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

FORM 8-K/A

(Amendment No. 3)

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): May 11, 2011

VistaGen Therapeutics, Inc.

(Exact name of Company as specified in its charter)

Nevada	**000-54014**	**20-5093315**
(State or other jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

384 Oyster Point Boulevard, No. 8 South San Francisco, California	**94080**
(Address of principal executive offices)	(Zip Code)

Company's telephone number, including area code: (650) 244-9997

Excaliber Enterprises, Ltd.
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Company under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

EXPLANATORY NOTE

Explanatory Note

This Amendment on Form 8-K/A ("Amendment") is being filed by VistaGen Therapeutics, Inc. (the "Company") to address certain comments received from the staff of the Securities Exchange and Commission ("Commission"), and amends the Form 8-K originally filed by the Company with Commission on May 16, 2011 ("Original Report"), as amended on June 8, 2011 and August 12, 2011 (the "Previous Amendments"). This Amendment should be read in conjunction with the Original Report, the Previous Amendments, and the Company's filings with the Commission subsequent to such reports.

Item 2.01. Completion of Acquisition or Disposition of Assets.

The information in response to this Item 2.01 corresponds to the Item numbers of Form 10.

ITEM 1. BUSINESS

Overview of Business ofExcaliber Enterprises, Ltd.

On October 6, 2005, the Company was incorporated as Excaliber Enterprises, Ltd. under the laws of the State of Nevada to market specialty gift baskets to real estate and health care professionals and organizations through the Internet. After assessing both the prospects associated with our original business plan and the opportunities associated with a merger with a business seeking the perceived advantages of being a publicly held corporation, we entered into the Merger Agreement with Merger Sub and VistaGen. Upon completion of the Merger, we adopted VistaGen's business plan.

Overview of Business of VistaGen Therapeutics, Inc.

VistaGen Therapeutics, Inc. ("VistaGen") is our wholly-owned subsidiary and a California corporation based in South San Francisco, California. VistaGen is a biotechnology company applying human pluripotent stem cell technology for drug rescue and cell therapy.

Drug rescue involves the combination of human pluripotent stem cell technology with modern medicinal chemistry to generate new chemical variants ("drug rescue variants") of promising small molecule drug candidates that pharmaceutical companies have discontinued during preclinical development ("put on the shelf") due to heart or liver toxicity. We anticipate that our stem cell technology platform, *Human Clinical Trials in a Test Tube* ™ , will allow us to assess the heart and liver toxicity profile of new drug candidates with greater speed and precision than nonclinical *in vitro* techniques and technologies currently used in the drug development process. Our drug rescue model is designed to leverage both the pharmaceutical company's prior investment in preclinical development of promising drug candidates put on the shelf and the predictive toxicology and drug development capabilities of our *Human Clinical Trials in a Test Tube* ™ platform.

Our *Human Clinical Trials in a Test Tube* ™ platform is based a combination of proprietary and exclusively licensed stem cell technologies, including technologies developed over the last 20 years by Canadian scientist, Dr. Gordon Keller, and Dr. Ralph Snodgrass, VistaGen's founder and our President and Chief Scientific Officer. Dr. Keller is currently the Director of the University Health Network's McEwen Centre for Regenerative Medicine in Toronto. Dr. Keller's research is focused on understanding and controlling stem cell differentiation (development) and production of multiple types of mature, functional, human cells from pluripotent stem cells, including heart cells and liver cells that can be used in our biological assay systems (drug screening systems) for drug rescue. Dr. Snodgrass has nearly 20 years experience in both academia and industry in the development and application of stem cell differentiation systems for drug discovery and development.

With mature heart cells produced from stem cells, we have developed *CardioSafe 3D*™, a three-dimensional ("3D") bioassay system. We believe *CardioSafe 3D*™ is capable of predicting the *in vivo* cardiac effects, both toxic and non-toxic, of small molecule drug candidates before they are tested in humans. Our immediate goal is to leverage *CardioSafe 3D*™ to generate and monetize a pipeline of small molecule drug candidates through drug rescue collaborations. We intend to expand our drug rescue capabilities by introducing *LiverSafe 3D*™, a human liver cell-based toxicity and metabolism bioassay system.

In parallel with our drug rescue activities, we plan to advance preclinical development of several cell therapy programs focused on heart, liver and cartilage repair, as well as next-generation autologous bone marrow transplantation. Each of these cell therapy programs is based on the proprietary differentiation and production capabilities of our *Human Clinical Trials in a Test Tube* ™ platform.

With grant funding from the U.S. National Institutes of Health ("NIH"), we are developing AV-101, an orally available small molecule prodrug candidate aimed at the multi-billion dollar neurological disease and disorders market. AV-101 is currently in Phase I development in the U.S. for treatment of neuropathic pain, a serious and chronic condition causing pain after an injury or disease of the peripheral or central nervous system. Neuropathic pain affects approximately 1.8 million people in the U.S. alone. To date, we have been awarded over $8.3 million of grant funding from the NIH for preclinical and Phase I clinical development of AV-101. We anticipate expanding our small molecule pipeline beyond AV-101 through *CardioSafe 3D*™ and *LiverSafe 3D*™ drug rescue programs.

We anticipate acquiring rights to drug candidates that pharmaceutical companies have put on the shelf due to heart or liver toxicity, collaborating with contract medicinal chemistry collaborators, and generating a pipeline of proprietary small molecule drug rescue variants which may be as effective and commercially promising as the pharmaceutical company's original (toxic) drug candidate but without the toxicity that caused it to be put on the shelf. We also anticipate having economic participation rights in each lead drug rescue variant generated in connection with our drug rescue programs.

Stem Cell Basics

Human stem cells have the potential to develop into mature cells in the human body. Human pluripotent stem cells can differentiate into any of the more than 200 types of cells in the human body, can be expanded readily, and have diverse medical research, drug development and therapeutic applications. We believe pluripotent stem cells can be used to develop numerous cell types and tissues that can mimic complex human biology, including heart and liver biology for our proposed drug rescue applications.

Pluripotent stem cells are either embryonic stem cells ("ES Cells") or induced pluripotent stem cells ("iPS Cells"). Both ES Cells and iPS Cells have the capacity to be maintained and expanded in an undifferentiated (undeveloped) state indefinitely. We believe these features make them useful research tools and a source of normal cell populations for creating bioassays to test potential toxicity of drug candidates and for cell therapy.

Embryonic Stem Cells (ES Cells)

ES Cells are derived from excess embryos that develop from eggs that have been fertilized in an in vitro fertilization ("IVF") clinic and then donated for research purposes with the informed consent of the donors after a successful IVF procedure. ES Cells are not derived from eggs fertilized in a woman's body. ES Cells are isolated when the embryo is approximately 100 cells, thus long before organs, tissues or nerves have developed.

ES Cells have the greatest and most documented potential to both self-renew (create large numbers of cells identical to themselves) and differentiate (develop) into any of the over 200 types of cells in the body. ES Cells undergo increasingly restrictive developmental decisions during their differentiation. These "fate decisions" commit the ES Cells to becoming only certain types of mature cells and tissues. At one of the first fate decision points, ES Cells differentiate into epiblasts. Although epiblasts cannot self-renew, they can differentiate into the major tissues of the body. This epiblast stage can be used as the starting population of cells that develop into millions of blood, heart, muscle, liver and pancreas cells, as well as neurons. In the next step, the presence or absence of certain growth factors, together with the differentiation signals resulting from the physical attributes of the culture techniques, induce the epiblasts to differentiate into neuroectoderm or mesendoderm cells. Neuroectoderm cells are committed to developing into cells of the skin and cells of the nervous system. Mesendoderm cells are precursor cells that differentiate into mesoderm and endoderm. Mesoderm cells develop into muscle, bone and blood, among other cell types. Endoderm cells develop into the internal organs such as the heart, liver, pancreas and intestines, among other cell types.

Induced Pluripotent Stem Cells (iPS Cells)

Over the past several years, developments in stem cell research have made it possible to obtain pluripotent stem cell lines from individuals without the use of embryos. iPS Cells are adult cells, typically human skin or fat cells, that have been genetically "reprogrammed" to behave like ES Cells by being forced to express genes necessary for maintaining the pluripotential property of ES Cells. Although researchers are exploring non-viral methods, most iPS Cells are produced by using various viruses to activate and/or express three or four genes required for the immature pluripotential property similar to ES Cells. It is not yet precisely known, however, how each gene actually functions to induce cellular pluripotency, nor whether each of the three or four genes is essential for this reprogramming. Although ES Cells and iPS Cells are believed to be similar in many respects, including their ability to form all cells in the body and to self-renew, scientists do not yet know whether they differ in clinically significant ways or have the same ability to self-renew and make more of themselves.

Although there are remaining questions in the field about the lifespan, clinical utility and safety of iPS Cells, we believe that the biology and differentiation capabilities of ES Cells and iPS Cells are likely to be comparable. There are, however, specific situations in which we may prefer to use iPS technologies based on the relative ease of generating pluripotent stem cells from:

- individuals with specific inheritable diseases and conditions that predispose the individual to respond differently to drugs; or
- individuals with specific variations in genes that directly affect drug levels in the body or alter the manner or efficiency of their metabolism, breakdown and elimination of drugs.

Because they can significantly affect the therapeutic and/or toxic effects of drugs, these genetic variations have an impact on drug development and the ultimate success of the drug. We believe that iPS technologies may allow the rapid and efficient generation of pluripotent stem cells from individuals with the desired specific genetic variation. These stem cells might then be used to develop stem cell-based bioassays, for both efficacy and toxicity screening, which reflect the effects of these genetic variations, as well as for cell therapy applications.

Current Drug Development Process

The current drug development process is designed to assess whether a drug candidate is both safe and effective at treating the disease to which it is targeted. A major challenge in that process is that conventional animal and *in vitro* testing can, at best, only approximate human biology. A pharmaceutical company can spend millions of dollars to discover, optimize and validate the potential efficacy of a promising lead drug candidate and advance it through nonclinical development, only to see it fail due to unexpected heart or liver toxicity. The pharmaceutical company then often discontinues the development program for the once promising drug candidate and it is simply put on the shelf despite the positive efficacy data indicating its potential therapeutic and commercial benefits. As a result, the pharmaceutical company's significant prior investment may be lost.

It has been estimated that the drug discovery, development and commercialization programs of major pharmaceutical companies have required an average investment of approximately $800 million to $1.7 billion and 12 to 15 years before a new drug candidate reaches the market. It is also estimated that about one-third of all potential new drugs candidates fail in preclinical or clinical trials due to safety concerns. In a 2004 white paper entitled "Stagnation or Innovation", the FDA noted that even only a 10% improvement in predicting the failure of a drug due to toxicity before the drug enters clinical trials could, when averaged over a pharmaceutical company's drug development efforts, avoid $100 million in development costs per marketed drug.

We believe there is an unmet need for predictive toxicology screening assays that more closely approximate human biology. By differentiating stem cells into mature, human cells which can then be used as the basis for our *in vitro* toxicology screening bioassays, we have the potential to identify drug candidates having human toxicity early in the drug development process, resulting in efficient focusing of resources on compounds with the highest probability of success. We believe this has the potential to substantially reduce development costs while producing effective and safer drugs.

Our Human Clinical Trials in a Test Tube ™ Platform for Drug Rescue

We intend to leverage investments by pharmaceutical companies in drug candidates that have been put on the shelf by combining our *Human Clinical Trials in a Test Tube*™ platform with medicinal chemistry and 3D "micro-organ" culture systems to create, together with our collaborators, new, safer, proprietary chemical variants of the original drug candidates. We refer to these chemical variants as "drug rescue variants". Drug rescue variants that retain the efficacy of the pharmaceutical company's original drug candidate, but with reduced toxicity, will be the focus of our drug rescue programs. We believe that our drug rescue business model will be able to demonstrate to pharmaceutical companies a potential opportunity to recapture value from their investment in drug candidates which they have put on the shelf during preclinical development.

Proprietary Stem Cell Differentiation Protocols

Through several years of research, Dr. Keller has developed proprietary stem cell differentiation protocols covering key conditions involved in the differentiation of a pluripotent stem cell. The human cells generated by following these proprietary differentiation protocols are integral to our *Human Clinical Trials in a Test Tube* ™ platform as we believe they are more clinically predictive of human biology than animal cells or human tumor cells currently used in drug discovery and development. Our exclusive licenses with NJH and MSSM related to proprietary stem cell differentiation protocols developed by Dr. Keller that cover, among other things, the following:

- specific growth and differentiation factors used in the tissue culture medium, applied in specific combinations, at critical concentrations, and at critical times unique to each desired cell type;

- modified developmental genes and the experimentally controlled regulation of developmental genes, which is critical for determining what differentiation path a cell will take; and

- biological markers characteristic of precursor cells, which are committed to becoming specific cells and tissues, and which can be used to identify, enrich and purify the desired mature cell type.

We believe our *Human Clinical Trials in a Test Tube* ™ platform will allow us to assess the toxicity profile of new drug candidates for a wide range of diseases and conditions with greater speed and precision than nonclinical *in vitro* techniques and technologies currently used by pharmaceutical companies in the drug development process.

