Hugh Taylor, M.D., who sits on our Scientific Advisory Board, is inventor of this technology and has published preclinical animal data demonstrating de novo production of insulin from ERC derived cells. Dr. Taylor is Professor of Obstetrics, Gynecology, and Reproductive Sciences, Professor of Molecular, Cellular, and Developmental Biology, and Professor of Women's Health at Yale, and is Chief of Obstetrics and Gynecology at Yale-New Haven Hospital. Based on demonstrated safety data of ERCs, as well as a FDA-cleared IND for another indication, we anticipate filing an IND application for using ERCs for treatment of Type 1 Diabetes. We anticipate completing a US preclinical study by the second half of 2014.

### *Type 1 Diabetes Market*

The incidence of Type 1 Diabetes has been increasing for the last 3-4 decades in the US, Europe and Australia. What is quite striking is that the disease is occurring much earlier in life. In European children 1-5 years of age the incidence is increasing at a rate of 5.4% annually, a rate much higher than other age groups. This increase in incidence will lead to a doubling of the number of cases in that age group in Europe in this decade. Similar trends are being seen



in the US. According to the Juvenile Diabetes Research Foundation an estimated three million Americans have Type 1 Diabetes. Currently, each diabetic patient costs the U.S. health care system more than \$10,000 per year. Insulin sales in the US for Type 1 Diabetics are \$2 billion per year. Complications of Type 1 Diabetes such as blindness, renal failure, peripheral artery disease and heart disease cost the healthcare system approximately \$14.9 billion per year.

## Commercialization Strategy

The key elements of our commercialization strategy are outlined below:

**Efficiently Conduct Clinical Development to Establish Clinical Proof of Concept with our Lead Product Candidates.** ERCs represent a novel therapeutic modality for the treatment of ischemia, CHF, and autoimmune diseases such as Type 1 Diabetes. ERCs may be administered intravenously, via catheter, intrathecally or by local injection. The cells appear to be responsive to their environment, homing to sites of injury and producing proteins such as cytokines and MMPs that may provide benefit in acute or chronic conditions. Additionally, ERCs may deliver therapeutic benefit through several distinct mechanisms of action, including stimulation of angiogenesis, reducing inflammation, and promoting tissue repair. We are conducting and planning a number of clinical studies with the intent to establish proof of concept in a number of important disease areas where the cell therapies would be expected to have benefit such as CLI and CHF. These studies do not feature large patient populations. Our focus is on conducting well-designed studies early in the clinical development process to establish a robust foundation for subsequent development, partnering activity and expansion into complementary areas. We are committed to a rigorous clinical and regulatory framework, which we believe has helped us to advance our programs efficiently, providing high quality, transparent regulatory submissions.

**Continue to Refine and Improve our Manufacturing and Related Processes and Deepen our Understanding of Therapeutic Mechanisms of Action.** A key aspect of the ERC product is its substantial expansion capacity in tissue culture relative to other stem cell types. This enables industrial scale production, which allows for greater consistency, specificity and cost of goods advantages over other stem cell therapies. We plan to build on this intrinsic biological advantage by continuing to advance and optimize our production and process development approaches, further developing new manufacturing techniques, and optimizing the supply chain to support late-stage development and commercialization of the ERCs. Additionally, we will continue to refine our understanding of our products' activities and mechanisms of action to enable optimization of administration and dosing and to prepare the foundation for product enhancements and next generation opportunities.

**Enter into Licensing or Product Co-Development Arrangements in Core Areas, while Out-Licensing Opportunities in Non-Core Areas.** In addition to our internal development efforts, an important part of our product development strategy is to work with collaborators and partners to accelerate product development, reduce our development costs, and broaden our commercial access. We will seek to enter into licensing and product co-development arrangements with qualified commercial partners to achieve these objectives.

Efficiently Explore New High Potential Therapeutic Applications, Leveraging Third-Party Research Collaborations and our Results from Related Areas. Our strategy includes establishing collaborative research relationships with investigators from research and clinical institutions across the United States, Asia and Europe. Some of these institutions at which we have, at some level, already established such relationships include: Yale University, Harvard University, University of California San Diego, University of Utah, Indiana University, University of Florida, and the University of Western Ontario. Through this network of collaborations, we have studied the effects of ERCs in a range of preclinical models that reflect various types of human disease or injury in the cardiovascular, neurological, and immunological areas. These collaborative relationships have enabled us to cost effectively explore where ERCs may have therapeutic relevance. We will seek to expand and deepen such relationships.

Continue to Expand our Intellectual Property Portfolio. We have an intellectual property estate that covers our proprietary products, and technologies, as well as methods of production and methods of use. Our intellectual property is important to our business and we take significant steps to protect its value. To maximize this value, it is important that valid patents ultimately are issued based upon our current and future patent applications. We have ongoing research and development efforts, both through internal activities and through collaborative research activities with others, which aim to develop new intellectual property and enable us to file patent applications that cover new uses of our existing technologies or product candidates, including ERC and other opportunities.

#### Intellectual Property

Our strategy is to establish an extensive portfolio of intellectual property. Part of our intellectual property portfolio consists of technology, trade secrets and know-how that we protect from being appropriated by third parties through the use of confidentiality agreements with our employees and licensees. Additionally, we are in the process of obtaining further protection for some of our intellectual property by filing patent applications with the United States Patent and Trademark Office ("PTO") and under the Patent Cooperation Treaty ("PCT"). If we do not obtain patent protection for our business, we would be subject to copycat competition and our business could suffer. We own (or in one case as noted below, we license-in) the following issued US patent and patent applications:

| <b>PATENT #</b>             | <b>PATENT NAME</b>   | <b>EXPIRATION DATE</b> |
|-----------------------------|--|------------------------|
| 8,241,621 (1)               | STEM CELL MEDIATED TREG ACTIVATION/EXPANSION FOR THERAPEUTIC IMMUNE MODULATION | 12/18/26               |
| <b>PATENT APPLICATION #</b> | <b>PATENT APPLICATION NAME</b>   | <b>FILING DATE</b>     |
| 11/353,692                  | METHOD FOR EXPANSION OF STEM CELLS   | 2/14/06                |
| 11/486,635                  | COMPOSITIONS OF PLACENTALLY-DERIVED STEM CELLS FOR THE TREATMENT OF CANCER     | 7/13/06                |
| 12/098,420                  | STEM CELL THERAPY FOR THE TREATMENT OF AUTISM AND OTHER DISORDERS              | 4/5/08                 |
| 12/127,697                  |  | 5/27/08                |

|            |   |          |
|------------|---|----------|
|            | ENDOMETRIAL STEM CELLS AND METHODS OF MAKING<br>AND USING SAME      |          |
| 12/470,438 | STEM CELL THERAPY FOR BLOOD VESSEL DEGENERATION                     | 5/21/09  |
| 12/730,145 | TREATMENT OF MUSCULAR DYSTROPHY                                     | 3/23/10  |
| 12/823,960 | METHOD FOR EXPANSION OF STEM CELLS                                  | 6/25/10  |
| 13/688,864 | METHODS OF INDUCING CELL DIFFERENTIATION WITH<br>PLACENTAL EXTRACTS | 11/29/12 |
| 12/681,600 | COMPOSITIONS AND METHODS OF STEM CELL THERAPY FOR<br>AUTISM         | 10/3/08  |

|                          |  |         |
|--------------------------|--|---------|
| 12/442,356               | ALLOGENEIC STEM CELL TRANSPLANTS IN NON-CONDITIONED RECIPIENTS | 9/20/07 |
| 13/756,310               | THERAPEUTIC IMMUNE MODULATION BY STEM CELL SECRETED EXOSOMES   | 1/31/13 |
| PCT/US2012/047611<br>(2) | ENDOMETRIAL DERIVED STEM CELLS AND THEIR METHODS OF USE        | 7/20/12 |

| <b>PROVISIONAL APPLICATION # (3)</b> | <b>APPLICATION NAME</b>  | <b>FILING DATE</b> |
|--------------------------------------|--|--------------------|
| 61/618974                            | ENDOMETRIAL REGENERATIVE CELLS FOR TREATMENT OF TRAUMATIC BRAIN INJURY   | 3/30/13            |
| 61/566460                            | RETROGRADE DELIVERY OF CELLS AND NUCLEIC ACIDS FOR TREATMENT OF CARDIOVASCULAR DISEASES                                | 12/3/12            |
| 61/867955                            | TREATMENT OF MUSCULOSKELETAL DEFECTS UTILIZING ENDOMETRIAL REGENERATIVE CELLS  | 8/20/13            |
| 61/625657                            | STEM CELLS AND STEM CELL GENERATED NANOPARTICLES FOR TREATMENT OF INFLAMMATORY CONDITIONS AND ACUTE RADIATION SYNDROME | 4/17/13            |
| 61/885909                            | TOLEROGENIC USES OF ENDOMETRIAL REGENERATIVE CELLS   | 10/2/13            |

On July 10, 2013 we entered into an agreement granting Cytori Therapeutics, Inc., an exclusive license to use our US patent #8,241,621, “Stem Cell Mediated Treg Activation” in the US and its territories for the field of autoimmune disease. Under the license agreement we received a one-time \$10,000 licensing fee and are entitled to an annual royalty payment of 3.5% on net sales of licensed products. The term of this license agreement will (1) automatically expire on the date on which the last of the claims of the patent expires, lapses or is declared to be invalid by a non-appealable decision of a court or other authority of competent jurisdiction. Either party has the right to terminate the agreement upon any breach of any material term or condition of the agreement by either party, which has not been corrected or cured within thirty (30) days after receipt of notice in writing identifying the breach. However, we do not expect to receive material revenue from this source for several years, if ever.

(2) Licensed from Yale University

The term “Provisional” indicates that a US Provisional patent application was filed with the PTO. A provisional (3) application is a legal document that establishes an early filing date, but which cannot potentially result in an issued patent unless the applicant files a regular non-provisional patent application within one year.

#### Manufacturing and Sources of Supply

Although we have no internal manufacturing activities, we have a cancellable manufacturing agreement with Cook General BioTechnology, LLC, to produce our ERCs under current good manufacturing practices (cGMP). Currently Cook is a sole-source provider and if we were to lose our arrangement with Cook we would experience a short-term

disruption until we could procure alternate manufacturing. Although we require access to sources of adult endometrial stem cells to support our research and development activities, such donor sources are readily available.

### Laboratory Facilities

We require access to laboratory equipment and facilities to support our business activities, which we obtain through outsourcing agreements and collaborations with third parties. We do not consider access to laboratory equipment and facilities to be a significant risk in pursuing our business interests.

### Competition

The biotechnology industry is characterized by rapidly evolving technology and intense competition. Although we are not aware of any competitors using ERCs as a therapy, our competitors include startup, development-stage, and major commercial companies offering services, techniques, treatments and services for producing, processing and marketing stem cell derived therapies from all classes of adult stem cells, as well as competing therapies that do not involve stem cells. Some of these companies are well established and possess technical, research and development, financial, manufacturing, reputational, regulatory affairs, and sales and marketing resources significantly greater than ours. In addition, many smaller biotech companies have formed strategic collaborations, partnerships and other types of alliances with larger, well-established industry competitors that afford these companies' potential research and development and commercialization advantages in product areas currently being pursued by us. Academic institutions and other public and private research organizations are also conducting and financing research activities which may produce products and processes directly competitive to those being commercialized by us. Moreover, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before we do. Competitors focusing primarily on stem cells include Aastrom Biosciences, Inc., Advanced Stem Cell Technology, Inc., Athersys, Inc., Biomet, Inc., Cytomedix, Inc., Harvest Technologies Corporation, International Stem Cell Corporation, Mesoblast Limited, Opexa Therapeutics, Osiris Therapeutics, Inc., Pluristem Therapeutics, Inc., and Stem Cells, Inc.

## Regulatory Approval (FDA)

The FDA approval process required to be complied with in order to market our potential products and therapeutics in the United States includes the following five steps:

Preclinical laboratory and animal tests must be conducted. Preclinical tests include laboratory evaluation of the cells and the formulation intended for use in humans for quality and consistency. In vivo studies are performed in normal animals and specific disease models to assess the potential safety and efficacy of the cell therapy product. Additional testing required includes identification of cellular distribution in animals, observation for potential of cellular transformation, and assurance that ectopic tissue is not formed as a result of cell administration.

An investigational new drug application, or IND, must be submitted to the FDA, and the IND must become effective before human clinical trials in the United States may commence. The IND submitted to the FDA contains, among other things, preclinical data, a proposed development plan and a proposed protocol for a study in humans. The IND becomes effective 30 days following receipt by the FDA, provided there are no questions, requests for delay or objections from the FDA. If the FDA has questions or concerns, it notifies the sponsor, and the IND will then be on clinical hold until a satisfactory response is made by the sponsor. In some situations the sponsor may be the investigator performing the clinical trial, in such situations the IND is said to be "Investigator Initiated".

Adequate and well-controlled human clinical trials must be conducted to establish the safety and efficacy of the product. Clinical trials involve the evaluation of a potential product under the supervision of a qualified physician, in accordance with a protocol that details the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA as part of the IND. The protocol for each clinical study must be approved by an independent institutional review board, or IRB, of the institution at which the study is conducted, and an informed consent of all participants must be obtained. The IRB reviews the existing information on the product, considers ethical factors, the safety of human subjects, the potential benefits of the therapy, the scientific/medical knowledge that will be generated from the study and the possible liability of the institution. The IRB is responsible for ongoing safety assessment of the subjects during the clinical investigation. Clinical development is traditionally conducted in three sequential phases.

Phase I studies are designed to evaluate safety in a small number of subjects in a selected patient population by assessing adverse effects, and may include multiple dose levels. This study may also gather preliminary evidence of a beneficial effect on the disease. Unlike pharmaceutical therapeutics in which Phase I trials are usually conducted in healthy volunteers, cell therapy Phase I studies are usually performed in patients afflicted with the indication for which the therapeutic is being developed to treat.

Phase II may involve studies in a limited patient population to determine biological and clinical effects of the product and to identify possible adverse effects and safety risks of the product in the selected patient population.

- Phase III trials would be undertaken to conclusively demonstrate clinical benefit or effect and to test further for safety within a broader patient population, generally at multiple study sites. Generally Phase III trials are performed in a double blind manner, meaning that neither the physician nor the patient know whether an active treatment or a placebo is being administered.

- Marketing authorization applications must be submitted to the FDA. In the area of biologics, such as cell therapy, the authorization for marketing is made under a Biologics License Application (BLA). The results of the preclinical studies and clinical studies are submitted to the FDA in the form of marketing approval authorization applications.

The FDA must approve the applications before any commercial sale or practice of the technology or product. Biologic product manufacturing establishments located in certain states also may be subject to separate regulatory and licensing requirements. The time for approval is affected by a number of factors, including relative risks and benefits demonstrated in clinical trials, the availability of alternative treatments and the severity of the disease, and animal studies or clinical trials that may be requested during the FDA review period.