Growth Factors that Direct and Stimulate the Differentiation Process

The proprietary and licensed technologies underlying our *Human Clinical Trials in a Test Tube* ™ platform allow us to direct and stimulate the differentiation process of human pluripotent stem cells. As an example, for pluripotent ES Cells, the epiblast is the first stage in differentiation. One biological factor that controls the first fate decision of the epiblast is the relative concentrations of serum growth factors and activin, a protein involved in early differentiation and many cell fate decisions. Eliminating serum growth factors and adding the optimal amount of activin is an important step in inducing the reproducible development of functional cells and, in our view, is essential for the development of a robust, efficient, and reproducible model of human biological systems suitable for drug rescue applications. The use of activin in these applications is core to many of the claims in the patent applications underlying our licensed technology. Replacing activin with continuous exposure to serum factors results in an inefficient and variable differentiation into cells of the heart, liver, blood and other internal organs. See Item 1, "Business – Mount Sinai School of Medicine Exclusive Licenses."

In addition to activin, Dr. Keller's studies have identified a number of other growth and serum-derived factors that play important roles in the differentiation of ES Cells. Some of the patents and patent applications underlying our licensed technology are directed to the use of a variety of specific growth factors that increase the efficiency and reproducibility of the pluripotent stem cell differentiation process. We have exclusive rights to certain patents and patent applications for the use of growth factor concentrations for ES Cell differentiation that we believe are core and essential for our drug rescue and development applications. See Item 1, "Business – Mount Sinai School of Medicine Exclusive Licenses" and "National Jewish Health Exclusive Licenses."

Developmental Genes that Direct and Stimulate the Differentiation Process

For the purpose of creating our *Human Clinical Trials in a Test Tube* ™ platform, we further control the differentiation process by controlling regulation of key developmental genes. By studying natural organ and tissue development, researchers have identified many genes that are critical to the normal differentiation, growth and functioning of tissues of the body. We engineer ES Cells in a way that enables us to regulate genes that have been identified as critical to control and direct the normal development of specific types of cells. We can then mimic human biology in a way that allows us to turn on and off the expression of a selected gene by the addition of a specific compound to a culture medium. By adding specific compounds, we have the ability to influence the expression of key genes that are critically important to the normal biology of the cell.

Cell Purification Approaches

The proprietary protocols we have licensed for our *Human Clinical Trials in a Test Tube* ™ platform also establish specific marker genes and proteins which can be used to identify, enrich, purify, and study important populations of intermediate precursor cells that have made specific fate decisions and are on a specific developmental pathway towards a mature functional cell. These protocols enable a significant increase in the efficiency, reproducibility, and purity of final cell populations. For example, we are able to isolate millions of purified specific precursor cells which, together with a specific combination of growth factors, develop full culture wells of functional, beating human heart cells. Due to their functionality and purity, we believe these cell cultures are ideal for supporting our drug rescue activities.

3D "Micro-Organ" Culture Systems

In addition to standard two-dimensional ("2D") cultures which work well for some cell types and assays, the proprietary stem cell technologies underlying our *Human Clinical Trials in a Test Tube* ™ platform enable us to grow large numbers of normal, non-transformed, human cells *in vitro* 3D "micro-organ" culture systems. For example, we can grow large numbers of normal, non-transformed, human heart cells *in vitro* in 3D micro-organ culture systems. The 3D micro-organ cultures induce the cells to grow, mature, and develop 3D cell networks and tissue structures. We believe these 3D cell networks and structures more accurately reflect the structures and biology inside the human body than traditional flat, 2D, single cell layers grown on plastic, which are widely used by pharmaceutical companies today. We believe that the more representative human biology afforded by the 3D system will yield responses to drug candidates that are more clinically predictive of human drug responses.

Medicinal Chemistry

Medicinal chemistry involves designing, synthesizing, modifying and developing small molecule drugs suitable for therapeutic use. It is a highly interdisciplinary science combining organic chemistry, biochemistry, physical chemistry, computational chemistry, pharmacology, and statistics. The combination of medicinal chemistry with our proprietary and licensed stem cell technologies underlying our *Human Clinical Trials in a Test Tube* ™ platform are the core components of our drug rescue business model. We intend to collaborate with medicinal chemistry companies to create a pipeline of effective and safer drug candidates from our successful drug rescue variants in a more efficient and cost-effective manner than the processes currently used for drug development.

We have established relationships with several medicinal chemistry companies with whom we expect to collaborate in connection with our drug rescue programs. The quality, efficiency and cost effectiveness of a project-based strategic services relationship with leading medicinal chemistry companies, rather than building a large internal medicinal chemistry team, is a key component of our business model.

Application of Stem Cell Technology to Drug Rescue

By using *CardioSafe 3D* ™ , we intend to identify and optimize a lead drug rescue variant (developed by our medicinal chemistry collaborator) with reduced heart toxicity compared to the original drug candidate. We believe each lead drug rescue variant will be a new drug candidate (to which we expect to have certain intellectual property and commercialization rights) that preserves the therapeutic potential of the original drug candidate, and thus retains its potential commercial value to a pharmaceutical company, but substantially reduces or eliminates its toxicity risks. We believe that focusing on failed drug candidates with positive efficacy data will allow us to leverage a pharmaceutical company's prior investment in the original drug candidate to develop our new lead drug rescue variant. We anticipate that this positive efficacy data will give us a "head start", resulting in faster, less expensive development of our drug rescue candidates than drug candidates discovered and developed using only conventional animal and *in vitro* testing.

CardioSafe 3D ™

We have used the proprietary stem cell technologies underlying our *Human Clinical Trials in a Test Tube* ™ platform to develop *CardioSafe 3D* ™ , a human heart cell-based toxicity screening assay that we believe is stable, reproducible and capable of generating data to allow our scientists to more accurately predict the *in vivo* cardiac effects, both toxic and non-toxic, of drug candidates. A single *CardioSafe 3D* ™ assay is stable for many weeks and can be used for evaluating the heart toxicity of numerous drug candidates.

We have completed an internal validation study to test the ability of *CardioSafe 3D* ™ to generate data to allow our scientists to predict the *in vivo* cardiac effects of drug candidates. The study included 10 drugs previously approved for human use by the FDA and one experimental research compound widely accepted for studying cardiac electrophysiological effects. We selected these drugs and the research compound because of their known toxic or non-toxic cardiac effects on human hearts that we believe represent the testing characteristics we expect to encounter during our drug rescue campaigns. More specifically:

- five of the FDA-approved drugs (astemizole, sotalol, cisapride, terfenadine and sertindole) were withdrawn from the market due to heart toxicity concerns;
- the other five FDA-approved drugs (fexofenadine, nifedipine, verapamil, lidocaine and propranolol) are currently available in the U.S. market and demonstrate certain measurable clinical non-toxic cardiac effects, one of which (fexofenadine) is a non-cardiotoxic drug variant (similar in concept to our planned rescued drug variants) of terfenadine (one of the FDA-approved drugs withdrawn from the market due to heart safety concerns); and
- the research compound (E-4031) failed in a small Phase I human clinical study before being discontinued due to heart toxicity concerns.

In our study analysis, we found that results obtained with *CardioSafe 3D* ™ were consistent with the known human cardiac effects of all 10 FDA-approved drugs and the experimental research compound. By using *CardioSafe 3D* ™ , we were also able to distinguish between the cardiac effects of terfenadine (Seldane™), withdrawn by the FDA due to cardiotoxicity, and the cardiac effects of the closely related fexofenadine (Allegra™), the non-cardiotoxic chemical variant of terfenadine.

The results obtained with *CardioSafe 3D* ™ were consistent with the cardiac effects of all five FDA-approved drugs that were later withdrawn from the market due to concerns of heart toxicity. With respect to the results for sertindole, *CardioSafe 3D* ™ indicated the same cardiac effects found in clinical testing that caused it to be withdrawn from the market. However, additional clinical studies have been conducted since the withdrawal of sertindole that have indicated lower incidents of severe cardiac effects than those originally predicted when the drug was withdrawn. As of the date of this report, sertindole has been approved for limited use by humans in the U.S. for the treatment of schizophrenia, but the cardiac effects of sertindole are still being researched.

We believe the results of our internal validation study indicate that *CardioSafe 3D* ™ may be effectively used to identify drug rescue variants with reduced heart toxicity by providing more accurate and timely indications of direct heart toxicity of drug candidates than animal models or *in vitro* tumor cell-based testing systems currently used by pharmaceutical companies.

We also believe that the preliminary results of the study support a central premise of our drug rescue business model, which is that by using our bioassay systems at the front end of the drug development process, we may help pharmaceutical companies recapture value from their prior investment in drug candidates that have been put on the shelf due to toxicity. This internal validation study has not been subject to peer review or third party validation. See Item 1A, “Risk Factors”.

With *CardioSafe 3D* ™ , we intend to focus a substantial portion of our resources over the next twelve months to attempt to rescue promising drug candidates that a pharmaceutical company has put on the shelf due to heart toxicity in preclinical studies, despite data indicating their promising therapeutic and commercial benefits.

LiverSafe 3D ™

Current human stem cell-based liver cell cultures produce proteins produced by and characteristic of immature and adult liver cells, including albumin and liver-specific enzymes important for normal drug metabolism. In addition, these liver cells have biochemical pathways and subcellular structures that are characteristic of normal human liver cells. Although they express many of the mature adult liver proteins and drug processing enzymes, they do not yet express certain essential enzymes at levels typically seen in mature adult liver cells.

Working with Dr. Keller, we anticipate that we will be able to produce stem cell-derived normal, non-transformed, fully mature human liver cells within twelve months of the date of this report. We expect these mature liver cells to support development and application of *LiverSafe 3D* ™ as our follow-on assay system suitable for use in predicting liver toxicity and liver metabolism of drug rescue candidates in a manner similar to the way we believe *CardioSafe 3D* ™ can predict heart toxicity. This liver cell research project has been funded, in part, through a grant from the California Institute of Regenerative Medicine ("CIRM"). We anticipate that our future research and development will focus on the improvement of techniques and production of engineered human ES Cell and iPS Cell lines used to develop mature functional liver cells as a biological system for testing drugs and liver repair.

Our Drug Rescue Business Model

Following the date of this report, we intend to initiate drug rescue programs focused on heart toxicity using our *CardioSafe 3D*™ heart cell bioassay system. We intend to select only those drug candidates that have positive efficacy data indicating their potential therapeutic and commercial benefits but have been put on the shelf due to heart toxicity in preclinical studies. Once we have acquired or licensed a drug candidate, the initial goal of our drug rescue program for that candidate will be to design and generate, with a medicinal chemistry collaborator, a portfolio of drug rescue variants. We plan to use *CardioSafe 3D* ™ to identify a lead drug rescue variant that demonstrates an improved therapeutic index compared to the original drug candidate (that is, equal or improved efficacy with reduced heart toxicity). We intend to validate that each lead drug rescue variant demonstrates reduced heart toxicity in both *CardioSafe 3D* ™ and in the same preclinical testing model that the pharmaceutical company used to determine heart toxicity for its original drug candidate. We anticipate that the results of these confirmatory animal safety studies will be drug rescue collaboration milestones demonstrating to a pharmaceutical company the improvement of our lead drug rescue variant compared to its original drug candidate.

Our *Human Clinical Trials in a Test Tube* ™ **Platform for Stem Cell Therapy**

Although we believe the best near term use of pluripotent stem cell technologies is in the context of drug rescue, we believe the therapeutic potential of pluripotent stem cells for cell transplant therapy and other applications will be significant in the long term.

Working with Dr. Keller and UHN, we intend to advance several pilot preclinical proof-of-concept studies with respect to iPS Cell-based cell therapy programs, including cartilage, heart and liver repair, as well as autologous bone marrow transplantation.

Strategic Transactions and Relationships

Strategic collaborations are a cornerstone of our corporate development strategy. We believe that our strategic outsourcing and sponsoring of application-focused research gives us flexible access to clinical expertise at a lower overall cost than attempting to develop such expertise internally, at least over the twelve-month period following the date of this report. In particular, we collaborate with the types of third parties identified below for the following functions:

- academic research institutions, such as UHN, for stem cell research collaborations;
- CROs, such as Cato Research Ltd., for regulatory and drug development expertise and to identify and assess potential drug rescue candidates; and
- medicinal chemistry companies to analyze drug rescue candidates and develop drug rescue variants.

McEwen Centre for Regenerative Medicine, University Health Network

University Health Network ("UHN") in Ontario, Canada consists of Toronto General Hospital, Toronto Western Hospital and Princess Margaret Hospital. The scope of research and complexity of cases at UHN has made it an international source for discovery, education and patient care. UHN has the largest hospital-based research program in Canada, with major research in transplantation, cardiology, neurosciences, oncology, surgical innovation, infectious diseases, and genomic medicine. UHN's McEwen Centre for Regenerative Medicine (UHN's "McEwen Centre") is the stem cell research affiliate of UHN.

In September 2007, we entered into a sponsored stem cell research and development collaboration with UHN. In December 2010, we extended the collaboration to September 2017. The primary goal of this ten-year collaboration is to leverage the stem cell research, technology and expertise of Dr. Gordon Keller, the Director of UHN's McEwen Centre, to develop and commercialize industry-leading human pluripotent stem cell differentiation technology and bioassay systems for drug rescue and cell therapy applications. This sponsored research collaboration builds on our existing strategic licenses from NJH and MSSM to certain stem cell technologies developed by Dr. Keller, and is directed to multiple stem cell-based research projects, including advancing use of human pluripotent stem cell-derived cardiomyocytes and hepatocytes to screen new drugs for potential heart toxicity and liver toxicity and for cell therapies for cartilage, heart and liver repair and autologous bone marrow transplantation. In April 2011, we further expanded the scope of the collaboration to include therapeutic and cell therapy applications of iPS Cells and cells derived from iPS Cells, create additional options to fund research and development with respect to future research projects relating to therapeutic applications of iPS Cells and certain cells derived from iPS Cells and extend the date that we shall have to exercise our options under the agreement. See Item 1, "Business – Sponsored Research Collaborations and Intellectual Property Rights – University Health Network, McEwen Centre for Regenerative Medicine, Toronto, Ontario", "Business – National Jewish Health Exclusive Licenses" and "Business – Mount Sinai School of Medicine Exclusive Licenses."