In September 2011, we received FDA clearance to initiate a dose-escalating Phase I clinical trial in patients with critical limb ischemia using our ERCs. We have not yet commenced this clinical trial. Continuation of clinical development will require substantial time, effort and expense.

Our research and development is based largely on the use of human stem and progenitor cells. The FDA has initiated a risk-based approach to regulating human cell, tissue and cellular and tissue-based products and has published current Good Tissue Practices and Good Manufacturing Practices regulations and guidance. As part of this approach, the FDA has published final rules for registration of establishments that engage in the recovery, screening, testing, processing, storage or distribution of human cells, tissues, and cellular and tissue-based products, and for the listing of such products. While we believe we are in compliance with all such practices and regulation, we are not required to register until we apply for licensure from the FDA for our product, subject to successful completion of human trials. In addition, the FDA has published rules for making suitability and eligibility determinations for donors of cells and tissue and for current Good Tissue Practices for manufacturers using them, which have recently taken effect. We cannot now determine the full effects of this regulatory initiative, including precisely how it may affect the clarity of regulatory obligations and the extent of regulatory burdens associated with our stem cell research and the manufacture and marketing of stem cell products.

#### Research and Development

We spent \$481,286 and \$353,408 on research and development activities in the years ended December 31, 2012 and 2011, respectively. In the six months ended June 30, 2013 we spent \$209,283 and in the six months ended June 30, 2012 we spent \$296,786.

#### Employees

As of December 31, 2012, we employed 3 full-time and 1 part-time employee. None of our employees are represented by a union or other collective bargaining agreement, and we consider our relations with our employees to be good. Our business model relies heavily on the outsourcing of research and development and general and administrative activities. We have established affiliations with numerous organizations throughout the world to help support our biotech activities.

#### **ITEM 1A. RISK FACTORS**

An investment in our common shares involves a high degree of risk and is subject to many uncertainties. These risks and uncertainties may adversely affect our business, operating results and financial condition. In such an event, the trading price for our common shares could decline substantially, and you could lose all or part of your investment. In order to attain an appreciation for these risks and uncertainties, you should read this annual report in its entirety and consider all of the information and advisements contained in this annual report, including the following risk factors and uncertainties.



## **Risks Relating to our Business**

*We have a history of losses and will likely incur future losses during the next few years as we attempt to expand our research and development endeavors.*

As of December 31, 2012, we had an accumulated deficit of \$13,309,214. As of June 30, 2013 the accumulated deficit increased to \$13,898,475. We expect to incur additional losses in the future. We do not have any marketing approval for any of our products, which makes it difficult for you to evaluate our future business prospects.

*Our auditor's report includes an explanatory paragraph regarding our ability to continue as a going concern.*

Our independent registered public accounting firm noted in their report accompanying our financial statements for the year ended December 31, 2012 that we had a significant accumulated deficit, that we had a working capital deficit and that a significant amount of additional capital will be necessary to advance the development of our products to the point at which we may become commercially viable. The firm's report stated that those conditions raised substantial doubt about our ability to continue as a going concern. Note 1 to our financial statements for the year ended December 31, 2012 describes management's plans to address these matters. We cannot assure you that our business plans will be successful in addressing these issues. This explanatory paragraph about our ability to continue as a going concern could affect our ability to obtain additional financing at favorable terms, if at all, as it may cause investors to lose faith in our long-term prospects. If we cannot successfully continue as a going concern, our shareholders may lose their entire investment in our common shares.

*Inadequate internal controls and accounting practices could lead to errors, which could negatively impact our business, financial condition, results of operations and cash flows.*

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to document the effectiveness of our internal control over financial reporting in accordance with an established internal control framework and to report on our management's conclusion as to the effectiveness of this internal control over financial reporting. We expect to incur significant costs to comply with this requirement. In connection with our audits of our financial statements for the periods ended December 31, 2012 and 2011, we identified certain material weaknesses in our internal control over financial reporting and segregation of duties. Such weaknesses include: designing and implementing effective internal control policies and procedures to ensure that information relative to financial reporting is identified, reviewed, reconciled and reported in a manner that supports reliable and timely financial reporting; designing and implementing effective internal control policies and procedures to ensure adequate segregations of duties, or to establish adequate mitigating controls; and designing and implementing effective internal control policies and procedures to ensure the proper application of U.S. generally accepted accounting principles to complex accounting transactions. Because of our inherent limitations, internal control over financial reporting may not allow us to prevent or detect misstatements.

Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

We prepared, and on March 21, 2013 we adopted, the Medistem Accounting Policies & Procedures, which cover, among other things, policies and procedures for the review and approval of all financial reports, as a remedial measure to address these weaknesses. To our knowledge, the material weaknesses had no effect on our financial statements to date.

Even if we are successful in remedying these material weaknesses, we may in the future discover other areas of our internal control over financial reporting that need improvement. There can be no assurance that the recent remedial measures we implemented to address prior and current material weaknesses will result in adequate internal control over financial reporting in the future. Any failure to implement our improved controls, or difficulties encountered in the future, could cause us to fail to meet our reporting obligations. If we are unable to conclude that we have effective internal control over financial reporting, or if our auditors are unable to provide an unqualified report regarding the effectiveness of internal control over financial reporting when required by applicable rules and regulations of the SEC, investors may lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our securities and negatively affect our efforts to obtain necessary financing. In addition, failure to comply with Section 404 could potentially subject us to sanctions or investigation by the SEC or other regulatory authorities. This could have a material adverse effect on our financial condition and results of operations.

***Our product development efforts may not yield any marketable products.***

Our success depends on our ability to successfully develop and obtain regulatory approval to market new adult stem cell products. We expect that a significant portion of the research that we will conduct will involve new and unproven technologies. We have no products on the market. We are just beginning clinical trials of our prospective products.

We may never achieve profitability. Our failure to achieve profitability could negatively impact the market price of our common stock. Even if we do become profitable, we cannot assure you that we would be able to sustain or increase profitability on a quarterly or annual basis.

***We need additional capital to conduct our operations and our ability to obtain the necessary funding is uncertain.***

We will require substantial capital resources in order to conduct our operations and develop our products, and our existing capital resources will not be sufficient to fund our planned operations. The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for our resource requirements in 2013 and beyond:

- the magnitude and scope of our research and development programs;
- the progress we make in our research and development programs;
- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- the time and costs involved in obtaining regulatory approvals; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

We do not have any committed sources of capital. Additional financing through strategic collaborations, public or private equity financings or other financing sources may not be available on acceptable terms, or at all. The receptivity of the public and private equity or debt markets to proposed financings is substantially affected by the general economic, market and political climate and by other factors which are unpredictable and over which we have no control. Additional equity and/or convertible debt financings, if we obtain them, could result in significant dilution to stockholders. Further, in the event that additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, stem cell therapies or proposed products that we would otherwise seek to develop and commercialize ourselves. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our programs, any of which could have a material adverse effect on our business.

As of September 30, 2013 we had \$510,000 in cash. We believe our existing available cash will enable us to meet our working capital requirements for at least the next 3 months. The estimated working capital requirement for the next 12 months is approximately \$2.1 million with an estimated burn rate of approximately \$175,000 per month.

***Any changes in the governmental regulatory classifications of our products could prevent, limit or delay our ability to market or develop our products.***

The FDA establishes regulatory requirements based on the classification of a product. Because our product development programs are designed to satisfy the standards applicable to biological licensure for our cellular products, any change in the regulatory classification or designation would affect our ability to obtain FDA approval of our products. Each of our cell products is, under current regulations, regulated as a biologic, and requires a BLA.

***We must successfully complete our clinical trials to be able to market our products.***

To be able to market therapeutic cell products in the United States, we must demonstrate, through extensive preclinical studies and clinical trials, the safety and efficacy of our processes and product candidates. If our clinical trials are not successful, our products will not be marketable. The results of early stage clinical trials do not ensure success in later clinical trials, and interim results are not necessarily predictive of final results.

Our ability to complete our clinical trials in a timely manner depends on many factors, including the rate of patient enrollment. Patient enrollment can vary with the size of the patient population, the proximity of suitable patients to clinical sites, perceptions of the utility of cell therapy for the treatment of certain diseases, and the patient eligibility criteria for the study.

Furthermore, the FDA monitors the progress of clinical trials and it may suspend or terminate clinical trials at any time due to patient safety or other considerations.

***We rely and will continue to rely on third parties to conduct our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates.***

We have engaged and we expect to continue to use contract research organizations (CRO) to assist in conduct of our clinical trials. There are numerous alternative sources to provide these services. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. Any third party 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 we experience significant delays in the progress of our clinical trials, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented. In addition, we and any provider that we retain will be

subject to Good Clinical Practice, or GCP requirements. If GCP and other regulatory requirements are not adhered to by us or our third-party providers, the development and commercialization of our product candidates could be delayed.

Any failure of such CRO to successfully accomplish clinical trial monitoring, data collection, safety monitoring and data management and the other services it provides for us in a timely manner and in compliance with regulatory requirements could have a material adverse effect on our ability to complete clinical development of our products and obtain regulatory approval. Problems with the timeliness or quality of the work of a CRO may lead us to seek to terminate the relationship and use an alternate service provider. However, making such changes may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be difficult to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

The CRO for our ongoing clinical trial in CHF at the Bakulev Scientific Center for Cardiovascular Surgery in Moscow, Russia, is Cromos Pharma, LLC, which is controlled by Vladimir Bogin, our Chairman of the Board of Directors, however, Dr. Bogin has recused himself from the conduct of the study.

***We are conducting ongoing clinical trials overseas.***

Our CHF trial is being conducted at the Bakulev Scientific Center for Cardiovascular Surgery, Moscow, Russia. Additionally, we cooperated with Shanghai Jia Fu Medical Apparatus Inc., a Chinese conglomerate, for a pilot CLI clinical study in China. Neither of these trials was FDA-approved. Investors and authorities in the United States often consider that clinical trial results from trials not conducted in the United States or Western Europe are less reliable than those from trials conducted in the United States or Western Europe. Therefore, it is possible the FDA may not honor some or all the data derived from overseas clinical trials.

***Even if we obtain regulatory approvals to sell our products, lack of commercial acceptance could impair our business.***

We will be seeking to obtain regulatory approvals to market our cell products for various therapeutic indications. Even if we obtain all required regulatory approvals, we cannot be certain that our products and processes will be accepted in the marketplace at a level that would allow us to operate profitably. Our products may be unable to achieve commercial acceptance for a number of reasons, such as the availability of alternatives that are less expensive, more effective, or easier to use; the perception of a low cost-benefit ratio for the product amongst physicians and hospitals; or an inadequate level of product support from ourselves or a commercial partner. Our technologies or product candidates may not be employed in all potential applications being investigated, and any reduction in applications would limit the market acceptance of our technologies and product candidates, and our potential revenues.



***The market for our products will be heavily dependent on third party reimbursement policies.***

Our ability to successfully commercialize our product candidates will depend on the extent to which government healthcare programs, such as Medicare and Medicaid, as well as private health insurers, health maintenance organizations and other third party payers will pay for our products and related treatments.

Reimbursement by third party payers depends on a number of factors, including the payer's determination that use of the product is safe and effective, not experimental or investigational, medically necessary, appropriate for the specific patient and cost-effective. Reimbursement in the United States or foreign countries may not be available or maintained for any of our product candidates. If we do not obtain approvals for adequate third party reimbursements, we may not be able to establish or maintain price levels sufficient to realize an appropriate return on our investment in product development. Any limits on reimbursement from third party payers may reduce the demand for, or negatively affect the price of, our products.

Managing and reducing health care costs has been a general concern of federal and state governments in the United States and of foreign governments. In addition, third party payers are increasingly challenging the price and cost-effectiveness of medical products and services, and many limit reimbursement for newly approved health care products. In particular, third party payers may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could decrease the price for products that we may develop, which would result in lower product revenues to us.

***If the potential of our stem cell therapies to treat diseases is not realized, the value of our technology and our development programs could be significantly reduced.***

We have not proven in clinical trials that our stem cell therapy will be a safe and effective treatment for any disease. Our stem cell therapies are 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 marketing approval or commercial use. We have not treated a sufficient number of patients to allow us to demonstrate efficacy or make a determination that serious unintended consequences will not occur. If the potential of our stem cell therapies to treat disease is not realized, the value of our technology and our development programs could be significantly reduced.

***Our product development programs are based on novel technologies and are inherently risky.***



We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our therapeutics creates significant challenges in regards to scientific issues, product development and optimization, manufacturing, government regulation, third-party reimbursement and market acceptance. For example, the FDA has relatively limited experience with stem cell therapies. The pathway to regulatory approval for our biologic drug candidates may accordingly be more complex and lengthy. As a result, the development and commercialization pathway for our therapies may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

***Restrictions on the use of stem cells arising from ethical, legal and social implications involving stem cells could prevent us from developing or gaining acceptance for commercially viable products based upon such stem cells and adversely affect the market price of our common stock.***

The use of human embryonic stem cells has given rise to ethical, legal and social issues regarding the appropriate use of these cells. While our business does not relate to this controversial area, the use of adult stem cells may become the subject of adverse commentary or publicity, or may be confused with the use of embryonic stem cells, either of which could significantly harm the market price for our common stock.

***Our patent applications might not result in the issuance of patents.***

A patent application gives no intellectual property protection; only an issued patent does. Many patent applications fail to result in issued patents or else patents may be granted for only a limited number of claims (or claims whose scope has been limited). Patent examiners have discretion in their review and there are various possible grounds for denying patent applications. We have one issued patent but we may not be successful in obtaining any future patents. We believe that obtaining broad patent protection in the US and other key countries is vital for our ultimate success.

***Some of the information and know-how that is critical to our business is not patentable and we may not be able to prevent others from obtaining this information and establishing competitive enterprises.***

We sometimes rely on trade secrets to protect our proprietary manufacturing technology, especially in circumstances in which we believe patent protection is not appropriate or available. We attempt to protect our proprietary manufacturing technology and other proprietary information in part by confidentiality agreements with our employees, consultants, collaborators and contractors. We cannot assure you that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors, any of which would harm our business significantly.

***Some of our competitors may develop technologies that are superior to or more cost-effective than ours, which may impact the commercial viability of our technologies and which may significantly damage our ability to sustain operations.***

The pharmaceutical and biotechnology industries are intensely competitive. Other pharmaceutical and biotechnology companies and research organizations currently engage in or have in the past engaged in efforts related to the biological mechanisms and disease conditions that are the focus of our programs. In addition, other products and therapies that could compete directly with the stem cell therapies that we are seeking to develop and market are being developed by pharmaceutical and biopharmaceutical companies and by academic and other research organizations.

***We may not be able to compete successfully because of the number and strength of our competitors and expected numerous market entrants and product introductions.***

We compete with numerous companies in the biotechnology industry. The biotechnology industry is characterized by rapidly evolving technology and intense competition. Our competitors include startup, development-stage, and major commercial companies offering services, techniques, treatments and services for producing, processing and marketing stem cell derived therapies from all classes of adult stem cells, as well as competing therapies that do not involve stem cells. Some of these companies are well established and possess technical, research and development, financial, manufacturing, reputational, regulatory affairs, and sales and marketing resources significantly greater than ours. In addition, many smaller biotech companies have formed strategic collaborations, partnerships and other types of alliances with larger, well-established industry competitors that afford these companies' potential research and development and commercialization advantages in product areas currently being pursued by us. Academic institutions and other public and private research organizations are also conducting and financing research activities which may produce products and processes directly competitive to those being commercialized by us. Moreover, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before we do. Competitors focusing primarily on stem cells include Aastrom Biosciences, Inc., Advanced Stem Cell Technology, Inc., Athersys, Inc., Biomet, Inc., Cytomedix, Inc., Harvest Technologies Corporation, International Stem Cell Corporation, Mesoblast Limited, Opexa Therapeutics, Osiris Therapeutics, Inc., Pluristem Therapeutics, Inc., and Stem Cells, Inc.

***There is significant competition in our industry for highly skilled employees and our failure to attract and retain technical and managerial personnel would adversely affect our business.***

We may not be able to successfully attract or retain highly skilled employees. Our inability to hire or retain highly qualified individuals may impede our ability to develop and commercially introduce our products that may adversely affect our business. Even if we are able to hire these individuals, we may be unable to retain them. Furthermore, there is market pressure to provide technical and managerial employees with stock options and other equity interests, which may dilute earnings per share.

***We may be unable to retain the services of our key people.***

Our future success depends, in significant part, upon the continuing service and performance of our senior management and other key personnel. In particular, our future depends on the continued services of Alan Lewis, Ph.D., our Chief Executive Officer, and Thomas Ichim, Ph.D. our President and Chief Scientific Officer. There is a risk that these individuals will not remain in our employ. If we lose the services of any of these individuals, our ability to effectively develop and manage our business effectively could be impaired. We do not have key-person life insurance on any of our key personnel. Dr. Ichim, who is a Canadian citizen, is currently permitted to work in the United States by virtue of his H1-B visa. He is seeking permanent residency status, but there is no assurance he will be able to obtain it. If Dr. Ichim is required to relocate outside the United States in order to continue working, and we were to continue his services, the resulting inefficiencies might adversely affect our business.

***Our sole-source vendor's failure to manufacture or supply the ERCs could impair our cell product development.***

Cook General BioTechnology, LLC, is our sole manufacturing supplier of ERCs. If Cook were to become unable or unwilling to continue to supply us, it would be difficult to obtain alternate sources of manufacturing supply on a short-term basis. If Cook fails to perform its obligations, it could impair or delay our ability to conduct our clinical trials or market our product candidates on a timely and cost-competitive basis.

***Defending lawsuits for alleged intellectual property infringements would, even if meritorious, be expensive and distract our management's focus. We may be unable to afford such litigation. Moreover, the outcome of litigation is always uncertain, and an unfavorable outcome in such litigation might seriously harm us.***

We cannot be certain that the services and products we deliver would not infringe valid patents, copyrights, trademarks or other intellectual property rights held by third parties. We may incur substantial expenses in defending against infringement claims, regardless of their merit. If we lack the resources for such litigation, our ability to defend ourselves would be compromised. In addition, litigation can be a serious distraction for key personnel who must assist with or participate in the litigation. If any claims are successfully asserted against us, we may be required to modify our technology or seek a license to use the infringing technology. We may not be able to do so on commercially reasonable terms, or at all. Successful infringement claims against us may also result in substantial monetary liability. Any of the foregoing could seriously harm our business.

***Failure to manage growth (if any) may adversely affect our business.***

We cannot be sure that we will be able to grow or manage growth. Any counterproductive scenarios, cash flow problems and expansion of operations will result in new and increased responsibilities for management, and will place a significant strain on our operating and financial systems. To accommodate any increased number of employees, locations and the increased size of operations, we will need to recruit and retain the appropriate personnel to manage operations. We will also need to significantly improve our operations, financial and management processes and systems. If we fail to successfully implement and integrate these systems, or if we are unable to expand these systems to accommodate our growth, we may have serious financial or operating difficulties and/or inadequate, inaccurate or non-timely financial and operational information, which could seriously harm our business.

### **Risks Relating to an Investment in our Securities**

***Our Chairman, Vice-Chairman, and a Board Member control a significant portion of our stock, and their interests may differ from those of other stockholders.***

As of June 30, 2013, 8,012,967 shares, or 59% of our outstanding shares, were controlled by Vladimir Bogin, M.D., our Chairman, Vladimir Zaharchook-Williams, our Vice-Chairman, and Sergey Sablin, Ph.D., member of the Board of Directors. Accordingly, they control the outcome of any corporate transaction or other matter submitted to the stockholders for approval, including mergers, acquisitions, consolidations and sales of all or substantially all of our assets, as well as the power to prevent or cause a change in control. The interests of these shareholders may differ from that of other investors. Moreover, this consolidation of voting power could also have the effect of delaying, deterring or preventing a change of control that might be beneficial to other investors.

***There is a limited public market for our shares of common stock.***

Our stock does not trade on any established market. Moreover, our stock is classified as a “penny stock” under SEC rules, which will limit its liquidity. There is presently a limited public market for our common stock. There is no assurance that an active trading market will develop or be sustained. Accordingly, you may have to hold the shares of common stock indefinitely and may have difficulty selling them if an active trading market does not develop.

***We do not expect to pay dividends on our common stock for the foreseeable future.***

We do not anticipate paying cash dividends on our common shares in the foreseeable future, and we cannot assure an investor that funds will be legally available to pay dividends, or that even if the funds are legally available, that any dividends will be paid.

***The application of the “Penny Stock” rules could adversely affect the market price of our common shares and increase your transaction costs to sell those shares.***

As long as the trading price of our common shares is below \$5 per share, the open-market trading of our common shares will be subject to the "penny stock" rules. The "penny stock" rules impose additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with assets in excess of \$1,000,000 or annual income exceeding \$200,000 or \$300,000 together with their spouse). For transactions covered by these rules, the broker-dealer must make a special suitability determination for the purchase of securities and have received the purchaser's written consent to the transaction before the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the broker-dealer must deliver, before the transaction, a disclosure schedule prescribed by the SEC relating to the penny stock market. The broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information on the limited market in penny stocks. These additional burdens imposed on broker-dealers may restrict the ability or decrease the willingness of broker-dealers to sell our common shares, and may result in decreased liquidity for our common shares and increased transaction costs for sales and purchases of our common shares as compared to other securities.

***Because we are a JOBS Act “emerging growth company,” our public disclosure requirements are reduced and certain other securities-law obligations do not apply to us.***

We qualify as an “emerging growth company” (EGC) under the Jumpstart Our Business Startups Act of 2012. An EGC may take advantage of public reporting requirements that are in certain respects reduced from those otherwise applicable to public companies. The reduced reporting requirements include having to present only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations, and reduced disclosure obligations regarding executive compensation. As an emerging growth company we are also exempt from certain provisions of the Sarbanes-Oxley Act of 2002 and the Securities Exchange Act of 1934, including provisions requiring independent registered public accounting firm attestation regarding our internal control structure and procedures for financial reporting, and provisions which deal with shareholder voting as to executive compensation and golden parachutes.

***Our financial statements may not be comparable to those of companies that comply with public company effective dates.***

We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(2) of the JOBS Act, thereby allowing us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to those of companies that comply with public company effective dates.

***We have the ability to designate and issue shares of additional series of preferred stock without our common stockholders’ consent.***

We have the ability to issue series of preferred stock that could have rights more favorable than the Common Stock. The Company is authorized to issue up to 200,000,000 shares of preferred stock. Under our articles of incorporation, unissued shares of preferred stock may be issued from time to time by our board of directors without stockholder approval in any number of series. Furthermore, the board of directors without stockholder approval may establish the voting and other rights, powers, preferences, qualifications, limitations and restrictions of each series of preferred stock. Any such issuances of preferred stock could adversely affect the rights of the holders of common stock by, among other things, establishing preferential dividends, liquidation rights or voting powers.

***Our board of directors could use our “blank check” preferred stock to delay, defer, or prevent a change of control.***

Our board of directors has the power to designate and issue one or more series of preferred stock, as described in the preceding paragraph. Such series could be given rights which have the effect of making it more difficult or expensive for a third party to acquire a majority of our outstanding voting stock, thereby delaying, deferring, or preventing a change of control that might be beneficial to investors.

## **ITEM 2. FINANCIAL INFORMATION**

### **Management's Discussion and Analysis of Financial Condition and Result of Operations**

The following discussion and analysis should be read in conjunction with the Financial Statements and Notes thereto appearing elsewhere in this Form 10 registration statement.

#### **Special Note Regarding Forward-Looking Statements**

In this document we make a number of statements, referred to as "forward-looking statements," that are intended to convey our expectations or predictions regarding the occurrence of possible future events or the existence of trends and factors that may impact our future plans and operating results. The safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995 does not apply to us. We note, however, that these forward-looking statements are derived, in part, from various assumptions and analyses we have made in the context of our current business plan and information currently available to us and in light of our experience and perceptions of historical trends, current conditions and expected future developments and other factors we believe to be appropriate in the circumstances. You can generally identify forward-looking statements through words and phrases such as "WILL," "SEEK", "ANTICIPATE", "BELIEVE", "ESTIMATE", "EXPECT", "INTEND", "PLAN", "BUDGET", "PROJECT", "MAY BE", "MAY CONTINUE", "MAY LIKELY RESULT", and similar expressions. When reading any forward looking-statement you should remain mindful that all forward-looking statements are inherently uncertain as they are based on current expectations and assumptions concerning future events or future performance of our company, and that actual results or developments may vary substantially from those expected as expressed in or implied by that statement for a number of reasons or factors, including those relating to:

- whether or not markets for our products develop and, if they do develop, the pace at which they develop;

- our ability to attract and retain the qualified personnel to implement our growth strategies;
  - our ability to obtain approval from the Food and Drug Administration for our products;
  - our ability to obtain and then protect the patents on our proprietary technology;
  - our ability to fund our short-term and long-term operating needs;
  - changes in our business plan and corporate strategies; and
- other risks and uncertainties discussed in greater detail in the sections of this document, including those captioned "Risk Factors" and "Management's Discussion and Analysis Of Financial Condition and Results of Operations."

Each forward-looking statement should be read in context with, and with an understanding of, the various other disclosures concerning our company and our business made elsewhere in this document as well as other public reports filed with the United States Securities and Exchange Commission (the "SEC"). You should not place undue reliance on any forward-looking statement as a prediction of actual results or developments. We are not obligated to update or revise any forward-looking statement contained in this document to reflect new events or circumstances unless and to the extent required by applicable law.

## **Overview**

We are a pre-revenue therapeutics company focused on the emerging field of regenerative medicine.

We are developing the Endometrial Regenerative Cell (ERC) universal donor adult stem cell product. ERCs were discovered by us in 2007, and preclinical tests have shown their likely ability to promote new blood vessel formation (angiogenesis), reduce inflammation, regulate immune system function, and augment tissue repair and healing. We believe ERCs have the potential to treat a range of diseases, including ischemic conditions, cardiovascular disease, certain neurological diseases, autoimmune diseases (such as Type 1 Diabetes), kidney failure, liver failure, pulmonary diseases and a range of orphan disease indications.

Our primary focus is to address the unmet medical needs in Critical Limb Ischemia (CLI), Congestive Heart Failure (CHF), and Type 1 Diabetes. We have been cleared by the Food and Drug Administration (FDA) to begin clinical studies of ERCs in the United States for CLI. In addition, we have initiated a Phase II clinical trial in CHF in



collaboration with a major cardiovascular center in Moscow, Russia. As noted above, the Russian regulatory system does not use "Phase" nomenclature and the FDA has not approved or cleared any clinical trials of ERCs for CHF in the U.S. or any other country. The FDA has no jurisdiction over our Russian clinical trial in CHF; however, we have structured and are endeavoring to conduct this trial in conformity with FDA guidelines, and this trial has been approved by Russian authorities. Nonetheless, we refer to this CHF clinical trial as a Phase II clinical trial, as it is a study to establish safety and efficacy. Investors and authorities in the United States often consider that clinical trial results from trials not conducted in the United States or Western Europe are less reliable than those from trials conducted in the United States or Western Europe. Therefore it is possible the FDA may not honor some or all the data derived from this trial.

### Comparison of Results of Operations for the Three Months ended June 30, 2013 and 2012

#### *Revenues*

We had no revenues for the three months ended June 30, 2013 and June 30, 2012.

#### *Research and Development (R&D) Expenses*

| <b>Three Months Ended</b> | <b>Research and</b> | <b>Change from</b> | <b>Percent Change</b>  |
|---------------------------|---------------------|--------------------|------------------------|
| <b>June 30,</b>           | <b>Development</b>  | <b>Prior Year</b>  | <b>from Prior Year</b> |
| 2013                      | \$ 97,484           | \$ (96,710)        | -50 %                  |
| 2012                      | \$ 194,194          |                    |                        |

Research and development expenses are comprised primarily of contracted research payments; the cost of internal research personnel; the cost of cell manufacturing; intellectual property expenses and travel expenses. For the three months ended June 30, 2013, research and development expenses decreased \$96,710 or 50% over the three months ended June 30 of the prior year, primarily due to decreased study expenses related to our Phase II CHF clinical study at the Bakulev Scientific Center for Cardiovascular Surgery. As noted above, the Russian regulatory system does not use "Phase" nomenclature and the FDA has not approved or cleared any clinical trials of ERCs for CHF in the U.S. or any other country. The FDA has no jurisdiction over our Russian clinical trial in CHF; however, we have structured and are endeavoring to conduct this trial in conformity with FDA guidelines, and this trial has been approved by Russian authorities. Please note, moreover, that investors and authorities in the United States often consider that clinical trial results from trials not conducted in the United States or Western Europe are less reliable than those from trials conducted in the United States or Western Europe. The U.S. Food and Drug Administration may not honor some or all the data derived from this trial.



As we continue to recruit subjects for our Phase II CHF study in Russia, we anticipate contract research and development expenses to increase through 2013. We also expect increased ERC production and shipment expenses as ERC inventories are replenished for the research site.