Cato Research and Cato BioVentures

Cato Research

Cato Research is a contract research and development organization ("CRO"), with international resources dedicated to helping a network of biotechnology and pharmaceutical companies navigate the regulatory approval process in order to bring new biologics, drugs, and medical devices to markets throughout the world. Cato Research has in-house capabilities to assist its sponsors with aspects of the drug development process, including, regulatory strategy, nonclinical and toxicology development, clinical development, data processing, data management, statistical analysis, regulatory applications, including INDs and NDAs, chemistry, manufacturing, and control programs, cGCP, cGLP and cGMP audit and compliance activities, and due diligence review of emerging technologies. Cato Research's senior management team, including co-founders Allen Cato, M.D., Ph.D. and Lynda Sutton, have over 20 years of experience interacting with the FDA and international regulatory agencies and a successful track record of product approvals.

Cato BioVentures

Cato Holding Company, doing business as Cato BioVentures ("Cato BioVentures"), is the venture capital affiliate of Cato Research. For over 20 years, Cato BioVentures and Cato Research have collaborated with biotechnology and pharmaceutical companies to advance a portfolio of platform technologies and product development programs. Cato BioVentures offers its biotechnology and pharmaceutical industry collaborators immediate access to the wide range of CRO services and expertise available from Cato Research, generally on a non-cash or partial-cash basis. Through strategic CRO service agreements with Cato Research, Cato BioVentures invests in therapeutics and medical devices, as well as platform technologies such as our *Human Clinical Trials in a Test Tube* ™ platform, which its principals believe are capable of improving the drug development process and the research and development productivity of a pharmaceutical company. Cato BioVentures often invests in a "bridge mode" to provide companies non-cash access to key CRO services in a manner and at a time that can extend the investee's internal development capabilities and financial runway in order to achieve key value-added developmental and regulatory milestones.

Our Relationship with Cato Research and Cato BioVentures

Prior to joining us as Chief Executive Officer in August 2009, Shawn K. Singh, JD, served as Managing Principal of Cato BioVentures. With co-founders Dr. Cato and Ms. Sutton, Mr. Singh designed and executed Cato BioVentures' CRO Service Capital ™ investment model. Mr. Singh also served as Chief Business Officer and General Counsel of Cato Research and was instrumental in expanding its CRO business in Canada, Europe and the United States.

Cato Research currently serves as the primary CRO providing strategic development and regulatory expertise and services with respect to our development of AV-101. See Item 1, "Business – AV-101."

Cato BioVentures is among our largest institutional investors. A significant portion of the VistaGen securities in Cato BioVentures' equity portfolio were acquired through its investment of CRO Service Capital ™ (that is, CRO services from Cato Research rendered to us on a strategic, non-cash basis) for development of AV-101.

As a result of a number of factors, including:

- the access Cato Research has to drug rescue candidates from its biotechnology and pharmaceutical industry network;
- Cato BioVentures' equity interest in VistaGen;
- Cato BioVentures' business model which involves partnering with innovators in exchange for an equity interest and product participation rights; and
- Mr. Singh's prior senior management experience with Cato BioVentures and Cato Research,

we anticipate that our relationship with Cato BioVentures and Cato Research may provide us with strategic access to potential drug rescue candidates. We further anticipate that this relationship will permit us not only to acquire or license drug rescue candidates from companies within their respective corporate networks, but also to leverage the CRO resources of Cato Research and financial community relationships of Cato BioVentures to assist our efforts to develop lead drug rescue candidates internally, should we elect to do so.

United States National Institutes of Health

Since our inception in 1998, the U.S. National Institutes of Health ("NIH") has awarded us a total of $11.3 million in non-dilutive research and development grants, including $2.3 million to support research and development of our Human Clinical Trials in a Test Tube™ platform and, as described below, a total of $8.8 million for nonclinical and Phase 1 clinical development of AV-101 (also referred to in scientific literature as "4-Cl-KYN"). AV-101, our lead small molecule drug candidate, is currently in Phase 1 clinical development in the U.S.

NIH awarded us $4.2 million in funding for development of AV-101 on June 22, 2009. The NIH increased this award amount to $4.6 million on July 19, 2010, under the Department of Health and Human Services Small Business Innovation Research ("SBIR") Program. The funded development project is entitled "Clinical Development of 4-Cl-KYN to Treat Pain" and is in response to a grant application and request for funding submitted to NIH by us on April 7, 2008, in which a detailed description of a development plan for AV-101 and related budget is provided. The development plan provides that we submit AV-101 to a systematic series of safety tests in human subjects under regulations governed by the U.S. Food and Drug Administration ("FDA"). As provided under terms and conditions of the NIH grant award, and as a federal grantee, we are required to adhere to certain federal cost accounting regulations, including limiting the submission of requests for periodic progress payments from the NIH to a reimbursement of actual costs incurred not to exceed a total of $4.6 million, and to completing the specified research plan by June 30, 2012. Other than limiting requests for progress payments to actual costs incurred, and having those costs verified annually by independent auditors, the funding is non-contingent and we retain all intellectual property rights. Prior to the fiscal year ended March 31, 2010, we received and completed similar SBIR grant awards from the NIH totaling approximately $4.2 million for nonclinical development of AV-101.

California Institute for Regenerative Medicine — Stem Cell Initiative (Proposition 71)

The California Institute for Regenerative Medicine ("CIRM") funds stem cell research at academic research institutions and companies throughout California. CIRM was established in 2004 with the passage of Stem Cell Initiative (Proposition 71) by California voters. The Stem Cell Initiative authorized $3.0 billion in funding for stem cell research in California, including research involving ES Cells, iPS Cells and adult stem cells. As a stem cell company based in California since 1998, we are eligible to apply for and receive grant funding under the Stem Cell Initiative. To date, as more particularly described below, we have been awarded approximately $1.0 million of non-dilutive grant funding from CIRM for stem cell research and development related to liver cells. This research and development focused on the improvement of techniques and the production of engineered human ES Cell lines used to develop mature functional liver cells as a biological system for testing drugs.

CIRM issued us a grant award of $971,558 on April 1, 2009 in response to our grant application submitted to CIRM titled "Development of an hES Cell-Base Assay System for Hepatocyte Differentiation Studies and Predictive Toxicology Drug Screening" on July 9, 2008, in which a detailed stem cell research proposal was presented. The research plan provided that our scientific personnel conduct certain experiments in our laboratories in South San Francisco, California, according to protocols approved in advance by CIRM. The period of funded research period began April 1, 2009 and extended through September 30, 2011, with payments made in advance by CIRM in the amount of $121,444 per quarter starting April 1, 2009. Annual scientific and financial reports to CIRM were required with a final scientific results report due October 1, 2011, and a final financial report due January 1, 2012. At the time of the award in 2009, funding was contingent upon the availability of funds in the California Stem Cell Research and Cures Fund in the California State Treasury. Inventions made under CIRM funding (if any) are owned by the State of California, and if we choose to exclusively license such invention, then our licensing revenue (if any) from the use of such licensed invention shall be subject to royalties equal to 25% of net revenue in excess of $500,000 per year, and revenue from commercial sales of products generated from the use of such license shall be subject to royalties in the range of 2% to 5% of commercial sales. All such royalty obligations are subject to aggregate maximums of three (3) times the amount of CIRM grant fund received leading to such invention.

NuPotential, Inc.

In January 2011, the National Heart, Lung and Blood Institute of the NIH awarded NuPotential, Inc. and VistaGen a grant of $499,765 to accelerate development of safer approaches to generate patient-specific iPS Cells for regenerative medicine, drug discovery and drug rescue.

Most approaches to produce human iPS Cells use retroviruses to activate and/or express multiple key genes, including an oncogene that is associated with production of cancer cells. The use of retroviruses and oncogenes are potentially problematic for clinical applications involving cells derived from iPS Cells due to the significant increased risk of inducing a cancer transformation. NuPotential's innovative cell programming technology involves the use of proprietary small molecule-based cell reprogramming processes for generating patient-specific iPS Cells instead of commonly-used retroviruses or cancer-inducing oncogenes. NuPotential's cell reprogramming technology could represent an improvement in the safety profile of iPS Cells.

The NIH grant is currently supporting further development of patient-specific iPS Cell programming processes by NuPotential, as well as our iPS Cell differentiation protocols and processes focused on the validation and use of the iPS Cells for cell therapy applications and in clinically-relevant bioassays for small molecule drug discovery and drug rescue. We anticipate that these patient-specific iPS Cells may play a key role in our cell therapy initiatives focused on heart and liver disease and cartilage-repair.

AV-101

We are currently working with Cato Research and other drug development service providers to develop AV-101, also known as "L-4-chlorokynurenine" and "4-Cl-KYN". AV-101 is a prodrug candidate for the treatment of neuropathic pain. Our current active AV-101 IND application on file at the FDA covers our initial Phase I clinical development of the drug candidate for neuropathic pain. Neuropathic pain is a serious and chronic condition causing pain after an injury or disease of the peripheral or central nervous system. The neuropathic pain market is large, including approximately 1.8 million people in the U.S. alone.

We believe the safety studies done in the initial Phase I clinical study of AV-101 will support development of AV-101 for other indications, including epilepsy and neurodegenerative diseases, such as Huntington's and Parkinson's. To date, the NIH has provided us with grant funding for substantially all of our AV-101 development expenses, including $8.2 million for preclinical and clinical development. We successfully completed our initial Phase I safety study of AV-101 for neuropathic pain in December 2010. We expect to complete our second AV-101 Phase I safety study during 2011.

AV-101 is an orally available prodrug that is converted in the brain into an active metabolite, 7-chlorokynurenic acid ("7-Cl-KYNA"), which regulates the N-methyl-D-aspartate ("NMDA") receptors. 7-Cl-KYNA is a synthetic analogue of kynurenic acid, a naturally occurring neural regulatory compound, and is one of the most potent and selective blockers of the regulatory GlyB-site of the NMDA receptor. In preclinical studies, AV-101 has very good oral bioavailability, is rapidly and efficiently transported across the blood-brain barrier, and is converted into 7-Cl-KYNA in the brain and spinal cord, preferentially, at the site of seizures and potential neural damage.

The effect of AV-101 on chronic neuropathic pain due to inflammation and nerve damage was assessed in rats by using the Chung nerve ligation model. AV-101 effects were compared to either saline and MK-801, or gabapentin (Neurontin™) as positive controls. Similarly to the therapeutic effects seen in the acute formalin and thermal pain models, AV-101 had a positive effect on chronic neuropathic pain in the Chung model that were greater than two (2) standard deviations of the control, with no adverse behavioral observations. As expected, MK-801 and gabapentin also demonstrated reduced pain readouts in the Chung model. The effects observed by AV-101 in both the acute and chronic neuropathic pain model systems was dose dependent, and was not associated with any side effects at the range of doses administered. Preclinical AV-101 data demonstrated the potential clinical utility of AV-101 as an analgesic.

Intellectual Property

Intellectual Property Rights Underlying our Human Clinical Trials in a Test Tube ™ Platform

We have established our intellectual property rights to the technology underlying our *Human Clinical Trials in a Test Tube* ™ platform through a combination of exclusive and non-exclusive licenses, patent, and trade secret laws. To our knowledge, we are the first stem cell company focused primarily on stem cell technology-based drug rescue. We have assembled an intellectual property portfolio around the use of pluripotent stem cell technologies in drug discovery and development and with specific application to drug rescue. The differentiation protocols we have licensed direct the differentiation of pluripotent stem cells through:

- a combination of growth factors (molecules that stimulate the growth of cells);
- modified developmental genes; and
- precise selection of immature cell populations for further growth and development.

By influencing key branch points in the cellular differentiation process, our pluripotent stem cell technologies can produce fully-differentiated, non-transformed, highly functional human cells *in vitro* in an efficient, highly pure and reproducible process.

As of the date of this report, we either own or have licensed 27 issued U.S. patents and 28 U.S. patent applications and certain foreign counterparts relating to the stem cell technologies that underlie our *Human Clinical Trials in a Test Tube* ™ platform. Our material rights and obligations with respect to these patents and patent applications are summarized below:

Licenses

National Jewish Health Exclusive Licenses

We have exclusive licenses to six issued U.S. patents held by NJH and a U.S. patent application filed by NJH. No foreign counterparts to these U.S. patents and patent application have been obtained. These U.S. patents and U.S. patent application contain claims covering composition of matter relating to specific populations of cells and precursors, methods to produce such cells, and applications of such cells for ES Cell-derived immature pluripotent precursors of all the cells of the mesoderm and endoderm lineages. Among other cell types, this covers cells of the heart, liver, pancreas, blood, connective tissues, vascular system, gut and lung cells.

Under this license agreement, we must pay to NJH 1% of our total revenues up to $30 million in each calendar year and 0.5% of all revenues for amounts greater than $30 million, with minimum annual payments of $25,000. Additionally, we are obligated under the agreement to make certain royalty payments on sales of products based on NJH's patents or the sublicensing of such technology. The royalty payments are subject to anti-stacking provisions which reduce our payments by a percentage of any royalty payments and fees paid to third parties who have licensed necessary intellectual property to us. This agreement remains in force for the life of the patents so long as neither party elects to terminate the agreement upon the other party's uncured breach or default of an obligation under the agreement. We also have the right to terminate the agreement at any time without cause.