### *General and Administrative Expenses*

| Three Months Ended               |                           |                                      |    |   |
|----------------------------------|---------------------------|--------------------------------------|----|---|
| June 30,                         |                           |                                      |    |   |
| General<br>and<br>Administrative | Change From<br>Prior Year | Percent<br>Change From<br>Prior Year |    |   |
| <b>2013</b>                      | \$217,280                 | \$ 21,455                            | 11 | % |
| <b>2012</b>                      | 195,825                   |                                      |    |   |

General and administrative expenses are comprised primarily of internal personnel expenses; non-cash compensation; professional fees and marketing efforts. For the three months ended June 30, 2013, general and administrative expenses increased \$21,455 or 11% over the prior year's second quarter, primarily due to accounting and legal fees associated with the process of returning to a public reporting status.

We expect general and administrative expenses to increase through 2013 as we complete the process of returning to a public reporting status. Once the non-recurring portions of the process of returning to a public reporting status are complete, we anticipate continued increased professional fee expenses associated with ongoing public reporting requirements and increased use of outside accounting and legal services for our continued operations and any financings.

### *Operating Loss*

| Three Months Ended |                           |                        |  |
|--------------------|---------------------------|------------------------|--|
| June 30,           |                           |                        |  |
| Operating<br>Loss  | Change From<br>Prior Year | Percent<br>Change From |  |

|             |             |            |       |
|-------------|-------------|------------|-------|
|             |             | Prior Year |       |
| <b>2013</b> | \$(314,764) | \$ 75,255  | -19 % |
| <b>2012</b> | (390,019)   |            |       |

For the three months ended June 30, 2013, the operating loss decreased \$75,255, or 19%, from over the three months ended June 30 of the prior year due to decreased research and development expenses, the specifics of which are described above.

We expect to incur continued operating losses through 2013 as we continue to develop ERC therapies.

### *Interest Expense*

| <b>Three Months</b> |                | <b>Change from</b> | <b>Percent Change</b>  |
|---------------------|----------------|--------------------|------------------------|
| <b>Ended</b>        | <b>Expense</b> | <b>Prior Year</b>  | <b>from Prior Year</b> |
| <b>June 30,</b>     |                |                    |                        |
| 2013                | \$(5,852)      | \$ (314)           | -5 %                   |
| 2012                | \$(6,166)      |                    |                        |

Interest expense is comprised primarily of interest accrued on our convertible debt and interest incurred on trade payables. For the three months ended June 30, 2013, the interest expense was essentially unchanged.

### *Income Tax Provision*

We are in a taxable loss position. We do not expect to incur income tax expense in the immediate future.

*Net Loss*

| Three Months Ended |             |             |             |   |
|--------------------|-------------|-------------|-------------|---|
| June 30,           |             |             | Percent     |   |
| Net Loss           | Change From | Change From | Change From |   |
|                    | Prior Year  | Prior Year  | Prior Year  |   |
| <b>2013</b>        | \$(320,616) | \$ 75,569   | -19         | % |
| <b>2012</b>        | (396,185)   |             |             |   |

Net losses in these periods were essentially the same as our operating losses in these periods, the specifics of which are described above.

**Comparison of Results of Operations for the Six Months ended June 30, 2013 and 2012***Revenues*

We had no revenues for the six months ended June 30, 2013 and June 30, 2012.

*Research and Development (R&D) Expenses*

| Six Months Ended | Research and | Change from  | Percent Change  |
|------------------|--------------|--------------|-----------------|
| June 30,         | Development  | Prior Year   | from Prior Year |
| 2013             | \$ 209,283   | \$ (87,503 ) | -29 %           |
| 2012             | \$ 296,786   |              |                 |

Research and development expenses are comprised primarily of contracted research payments; the cost of internal research personnel; the cost of cell manufacturing; intellectual property expenses and travel expenses. For the six months ended June 30, 2013, research and development expenses decreased \$87,503 or 29% over the six months

ended June 30 of the prior year, primarily due to decreased study expenses related to our Phase II CHF clinical study at the Bakulev Scientific Center for Cardiovascular Surgery. As noted above, the Russian regulatory system does not use “Phase” nomenclature, and the U.S. Food and Drug Administration has not approved or cleared any clinical trials of ERCs for CHF in any country. Please note, moreover, that investors and authorities in the United States often consider that clinical trial results from trials not conducted in the United States or Western Europe are less reliable than those from trials conducted in the United States or Western Europe. The U.S. Food and Drug Administration may not honor some or all the data derived from this trial.

As we continue to recruit subjects for our Phase II CHF study in Russia, we anticipate contract research and development expenses to increase through 2013. We also expect increased ERC production and shipment expenses as ERC inventories are replenished for the research site.

### *General and Administrative Expenses*

#### **Six Months**

| <b>Ended</b>    | <b>General and<br/>Administrative</b> | <b>Change from<br/>Prior Year</b> | <b>Percent Change<br/>from Prior Year</b> |   |
|-----------------|---------------------------------------|-----------------------------------|---|---|
| <b>June 30,</b> |                                       |                                   |   |   |
| 2013            | \$ 368,273                            | \$ 112,628                        | 44  | % |
| 2012            | \$ 255,645                            |                                   |   |   |

General and administrative expenses are comprised primarily of internal personnel expenses; non-cash compensation; professional fees and marketing efforts. For the six months ended June 30, 2013, general and administrative expenses increased \$112,628 or 44% over the six months ended June 30 of the prior year, primarily due to \$192,366 of restricted share and stock option issuance compensation expense and accounting and legal fees associated with returning to a public reporting status.

We expect general and administrative expenses to increase through 2013 as we complete the process of returning to a public reporting status. Once the non-recurring portions of the process of returning to a public reporting status are complete, we anticipate continued increased professional fee expenses associated with ongoing public reporting requirements and increased use of outside accounting and legal services for our continued operations and any financings.

*Operating Loss*

| <b>Six Months</b> |                       | <b>Change from</b> | <b>Percent Change</b>  |
|-------------------|-----------------------|--------------------|------------------------|
| <b>Ended</b>      | <b>Operating Loss</b> | <b>Prior Year</b>  | <b>from Prior Year</b> |
| <b>June 30,</b>   |                       |                    |                        |
| 2013              | \$ (577,556 )         | \$ (25,125 )       | 5 %                    |
| 2012              | \$ (552,431 )         |                    |                        |

For the six months ended June 30, 2013, the operating loss increased \$25,125, or 5%, due to increased general and administrative expenses, the specifics of which are described above.

We expect to incur continued operating losses through 2013 as we continue to develop ERC therapies.

*Interest Expense*

| <b>Six Months</b> |                         | <b>Change from</b> | <b>Percent Change</b>  |
|-------------------|-------------------------|--------------------|------------------------|
| <b>Ended</b>      | <b>Interest Expense</b> | <b>Prior Year</b>  | <b>from Prior Year</b> |
| <b>June 30,</b>   |                         |                    |                        |
| 2013              | \$ 11,705               | \$ 1,377           | 13 %                   |
| 2012              | \$ 10,328               |                    |                        |

Interest expense is comprised primarily of interest accrued on our convertible debt and interest incurred on trade payables. For the six months ended June 30, 2013, interest expense increased \$1,377, or 13%, over the six months ended June 30 of the prior year due to higher convertible note balances.

*Income Tax Provision*

We are in a taxable loss position. We do not expect to incur income tax expense in the immediate future.

*Net Loss***Six Months**

| <b>Ended</b>    | <b>Net Loss</b> | <b>Change from<br/>Prior Year</b> | <b>Percent Change<br/>from Prior Year</b> |
|-----------------|-----------------|-----------------------------------|---|
| <b>June 30,</b> |                 |                                   |   |
| 2013            | \$(589,261)     | \$ 26,502                         | 5 %                                       |
| 2012            | \$(562,759)     |                                   |   |

Net losses in these periods were essentially the same as our operating losses in these periods, the specifics of which are described above.

**Comparison of Results of Operations for the Years Ended December 31, 2012 and 2011***Revenues*

| <b>Year Ended</b>   | <b>Revenues</b> | <b>Change from<br/>Prior Year</b> | <b>Percent Change<br/>from Prior Year</b> |
|---------------------|-----------------|-----------------------------------|---|
| <b>December 31,</b> |                 |                                   |   |
| 2012                | \$-             | \$ (125,000 )                     | (100 )%                                   |
| 2011                | \$ 125,000      |                                   |   |

Revenues generated in 2011 were from a one-time sale of four families of non-core patent applications to an unrelated party for \$125,000. We do not anticipate generating revenues in the year ended December 31, 2013.

*Research and Development (R&D) Expenses*

| <b>Year Ended</b>   | <b>Research and<br/>Development</b> | <b>Change from<br/>Prior Year</b> | <b>Percent Change<br/>from Prior Year</b> |
|---------------------|-------------------------------------|-----------------------------------|---|
| <b>December 31,</b> |                                     |                                   |   |
| 2012                | \$ 481,286                          | \$ 127,878                        | 36 %                                      |



2011           \$ 353,408

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Research and development expenses are comprised primarily of contracted research payments; the cost of internal research personnel; the cost of cell manufacturing; intellectual property expenses and travel expenses. For the year ended December 31, 2012, research and development expenses increased \$127,878 or 36% over the prior year, primarily due to increased study expenses related to our Phase II CHF clinical study at the Bakulev Scientific Center for Cardiovascular Surgery. As noted above, the Russian regulatory system does not use “Phase” nomenclature, and the U.S. Food and Drug Administration has not approved or cleared any clinical trials of ERCs for CHF in any country. Please note, moreover, that investors and authorities in the United States often consider that clinical trial results from trials not conducted in the United States or Western Europe are less reliable than those from trials conducted in the United States or Western Europe. The U.S. Food and Drug Administration may not honor some or all the data derived from this trial.

As we continue to recruit subjects on our Phase II CHF study in Russia, we anticipate contract research and development expenses to increase through 2013. We also expect increased ERC production and shipment expenses as ERC inventories are replenished for the research site. The study is scheduled to continue into 2015. In addition, we will incur additional research and development expenses if we begin our critical limb ischemia (CLI) clinical trial.

#### *General and Administrative Expenses*

| <b>Year Ended</b>   | <b>General and</b>    | <b>Change from</b> | <b>Percent Change</b>  |   |
|---------------------|-----------------------|--------------------|------------------------|---|
| <b>December 31,</b> | <b>Administrative</b> | <b>Prior Year</b>  | <b>from Prior Year</b> |   |
| 2012                | \$ 384,111            | \$ 75,436          | 24                     | % |
| 2011                | \$ 308,675            |                    |                        |   |

General and administrative expenses are comprised primarily of internal personnel expenses; non-cash compensation; professional fees and marketing efforts. For the year ended December 31, 2012, general and administrative expenses increased \$75,436 or 24% over the prior year, primarily due to the restricted stock issuance, in 2012 that resulted in \$88,296 of compensation expense. There was no such restricted stock issuance in 2011.

We expect general and administrative expenses to increase through 2013 as we complete the process of returning to a public reporting status. Once the non-recurring portions of the process of returning to a public reporting status are complete, we anticipate continued increased professional fee expenses associated with ongoing public reporting requirements and increased use of outside accounting and legal services for our continued operations and any financings.

#### *Operating Loss*

| <b>Year Ended</b>   | <b>Operating Loss</b> | <b>Change from</b> | <b>Percent Change</b>  |
|---------------------|-----------------------|--------------------|------------------------|
| <b>December 31,</b> |                       | <b>Prior Year</b>  | <b>from Prior Year</b> |
| 2012                | \$ (865,397 )         | \$ 328,314         | 61 %                   |
| 2011                | \$ (537,083 )         |                    |                        |

For the year ended December 31, 2012, the operating loss increase of \$328,314, or 61%, was due primarily to increased general and administrative expenses, the specifics of which are described above.

We expect to incur continued operating losses through 2013 as we seek to develop ERC therapies through clinical trials and other research.

*Interest Expense*

| <b>Year Ended</b>   | <b>Expense</b> | <b>Change from</b> | <b>Percent Change</b>  |
|---------------------|----------------|--------------------|------------------------|
| <b>December 31,</b> |                | <b>Prior Year</b>  | <b>from Prior Year</b> |
| 2012                | \$17,732       | \$ 8,954           | 102 %                  |
| 2011                | \$8,778        |                    |                        |

Interest expense is comprised primarily of interest accrued on our convertible debt and interest incurred on trade payables. For the year ended December 31, 2012, the interest expense increase of \$8,954, or 102%, was due to higher convertible note balances.

*Income Tax Provision*

We are in a taxable loss position. We do not expect to incur income tax expense in the immediate future.

*Net Loss*

| <b>Year Ended</b>   | <b>Net Loss</b> | <b>Change from</b> | <b>Percent Change</b>  |
|---------------------|-----------------|--------------------|------------------------|
| <b>December 31,</b> |                 | <b>Prior Year</b>  | <b>from Prior Year</b> |
| 2012                | \$(883,129)     | \$ 339,082         | 62 %                   |
| 2011                | \$(544,047)     |                    |                        |

Net losses in these periods were essentially the same as our operating losses in these periods, the specifics of which are described above.

**Liquidity and Capital Resources**

We require significant additional cash resources to fund the expenditures necessary to maintain our operating infrastructure, to pay for research and development activities, and to pay our personnel and management team. As we seek to further expand our pre-clinical and clinical programs and expand our intellectual property portfolio, we will need cash to fund such activities and enable in-licensing opportunities and other research and development endeavors.

We have historically relied on financing activities to provide the cash needed for our operating expenses. At December 31, 2012, we had cash of \$6,654. As of June 30, 2013 we had cash of \$12,899.

On August 19, 2013, we borrowed \$500,000 from Randber, LLC, an entity 50% controlled by our Vice Chairman Vladimir Zaharchook-Williams, against a \$500,000 convertible note with a conversion price of \$0.50 per share. The note matures on August 19, 2015. However, we cannot use the funds except upon the approval of Mr. Zaharchook-Williams given from time to time; if we violate this restriction, the note shall become payable on demand.

We expect that cash infusions from future equity or debt offerings, or both, will permit us to finance our existing operating activities for the next 12 months. As of September 30, 2013 we had \$510,000 in cash. We believe our existing available cash will enable us to meet our working capital requirements for at least the next 3 months. The estimated working capital requirement for the next 12 months approximately \$2.1 million with an estimated burn rate of approximately \$175,000 per month.

Without such financings, however, we would be unable to continue operations. There can be no assurance that such equity or borrowings will be available or, if available, will be at rates or prices acceptable to us. Our independent registered public accounting firm has stated in their audit report dated July 8, 2013, that there is substantial doubt about our ability to continue as a going concern.

#### **Cash Flows for the Six Months Ended June 30, 2013 and 2012 and the Years Ended December 31, 2012 and 2011**

##### *Operating Activities*

Cash used for operating activities for the six months ended June 30, 2013 was \$176,255 compared to \$379,544 for the six months ended June 30, 2012. The large decrease in such use of cash, even though our net losses in the two periods were nearly the same, relates primarily to large increases in accounts payable and stock-based compensation for the 2013 period.

Cash used for operating activities for the year ended December 31, 2012 was \$654,989 compared to \$474,215 for the year ended December 31, 2011. The increase relates primarily to 2012's increased contracted research and development expenses, cash personnel compensation and marketing expense.

##### *Investing Activities*

We had no material cash flows for investing activities for the six months ended June 30, 2013 and 2012

We had no material cash flows for investing activities for the years ended December 31, 2012 and 2011.

*Financing Activities*

Cash provided by financing activities for the six months ended June 30, 2013 totaled \$182,500 compared to \$498,420 for the six months ended June 30, 2012. Funds were secured through the issuance of common stock and, to a lesser extent, convertible notes.

Cash provided by financing activities for the year ended December 31, 2012 was \$575,376 compared to \$549,000 for the year ended December 31, 2011. Funds were secured through the issuance of common stock and convertible notes.

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

**Critical Accounting Policies, Judgments and Estimates**

*Significant Recent Accounting Pronouncements*

Management has evaluated significant recent accounting pronouncements that are not yet effective for the Company and does not believe any such pronouncements will have a significant effect on our present or future financial statements.

*Use of Estimates*

The preparation of financial statements in conformity with United States generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. Actual results could differ materially from those estimates.

*Cash and Cash Equivalents*

Accounting standards define "cash and cash equivalents" as any short-term, highly liquid investment that is both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of changes in interest rates. For the purpose of financial statement presentation, we consider all highly liquid investment instruments with original maturities of three months or less when purchased, or any investment redeemable without penalty or loss of interest, to be cash equivalents. As of June 30, 2013 and 2012 and December 31, 2012 and 2011, we had no assets that were classified as cash equivalents.

*Fair Value of Financial Instruments*

The carrying amount of our cash, accounts payable and accrued liabilities approximates their estimated fair values due to the short-term maturities of those financial instruments. The carrying amount of the notes payable approximates their fair value due to the short maturity of the notes and as the interest rate approximates current market interest rates for similar instruments.

We do not have any assets or liabilities that are measured at fair value on a recurring basis and, during the years ended December 31, 2012 and 2011, did not have any assets or liabilities that were measured at fair value on a nonrecurring basis.

*Concentration of Credit Risk*

Cash is maintained at one financial institution in a checking account. In October 2008, the Federal Deposit Insurance Corporation increased the maximum level of deposit insurance at financial institutions from \$100,000 to \$250,000. Our cash balances were below such insured amounts at both June 30, 2013 and 2012 and December 31, 2012 and 2011.

*Long-lived Assets*

ASC 360 "*Impairment or Disposal of Long-Lived Assets*" requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.



We evaluate long-lived assets for impairment annually or whenever changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. If assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amounts exceed the fair values of the assets. Assets to be disposed of are reported at the lower of carrying values or fair values, less costs of disposal.

*Revenue Recognition*

We recognize revenues when such revenues are earned in accordance with the relevant agreements and are considered collectible.

*Stock-based Compensation*

We account for stock-based compensation in accordance with ASC 718, " *Compensation - Stock Compensation* " ("ASC 718"). ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model.

We estimate the fair value of stock options granted using the Black-Scholes-Merton option-pricing model.

We account for employee share-based payment awards classified as equity awards using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period, net of estimated forfeitures. We estimate forfeitures based on historical experience and anticipated future conditions.

When stock options are granted as consideration for services provided by consultants and other non-employees, the grant is accounted for based on the fair value of the consideration received or the fair value of the stock options issued, whichever is more reliably measurable. The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the accelerated method.

The assumptions below are relevant to restricted shares granted in 2012:

In accordance with ASC 718, restricted stock awards are measured at their grant date fair value. All restricted shares to employees and non-employees granted in 2012 were granted for nominal consideration; therefore their fair value was equal to the fair value on the date of issuance. The estimated fair value of the restricted stock of \$0.20 per share is being recognized as compensation expense on a straight-line basis over the vesting period of five years.

*New or Revised Accounting Standards That Have Different Effective Dates for Public and Private Companies*

We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(2) of the JOBS Act, thereby allowing us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to those of companies that comply with public company effective dates.

*Quantitative and Qualitative Disclosures About Market Risk*

Market risk represents the risk of loss that may impact our financial position, results of operations, or cash flows due to adverse changes in financial and commodity market prices and rates. As of June 30, 2013 and December 31, 2012 we do not believe we are exposed to significant market risks due to changes in U.S. interest rates or foreign currency exchange rates as measured against the U.S. dollar.

*Inflation and Seasonality*

We do not believe that our operations are significantly impacted by inflation. Our business is not seasonal in nature.

**ITEM 3. PROPERTIES**

We lease office space located at 9255 Towne Centre Drive, Suite 450, San Diego, California 92121, that serves as our corporate headquarters. Our lease term is month to month, and has a monthly base rent of \$700. We may procure additional space as we add employees and expand geographically. We believe that our facilities are adequate to meet our needs for the immediate future, and that, should it be needed, suitable additional space will be available to accommodate any such expansion of our operations.

**ITEM 4. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of June 30, 2013 for: each person whom we know beneficially owns more than 5% of our capital stock; each of our directors; each of our named executive officers; and all of our directors and executive officers as a group.



Beneficial ownership is calculated pursuant to Rule 13d-3(d)(1) of the Securities Exchange Act of 1934. Under Rule 13d-3(d)(1), shares not outstanding that are subject to options, warrants, rights or conversion privileges exercisable by a person within 60 days are deemed outstanding for the purpose of calculating the number and percentage owned by such person but not deemed outstanding for the purpose of calculating the percentage owned by any other person listed. Except where otherwise noted, we believe that each individual or entity named has sole investment and voting power with respect to the shares of Common Stock indicated as beneficially owned by such person, subject to community property laws, where applicable.

The address of each beneficial owner listed in the table below is c/o Medistem Inc., 9255 Towne Centre Drive, Suite 450, San Diego, California 92121.

| Name and Address   | Amount and<br>Nature<br>of | Percentage of<br>Beneficial<br>Ownership |   |
|--|----------------------------|--|---|
|  | Beneficial<br>Ownership    |  |   |
| Vladimir Bogin(1)  | 3,593,759                  | 26.6                                     | % |
| Vladimir Zaharchook-Williams(1)(2)   | 3,065,186                  | 22.2                                     | % |
| Thomas E. Ichim(1)(3)  | 1,537,879                  | 11.3                                     | % |
| Sergey O. Sablin(1)  | 1,496,879                  | 11.1                                     | % |
| Alan J. Lewis(4)   | 404,300                    | 2.9                                      | % |
| John Chiplin(5)  | 25,000                     | *  |   |
| All Current Directors and Executive Officers as a Group, 9 members<br>(1)(2)(3)(4)(5)(6) | 10,492,550                 | 72.0                                     | % |

\* Represents less than 1%.

(1) Includes unvested restricted shares owned by Dr. Bogin (1,714,286 shares), Mr. Zaharchook-Williams (1,142,857 shares), Dr. Sablin (857,143 shares), and Dr. Ichim (514,286 shares) and Mr. Dickerson (186,214 shares).

(2) Includes 500,000 shares owned by Randber LLC, of which Mr. Zaharchook-Williams is 50% owner. Also includes 142,857 shares underlying a convertible promissory note owned by Randber LLC. Also includes 150,000 shares underlying a convertible promissory note owned by Mr. Zaharchook-Williams.

(3) Includes 123,500 shares underlying stock options.

(4) Includes 404,300 shares underlying stock options.

(5) Includes 25,000 shares underlying stock options.

(6) Includes 162,500 shares underlying stock options in favor of Mr. Salvador. Includes 20,833 shares underlying stock options in favor of Mr. Dickerson.

As of June 30, 2013, there were no preferred shares (and no derivative securities overlying preferred shares) issued and outstanding.

## ITEM 5. DIRECTORS AND EXECUTIVE OFFICERS

The names, ages and positions of our directors and executive officers are listed below:

| <b>Name</b>                     | <b>Age</b> | <b>Position(s)</b>                               |
|---------------------------------|------------|--|
| Alan J. Lewis, Ph.D.            | 67         | Director, Chief Executive Officer                |
| Thomas E. Ichim, Ph.D.          | 37         | Director, President and Chief Scientific Officer |
| John P. Salvador, J.D.          | 45         | Chief Operations Officer                         |
| Donald F. Dickerson             | 48         | Chief Financial Officer                          |
| Vladimir Bogin, M.D.(2)         | 40         | Chairman   |
| Vladimir Zaharchook-Williams(1) | 47         | Vice Chairman                                    |
| Sergey Sablin(2)                | 53         | Director   |
| John Chiplin, Ph.D.(2)          | 54         | Director   |
| Herm Rosenman(1)                | 65         | Director   |

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

## Executive Officers

*Alan J. Lewis, Ph.D.*, has served on our Board of Directors and as our Chief Executive Officer since October 2012. Dr. Lewis was elected to the Board of Directors as a result of his appointment as our Chief Executive Officer of Medistem, and his in depth knowledge of the pharmaceutical industry. From November 2011 to October 2012, Dr. Lewis served as a member of the Boards of Directors of Cytochroma, Inc. (since acquired by OPKO Health), Biotica Technology Limited and America Stem Cell, Inc., as well as advising Medistem. From July 2010 to November 2011, he served as President, CEO and Chairman of Ambit BioSciences, and from January 2009 to June 2010 served as President and CEO of the Juvenile Diabetes Research Foundation. From January 2006 to December 2008, he was President, CEO and Director of Novocell, Inc., a private stem cell company. From February 1994, served as CEO and Director of Signal Pharmaceuticals before its acquisition in June 2000 by Celgene, Inc., a biopharmaceutical company, after which he served as President of the Signal Research Division at Celgene until January 2006. From February 1989 to February 1994, Dr. Lewis held the position of Vice President of Research at Wyeth-Ayerst, where he led research efforts in diabetes, CNS, cardiovascular, inflammatory, allergy, and bone metabolism diseases. Dr. Lewis has also served as a Director of BioMarin Pharmaceutical Inc., since June 2005. He holds a Ph.D. in pharmacology from the University of Wales in Cardiff and completed his postdoctoral training at Yale University.

*Thomas E. Ichim, Ph.D.*, served as our Chief Executive Officer from March 2008 to October 2012 and since October 2012 has served as our President and Chief Scientific Officer. Dr. Ichim was elected to the Board of Directors as a result of his appointment as our Chief Scientific Officer, and his in depth knowledge of the pharmaceutical industry and of our company. Dr. Ichim is a seasoned biotechnology entrepreneur and has founded/co-founded several companies including Medvax Pharma Corp, ToleroTech Inc., bioRASI, and OncoMune LLC. To date he has published 87 peer-reviewed articles and is co-editor of the textbook “RNA Interference: From Bench to Clinical Translation”. Dr. Ichim is an ad-hoc editor and sits on several editorial boards. Dr. Ichim is inventor on over 30 patents and patent applications.

*John P. Salvador* has served as our Chief Operating Officer since December 2012. Previously, since February 2010, Mr. Salvador served as Director of Corporate Communications and Investor Relations for Aethlon Medical, Inc. From April 2007 to January 2010, Mr. Salvador served as Executive Director of Business, Legal Affairs and Investor Relations for Left Behind Games, Inc., a religious oriented video game company. Mr. Salvador, from March 2005 to March 2007, also served as head of investor relations for People’s Choice Financial Corporation. Mr. Salvador holds a Juris Doctor from Boston University.

*Donald F. Dickerson* has served as our Chief Financial Officer since August 2011. Mr. Dickerson also functions as our Chief Accounting Officer and Controller. From March 2009 to August 2011, Mr. Dickerson served as Managing Director of GMT Ventures, a venture capital firm. From April 2005 to August 2009, Mr. Dickerson served as a Vice President of Finance for JPMorgan Chase & Co. Mr. Dickerson has over 24 years of successful experience in senior business management leadership roles. Working in diverse business environments spanning Fortune 500 companies such as Boeing and Dell to smaller start-ups in the clinical trials arena, he has successfully launched domestic and international divisions and has re-engineered existing operations to accelerate sales and profit growth. Mr. Dickerson

holds an MBA from the University of Southern California.

### **Non-Executive Directors**

*Vladimir Bogin, M.D.*, joined our Board of Directors in July 2010 and serves as our Chairman of the Board of Directors. Dr. Bogin was elected to the Board of Directors as a result of his investment in the company and his in depth knowledge and experience in clinical research in the US and Russia. Since August 2006, Dr. Bogin has also served as Chief Executive Officer for Cromos Pharma, LLC, a contract research organization (CRO) that he founded, and that specializes in biopharmaceutical clinical outsourcing to Russia, Ukraine and countries of Eastern Europe. For over 15 years, Dr. Bogin has been involved in the drug development cycle, from basic discovery research, to clinical trial initiation, to multi-center Phase III and IV trials. Dr. Bogin was trained at Yale and Brown, received his M.D. degree from Moscow State University of Medicine and Dentistry and held director-level positions with several international pharmaceutical companies before founding Cromos Pharma, LLC.

*Vladimir Zaharchook-Williams, M.B.A.* , joined our Board of Directors in July 2010 and serves as our Vice Chairman of the Board of Directors. Mr. Zaharchook-Williams was elected to the Board of Directors as a result of his investment in the company and his in depth knowledge and experience in the investment community in the US and Russia. Since 1996, Mr. Zaharchook-Williams has been a Principal at Prudential Northwest Properties where he advises on residential sales and real estate development for private investors. The Wall Street Journal has named Mr. Zaharchook-Williams as one of the most successful Real Estate Brokers in the U.S. for 7 years running. Previous to Prudential Northwest Properties, he organized private business enterprises in the Post-Soviet Russia, helped develop the banking sector, and occupied top managerial positions in a number of Russian companies including Formika and Kronos. Mr. Zaharchook-Williams was awarded both a Bachelors and a Master's degree from the St. Petersburg University of Economics & Finance. He is also a graduate of the School of Bank Managers in Moscow, Russia, and the School of Upper Managerial Personnel for Insurance Companies also located in Moscow, Russia. Mr. Zaharchook-Williams has over 20 publications in the field of Currency/Monetary Circulation and Banking Loans.



*Sergey O. Sablin, Ph.D.*, joined our Board of Directors in July 2010. In October 2003, Dr. Sablin co-founded Medivation, Inc., which became a \$4 billion biopharmaceutical corporation traded on NASDAQ, and served as its Scientific Director until December 2005. Dr. Sablin was elected to the Board of Directors as a result of his investment in the company and his in depth knowledge of the pharmaceutical industry in the US and Russia. In May 1998 Dr. Sablin founded Selena Pharmaceuticals, Inc., a company focused on research and development of medications to treat neurological disorders, and served as its CEO until December 2008. Since January 2008 to present, Dr. Sablin has also served as Partner for D2E, LLC, a company that is focused on research and development of medications to treat neurological disorders. In addition, from December 2010 to December 2011, Dr. Sablin served as a member of the Investment Committee of Bio-Fund, Russian Venture Company, a venture group specializing in the biotechnology sector. Dr Sablin received his Ph.D. in biochemistry from the Lomonosov Moscow State University and is an author of over 40 scientific publications and patents.