Mount Sinai School of Medicine Exclusive Licenses

We have an exclusive, field restricted, license to one U.S. patent and three U.S. patent applications, one of which has been allowed, and their foreign counterparts filed by MSSM. Foreign counterparts have been filed in Australia, Canada, Europe (two), Japan, Hong Kong and Singapore. One of the U.S. applications has been issued and the foreign counterpart in Singapore has been issued, while the two counterparts in Europe are pending. These patent applications have claims covering composition of matter relating to specific populations of cells and precursors, methods to produce such cells, and applications of such cells, including:

- the use of certain growth factors to generate mesoderm (that is, the precursors capable of developing into cells of the heart, blood system, connective tissues, and vascular system) from human ES Cells;

- the use of certain growth factors to generate endoderm (that is, the precursors capable of developing into cells of the liver, pancreas, lungs, gut, intestines, thymus, thyroid gland, bladder, and parts of the auditory system) from human ES Cells; and

- applications of cells derived from mesoderm and endoderm precursors, especially those relating to drug discovery and testing for applications in the field of in vitro drug discovery and development applications.

This license agreement requires us to pay annual maintenance fees, a patent issue fee and royalty payments based on product sales and services that are covered by the MSSM patent applications, as well as for any revenues received from sublicensing. Any drug candidates that we develop will only require royalty payments to the extent they require the practice of the licensed technology. To the extent we incur royalty payment obligations from other business activities, the royalty payments are subject to anti-stacking provisions which reduce our payments by a percentage of any royalty payments or fees paid to third parties who have licensed necessary intellectual property to us. The license agreement will remain in force for the life of the patents so long as neither party terminates the agreement for cause (i) due to a material breach or default in performance of any provision of the agreement that is not cured within 60 days or (ii) in the case of failure to pay amounts due within 30 days.

Wisconsin Alumni Research Foundation Non-Exclusive License

We have non-exclusive licenses to 23 issued stem cell-related U.S. patents, 19 stem cell-related U.S. patent applications, of which two have been allowed, and certain foreign counterparts held by WARF, for applications in the field of *in vitro* drug discovery and development. Foreign counterparts have been filed in Australia, Canada, Europe, China, India, Hong Kong, Israel, Brazil, South Korea, India, Mexico, and New Zealand. The subject matter of these patents includes specific human ES Cell lines and composition of matter and use claims relating to human ES Cells important to drug discovery, and drug rescue screening. We have rights to:

- use the technology for internal research and drug development;
- provide discovery and screening services to third parties; and
- market and sell research products (that is, cellular assays incorporating the licensed technology).

This license agreement requires us to make royalty payments based on product sales and services that incorporate the licensed technology. We do not believe that any drug rescue candidates to be developed by us will incorporate the licensed technology and, therefore, no royalty payments will be payable. Nevertheless, there is a minimum royalty of $20,000 per calendar year. There are also milestone fees related to the discovery of therapeutic molecules, though no royalties are owed on such molecules. The royalty payments are subject to anti-stacking provisions which reduce our payments by a percentage of any royalty payments paid to third parties who have licensed necessary intellectual property to us. The agreement remains in force for the life of the patents so long as we pay all monies due and do not breach any covenants, and such breach or default is uncured for 90 days. We may also terminate the agreement at any time upon 60 days' notice. There are no reach through royalties on customer-owned small molecule or biologic drug products developed using the licensed technologies.

Our Patents

We have filed a U.S. patent application on liver stem cells and their applications in drug development relating to toxicity testing. Of the related international filings, European and Korean patents were issued. The European patent has been validated in 11 European countries. We have filed a U.S. patent application, with foreign counterpart filing in Canada and Europe, directed to methods for producing human pluripotent stem cell-derived endocrine cells of the pancreas, with a specific focus on beta-islet cells, the cells that produce insulin, and their uses in diabetes drug discovery and screening. In addition, we have filed a U.S. provisional patent application on a novel, non-viral, approach to produce iPS Cells.

The material patents currently related to the generation of human heart and liver cells for use in connection with our drug rescue activities are set forth below:

Territory	Patent No.	General Subject Matter	Expiration
US	7,763,466	Method to produce endoderm cells	May 20, 2025
US	7,955,849	Method of enriching population of mesoderm cells	May 19, 2023

The principle U.S. method of use patent related to AV101 expired in February 2011. Foreign counterparts to that U.S. patent expire in February 2012. Our commercial protection strategy with respect to AV-101 involves the New Drug Product Exclusivity provided by the FDA under section 505(c)(3)(E) and 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act ("FDCA"). The FDA's New Drug Product Exclusivity is available for new chemical entities ("NCEs") such as AV-101, which, by definition, are innovative and have not been approved previously by the FDA, either alone or in combination. The FDA's New Drug Product Exclusivity protection provides the holder of an FDA-approved new drug application ("NDA") five (5) years of protection from new competition in the U.S. marketplace for the innovation represented by its approved new drug product. This protection precludes FDA approval of certain generic drug applications under section 505(b)(2) of the FDCA, as well certain abbreviated new drug applications ("ANDAs"), during the five (5)-year exclusivity period, except that such applications may be submitted after four (4) years if they contain a certification of patent invalidity or non-infringement.

Trade Secrets

We rely, in part, on trade secrets for protection of some of our intellectual property. We attempt to protect trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Our employees and consultants also sign agreements requiring that they assign to us their interests in patents and copyrights arising from their work for us.

Sponsored Research Collaborations and Intellectual Property Rights

University Health Network, McEwen Centre for Regenerative Medicine, Toronto, Ontario

We are currently sponsoring stem cell research by Dr. Gordon Keller, Director of the UHN's McEwen Centre, focused on developing improved methods for differentiation of cardiomyocytes (heart cells) from pluripotent stem cells, and their uses as biological systems for drug discovery and drug rescue, as well as cell therapy. Pursuant to our sponsored research collaboration agreement with UHN, we have the right to acquire exclusive worldwide rights to any inventions arising from these studies under pre-negotiated terms. Such pre-negotiated terms provide for royalty payments based on product sales that incorporate the licensed technology and milestone payments based on the achievement of certain events. Any drug rescue candidates that we develop will not incorporate the licensed technology and, therefore, will not require any royalty payments. To the extent we incur royalty payment obligations from other business activities, the royalty payments will be subject to anti-stacking provisions which reduce our payments by a percentage of any royalty payments paid to third parties who have licensed necessary intellectual property to us. These licenses will remain in force for so long as we have an obligation to make royalty or milestone payments to UHN, but may be terminated earlier upon mutual consent, by us at any time, or by UHN for our breach of any material provision of the license agreement that is not cured within 90 days. We also have the exclusive option to sponsor research for similar cartilage, liver, pancreas and blood cell projects with similar licensing rights.

The sponsored research collaboration agreement with UHN, as amended, has a term of ten years, ending on September 18, 2017. The options to sponsor research for therapeutic and cell therapy applications of iPS Cells and cells derived from iPS Cells, including programs involving cartilage, liver, pancreas and blood cells derived from iPS Cells, expire on April 30, 2012. The agreement is subject to renewal upon mutual agreement of the parties and subject to automatic extensions for options that we exercise prior to April 30, 2012 so that such additional project will have a three year term from the date of our exercise of our option. The agreement may be terminated earlier upon a material breach by either party that is not cured within 30 days. UHN may elect to terminate the agreement if we become insolvent or if any license granted pursuant to the agreement is prematurely terminated. We have the option to terminate the agreement if Dr. Keller stops conducting his research or ceases to work for UHN.

AV-101- Related Intellectual Property

We have exclusive licenses to 7 issued U.S. patents related to the use and function of AV-101, and various CNS-active molecules related to AV-101. These underlying patents are held by the University of Maryland, Baltimore, the Cornell Research Foundation, Inc. and Aventis, Inc. Many of these issued patents have corresponding foreign patents.

Under the terms of the license agreement, we are obligated to make royalty payments on 2% of net sales of products using the patent rights, including products containing compounds covered by the patent rights. Additionally, we must pay a 1% royalty on net sales of combination products that use the patent rights, or contain compounds covered by the patent rights, but also contain a non-licensed component, so long as the non-licensed component is also sold separately in at least one country. We anticipate that any sales of AV-101 will be subject to a 2% royalty. There are no license, milestone or maintenance fees under the agreement. The agreement remains in force until the later of: (i) the expiration or invalidation of the last patent right; and (ii) 10 years after the first commercial sale of the first product that uses the patent rights or contains a compound covered by the patent rights. This agreement may also be terminated earlier at the election of the licensor upon our failure to pay any monies due, our failure to provide updates and reports to the licensor, our failure to provide the necessary financial and other resources required to develop the products, or our failure to cure within 90 days any breach of any provision of the agreement. We may also terminate the agreement at any time upon 90 days' written notice so long as we make all payments due through the effective date of termination.

Competition

We believe that our *Human Clinical Trials in a Test Tube* ™ platform is capable of being competitive in growing markets for pluripotent stem cell technology-based drug discovery, drug rescue, cell therapy, and other applications. We have elected to focus a substantial portion of our resources on drug rescue applications and, to a lesser but increasingly significant degree, on emerging iPS Cell-based cell therapy applications.

We believe that the technologies underlying our *Human Clinical Trials in a Test Tube* ™ platform and our primary focus on drug rescue opportunities provide us substantial advantages. Although we believe that our model for the application of pluripotent stem cell technologies for drug rescue is novel, competition may increase considerably as the use of stem cell technologies for drug discovery, rescue and development continues to increase throughout the pharmaceutical and biotechnology industries.

Competition may arise, especially as to cell therapy applications, from academic research institutions worldwide, as well as stem cell companies that seek to sell *in vitro* heart cell, liver cell and other cellular assays and cell populations, including stem cell-based assays and stem cell-derived cells for predictive toxicity screening, including Advanced Cell Technology, Inc., BioTime, Cellartis AB, Cellular Dynamics International, Inc., California Stem Cell, Inc., Cellerant Therapeutics, Inc., Cellzdirect Inc., Cambrex Corporation, HemoGenix, International Stem Cell Corp., iPierian Inc., Stem Cells, Inc. and Stemina BioMarker Discovery, Inc., and possibly others. Pharmaceutical companies may also develop their own stem cell-based research programs. We anticipate that acceptance of pluripotent stem cell technology, including our *Human Clinical Trials in a Test Tube* ™ platform, will increase at pharmaceutical and biotechnology companies over at least the next five years, providing us with drug rescue and cell therapy partnering opportunities.

With respect to AV-101, we believe that a range of pharmaceutical and biotechnology companies have programs to develop small molecule drug candidates for the treatment of epilepsy, neuropathic pain and Parkinson's disease, including Abbott Laboratories, GlaxoSmithKline plc, Johnson & Johnson Inc., Novartis AG, Pfizer Inc., and Warner-Lambert Company. We expect that AV-101 will have to compete with a variety of therapeutic products and procedures.

Government Regulation

United States

With respect to our stem cell research and development in the U.S., the U.S. government has established requirements and procedures relating to the isolation and derivation of certain stem cell lines and the availability of federal funds for research and development programs involving those lines. All of the stem cell lines that we are using were either isolated under procedures that meet U.S. government requirements and are approved for funding from the U.S. government, or were isolated under procedures that meet U.S. government requirements and are approved for use by regulatory bodies associated with the CIRM.

With respect to drug development, government authorities at the federal, state and local levels in the U.S. and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing, pricing and export and import of pharmaceutical products such as those we are developing. In the U.S., pharmaceuticals, biologics and medical devices are subject to rigorous FDA regulation. Federal and state statutes and regulations in the United States govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, export, record keeping, approval, marketing, advertising and promotion of our potential drug rescue variants. The information that must be submitted to the FDA in order to obtain approval to market a new drug varies depending on whether the drug is a new product whose safety and effectiveness has not previously been demonstrated in humans, or a drug whose active ingredient(s) and certain other properties are the same as those of a previously approved drug. Product development and approval within this regulatory framework takes a number of years and involves significant uncertainty combined with the expenditure of substantial resources.

Canada

In Canada, stem cell research and development is governed by two policy documents and by one legislative statute: the Guidelines for Human Pluripotent Stem Cell Research (the "Guidelines") issued by the Canadian Institutes of Health Research; the Tri-Council Statement: Ethical Conduct for Research Involving Humans (the "TCPS"); and the Assisted Human Reproduction Act (the "Act"). The Guidelines and the TCPS govern stem cell research conducted by, or under the auspices of, institutions funded by the federal government. Should we seek funding from Canadian government agencies or should we conduct research under the auspices of an institution so funded, we may have to ensure the compliance of such research with the ethical rules prescribed by the Guidelines and the TCPS.

The Act subjects all research conducted in Canada involving the human embryo, including ES Cell derivation (but not the stem cells once derived), to a licensing process overseen by a federal licensing agency. However, as of the date of this report, the provisions of the Act regarding the licensing of ES Cell derivation were not in force

We are not currently conducting stem cell research in Canada. We are, however, sponsoring stem cell research by Dr. Gordon Keller at UHN's McEwen Centre. We anticipate conducting stem cell research (with both ES Cells and iPS Cells), in collaboration with Dr. Keller and is research team, at UHN during 2011 and beyond pursuant to our long term sponsored research collaboration with Dr. Keller and UHN. Should the provisions of the Act come into force, we may have to apply for a license for all ES Cell research we may sponsor or conduct in Canada and ensure compliance of such research with the provisions of the Act.