*John Chiplin, Ph.D.*, joined our Board of Directors in January 2013. Dr. Chiplin has over 25 years of experience as a biopharmaceutical executive. Dr. Chiplin was elected to the Board of Directors because of his in depth knowledge of the pharmaceutical industry. Since January 2000, Dr. Chiplin has served as Managing Director of Newstar Ventures, Ltd., an international investment fund, focused on providing direct investments, advisory, and independent analytical capabilities to small-medium sized companies. In addition, since May 2012, Dr. Chiplin has also served as Chief Executive Officer of Polynoma, Inc., a biotech company with a cancer vaccine product in Phase III clinical trials. In January 2007, Dr. Chiplin founded Arana Therapeutics, a new generation antibody developer, and served as its Chief Executive Officer until its acquisition in August 2009 by Cephalon, Inc. From January 2006 Dr. Chiplin also served on the Board of Directors of Domantis, Inc., until its acquisition by GlaxoSmithKline in December 2006. Before founding Arana, Dr. Chiplin was Managing Director of U.K. based ITI Life Sciences investment Fund. Dr. Chiplin holds Pharmacy and Doctoral degrees from the University of Nottingham, UK.

*Herm Rosenman* joined our Board of Directors in May 2013 and serves as the Chair of our Audit Committee. Mr. Rosenman was elected to the Board of Directors because of his in depth knowledge of public companies and the pharmaceutical industry. Before joining our Board, Mr. Rosenman was the Senior Vice President of Finance and Chief Financial Officer of Gen-Probe Incorporated, where he was instrumental in its 2002 IPO, as well as in its later 2012 sale to Hologic, Inc. for \$3.7 billion. Preceding his work with Gen-Probe, Mr. Rosenman served as President and Chief Executive Officer of Ultra Acquisition Corp. (1997-2000); President and Chief Executive Officer of RadNet Management, Inc. (1994-1997); Chief Financial Officer of Rexene Corp. (1988-1990); and partner at Coopers & Lybrand (now PricewaterhouseCoopers LLP) through 1988. Mr. Rosenman has served in board, audit chair, and lead independent director capacities at ARYx Therapeutics (NASDAQ), Infinity Pharmaceuticals, Inc. (NASDAQ), Emphasys Medical, Inc., and Discovery Partners International, Inc. (NASDAQ). A CPA, Mr. Rosenman received a B.B.A. in finance and accounting from Pace University and an M.B.A. in finance from the Wharton School of the University of Pennsylvania.

## **Family Relationships**

There are no family relationships between or among any of our directors or executive officers.

There are no arrangements or understandings between any two or more of our directors or executive officers, and there is no arrangement, plan or understanding as to whether non-management shareholders will exercise their voting rights to continue to elect the current Board of Directors. There are also no arrangements, agreements or understandings between non-management shareholders that may directly or indirectly participate in or influence the management of our affairs.

### **Involvement in Legal Proceedings**

To the best of our knowledge, during the past ten years, none of the following occurred with respect to a present or former director or executive officer of the Company: (1) any bankruptcy petition filed by or against such person or any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time; (2) any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses); (3) being subject to any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of any competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities; (4) being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodities Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacated; and (5) being the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of any federal or state securities or commodities law or regulation, law or regulation respecting financial institutions or insurance companies or law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or (6) being 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 Securities Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or associated persons.

## **Code of Conduct**

On February 28, 2008, the Board of Directors approved a "Code of Conduct," which applies to our Board of Directors, executive officers and employees. The Code of Conduct is posted on our website, [www.medisteminc.com](http://www.medisteminc.com).

## **Committees of the Board of Directors**

Our board of directors has the following standing committees: an Audit Committee and a Compensation Committee. The charters of our Audit and Compensation Committees, are posted on our website, [www.medisteminc.com](http://www.medisteminc.com).

## **Compensation Committee**

John Chiplin (the Chairman), Vladimir Bogin, and Sergey Sablin serve as members of the Compensation Committee. Our Board of Directors has delegated to the Compensation Committee strategic and administrative responsibility on a broad range of issues. The Compensation Committee's basic responsibility is to assure that the Chief Executive Officer, other officers, and key management are compensated effectively in a manner consistent with our compensation strategy and competitive practice. In addition, the Compensation Committee is responsible for establishing general compensation guidelines for non-management employees.

The Compensation Committee will be responsible for overseeing and, as appropriate, making recommendations to the Board regarding the annual salaries and other compensation of our executive officers, our general employee compensation and other policies and providing assistance and recommendations with respect to our compensation policies and practices. The Compensation Committee is authorized to carry out these activities and other actions reasonably related to the Compensation Committee's purposes or assigned by the Board from time to time. The Committee's specific responsibilities are delineated in its charter.

## **Audit Committee**

Herm Rosenman (the Chairman), and Vladimir Zaharchook-Williams serve as members of the Audit Committee. We believe that Mr. Rosenman is an "audit committee financial expert" as that term is defined by Item 407 of Regulation S-K.

The Audit Committee assists the Board of Directors in its oversight of the quality and integrity of our accounting, auditing, and reporting practices. The Audit Committee's role includes overseeing the work of our internal accounting and financial reporting and auditing processes and discussing with management our processes to manage business and financial risk, and compliance with significant applicable legal, ethical, and regulatory requirements. The Audit Committee is responsible for the appointment, compensation, retention, and oversight of the independent auditor engaged to prepare or issue audit reports on our financial statements and internal control over financial reporting. The Audit Committee relies on the expertise and knowledge of management in carrying out its oversight responsibilities. The Audit Committee's specific responsibilities are delineated in its charter.

### **Nominating Committee**

We do not have a formal Nominating Committee, however our Board of Directors acts in this capacity.

### **Board Leadership Structure**

Separate people will hold the positions of Chairman of the Board and Chief Executive Officer. Vladimir Bogin is the Chairman of the Board. The Chairman of the Board will provide leadership to the board and work with the board to define its structure and activities in the fulfillment of its responsibilities. The Chairman of the Board will set the board agendas with board and management input, facilitate communication among directors, provide an appropriate information flow to the board and preside at meetings of the board of directors and shareholders. The Chairman of the Board will work with other board members to provide strong, independent oversight of the company's management and affairs. Future modification of the board leadership structure will be made at the sole discretion of our board of directors.

## **ITEM 6. EXECUTIVE COMPENSATION**

The following table sets forth for the two years ended December 31, 2012 and December 31, 2011 the compensation awarded to, paid to, or earned by each person who in 2012 served as our Chief Executive Officer, and our executive officers whose total compensation during the year ended December 31, 2012 exceeded \$100,000.

**Summary Compensation Table**

| Name and<br>Principal<br>Position                          | Year | Salary<br>(\$) | Bonus<br>(\$) | Stock<br>Awards<br>(\$) | Option<br>Awards<br>(\$) | Non-Equity                                | Nonqualified                              | All                           | Total   |
|--|------|----------------|---------------|-------------------------|--------------------------|---|---|-------------------------------|---------|
|  |      |                |               |                         |                          | Incentive<br>Plan<br>Compensation<br>(\$) | Deferred<br>Compensation<br>Earnings (\$) | Other<br>Compensation<br>(\$) |         |
| Alan J. Lewis (1)<br>Chief Executive Officer               | 2012 | -              | -             | -                       | 10,784                   | -   | -   | -                             | 10,784  |
|  | 2011 | -              | -             | -                       | -                        | -   | -   | -                             | -       |
| Thomas E. Ichim<br>President & Chief<br>Scientific Officer | 2012 | 147,500        | 20,000        | 102,857                 | -                        | -   | -   | -                             | 270,357 |
|  | 2011 | 132,140        | -             | -                       | -                        | -   | -   | -                             | 132,140 |

(1) Dr. Lewis became an officer on October 6, 2012 and did not accrue nor receive any compensation from October 6, 2012 through December 31, 2012, because the contingency set forth in his employment agreement has not been met.

**Outstanding Equity Awards at Fiscal Year-End**

The following table presents, for each named executive officer, information regarding outstanding stock options and restricted stock held as of December 31, 2012:

| Name | Option Awards   |   |                            |                        | Stock Awards                            |   |
|------|---|---|----------------------------|------------------------|---|---|
|      | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price (\$) | Option Expiration Date | Number of Shares or Units that Have not | Market Value of Shares or Units of Stock that |
|      |   |   |                            |                        |   |   |

|                        |        |   |       |         | Vested<br>(#) | Have<br>not<br>Vested<br>\$(6) |
|------------------------|--------|---|-------|---------|---------------|--------------------------------|
| <b>Alan J. Lewis</b>   | 50,000 | - | .35   | 1/14/17 | -             | -                              |
|                        | 4,000  | - | 12.50 | 2/1/16  |               |                                |
|                        | 2,000  | - | 10.00 | 7/3/16  |               |                                |
| <b>Thomas E. Ichim</b> | 80,000 | - | 3.00  | 1/2/17  | 514,286(5)    | 591,429                        |

We did not engage in any repricings or other modifications or cancellations to any of our named executive officers' outstanding option awards during the year ended December 31, 2012.

### Employment Agreements

On October 6, 2012, we entered into an employment agreement with Dr. Lewis. Pursuant to the agreement, Dr. Lewis is entitled to receive a base salary of \$350,000 and is eligible for year-end bonus awards based upon individual performance. The employment agreement provides, however, that Dr. Lewis will not accrue nor receive any salary until such time that we close a debt or equity financing in which the gross proceeds to the Company equals or exceeds \$3 million; or complete a corporate partnership transaction that includes gross proceeds to the Company of at least \$3 million to support our general and administrative expenses. The employment agreement called for us to issue 1,183,000 stock options to Dr. Lewis. The employment agreement does not have a fixed termination date.

On March 18, 2008, Dr. Ichim was appointed Chief Executive Officer and served in that capacity until October 6, 2012, when he became our President and Chief Scientific Officer.

On October 6, 2012, we entered into an employment agreement with Dr. Ichim. Pursuant to the agreement, Dr. Ichim is entitled to receive a base salary of \$275,000 and is eligible for year-end bonus awards based upon individual performance. The employment agreement provides, however, that Dr. Ichim will not accrue nor receive any salary until such time that we close a debt or equity financing in which the gross proceeds to the Company equals or exceeds \$3 million; or complete a corporate partnership transaction that includes gross proceeds to the Company of at least \$3 million to support our general and administrative expenses. The employment agreement called for us to issue 300,000 stock options to Dr. Ichim. The employment agreement does not have a fixed termination date.

In addition, for approximately six months after October 6, 2012, Dr. Ichim received cash payments totaling \$98,500 from us, which we have characterized as additional compensation.

On October 6, 2012, we entered into an employment agreement with Mr. Dickerson. Pursuant to the agreement, Mr. Dickerson is entitled to receive a monthly base salary of \$4,000, and is eligible for year-end bonus awards based upon individual performance. The employment agreement provides, however, that Mr. Dickerson will not accrue nor receive any salary until such time that we close a debt or equity financing in which the gross proceeds to the Company equals or exceeds \$3 million; or complete a corporate partnership transaction that includes gross proceeds to the Company of at least \$3 million to support our general and administrative expenses. The employment agreement called for us to issue 100,000 stock options to Mr. Dickerson. The employment agreement does not have a fixed termination date.

On November 1, 2012, we entered into an employment agreement with John P. Salvador. Pursuant to the agreement, Mr. Salvador is entitled to receive a base salary of \$200,000 and is eligible for year-end bonus awards based upon individual performance. The employment agreement provides, however, that Mr. Salvador will not accrue nor receive any salary until such time that we close a debt or equity financing in which the gross proceeds to the Company equals or exceeds \$3 million; or complete a corporate partnership transaction that includes gross proceeds to the Company of at least \$3 million to support our general and administrative expenses. The employment agreement called for us to issue 500,000 stock options to Mr. Salvador. The employment agreement does not have a fixed termination date.

### **Restricted Stock Awards**

On June 16, 2012 our Board of Directors awarded unvested restricted shares to certain Board and management members as compensation for services rendered from 2010 through 2012. Dr. Bogin was granted 1,714,286 restricted shares, Mr. Zaharhook-Williams was granted 1,142,857 restricted shares, Dr. Sablin was granted 857,143 restricted shares, Dr. Ichim was granted 514,286 restricted shares and Mr. Dickerson was granted 186,214 restricted shares. These unvested restricted shares will vest on the earliest of June 16, 2017, or the closing of an underwritten public offering of shares of our Common Stock for gross proceeds of at least \$20,000,000, or the occurrence of a change in control; provided that these shares may be repurchased by us for a nominal price if, before they vest, we have not raised at least \$1,200,000 from stock sales between June 16, 2012 and May 1, 2015. We valued the compensatory aspect of these issuances at \$0.20 per share.

### **Director Compensation**

The following director compensation disclosure reflects all compensation awarded to, earned by or paid to the directors as such for the year ended December 31, 2012.

| Name                         | Fees                        | Stock          | Option      | Non-Equity                       | Nonqualified                        | All Other         | Total   |
|------------------------------|-----------------------------|----------------|-------------|----------------------------------|-------------------------------------|-------------------|---------|
|                              | Earned or Paid in Cash (\$) | Awards (\$)(1) | Awards (\$) | Incentive Plan Compensation (\$) | Deferred Compensation Earnings (\$) | Compensation (\$) |         |
| Vladimir Bogin               | -                           | 342,857        | -           | -                                | -                                   | -                 | 342,857 |
| Vladimir Zaharchook-Williams | -                           | 228,571        | -           | -                                | -                                   | -                 | 228,571 |
| Sergey O. Sablin             | -                           | 171,429        | -           | -                                | -                                   | -                 | 171,429 |

(1) See "Restricted Stock Awards" above.

(2) Includes compensation for services rendered from 2010 through 2012.

### Directors Compensation Program

We have entered into Director Services Agreements with each of the members of our Board of Directors.

In March 2005, we adopted our 2005 Officer and Director Equity Ownership Plan (the "2005 Equity Ownership Plan") which advances our interests by helping us to obtain and retain the services of outside directors upon whose judgment, initiative, efforts and/or services we are substantially dependent, by offering to or providing those persons with incentives or inducements affording them an opportunity to become owners of our capital stock.