Foreign

In addition to regulations in the U.S., we may be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the U.S. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Subsidiaries and Inter- Corporate Relationships

VistaGen is our wholly-owned subsidiary. VistaGen has two wholly-owned subsidiaries, VistaStem Canada Inc., a corporation incorporated pursuant to the laws of the Province of Ontario, intended to facilitate our stem cell-based research and development and drug rescue activities in Ontario, Canada, including our collaboration with Dr. Keller and UHN, and Artemis Neuroscience, Inc., a corporation incorporated pursuant to the laws of the State of Maryland and focused on the clinical development of AV-101. The operations of each of VistaGen and each of its subsidiaries are managed by our management team based in South San Francisco, California.

Employees

We have seven full-time employees, four of whom have doctorate degrees. We anticipate adding up to four additional employees, including at least one of whom will have a doctorate degree, within the next twelve months. Currently, five full-time employees work in research and development and laboratory support services and two full-time employees work in general and administrative roles. Staffing for all other functional areas is achieved through strategic relationships with service providers and consultants, each of whom provides services on an as-needed basis, including human resources and payroll, accounting, information technology, facilities, stock plan administration, web site maintenance, regulatory affairs, and FDA program management. In addition, we currently conduct some of our research and development efforts through sponsored research relationships with stem cell scientists at academic research institutions in the U.S. and Canada, including Dr. Keller's laboratories at UHN. See Item 1, "Business – Strategic Transactions and Relationships."

ITEM 1A. RISK FACTORS

Risks Related to Our Business

We have never rescued a drug candidate and cannot be certain that we will be able to do so in the future.

Our ability to rescue drug candidates is highly dependent upon the accuracy and efficiency of our *Human Clinical Trials in a Test Tube* ™ platform. We have no operating history with respect to the rescue of drug candidates and cannot be certain we will be able to develop or rescue drug candidates in the future. There are a number of factors that may impact our ability to rescue a drug candidate, including:

- Our ability to identify promising drug candidates that pharmaceutical companies have put on the shelf due to heart or liver toxicity concerns. We have no prior experience in identifying drug candidates that may be suitable for our proposed drug rescue model. If we cannot identify drugs that can be rescued in an efficient and cost-effective manner, our business will be adversely affected.

- Our ability to negotiate licenses with pharmaceutical companies to drug candidates that the pharmaceutical companies have put on the shelf due to heart or liver toxicity concerns. We have no experience in negotiating these licenses and there can be no assurances that we will be able to obtain licenses on commercially reasonable terms, if at all. If we are unable to obtain licenses to drug candidates we seek to rescue, our business will be adversely affected.

- Our medicinal chemistry collaborators' ability to design and produce a range of drug rescue variants that are structurally related to the original drug candidate that was put on the shelf. If our chosen medicinal chemistry collaborators are unsuccessful for any reason in designing and producing these drug rescue variants, our business will be adversely affected.

- Our ability to execute our drug rescue programs in a timely and cost-effective manner. If our drug rescue programs are less efficient and more expensive than we expect, our business will be adversely affected.

- Our ability to research, develop, obtain regulatory approval for, manufacture, introduce, market, and distribute our drug rescue variants, or secure a collaborator to provide financial and other assistance with these steps. The time necessary to achieve these goals for any individual pharmaceutical product is long and can be uncertain. Only a small number of research and development programs ultimately result in commercially successful drugs. We cannot assure you that toxicity results indicated by our drug rescue testing models are indicative of results that would be achieved in future animal studies, in *in vitro* testing or human clinical studies, all or some of which will be required in order to obtain regulatory approval of our drug rescue variants.

Our independent auditors have expressed substantial doubt about our ability to continue as a going concern.

Our consolidated financial statements for the year ended March 31, 2010 included elsewhere in this report, have been prepared assuming that we will continue to operate as a going concern. The report of our independent registered public accounting firm on our consolidated financial statements includes an explanatory paragraph discussing conditions that raise a substantial doubt about our ability to continue as a going concern. We incurred accumulated losses of $33.1 million and $39.0 million, and shareholders' deficit of $26.3 million and $29.8 million as of March 31, 2010 and December 31, 2010, respectively. Our cash and equivalents, including contract payments receivable, was $448,000 and $535,000 as of March 31, 2010 and December 31, 2010, respectively.

We require additional funds to continue operations. These funds, if available, may be from one or more public or private stock offerings, borrowings under bank or lease lines of credit, grants awards or other sources. Any additional financing may not be available on a timely basis on terms acceptable to us, or at all. Our ability to obtain such financing may be impaired by the current economic conditions and the lack of liquidity in the credit markets. Such financing, if available, may also be dilutive to stockholders or may require us to grant a lender a security interest in our assets. The amount of money we will need will depend on many factors, including:

- revenues, if any, generated by the development or licensing of a drug rescue candidate;
- expenses we incur in developing and selling our drug rescue applications;
- the commercial success of our research and development efforts; and
- the emergence of competing technological developments.

If we are unable to secure additional funding or adequate funds are not available, we may have to discontinue operations; delay development or commercialization of our *Human Clinical Trials in a Test Tube* ™ platform and our drug rescue applications; license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize; reduce marketing, customer support, or other resources devoted to our system; or any combination of these activities. Any of these results would materially harm our business, financial condition, and results of operations, and there can be no assurance that any of these results will result in cash flows that will be sufficient to fund our current or future operating needs.

Our internal validation study of CardioSafe 3D ™ ***has not been subject to peer review or third party validation.***

Our internal validation study, conducted to validate the ability of our *CardioSafe 3D* ™ assay system to predict the cardiac effects of prospective drug rescue candidates referred to under "Business – Application of Stem Cell Technology to Drug Rescue – *CardioSafe 3D*™", has not been subject to peer review or third party validation. It is possible that the results we obtained from our internal validation study may not be able to be replicated by third parties. If third parties cannot replicate such results, it will be difficult to negotiate and obtain licenses from pharmaceutical companies to drug candidates we seek to rescue. Even if such results can be replicated, pharmaceutical companies may nevertheless conclude their current drug testing models are better than our testing model, *CardioSafe3D* ™ , and that our testing model does not merit a license to the drug candidate we seek to rescue. Our business model is predicated on our ability to obtain licenses from pharmaceutical companies to promising drug rescue candidates. If we cannot obtain licenses to suitable drug rescue candidates, our business will be adversely affected.

CardioSafe 3D ™ ***is still in an early stage of development and we cannot say with certainty that it will be more efficient or accurate at predicting the toxicity of drug candidates than the drug testing models currently used by pharmaceutical companies.***

The success of our plan to rescue drug candidates is dependent upon *CardioSafe 3D* ™ and any other predictive toxicology screening bioassay systems we develop being more accurate and efficient than current animal and tumor cell-based testing models. The accuracy and efficiency of our bioassay systems is central to our ability to rescue drugs. If our bioassay systems are less accurate and less efficient than current animal and tumor cell-based testing models, our business will be adversely affected.

We have a history of losses and anticipate future losses, and continued losses could impair our ability to sustain operations.

We have incurred operating losses every year since our operations began in July 1998. As of December 31, 2010, our accumulated deficit since inception was approximately $39.0 million. Losses have resulted principally from costs incurred in connection with our research and development activities and from general and administrative costs associated with our operations. We expect to incur additional operating losses and, as our research and development efforts, and drug rescue- and stem cell therapy-related activities continue, we expect our operating losses to increase.

Substantially all of our revenues to date have been from research support payments under collaboration agreements, government and private foundation grants, and revenues from our stem cell technology licensing arrangements. Our near-term revenues are highly dependent on entering into stem cell technology-based drug rescue and development collaborations with pharmaceutical companies and strategic predictive toxicology screening collaborations with government entities. In the event that we are unable to generate projected revenues related to drug rescue or predictive toxicology screening collaborations or government grants, we will need to modify our operating plan to the extent necessary to make up for the revenue shortfall which would harm our business and prospects. We may not be successful in entering into any new collaboration or license agreement that results in material or timely revenues. We do not expect that the revenues generated from these arrangements will be sufficient alone to continue or expand our stem cell research, drug rescue, drug development and stem cell therapy activities and otherwise sustain our operations. In addition, in order to fund a substantial portion of future operations, we will need to secure additional capital.

We also expect to experience negative cash flows for the foreseeable future as we fund our operating losses and capital expenditures. This will result in decreases in our working capital, total assets and shareholders' equity, which may not be offset by future funding. We will need to generate significant revenues to achieve profitability. We may not be able to generate these revenues, and we may never achieve profitability. Our failure to achieve profitability could negatively impact the value of our 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 will need substantial additional capital to conduct our operations, complete our research and development activities, develop our stem cell technology platform, execute our drug rescue and cell therapy business model, 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 stem cell technology platform, and execute our drug rescue and cell therapy business model, and we cannot assure you that our existing capital resources, even after completion of the Merger, will be sufficient to fund our current and planned operations. There can be no assurances that we will be able to raise more capital or on what terms. We may seek additional funds from public and private stock offerings, borrowings under lease lines of credit or government loan programs, or other sources. The timing and degree of any future capital requirements will depend on many factors, including: revenues generated, if any; the commercial success of our research and development efforts; the emergence of competing technological developments; the accuracy of the assumptions underlying our estimates for our capital needs; the magnitude and scope of our research and development programs; our ability to enter into collaboration agreements; our ability to successfully obtain additional grant funding from government agencies and private research organizations that support research such as ours; our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing; the number and type of drug rescue and other pipeline opportunities that we pursue and develop; 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 additional capital. Additional financing through strategic collaborations, public or private equity financings, capital lease transactions or other financing sources may not be available on acceptable terms, or at all. The receptivity of the public and private equity 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 financings, if we obtain them, could result in significant dilution to our shareholders. Further, in the event that additional funds are obtained through arrangements with collaborators, these arrangements will likely require us to relinquish rights to some of our technologies, product candidates 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, reduce marketing or other resources devoted to our products and technologies. Any of these results could have a material adverse effect on our business.

If we cannot continue to obtain grant funding from government entities or private research foundations or research, drug rescue and development funding from pharmaceutical or biotechnology companies, or if we fail to replace these sources of funding, our ability to continue operations will be harmed.

Historically we have funded a substantial portion of our operating expenses from U.S. government and private grant funding and funding from pharmaceutical companies with which we have collaborative relationships. In order to fund a substantial portion of future operations, particularly future operations related to our proposed drug rescue activities and development of AV-101, we will need to apply for and receive additional grant funding from governments and governmental organizations such as NIH, the NIH's National Institute of Neurological Disease and Stroke, the California Institute for Regenerative Medicine and the government of the Province of Ontario, Canada, however, we may not secure any additional funding from any governmental organization or private research foundation or otherwise. We cannot assure you that we will continue to receive grant funding. If grant funds are no longer available or the funds no longer meet our needs, some of our current and future operations may be delayed or terminated. In addition, our business, financial condition and results of operations will be adversely affected if we are unable to obtain grants or replace these sources of funding.

If we cannot enter into and successfully manage a sufficient number of drug rescue and predictive toxicology screening collaborations with pharmaceutical or biotechnology companies or government entities it will harm our ability to develop drug rescue candidates for our drug pipeline and fund our future operations.

A principal element of our drug rescue business model is to enter into multiple stem cell technology-based drug rescue and predictive toxicology screening collaborations with established pharmaceutical and biotechnology companies and government entities to finance or otherwise assist in the rescue, development, marketing and manufacture of drugs developed utilizing our stem cell-based toxicity screening assays. Our goal is to derive a recurring stream of revenues principally from research and development payments, license fees, milestone payments and royalties from our projected drug rescue and predictive toxicology screening collaborations. Our prospects, therefore, will depend in large part upon our ability to attract and retain collaborators and to rescue and develop drug candidates that meet the requirements of our prospective collaborators. In addition, our collaborators will generally have the right to abandon research projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed-upon research terms. There can be no assurance that we will be successful in establishing multiple future collaborations on acceptable terms or at all, that current or future collaborations will not terminate funding before completion of projects, that our existing or future collaborative arrangements will result in successful product commercialization or that we will derive any revenues from such arrangements. To the extent that we are unable to maintain existing or establish new drug rescue and predictive toxicology screening collaborations, it would require substantial additional capital for us to undertake research, development and commercialization activities on our own.

In varying degrees for each of the drug candidates we may seek to rescue and develop during the next 18 months, we will likely rely on our collaborators to develop, conduct human clinical trials on, obtain regulatory approvals for, manufacture, market and/or commercialize our drug rescue pipeline candidates. Such collaborators' diligence and dedication of resources in conducting these activities will depend on, among other things, their own competitive, marketing and strategic considerations, including the relative advantages of competitive products. The failure of our collaborators to conduct their collaborative activities successfully and diligently would have a material adverse effect on us.

Some of our competitors or pharmaceutical companies 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 pluripotent stem cell biology-based assay systems and drug candidates that could compete directly with the bioassay technologies and product candidates that we seek to discover, develop and commercialize currently exist or are being developed by pharmaceutical and biotechnology companies and by academic and other research organizations.

Many of the pharmaceutical and biotechnology companies developing and marketing these competing products and technologies have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing and distribution. Pharmaceuticals companies with whom we are seeking to collaborate may develop their own competing internal programs.

Small companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Academic institutions, government agencies and other public and private research organizations are conducting research, seeking patent protection and establishing collaborative arrangements for research, clinical development and marketing of products similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel, obtaining collaborators and licensees, as well as in acquiring technologies complementary to our programs.

In addition to the above factors, we expect to face competition in the areas of evaluation of product efficacy and safety, the timing and scope of regulatory consents, availability of resources, reimbursement coverage, price and patent position, including potentially dominant patent positions of others.