It is the policy of the Board of Directors that, during any time we are a publicly reporting company, a newly elected independent director (within the meaning of the SEC's rules and the independence requirements in the listing requirements of NASDAQ Marketplace Rule 4200(a)(15), may receive under the 2005 Equity Ownership Plan a one-time grant of a non-qualified stock option for shares of our common stock as determined by our Compensation Committee. Additionally, each director may also receive an annual grant of a non-qualified stock option for shares of our common stock as determined by our Compensation Committee. Furthermore, annually the Chair of the Compensation Committee may receive an additional grant of a non-qualified stock option for shares of our common stock as determined by our Compensation Committee. Furthermore, annually the Chair of the Audit Committee may receive an additional grant of a non-qualified stock option for shares of our common stock as determined by our Compensation Committee. The exercise price for the options under the 2005 Equity Ownership Plan will equal the closing price of our common stock on the award date.





## **ITEM 7. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

On September 18, 2013, Dr. Bogin, Mr. Zaharchook-Williams, Dr. Sablin, Dr. Ichim, and an unaffiliated person sold 100% of the ownership interests in Unicell Bio International, LLC, a Delaware limited liability company, to us for \$5.00. Unicell Bio International, LLC holds an 82% interest in ERCCell, LLC, our Moscow based ERC Russia/Commonwealth of Independent States commercialization partner, resulting in us now holding a direct 100% ownership interest in Unicell Bio International, LLC, and an indirect 82% ownership interest in ERCCell, LLC. This structure is designed to enable us to do business in the territory of Russia and other former Soviet republics. The two limited liability companies are consolidated subsidiaries of the Company. An unaffiliated person holds an 18% interest in ERCCell, LLC.

On August 19, 2013, we borrowed \$500,000 from Randber, LLC, an entity 50% controlled by our Vice Chairman Vladimir Zaharchook-Williams, against a \$500,000 convertible note with a conversion price of \$0.50 per share. The note matures on August 19, 2015. However, we cannot use the funds except upon the approval of Mr. Zaharchook-Williams given from time to time; if we violate this restriction, the note shall become payable on demand.

On October 15, 2012, we borrowed \$50,000 from Randber, LLC against a \$50,000 convertible note with a conversion price of \$0.35 per share. The note matures on October 15, 2014.

On June 16, 2012, we issued 4,414,786 restricted shares as non-cash compensation to Dr. Bogin (1,714,286 shares), Mr. Zaharchook-Williams (1,142,857 shares), Dr. Sablin (857,143 shares), and Dr. Ichim (514,286 shares) and Mr. Dickerson (186,214 shares). The specifics of this issuance are discussed in Note 5 to the financial statements.

Cromos Pharma, LLC, a full service contract-research organization (CRO) controlled by Dr. Bogin, our Chairman of the Board of Directors, provides oversight of our CHF clinical trial at the Bakulev Scientific Center for Cardiovascular Surgery, however, Dr. Bogin has recused himself from the conduct of the study. ERCCell, LLC invoices us for services provided by Cromos Pharma, LLC, and ERCCell, LLC then pays Cromos Pharma, LLC for such services. In 2012, our indirect expenses for Cromos Pharma, LLC in connection with the CHF clinical trial were \$17,500; we expect our indirect expenses in 2013 for Cromos Pharma, LLC in connection with the CHF clinical trial will total approximately \$153,000.

### **Director Independence**

The Board of Directors has determined that each of Dr. Chiplin and Mr. Rosenman are independent directors within the meaning of the SEC's rules and also satisfy the independence requirements specified in the listing requirements of NASDAQ Marketplace Rule 4200(a)(15). The Company currently has a compensation and audit committee. Of the members of the Company's board of directors, each of Dr. Chiplin and Mr. Rosenman satisfy the NASDAQ independence standards for members of such committees.

## **ITEM 8. LEGAL PROCEEDINGS**

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We currently have no material legal proceedings pending.

## **ITEM 9. MARKET PRICE OF AND DIVIDENDS ON THE REGISTRANT'S COMMON EQUITY, AND RELATED STOCKHOLDER MATTERS**

Quotations for the common stock of Medistem Inc. are included in the OTC Markets Group, Inc. Pink Sheets ("Pink Sheets") system under the symbol "MEDS." The following table sets forth for the respective periods indicated the prices of the common stock in the over-the-counter market, as reported and summarized on the Pink Sheets. We do not consider quotations during these periods to reflect an "established public market." Such prices are based on inter-dealer bid and ask prices, without markup, markdown, commissions, or adjustments and may not represent actual transactions.

| <b>Three Months Ended</b> | <b>High Bid</b> | <b>Low Bid</b> |
|---------------------------|-----------------|----------------|
| March 31, 2011            | \$ 0.52         | \$ 0.21        |
| June 30, 2011             | \$ 0.40         | \$ 0.16        |
| September 30, 2011        | \$ 0.60         | \$ 0.16        |
| December 30, 2011         | \$ 0.50         | \$ 0.25        |
| March 30, 2012            | \$ 3.00         | \$ 0.28        |
| June 29, 2012             | \$ 2.50         | \$ 0.68        |
| September 28, 2012        | \$ 1.90         | \$ 0.90        |
| December 31, 2012         | \$ 1.50         | \$ 1.00        |
| March 28, 2013            | \$ 2.00         | \$ 0.87        |
| June 28, 2013             | \$ 1.51         | \$ 0.80        |

### **Holders**

At June 30, 2013, we had 13,559,476 outstanding shares of common stock and there were approximately 92 holders of record of our common stock.

At June 30, 2013, the number of shares of our common stock underlying outstanding derivative securities was 5,456,688, and the number of shares of common stock that could be sold pursuant to SEC Rule 144 (or that we have agreed to register for resale) is 4,715,529.

### **Transfer Agent**

The transfer agent and registrar for our common stock is American Registrar & Transfer Co., located at 342 East 900 South, Salt Lake City, UT 84111.

### **Share Capital**

We are authorized to issue up to 300,000,000 shares of our common stock and 200,000,000 shares of preferred stock.

### **Dividends**

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to declare or pay any dividends in the foreseeable future. Any further determination to pay dividends on our capital stock will be at the discretion of our Board of Directors and will depend on our financial condition, results of operations, capital requirements and other factors that our Board of Directors considers relevant.

### Equity Compensation Plan Information

The table below sets forth certain information as of December 31, 2012 regarding the shares of the Company's common stock available for grant or granted under stock option plans and other compensation arrangements that (i) were adopted by the Company's stockholders and (ii) were not adopted by the Company's stockholders.

| <b>Plan Category</b>  | <b>Number of securities to be issued upon exercise of outstanding options, and rights</b> | <b>Weighted-average exercise price of outstanding options, and rights (\$)</b> | <b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in 1st column)</b> |
|---|---|--|--|
| Equity compensation plans approved by security holders <sup>(1)</sup> | 1,873,748   | 0.61   | 33,126,252   |
| Equity compensation plans not approved by security holders            | -   | -  | -  |

<sup>(1)</sup> Represents shares of common stock that may be issued pursuant to options granted and available for future grant under the 2005 Officer and Director Equity Ownership Plan.

Our 2005 Officer and Director Equity Ownership Plan permits the grant of nonqualified stock options, incentive stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, performance units, and stock-based awards to our employees, directors, consultants, and other service providers. The plan is administered by our Board of Directors (or its Executive Committee, if any), which determines the terms and conditions upon which awards may be made and exercised. As of December 31, 2012, the maximum number of shares of our common stock that could be issued pursuant to awards made under the plan was 35,000,000. As of December 31, 2012 the maximum number of shares of common stock that may be granted under any award to any one person in a calendar year was 5,000,000. During 2013 these maximums were reduced to 5,500,000 shares and 300,000 shares, respectively.

#### **ITEM 10. RECENT SALES OF UNREGISTERED SECURITIES**

In the three years preceding the effective date of this registration statement on Form 10, we sold or issued the following securities not registered under the Securities Act in reliance upon the exemption from registration set forth in Section 4(a)(2) of the Securities Act (or, in the case of note conversions, set forth in Section 3(a)(9) of the Securities Act). No underwriting discounts or commissions were payable with respect to any of the following transactions.

On October 7, 2013, the Company issued 200,000 shares of common stock to an accredited investor for \$100,000.

On September 25, 2013, the Company issued 100,000 shares of common stock to an accredited investor upon the exercise of a warrant with an exercise price of \$0.35 per share.

On August 19, 2013, we issued to Randber, LLC, an entity controlled by Mr. Zaharchook-Williams, at par, a \$500,000 two-year, convertible note with a conversion price of \$0.50 per share.

From August 2013 to September 2013, we issued 110,400 shares of common stock to four accredited investors upon their exercise for cash of warrants at a temporarily available exercise price of \$0.50 per share. (The original exercise price of the warrants was \$0.75 per share.)

From June 2013 to August 2013, we issued a total of 109,500 shares of common stock to four accredited investors for \$109,500.

In April 2013, we issued 100,000 shares of common stock to one individual for consultancy services valued at \$20,000.

From January 2013 to March 2013, we issued a total of 227,084 shares of common stock to four accredited investors for \$132,500.

On February 27, 2013, we issued 50,000 shares of common stock to an accredited investor upon the exercise of a warrant with an exercise price of \$0.75 per share for \$37,500.

On February 26, 2013, we issued to Mr. Zaharchook-Williams, at par, a \$2,500 two-year, 5%, convertible note with a conversion price of \$0.35 per share.

On January 17, 2013, we issued, at par, a \$10,000 two-year, two-year convertible note with a conversion price of \$1.20 per share to an accredited investor.

In October 2012, we issued a total of 22,467 shares of common stock to three accredited investors for \$26,960.

On October 15, 2012, we issued to Randber, LLC, an entity 50% controlled by Mr. Zaharchook-Williams, at par, a \$50,000 two-year convertible note with a conversion price of \$0.35 per share.

In August 2012, we issued 24,000 shares of common stock to one individual for consultancy services valued at \$4,800.

In July 2012, we issued 50,000 shares of common stock to one individual for consultancy services valued at \$10,000.

On July 18, 2012, we issued 600,000 shares of common stock to Dr. Bogin, and 130,000 shares of common stock to another convertible noteholder upon their conversion of principal and interest of convertible notes payable in the aggregate amount of \$144,000.

On June 16, 2012, we issued 4,414,786 restricted shares as non-cash compensation to Dr. Bogin (1,714,286 shares), Mr. Zaharchook-Williams (1,142,857 shares), Dr. Sablin (857,143 shares), and Dr. Ichim (514,286 shares) and Mr. Dickerson (186,214 shares). The specifics of this issuance are discussed in Note 5 to the financial statements.

On June 8, 2012, we issued 40,000 shares of common stock to a convertible note holder upon conversion of principal and interest of a convertible note payable in the amount of \$30,000, at the stated conversion price of \$0.75 per share. We had issued this convertible note to the investor on May 8, 2012, at par.

On April 27, 2012, we issued 123,000 shares of common stock to an accredited investor upon his exercise for cash of a warrant with an exercise price of \$0.29 per share.

From January to April 2012, we issued 90,400 shares of common stock to four accredited investors, for a total of \$45,200.

From January to April 2012, we issued 135,333 shares of common stock to six accredited investors, for a total of \$162,220.

In April 2012, we issued 20,833 shares of common stock and 100,000 common stock warrants, with an exercise price of \$0.35 and a term of five years, to an accredited investor for \$25,000.

In May 2012, we issued to two accredited investors, at par, two-year convertible notes with an aggregate principal amount of \$200,000 and a conversion price of \$1.20 per share.

On November 30, 2011, we issued 500,000 shares of common stock to Randber LLC, an entity 50% controlled by Mr. Zaharchook-Williams, upon its conversion of principal and interest of a convertible note payable in the aggregate amount of \$100,000 in accordance with the terms of the note. We had issued this convertible note to Randber, LLC, on April 1, 2011, at par.

In May 2011, we issued 610,000 shares of common stock, 610,000 common stock warrants, exercisable for five years at an exercise price of \$0.75 per share, and 610,000 common stock warrants, exercisable for five years at an exercise price of \$1.95 per share to seven accredited investors for a total of \$305,000.



In December 2010, we issued to an accredited investor, at par, a \$25,000 two-year convertible note with a conversion price of \$0.20 per share. In December 2012 the accredited investor agreed to extend the term of the convertible note to December 2013.

In November 2010, we issued 639,736 shares of common stock to Dr. Sablin for a total of \$50,000.

## **ITEM 11. DESCRIPTION OF REGISTRANT'S SECURITIES TO BE REGISTERED**

The holders of our common stock, \$0.0001 par value per share, are entitled to one vote for each share held of record on all matters submitted to a vote of shareholders.

The holders of our common stock are entitled to receive dividends, as, if and when declared by our board of directors, out of funds legally available therefor, subject to any statutory or contractual restrictions on the payment of dividends.

In the event of our liquidation, dissolution or winding up, the holders of our common stock shall only be entitled to a distribution of assets after payment in full of the liquidation values to the holders of our preferred stock, if any.

The holders of our common stock do not have preemptive, subscription, redemption or conversion rights.

## **ITEM 12. INDEMNIFICATION OF DIRECTORS AND OFFICERS**

Our articles of incorporation provide that we will, to the full extent permitted by law, indemnify and advance or reimburse the expenses of anyone made a party to a proceeding because he is or was a director of the Company. Our Bylaws provide that we will indemnify every director, officer, or employee of the Company against all expenses and liabilities, including counsel fees, reasonably incurred by or imposed upon him in connection with any proceedings to which he may become involved, by reason of his service as (by request of the Company), being or having been a director, officer, employee or agent of the Company. Moreover, we have entered into indemnification agreements with each of our members of the Board of Directors and our Chief Executive Officer, Chief Scientific Officer, Chief Operations Officer, and Chief Financial Officer.

We maintain directors' and officers' liability insurance policies, which insure against liabilities that directors or officers may incur in such capacities. These insurance policies, together with the indemnification agreements, may be sufficiently broad to permit indemnification of our directors and officers for liabilities, including reimbursement of expenses incurred, arising under the securities laws or otherwise.

### **ITEM 13. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements of Medistem Inc. as identified in and incorporated into Item 15 of this Form 10 registration statement are set forth beginning on page F-1.

### **ITEM 14. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

### **ITEM 15. FINANCIAL STATEMENTS AND EXHIBITS**

(a) Financial Statements filed as part of this Form 10 registration statement:

|   |      |
|---|------|
| Report of Independent Registered Public Accounting Firm                                       | F-1  |
| Audited financial statements of Medistem Inc.:  |      |
| Balance Sheets at December 31, 2012 and 2011  | F-2  |
| Statements of Operations for the years ended December 31, 2012 and 2011                       | F-3  |
| Statements of Changes in Stockholders' Deficit for the years ended December 31, 2012 and 2011 | F-4  |
| Statements of Cash Flows for the years ended December 31, 2012 and 2011                       | F-5  |
| Notes to Financial Statement  | F-6  |
| Interim financial statements of Medistem Inc.:  |      |
| Balance Sheets at June 30, 2013 (unaudited) and December 31, 2012                             |      |
| Statements of Operations for the six months ended June 30, 2013 and 2012 (unaudited)          | F-19 |
| Statements of Cash Flows for the six months ended June 30, 2013 and 2012 (unaudited)          | F-20 |
| Notes to Financial Statements   | F-21 |

(b)Exhibits

- 3.1 Articles of Incorporation (Filed with the Company's Form SB-2 registration statement dated September 27, 2002 and incorporated by reference)
- 3.2 November 4, 2005 Certificate of Amendment\*\*
- 3.3 February 13, 2006 Certificate of Amendment\*\*
- 3.4 February 27, 2006 Certificate of Designation (Filed with the Company's Form 10-KSB annual report on March 30, 2006 and incorporated by reference)
- 3.5 July 14, 2008 Certificate of Amendment\*\*
- 3.6 Bylaws (Filed with the Company's Form SB-2 registration statement dated September 27, 2002 and incorporated by reference)
- 10.1 2005 Officer and Director Equity Ownership Plan (Filed with the Company's Form 10K-SB annual report dated March 30, 2006 and incorporated by reference)+
- 10.1.1 Form of Non-Statutory Stock Option Agreement\*\*+
- 10.2 Form of Director Service Agreement\*\*+
- 10.3 Form of Director Indemnification Agreement\*\*+
- 10.4 Alan J. Lewis Employment Agreement, dated October 6, 2012\*\*+
- 10.5 Thomas E. Ichim Employment Agreement, dated October 6, 2012\*\*+
- 10.6 John P. Salvador Employment Agreement, dated November 1, 2012\*\*+
- 10.7 Donald F. Dickerson Employment Agreement, dated October 6, 2012\*\*+
- 10.8 Form of Restricted Stock Purchase Agreement, dated June 16, 2012\*\*+ (Agreements on this form were entered into with Vladimir Bogin (for 1,714,857 shares), Vladimir Zaharchook-Williams (for 1,142,857 shares), Sergey Sablin (for 857,143 shares), Thomas Ichim (for 514,286 shares), and Donald Dickerson (for 186,214 shares)
- 10.9 License Agreement, dated November 1, 2011, with ERCCell, LLC \*\*
- 10.10 Form of Promissory Note (with conversion feature) (Notes on this form with an aggregate principal balance of \$87,500 are outstanding.)\*\*+
- 10.11 Form of "6%" Promissory Note (with conversion feature) (Notes on this form with an aggregate principal balance of \$200,000 are outstanding.)\*\*

- 10.12 Promissory Note for \$500,000 dated August 19, 2013 (with conversion feature), issued by us in favor of Randber, LLC\*\*
- 10.13 Form of 2011 Warrants\*\*
- 10.14 Form of 2012 Warrants\*\*
- 10.15 Exclusive License Agreement, dated March 2, 2012, with Yale University \*\*  
Form of Sale of LLC Interest Agreement . By agreements on this form executed and delivered as of September 18, 2013 with five respective persons, we acquired 100% of the equity interest in Unicell Bio International, LLC. \*
- 10.17 Patent License Agreement, dated July 10, 2013, between Cytori Therapeutics, Inc., and us.\*

+ Indicates a management contract or compensatory plan or arrangement

\* Filed herewith

\*\* Previously filed as Form 10 exhibit

## **SIGNATURES**

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: November 8, 2013  
MEDISTEM INC.

By: /s/ Alan J. Lewis  
Alan J. Lewis, Ph.D., Chief Executive Officer

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders

Medistem Inc.

We have audited the accompanying balance sheets of Medistem Inc. (the "Company") as of December 31, 2012 and 2011, and the related statements of operations, changes in stockholders' deficit and cash flows for each of the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that were appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we do not express an opinion thereon. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Medistem Inc. as of December 31, 2012 and 2011, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, has negative working capital of \$130,716, has an accumulated deficit of \$13,309,214 and a stockholders' deficit of \$384,942 as of December 31, 2012 and has no current source of revenues. These factors, among others discussed in Note 1, raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/S/ SQUAR, MILNER, PETERSON, MIRANDA & WILLIAMSON, LLP

San Diego, California

July 8, 2013

Medistem Form 10 Page

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**MEDISTEM INC.****BALANCE SHEETS**

|  | <b>December 31,</b> |                   |
|--|---------------------|-------------------|
|  | <b>2012</b>         | <b>2011</b>       |
| <b>ASSETS</b>  |                     |                   |
| <b>Current Assets:</b>   |                     |                   |
| Cash   | \$6,654             | \$86,762          |
| Prepaid expenses and other current assets  | -                   | 20,000            |
| <b>Total current assets</b>  | <b>6,654</b>        | <b>106,762</b>    |
| Property and equipment, net  | 6,983               | 14,375            |
| <b>Total assets</b>  | <b>\$13,637</b>     | <b>\$121,137</b>  |
| <b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>   |                     |                   |
| <b>Current Liabilities:</b>  |                     |                   |
| Accounts payable   | \$64,443            | \$29,994          |
| Other current liabilities  | 47,927              | 28,507            |
| Current portion of convertible debt  | 25,000              | 25,000            |
| <b>Total current liabilities</b>   | <b>137,370</b>      | <b>83,501</b>     |
| Convertible debt, less current portion (including related party amounts of \$258,521 and \$128,298 at December 31, 2012 and 2011, respectively).             | 261,209             | 148,571           |
| <b>Total liabilities</b>   | <b>398,579</b>      | <b>232,072</b>    |
| <b>Commitments</b>   |                     |                   |
| <b>Stockholders' deficit:</b>  |                     |                   |
| Preferred stock, \$0.0001 par value, 200,000,000 shares authorized none issued and outstanding   | -                   | -                 |
| Common stock, \$0.0001 par value, 300,000,000 shares authorized, 13,257,801 and 7,606,982 issued and outstanding at December 31, 2012 and 2011, respectively | 1,326               | 761               |
| Paid-in capital  | 12,922,946          | 12,314,389        |
| Accumulated deficit  | (13,309,214)        | (12,426,085)      |
| <b>Total stockholders' deficit</b>   | <b>(384,942 )</b>   | <b>(110,935 )</b> |
| <b>Total liabilities and stockholders' deficit</b>   | <b>\$13,637</b>     | <b>\$121,137</b>  |

See accompanying notes to financial statements.





**MEDISTEM INC.****STATEMENTS OF OPERATIONS**

|   | Years ended December 31, |               |
|---|--------------------------|---------------|
|   | 2012                     | 2011          |
| <b>Revenues</b>                                   | \$-                      | \$ 125,000    |
| <b>Operating expenses:</b>                        |                          |               |
| Research and development                          | 481,286                  | 353,408       |
| General and administrative                        | 384,111                  | 308,675       |
| <b>Total operating expenses</b>                   | 865,397                  | 662,083       |
| <b>Operating loss</b>                             | (865,397 )               | (537,083 )    |
| <b>Other income (expense):</b>                    |                          |               |
| Interest expense                                  | (17,732 )                | (8,778 )      |
| Interest income                                   | -                        | 1,814         |
| <b>Total other income (expense)</b>               | (17,732 )                | (6,964 )      |
| <b>Net loss</b>                                   | \$ (883,129 )            | \$ (544,047 ) |
| <b>Net loss per share:</b>                        |                          |               |
| Basic and diluted                                 | \$ (0.09 )               | \$ (0.08 )    |
| <b>Weighted average common shares outstanding</b> |                          |               |
| Basic and diluted                                 | 10,296,741               | 6,803,922     |

See accompanying notes to financial statements.

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**MEDISTEM INC.****STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT**

|   | Common Stock |          | Preferred Stock |        | Paid in Capital | Accumulated Deficit | Total       |
|---|--------------|----------|-----------------|--------|-----------------|---------------------|-------------|
|   | Shares       | Amount   | Shares          | Amount |                 |                     |             |
| <b>Balance at December 31, 2010</b>                         | 6,496,982    | \$ 650   | -               | -      | \$ 11,750,480   | \$(11,882,038 )     | \$(130,908) |
| Net loss  | -            | -        | -               | -      | -               | (544,047 )          | (544,047)   |
| Issuance of common stock                                    | 610,000      | 61       | -               | -      | 304,939         | -                   | 305,000     |
| Conversion of convertible debt to common stock              | 500,000      | 50       | -               | -      | 104,154         | -                   | 104,204     |
| Amortization of stock-based compensation awards             | -            | -        | -               | -      | 154,816         | -                   | 154,816     |
| <b>Balance at December 31, 2011</b>                         | 7,606,982    | \$ 761   | -               | -      | \$ 12,314,389   | \$(12,426,085 )     | \$(110,935) |
| Net loss  | -            | -        | -               | -      | -               | (883,129 )          | (883,129)   |
| Issuance of common stock                                    | 392,033      | 39       | -               | -      | 295,337         | -                   | 295,376     |
| Conversion of convertible debt to common stock              | 770,000      | 77       | -               | -      | 184,805         | -                   | 184,882     |
| Amortization of stock-based compensation awards             | -            | -        | -               | -      | 25,768          | -                   | 25,768      |
| Non-cash compensation – Issuance of restricted common stock | 4,414,786    | 442      | -               | -      | 87,854          | -                   | 88,296      |
| Non-cash compensation – issuance of common stock            | 74,000       | 7        | -               | -      | 14,793          | -                   | 14,800      |
| <b>Balance at December 31, 2012</b>                         | 13,257,801   | \$ 1,326 | -               | -      | \$ 12,922,946   | \$(13,309,214 )     | \$(384,942) |

See accompanying notes to financial statements

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**MEDISTEM INC.****STATEMENTS OF CASH FLOWS**

|   | <b>Years ended December 31,</b> |                   |
|---|---------------------------------|-------------------|
|   | 2012                            | 2011              |
| <b>Cash flows from operating activities:</b>                                      |                                 |                   |
| Net Loss  | \$ (883,129 )                   | \$ (544,047 )     |
| <b>Adjustment to reconcile net loss to net cash used in operating activities:</b> |                                 |                   |
| Depreciation  | 7,887                           | 7,787             |
| Non-cash interest on convertible debt   | 17,516                          | 8,778             |
| Stock based compensation  | 128,869                         | 154,816           |
| <b>Changes in assets and liabilities:</b>   |                                 |                   |
| Withholding tax payable   | 19,419                          | 15,011            |
| Other current assets  | 20,000                          | (20,000 )         |
| Other assets  | -                               | 766               |
| Accounts payable  | 34,449                          | 2,674             |
| Other current liabilities   | -                               | (100,000 )        |
| <b>Net cash used in operating activities</b>                                      | <b>(654,989 )</b>               | <b>(474,215 )</b> |
| <b>Cash flows from investing activities:</b>                                      |                                 |                   |
| Purchase of computer equipment  | (495 )                          | -                 |
| <b>Net cash used in investing activities</b>                                      | <b>(495 )</b>                   | <b>-</b>          |
| <b>Cash flows from financing activities:</b>                                      |                                 |                   |
| Proceeds from issuance of convertible notes                                       | 280,000                         | 244,000           |
| Proceeds from issuance of equity securities                                       | 295,376                         | 305,000           |
| <b>Net cash provided by financing activities</b>                                  | <b>575,376</b>                  | <b>549,000</b>    |
| Change in cash  | (80,108 )                       | 74,785            |
| Cash beginning of year  | 86,762                          | 11,977            |
| Cash end of year  | \$ 6,654                        | \$ 86,762         |
| <b>Supplemental disclosure of cash flow information:</b>                          |                                 |                   |
| <b>Non-Cash investing and financing activities:</b>                               |                                 |                   |
| Conversion of convertible debt into common stock                                  | \$ 184,882                      | \$ 104,204        |

See accompanying notes to financial statements.

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**MEDISTEM INC.**

**NOTES TO FINANCIAL STATEMENTS**

**NOTE 1. ORGANIZATION, GOING CONCERN, RISKS AND UNCERTANTIES, AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**ORGANIZATION**

Medistem Inc. (the “Company”) was organized under the laws of the State of Nevada as SCG Holdings, Inc. On November 4, 2005, SCG Holdings filed with the Secretary of State of Nevada an amendment to its Articles of Incorporation to effect a corporate name change to “Medistem Laboratories, Inc.”

On July 14, 2008, the Company filed with the Secretary of State of Nevada an amendment to its Articles of Incorporation to effect a corporate name change to Medistem Inc.

The Company’s primary business objective is to develop and ultimately commercialize safe and efficacious adult stem cell therapies to address unmet medical needs. The Company anticipates that therapies generated using its product platform will be scalable and reimbursable.

**GOING CONCERN**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the ordinary course of business. The Company incurred continuing losses from operations and has negative working capital of \$130,716, an accumulated deficit of \$13,309,214 and a stockholders’ deficit of \$384,942 at December 31, 2012 and has no current source of revenues. These factors, among other matters, raise substantial doubt about the Company’s ability to continue as a going concern. A significant amount of additional capital will be necessary to advance the development of the Company’s products to the point at which they may become commercially viable. The Company intends to fund operations, working capital and other cash requirements (consisting of accounts payable, accrued liabilities, amounts due to related parties and amounts due under various notes payable) for the fiscal year ending December 31, 2013 through debt and/or equity financing arrangements.

The Company is currently addressing the liquidity issue by seeking additional investment capital through private placements of common stock and debt. The Company believes cash on hand and funds expected to be received from additional private investment will be sufficient to meet liquidity needs for fiscal 2013. However, no assurance can be given that the Company will receive any funds in addition to the funds it has received to date.

The successful outcome of future activities cannot be determined at this time and there is no assurance that, if achieved, the Company will have sufficient funds to execute its intended business plan or generate positive operating results.

The financial statements do not include any adjustments related to this uncertainty and as to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should the Company be unable to continue as a going concern.

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## RISKS AND UNCERTAINTIES

The Company operates in an industry that is subject to intense competition, government regulation and rapid technological change. The operations are subject to significant risk and uncertainties including financial, operational, technological and regulatory risk, and the potential risk of business failure.

## USE OF ESTIMATES

The Company prepares financial statements in conformity with generally accepted accounting principles (GAAP), which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting periods. Significant estimates made by management include, among others, revenue recognition, realization of long-lived assets, valuation of derivative liabilities, estimating fair value associated with debt and equity transactions and valuation of deferred tax assets. Actual results could differ from those estimates.

## CASH AND CASH EQUIVALENTS

Accounting standards define "cash and cash equivalents" as any short-term, highly liquid investment that is both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of changes in interest rates. For the purpose of financial statement presentation, the Company considers all highly liquid investment instruments with original maturities of three months or less when purchased, or any investment redeemable without penalty or loss of interest, to be cash equivalents. As of December 31, 2012 and 2011, the Company had no assets that were classified as cash equivalents.