As a result of the foregoing, our competitors may develop more effective or more affordable products, or achieve earlier patent protection or product commercialization than we do. Most significantly, competitive products may render any technologies and product candidates that we develop obsolete, which would negatively impact our business and ability to sustain operations.

Restrictions on the use of ES Cells, political commentary and the ethical and social implications of research involving ES 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.

Some of our most important programs involve the use of ES Cells. Some believe the use of ES Cells gives rise to ethical and social issues regarding the appropriate use of these cells. Our research related to ES Cells may become the subject of adverse commentary or publicity, which could significantly harm the market price of our Common Stock.

Certain political and religious groups in the United States have voiced opposition to ES Cell technology and practices. All procedures we use to obtain clinical samples and the procedures we use to isolate ES Cells are consistent with the informed consent and ethical guidelines promulgated by the U.S. National Academy of Science, the International Society of Stem Cell Research (“ISSCR”), and the NIH. These procedures and documentation have been reviewed by an external Stem Cell Research Oversight Committee, and all cell lines we use have been approved under these guidelines. We use stem cells derived from human embryos that have been created for use in *in vitro* fertilization (“IVF”) procedures but that have been donated with appropriate informed consent for research use after a successful IVF procedure because they are no longer desired or suitable for IVF. Many research institutions, including some of our scientific collaborators, have adopted policies regarding the ethical use of human embryonic tissue. These policies may have the effect of limiting the scope of research conducted using ES Cells, thereby impairing our ability to conduct research in this field.

The U.S. government and its agencies on July 7, 2009 published guidelines for the ethical derivation of human ES Cells required for receiving federal funding for ES Cell research. All of the ES Cell lines we use meet these guidelines for NIH funding. In the U.S., the President’s Council on Bioethics monitors stem cell research, and may make recommendations from time to time that could place restrictions on the scope of research using human embryonic or fetal tissue. Although numerous states in the U.S. are considering, or have in place, legislation relating to stem cell research, including California whose voters approved Proposition 71 to provide up to $3 billion of state funding for stem cell research in California, it is not yet clear what affect, if any, state actions may have on our ability to commercialize stem cell technologies. The use of embryonic or fetal tissue in research (including the derivation of ES Cells) in other countries is regulated by the government, and varies widely from country to country. These regulations may affect our ability to commercialize ES Cell-based bioassay systems.

Government-imposed restrictions with respect to use of ES Cells in research and development could have a material adverse effect on us by harming our ability to establish critical collaborations, delaying or preventing progress in our research and development, and causing a decrease in the market interest in our stock. These ethical concerns do not apply to iPS Cells because their derivation does not involve the use of embryonic tissues.

We have assumed that the biological capabilities of iPS Cells and ES Cells for in vitro bioassays is likely to be comparable. If it is discovered that this assumption is incorrect, our ability to develop our Human Clinical Trials in a Test Tube ™ platform could be harmed.

We plan to use both ES Cells and iPS Cells as the basis for the continued development of our *Human Clinical Trials in a Test Tube* ™ platform. With respect to iPS Cells, scientists are still unsure about the clinical utility, life span, and safety of such cells, and whether such cells differ in any clinically significant ways from ES Cells. If we discover that iPS Cells will not be useful for whatever reason for our *Human Clinical Trials in a Test Tube* ™ platform, we could be limited to using only ES Cells. This could negatively affect our ability to develop our *Human Clinical Trials in a Test Tube* ™ platform, particularly in circumstances where it would be preferable to produce iPS Cells to reflect the effects of desired specific genetic variations.

Risks Related to the Regulation of Biological Products

Some of our products, especially our potential stem cell therapy products, and the products of our collaboration partners, may be subject to the biological product regulations. During their clinical development, biological products are regulated pursuant to Investigational New Drug ("IND") requirements. Product development and approval takes a number of years, involves the expenditure of substantial resources and is uncertain. Many biological products that appear promising ultimately do not reach the market because they cannot meet FDA or other regulatory requirements. In addition, there can be no assurance that the current regulatory framework will not change through regulatory, legislative or judicial actions or that additional regulation will not arise during our product development that may affect approval, delay the submission or review of an application, if required, or require additional expenditures by us.

The activities required before a new biological product may be approved for marketing in the U.S. primarily begin with preclinical testing, which includes laboratory evaluation and animal studies to assess the potential safety and efficacy of the product as formulated. Results of preclinical studies are summarized in an IND application to the FDA. Human clinical trials may begin 30 days following submission of an IND application, unless the FDA requires additional time to review the application or raise questions.

Clinical testing involves the administration of the drug or biological product to healthy human volunteers or to patients under the supervision of a qualified principal investigator, usually a physician, pursuant to an FDA-reviewed protocol. Each clinical study is conducted under the auspices of an institutional review board ("IRB") at each of the institutions at which the study will be conducted. A clinical plan, or "protocol," accompanied by the approval of an IRB, must be submitted to the FDA as part of the IND application prior to commencement of each clinical trial. Human clinical trials are conducted typically in three sequential phases. Phase I trials consist of, primarily, testing the product's safety in a small number of patients or healthy volunteers. In Phase II, the safety and efficacy of the product candidate is evaluated in a specific patient population. Phase III trials typically involve additional testing for safety and clinical efficacy in an expanded patient population at geographically dispersed sites. The FDA may order the temporary or permanent discontinuance of a preclinical or clinical trial at any time for a variety of reasons, particularly if safety concerns exist.

A company seeking FDA approval to market a biological product must file a Biologics License Application ("BLA"). In addition to reports of the preclinical and human clinical trials conducted under the IND application, the BLA includes evidence of the product's safety, purity, potency and efficacy, as well as manufacturing, product identification and other information. Submission of a BLA does not assure FDA approval for marketing. The application review process generally takes one to three years to complete, although reviews of drugs and biological products for life-threatening diseases may be accelerated or expedited. However, the process may take substantially longer.

The FDA requires at least one and often two properly conducted, adequate and well-controlled clinical studies demonstrating efficacy with sufficient levels of statistical assurance. However, additional information may be required. Notwithstanding the submission of such data, the FDA ultimately may decide that the BLA does not satisfy the regulatory criteria for approval and not approve the application. The FDA may impose post-approval obligations, such as additional clinical tests following BLA approval to confirm safety and efficacy (Phase IV human clinical trials). The FDA may, in some circumstances, also impose restrictions on the use of the biological product that may be difficult and expensive to administer. Further, the FDA requires reporting of certain safety and other information that becomes known to a manufacturer of an approved biological product. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market.

Prior to approving an application, the FDA will inspect the prospective manufacturer to ensure that the manufacturer conforms to the FDA's current good manufacturing practice ("cGMP") regulations that apply to biologics. To comply with the cGMP regulations, manufacturers must expend time, money and effort in product recordkeeping and quality control to assure that the product meets applicable specifications and other requirements. The FDA periodically inspects manufacturing facilities in the U.S. and abroad in order to assure compliance with applicable cGMP requirements. Our failure to comply with the FDA's cGMP regulations or other FDA regulatory requirements could have a significant adverse effect on us.

After a product is approved for a given indication in a BLA, subsequent new indications or dosage levels for the same product are reviewed by the FDA via the filing and approval of a BLA supplement. The BLA supplement is more focused than the BLA and deals primarily with safety and effectiveness data related to the new indication or dosage. Applicants are required to comply with certain post-approval obligations, such as compliance with cGMPs.

Entry into clinical trials with one or more drug or biologic product candidates may not result in any commercially viable products.

We may never generate revenues from drug or biologic product sales because of a variety of risks inherent in our business, including the following risks:

- clinical trials may not demonstrate the safety and efficacy of our product candidates;
- completion of clinical trials may be delayed, or costs of clinical trials may exceed anticipated amounts;
- we may not be able to obtain regulatory approval of our products, or may experience delays in obtaining such approval;
- we may not be able to manufacture our product candidates economically on a commercial scale;
- we and any licensees of ours may not be able to successfully market our products;
- physicians may not prescribe our product candidates, or patients or third party payors may not accept such product candidates;
- others may have proprietary rights which prevent us from marketing our products; and
- competitors may sell similar, superior or lower-cost products.

Risks Related to Our Intellectual Property

If we fail to meet our obligations under license agreements, we may lose our rights to key technologies on which our business depends.

Our business depends on several critical technologies that are based in part on patents licensed from third parties. Those third-party license agreements impose obligations on us, such as payment obligations and obligations to diligently pursue development of commercial products under the licensed patents. If a licensor believes that we have failed to meet our obligations under a license agreement, the licensor could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a loss of the licensed rights. During the period of any such litigation our ability to carry out the development and commercialization of potential products could be significantly and negatively affected. If our license rights were restricted or ultimately lost, our ability to continue our business based on the affected technology would be severely adversely affected.

It is uncertain what ownership rights, if any, we will obtain over intellectual property we derive from licenses by pharmaceutical companies to lead drug rescue candidates and drug rescue variants.

We expect to negotiate and obtain licenses from pharmaceutical companies to drug rescue candidates that these companies have put on the shelf (discontinued development) because of toxicity and, in the near-term, heart toxicity specifically, as well as drug rescue variants derived from the drug rescue candidates. Although we have substantial experience in negotiating licenses to drug candidates and stem cell technologies, we have limited experience in negotiating licenses to drug candidates and drug rescue variants related to our drug rescue business model, and there can be no assurances that we will obtain ownership rights over intellectual property we derive from our licenses to the drug rescue candidates, including rights to drug rescue variants. Such intellectual property may include rights to drug rescue variants that we discover to be safer than and as effective as the original drug rescue candidate. If we are unable to obtain ownership rights over intellectual property related to drug rescue variants, our business will be adversely affected.

If we are not able to obtain and enforce patent protection or other commercial protection for AV-101 or our pluripotent stem cell technologies, the value of AV-101 and our stem cell technologies and product candidates will be harmed.

Commercial protection of AV-101 and our proprietary pluripotent stem cell technologies is critically important to our business. Our success will depend in large part on our ability to obtain and enforce our patents and maintain trade secrets, both in the U.S. and in other countries.

Additional patents may not be granted, and our existing U.S. and foreign patents might not provide us with commercial benefit or might be infringed upon, invalidated or circumvented by others. In addition, the availability of patents in foreign markets, and the nature of any protection against competition that may be afforded by those patents, is often difficult to predict and vary significantly from country to country. We, our licensors, or our licensees may choose not to seek, or may be unable to obtain, patent protection in a country that could potentially be an important market for AV-101 and our stem cell technologies.

The patent positions of pharmaceutical and biopharmaceutical companies, including ours, are highly uncertain and involve complex legal and technical questions. In particular, legal principles for biotechnology patents in the U.S. and in other countries are evolving, and the extent to which we will be able to obtain patent coverage to protect our technology, or enforce issued patents, is uncertain.

For example, the European Patent Convention prohibits the granting of European patents for inventions that concern “uses of human embryos for industrial or commercial purposes”. The European Patent Office is presently interpreting this prohibition broadly, and is applying it to reject patent claims that pertain to human embryonic stem cells. However, this broad interpretation is being challenged through the European Patent Office appeals system. As a result, we do not yet know whether or to what extent we will be able to obtain European patent protection for our proprietary ES Cell-based technology and systems.

Publication of discoveries in scientific or patent literature tends to lag behind actual discoveries by at least several months and sometimes several years. Therefore, the persons or entities that we or our licensors name as inventors in our patents and patent applications may not have been the first to invent the inventions disclosed in the patent applications or patents, or the first to file patent applications for these inventions. As a result, we may not be able to obtain patents for discoveries that we otherwise would consider patentable and that we consider to be extremely significant to our future success.

Where several parties seek U.S. patent protection for the same technology, the U.S. Patent and Trademark Office (“U.S. PTO”) may declare an interference proceeding in order to ascertain the party to which the patent should be issued. Patent interferences are typically complex, highly contested legal proceedings, subject to appeal. They are usually expensive and prolonged, and can cause significant delay in the issuance of patents. Moreover, parties that receive an adverse decision in interference can lose patent rights. Our pending patent applications, or our issued patents, may be drawn into interference proceedings, which may delay or prevent the issuance of patents or result in the loss of issued patent rights. If more groups become engaged in scientific research related to ES Cells, the number of patent filings by such groups and therefore the risk of our patents or applications being drawn into interference proceedings may increase. The interference process can also be used to challenge a patent that has been issued to another party.

Outside of the U.S., certain jurisdictions, such as Europe, Japan, New Zealand and Australia, permit oppositions to be filed against the granting of patents. Because our intent is to commercialize our products internationally, securing both proprietary protection and freedom to operate outside of the U.S. is important to our business.

Patent opposition proceedings are not currently available in the U.S. patent system, but legislation is pending to introduce them. However, issued U.S. patents can be re-examined by the U.S. PTO at the request of a third party. Patents owned or licensed by us may therefore be subject to re-examination. As in any legal proceeding, the outcome of patent re-examinations is uncertain, and a decision adverse to our interests could result in the loss of valuable patent rights.

Successful challenges to our patents through interference, opposition or re-examination proceedings could result in a loss of patent rights in the relevant jurisdiction(s). As more groups become engaged in scientific research and product development areas of hES Cells, the risk of our patents being challenged through patent interferences, oppositions, re-examinations or other means will likely increase. If we institute such proceedings against the patents of other parties and we are unsuccessful, we may be subject to litigation, or otherwise prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those patents or develop or obtain alternative technologies, any of which could harm our business.

Furthermore, if such challenges to our patent rights are not resolved promptly in our favor, our existing business relationships may be jeopardized and we could be delayed or prevented from entering into new collaborations or from commercializing certain products, which could materially harm our business.

The confidentiality agreements that are designed to protect our trade secrets could be breached, and we might not have adequate remedies for the breach. Additionally, our trade secrets and proprietary know-how might otherwise become known or be independently discovered by others, all of which could materially harm our business.

We may have to engage in costly litigation to enforce or protect our proprietary technology, particularly our pluripotent stem cell technology and systems, or to defend challenges to our proprietary technology by our competitors, which may harm our business, results of operations, financial condition and cash flow.

Litigation may be necessary to protect our proprietary rights, especially our rights to our pluripotent stem cell technology and bioassay systems. Such litigation is expensive and would divert material resources and the time and attention of our management. We cannot be certain that we will have the required resources to pursue litigation or otherwise to protect our proprietary rights. In the event that we are unsuccessful in obtaining and enforcing patents, our business would be negatively impacted. Further, our patents may be challenged, invalidated or circumvented, and our patent rights may not provide proprietary protection or competitive advantages to us.

Patent litigation may also be necessary to enforce patents issued or licensed to us or to determine the scope and validity of our proprietary rights or the proprietary rights of others. We may not be successful in any patent litigation. An adverse outcome in a patent litigation, patent opposition, patent interference, or any other proceeding in a court or patent office could subject our business to significant liabilities to other parties, require disputed rights to be licensed from other parties or require us to cease using the disputed technology, any of which could severely harm our business.

We may be subject to litigation that will be costly to defend or pursue and uncertain in its outcome.

Our business may bring us into conflict with our licensees, licensors, or others with whom we have contractual or other business relationships, or with our competitors or others whose interests differ from ours. If we are unable to resolve such conflicts on terms that are satisfactory to all parties, we may become involved in litigation brought by or against us. Any such litigation is likely to be expensive and may require a significant amount of management’s time and attention, at the expense of other aspects of our business. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities, or otherwise affect our legal or contractual rights, which could have a significant adverse effect on our business.

Much 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 rely, in significant part, on trade secrets to protect our proprietary technologies, especially in circumstances that we believe patent protection is not appropriate or available. We attempt to protect our proprietary technologies 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.

We may be subject to infringement claims that are costly to defend, and which may limit our ability to use disputed technologies and prevents us from pursuing research and development or commercialization of potential products.

Our commercial success depends significantly on our ability to operate without infringing patents and the proprietary rights of others. Our technologies may infringe on the patents or proprietary rights of others. In addition, we may become aware of discoveries and technology controlled by third parties that are advantageous to our programs. In the event our technologies infringe the rights of others or we require the use of discoveries and technologies controlled by third parties, we may be prevented from pursuing research, development or commercialization of potential products or may be required to obtain licenses to those patents or other proprietary rights or develop or obtain alternative technologies. We have obtained licenses from several universities and companies for technologies that we anticipate incorporating into our *Human Clinical Trials in a Test Tube* ™ platform, and are in negotiation for licenses to other technologies. We may not be able to obtain a license to patented technology on commercially favorable terms, or at all. If we do not obtain a necessary license, we may need to redesign our technologies or obtain rights to alternate technologies, the research and adoption of which could cause delays in product development. In cases where we are unable to license necessary technologies, we could be prevented from developing certain potential products. Our failure to obtain alternative technologies or a license to any technology that we may require to research, develop or commercialize our product candidates would significantly and negatively affect our business.

Risks Related to Development, Clinical Testing and Regulatory Approval of Drug Candidates

We have limited experience as a corporation conducting clinical trials, or in other areas required for the successful commercialization and marketing of drug candidates.

We will need to receive regulatory approval for any product candidate before it may be marketed and distributed. Such approval will require, among other things, completing carefully controlled and well-designed clinical trials demonstrating the safety and efficacy of each product candidate. This process is lengthy, expensive and uncertain. As a company, we have limited experience in conducting clinical trials. Such trials will require additional financial and management resources, collaborators with the requisite clinical experience or reliance on third party clinical investigators, contract research organizations and consultants. Relying on third parties may force us to encounter delays that are outside of our control, which could materially harm our business.

We also do not currently have marketing and distribution capabilities for product candidates. Developing an internal sales and distribution capability would be an expensive and time-consuming process. We may enter into agreements with collaborators or third parties that would be responsible for marketing and distribution. However, these collaborators or third parties may not be capable of successfully selling any of our product candidates.

Because we and our collaborators must complete lengthy and complex development and regulatory approval processes required to market drug products in the U.S. and other countries, we cannot predict whether or when we or our collaborators will be permitted to commercialize our product candidates or product candidates to which we have commercial rights.

Federal, state and local governments in the U.S. and governments in other countries have significant regulations in place that govern many of our activities and may prevent us from creating commercially viable products derived from our drug rescue and stem cell therapy operations.

The regulatory process, particularly for pharmaceutical product candidates, is uncertain, can take many years and requires the expenditure of substantial resources. Any product candidate that we or our collaborators develop must receive all relevant regulatory agency approvals before it may be marketed in the U.S. or other countries. Biological drugs and non-biological drugs are rigorously regulated. In particular, human pharmaceutical therapeutic product candidates are subject to rigorous preclinical and clinical testing and other requirements by the FDA in the U.S. and similar health authorities in other countries in order to demonstrate safety and efficacy. Because our product candidates involve or are expected to involve the application of new technologies or are based upon new therapeutic approaches, they may be subject to substantial additional review by various government regulatory authorities, and, as a result, the process of obtaining regulatory approvals for them may proceed more slowly than for drug candidates based upon more conventional technologies. We may never obtain regulatory approval to market our drug candidates.

Data obtained from preclinical and clinical activities is susceptible to varying interpretations that could delay, limit or prevent regulatory agency approvals. In addition, delays or rejections may be encountered as a result of changes in regulatory agency policy during the period of product development and/or the period of review of any application for regulatory agency approval for a product candidate. Delays in obtaining regulatory agency approvals could significantly harm the marketing of any product that we or our collaborators develop, impose costly procedures upon our activities or the activities of our collaborators, diminish any competitive advantages that we or our collaborators may attain, or adversely affect our ability to receive royalties and generate revenues and profits.

If we obtain regulatory agency approval for a new product, this approval may entail limitations on the indicated uses for which it can be marketed that could limit the potential commercial use of the product. Additionally, approved products and their manufacturers are subject to continual review, and discovery of previously unknown problems with a product or its manufacturer may result in restrictions on the product or manufacturer, including withdrawal of the product from the market. The sale by us or our collaborators of any commercially viable product will be subject to government regulation from several standpoints, including the processes of manufacturing, advertising and promoting, selling and marketing, labeling and distribution. Failure to comply with regulatory requirements can result in severe civil and criminal penalties, including but not limited to product recall or seizure, injunction against product manufacture, distribution, sales and marketing and criminal prosecution. The imposition of any of these penalties could significantly impair our business, financial condition and results of operations.

Entry into clinical trials with one or more drug or biologic candidates may not result in any commercially viable products.

We may never generate revenues from product sales because of a variety of risks inherent in our business, including the following risks:

- clinical trials may not demonstrate the safety and efficacy of our drug rescue variants or stem cell therapies;
- completion of clinical trials may be delayed, or costs of clinical trials may exceed anticipated amounts;
- we may not be able to obtain regulatory approval of our drug rescue variants or biologics, or may experience delays in obtaining such approval;
- we may not be able to manufacture our drug rescue variants economically on a commercial scale;
- we and any licensees of ours may not be able to successfully market our drug rescue variants;
- physicians may not prescribe our products, or patients or third party payors may not accept our drug rescue variants or stem cell therapies;
- others may have proprietary rights which prevent us from marketing our drug rescue variants or stem cell therapies; and
- competitors may sell similar, superior or lower-cost products.

To be successful, our drug rescue variants and stem cell therapies must be accepted by the healthcare community, which can be very slow to adopt or unreceptive to new technologies and products.

Our drug rescue variants and stem cell therapies, if approved for marketing, may not achieve market acceptance because hospitals, physicians, patients or the medical community in general may decide not to accept and utilize these products. The drug rescue variants and stem cell therapies that we are attempting to develop may represent substantial departures from established treatment methods and will compete with a number of conventional drugs and therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- our establishment and demonstration to the medical community of the clinical efficacy and safety of our drug rescue variants and stem cell therapies;
- our ability to create product candidates that are superior to alternatives currently on the market;
- our ability to establish in the medical community the potential advantage of our treatments over alternative treatment methods; and
- reimbursement policies of government and third-party payors.

If the healthcare community does not accept our developed drug rescue variants or stem cell therapies for any of the foregoing reasons, or for any other reason, our business would be materially harmed.

Risks Related to Our Dependence on Third Parties

Our reliance on the activities of our non-employee advisors, consultants, research institutions and scientific contractors, whose activities are not wholly within our control, may lead to delays in development of our product candidates.

We rely upon and have relationships with scientific consultants at academic and other institutions, some of whom conduct research at our request, and other advisors, contractors and consultants with expertise in drug discovery, drug development, medicinal chemistry, regulatory strategy, corporate development or other matters. These parties are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. We have limited control over the activities of our advisors, consultants and contractors and, except as otherwise required by our collaboration and consulting agreements, can expect only limited amounts of their time to be dedicated to our activities.

In addition, we have formed, and anticipate forming, sponsored research collaborations with academic and other research institutions throughout the world. We are highly dependent on these sponsored research collaborations for the development of our intellectual property. These research facilities may have commitments to other commercial and non-commercial entities. There can also be no assurances that any intellectual property will be created from our sponsored research collaborations and, even if it is created, that the intellectual property will have any value or application to our business. We have limited control over the operations of these laboratories and can expect only limited amounts of their time to be dedicated to our research goals.

If any third party with whom we have or enter into a relationship is unable or refuses to contribute to projects on which we need their help, our ability to generate advances in our technologies and develop our product candidates could be significantly harmed.

Our business model involves reliance on collaborations with other companies.

Our business model contemplates making arrangements with third parties:

- to access failed drug candidates to rescue and develop;
- to license drug rescue variants that we develop; and
- to perform stem cell research and development and supply services, such as medicinal chemistry, that is our key to our future success.

Our strategy is to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others for the research, development and clinical testing. There can be no assurance, however, that we will be able to establish such additional collaborations on favorable terms, if at all, or that our current or future collaborative arrangements will be successful.

Should any collaborator fail to develop or commercialize successfully any product candidates to which it has rights, or any of the collaborator's product candidates to which we may have rights, our business may be adversely affected. In addition, while we believe that collaborators will have sufficient economic motivation to continue their funding, there can be no assurance that any of these collaborations will be continued or result in successfully commercialized product candidates. Failure of a collaborator to continue funding any particular program could delay or halt the development or commercialization of any product candidates arising out of such program. In addition, there can be no assurance that the collaborators will not pursue alternative technologies, change strategy, re-allocate resources, terminate our agreement, develop alternative product candidates either on their own or in collaboration with others, including our competitors.

If a conflict of interest arises between us and one or more of our collaborators, they may act in their own self-interest and not in our interest or in the interest of our shareholders. Some of our collaborators are conducting, and any of our future collaborators may conduct, multiple product candidate development efforts within the disease area that is the subject of collaboration with us.

Given these risks, our current and future collaborative efforts with third parties may not be successful. Failure of these efforts could require us to devote additional internal resources to the activities currently performed, or to be performed, by third parties, to seek alternative third-party collaborators, or to delay product candidate development or commercialization, which could have a material adverse effect on our business, financial conditions or results of operations.

Risks Related to Our Operations

We depend on key scientific and management personnel and collaborators for the implementation of our business plan, the loss of whom would slow our ability to conduct research and develop and impair our ability to compete.

Our future success depends to a significant extent on the skills, experience and efforts of our executive officers and key employees of our scientific staff. Competition for personnel is intense and we may be unable to retain our current personnel, attract or assimilate other highly qualified management and scientific personnel in the future. The loss of any or all of these individuals would result in a significant loss in the knowledge and experience that we, as an organization, possess and could harm our business and might significantly delay or prevent the achievement of research, development or business objectives. Our management and key employees can terminate their employment with us at any time.

We also rely on consultants, advisors and strategic collaborators, especially our strategic collaboration with Dr. Gordon Keller, who assists us in formulating our stem cell research and development strategies. We face intense competition for qualified individuals from numerous pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions. We may not be able to attract and retain these individuals on acceptable terms. Failure to do so could materially harm our business.

Although the current term of our sponsored research collaboration agreement with UHN and Dr. Keller does not expire until September 2017, there can be no assurances that we will be able to renew or extend the agreement beyond 2017 on mutually agreeable terms. Additionally, there can be no assurances that we will receive any invention notices or secure a license to any intellectual property resulting from such sponsored research.

We will need to hire additional highly specialized, skilled personnel to achieve our business plan. Our inability to hire qualified personnel in a timely manner will harm our business.

Our ability to execute on our business plan will largely depend on the talents and efforts of highly skilled individuals with specialized training in the field of stem cell research and drug candidate screening. Our future success depends on our ability to identify, hire and retain these highly skilled personnel during our early stages of development. Competition in our industry for qualified employees with the specialized training we require is intense. In addition, our compensation arrangements may not always be successful in attracting the new employees we require. Our ability to execute our drug rescue business model effectively depends on our ability to attract these new employees.

Our activities involve hazardous materials, and improper handling of these materials by our employees or agents could expose us to significant legal and financial penalties.

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. As a consequence, we are subject to numerous environmental and safety laws and regulations, including those governing laboratory procedures exposure to blood-borne pathogens and the handling of bio-hazardous materials. We may be required to incur significant costs to comply with current or future environmental laws and regulations and may be adversely affected by the cost of compliance with these laws and regulations.

Although we believe that our safety procedures for using, handling, storing and disposing of hazardous materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, state or federal authorities could curtail our use of these materials and we could be liable for any civil damages that result, the cost of which could be substantial. Further, any failure by us to control the use, disposal, removal or storage, or to adequately restrict the discharge, or assist in the cleanup, of hazardous chemicals or hazardous, infectious or toxic substances could subject us to significant liabilities, including joint and several liability under certain statutes. Any such liability could exceed our resources and could have a material adverse effect on our business, financial condition and results of operations. Additionally, an accident could damage our research and manufacturing facilities and operations.

Additional federal, state and local laws and regulations affecting us may be adopted in the future. We may incur substantial costs to comply with these laws and regulations and substantial fines or penalties if we violate any of these laws or regulations.

We may not be able to obtain or maintain sufficient insurance on commercially reasonable terms or with adequate coverage against potential liabilities in order to protect ourselves against product liability claims.

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic products and testing technologies. We may become subject to product liability claims if the use of our potential products is alleged to have injured subjects or patients. This risk exists for product candidates tested in human clinical trials as well as potential products that are sold commercially. In addition, product liability insurance is becoming increasingly expensive. As a result, we may not be able to obtain or maintain product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities that could have a material adverse effect on our business.

Our business is subject to the risks of earthquakes, fire, floods and other natural catastrophic events, and to interruption by man-made problems such as computer viruses or terrorism.

Our corporate headquarters are located in the San Francisco Bay Area, a region known for seismic activity. A significant natural disaster, such as an earthquake, fire or a flood, could harm our business. In addition, our servers are vulnerable to computer viruses, break-ins and similar disruptions from unauthorized tampering with our computer systems. In addition, acts of terrorism or war could cause disruptions in our business or the economy as a whole.

We may select and develop product candidates that fail.

We may select for development and expend considerable resources including time and money on product candidates that fail to complete trials, obtain regulatory approval or achieve sufficient sales, if any, to be profitable**.**

Additional Risks

Our principal shareholders and management own a significant percentage of our stock and will be able to exercise significant influence.

Our executive officers, directors and principal shareholders and their affiliates own a significant percentage of our outstanding capital stock. Accordingly, these shareholders may be able to determine the composition of a majority of our Board of Directors, retain the voting power to approve certain matters requiring shareholder approval, and continue to have significant influence over our affairs. This concentration of ownership could have the effect of delaying or preventing a change in our control. See Item 4 of this report, “Security Ownership of Certain Beneficial Owners and Management” for further information about the ownership of our capital stock by our executive officers, directors, and principal shareholders.

If we require future capital, we may not be able to secure additional funding in order to expand our operations and develop new products.

We may seek additional funds from public and private stock offerings, borrowings under lease lines of credit, or other sources. This additional financing may not be available on a timely basis on terms acceptable to us, or at all. Additional financing may be dilutive to shareholders or may require us to grant a lender a security interest in our assets. The amount of money we will need will depend on many factors, including:

- revenues generated, if any;
- development expenses incurred;
- the commercial success of our research and development efforts; and
- the emergence of competing technological developments.

If adequate funds are not available, we may have to delay development or commercialization of our product candidates and technologies or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support, or other resources devoted to our products and technologies. Any of these results would materially harm our business, financial condition and results of operations.

The market price of our Common Stock will fluctuate significantly in response to factors, some of which are beyond our control.

We anticipate that the market price of our Common Stock will fluctuate significantly in response to many factors, some of which are beyond our control, including the announcement of new products or product enhancements by us or our competitors, developments concerning intellectual property rights and regulatory approvals, quarterly variations in our and our competitors’ results of operations, changes in earnings estimates or recommendations by any securities analysts, developments in our industry, and general market conditions and other factors, including factors unrelated to our own operating performance or the condition or prospects of the biotechnology industry.

Further, the stock market in general, and securities of small-cap companies in particular, have recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our Common Stock, which could cause a decline in the value of our Common Stock. You should also be aware that price volatility might be worse if the trading volume of our Common Stock is low.

There may not ever be an active market for our Common Stock.

Although our Common Stock is quoted on the OTC Bulletin Board, our public float is currently limited and trading of our Common Stock may be extremely sporadic. For example, several days may pass before any shares are traded. There can be no assurance that an active market for our Common Stock will develop. Accordingly, investors must bear the economic risk of an investment in our Common Stock for an indefinite period of time.

Because we became a public company by means of a strategic reverse merger, we may not be able to attract the attention of investors or major brokerage firms.

Because we became a public company by means of a strategic reverse merger transaction rather than through a traditional initial public offering involving an investment banking or brokerage firm, securities analysts or major brokerage firms may not provide coverage of us because there may be limited incentive to recommend the purchase of our Common Stock.

Because we became a public company as a result of a reverse merger with a public shell, unknown liabilities may adversely affect our financial condition.

We became a public company by means of a strategic reverse merger with a public shell. While management conducted extensive due diligence prior to consummating our strategic reverse merger, in the event the public shell contained undisclosed liabilities, and management was unable to address or otherwise offset such liabilities, such liabilities may materially, and adversely affect our financial condition. As a result of the risks associated with unknown liabilities, potential investors may be unsure or unwilling to invest in the Company.

We will incur significant costs to ensure compliance with corporate governance, federal securities law and accounting requirements.

Since becoming a public company by means of a strategic reverse merger, we are subject to the periodic reporting and other requirements of the federal securities laws, rules and regulations. We have incurred and will incur significant costs to comply with such requirements, including accounting and related auditing costs, and costs to comply with corporate governance and other costs of operating a public company. The filing and internal control reporting requirements imposed by federal securities laws, rules and regulations are rigorous and we may not be able to meet them, resulting in a possible decline in the price of our common stock and our inability to obtain future financing. Any failure to comply or adequately comply with federal securities laws, rules or regulations could subject us to fines or regulatory actions, which may materially adversely affect our business, results of operations and financial condition.

Our compliance with the Sarbanes-Oxley Act and SEC rules concerning internal controls may be time consuming, difficult and costly.

Our management team has limited experience as officers of a publicly-traded company, and we have never operated as a publicly-traded company. It may be time consuming, difficult and costly for us to develop and implement the internal controls and reporting procedures required by Sarbanes-Oxley. We will need to hire additional financial reporting, internal controls and other finance staff in order to develop and implement appropriate internal controls and reporting procedures. If we are unable to comply with Sarbanes-Oxley's internal controls and disclosure requirements, we may not be able to obtain the independent registered public accounting firm attestations that Sarbanes-Oxley Act requires publicly-traded companies to obtain. If it is determined that we have a material weakness in our internal control over financial reporting, we could incur additional costs and suffer adverse publicity and other consequences of any such determination.

We cannot assure you that our Common Stock will be liquid or that our Common Stock will be listed on the New York Stock Exchange, the Nasdaq Stock Market, or other similar exchanges.

We do not yet meet the initial listing standards of the New York Stock Exchange, the Nasdaq Stock Market, or other similar exchanges. Until our Common Stock is listed on an exchange, we anticipate that it will remain quoted on the OTC Bulletin Board, another over-the-counter quotation system, or in the "pink sheets." In those venues, however, investors may find it difficult to obtain accurate quotations as to the market value of our Common Stock. In addition, if we failed to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our Common Stock, which may further affect their liquidity. This would also make it more difficult to raise additional capital.

There may be issuances of shares of Preferred Stock in the future.

Although we do not currently have any shares of Preferred Stock outstanding, we are authorized to issue up to 10.0 million shares of Preferred Stock. As a result, our Board of Directors could authorize an amendment of our Articles of Incorporation to authorize the issuance of a series of Preferred Stock in the future and such Preferred Stock could grant holders preferred rights to our assets upon liquidation, the right to receive dividends before dividends would be declared to holders of our Common Stock, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the Common Stock. In the event and to the extent that we do issue Preferred Stock in the future, the rights of holders of our Common Stock could be impaired thereby, including without limitation, with respect to liquidation.

Our Common Stock may be considered a "penny stock."

The Securities and Exchange Commission ("SEC") has adopted regulations which generally define "penny stock" to be an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. In the event that the market price of our Common Stock is less than $5.00 per share and therefore may be considered a "penny stock," broker and dealers effecting transactions in our Common Stock must disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell our Common Stock and may affect your ability to sell the shares of our Common Stock. In addition, as long as our Common Stock remains quoted on the OTC Bulletin Board, investors may find it difficult to obtain accurate quotations of the stock, and may find few buyers to purchase such stock and few market makers to support its price.

We do not intend to pay cash dividends on our Common Stock in the foreseeable future.

We have never declared or paid any dividends on our shares of Common Stock and we do not currently anticipate paying any such dividends in the foreseeable future. Any payment of cash dividends will depend upon our financial condition, contractual restrictions, financing agreement covenants, solvency tests imposed by corporate law, results of operations, anticipated cash requirements and other factors and will be at the discretion of our Board of Directors. Furthermore, we may incur indebtedness that may severely restrict or prohibit the payment of dividends.

We are at risk of securities class action litigation that could result in substantial costs and divert management's attention and resources.

In the past, securities class action litigation has been brought against a company following periods of volatility in the market place of its securities, particularly following the company's initial public offering. Due to the potential volatility of our stock price, we may be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources.

ITEM 5. DIRECTORS AND EXECUTIVE OFFICERS

Our senior management is composed of individuals with significant management experience. The following table sets forth specific information regarding our executive officers and directors as of the date of this report:

Name	Age	Position
Shawn K. Singh, J.D.	48	Chief Executive Officer and Director
H. Ralph Snodgrass, Ph.D. [3]	61	President, Chief Scientific Officer and Director
A. Franklin Rice, MBA	57	Chief Financial Officer and Secretary
Jon S. Saxe	74	Director
Stephanie Y. Jones [1]	37	Director
Matthew L. Jones [2]	42	Director
Gregory A. Bonfiglio, J.D.[3]	58	Director
Brian J. Underdown, PhD. [3]	70	Director

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[1] Former President and Chief Executive Officer prior to May 11, 2011 and current director until the expiration of the Rule 14f-1 Notice Review Period.

[2] Current director until the expiration of the Rule 14f-1 Notice Review Period.

[3] We anticipate that Dr. Snodgrass, Mr. Bonfiglio and Mr. Underdown will become directors upon the expiration of the Rule 14f-1 Notice Review Period.

The following is a brief summary of the background of each of our executive officers, and directors, including their principal occupation during the five preceding years. All directors serve until their successors are elected and qualified.

Shawn K. Singh, J.D. joined as VistaGen's Chief Executive Officer in August 2009; he joined VistaGen's Board of Directors in 2000. Upon completion of the Merger, Mr. Singh became Chief Executive Officer and a director of Excaliber. Mr. Singh served on VistaGen's management team on a part-time basis from late-2003, following VistaGen's acquisition of Artemis Neuroscience, of which he was President, to August 2009. Mr. Singh has 20 years of experience working with biotechnology, medical device and pharmaceutical companies, both private and public. From February 2001 to August 2009, Mr. Singh served as Managing Principal of Cato BioVentures, a life science venture capital firm and one of our largest institutional investors, and as Chief Business Officer and General Counsel of Cato Research, a global contract research organization affiliated with Cato BioVentures. Mr. Singh served as President (part-time) of Echo Therapeutics (OTCBB: ECTE), from September 2007 to June 2009 and as Chief Executive Officer (part-time) of Hemodynamic Therapeutics from November 2004 to August 2009. From late-2000 to February 2001, Mr. Singh served as Managing Director of Start-Up Law, a management consulting firm serving early-stage biotechnology companies. Mr. Singh served as Chief Business Officer of SciClone Pharmaceuticals (Nasdaq: SCLN) from late-1993 to late-2000 and as a corporate finance associate of Morrison & Foerster LLP, an international law firm, from 1991 to late-1993. Mr. Singh also currently serves as a member of the Board of Directors of Echo Therapeutics (OTCBB: ECTE), a medical device company focused on diabetes management, Armour Therapeutics, a privately-held company focused on prostate cancer, and Hemodynamic Therapeutics, a privately-held company focused on cardiovascular disease. Mr. Singh is a member of the State Bar of California.

The Nominating and Corporate Governance Committee believes that Mr. Singh possesses substantial expertise in senior leadership roles leading biotechnology, biopharmaceutical and medical device companies from product introduction through commercialization, and that such expertise is extremely valuable to the Board of Directors and the Company as it executes its business plan. In addition, the Board of Directors values the input provided by Mr. Singh given his extensive legal and venture capital experience working with multiple privately- and publicly-held biotechnology, pharmaceutical and medical device companies.

H. Ralph Snodgrass, Ph.D. founded VistaGen in 1998 and served as VistaGen's Chief Executive Officer until August 2009. Upon completion of the Merger, Dr. Snodgrass became our President and Chief Scientific Officer. Dr. Snodgrass will become a director of Excaliber upon the effective date of the resignations of Stephanie Y. Jones and Matthew L. Jones. Prior to joining us, Dr. Snodgrass was a key member of the executive management team which lead Progenitor, Inc., a biotechnology company focused on developmental biology, through its initial public offering, and was its Chief Scientific Officer from June 1994 to May 1998, and its Executive Director from July 1993 to May 1994. He received his Ph.D. in immunology from the University of Pennsylvania, and has more than 15 years of experience in senior biotechnology management and over 10 years research experience as a professor at the Lineberger Comprehensive Cancer Center, University North Carolina Chapel Hill School of Medicine, and as a member of the Institute for Immunology, Basel, Switzerland. Dr. Snodgrass is a past Board Member of the Emerging Company Section of the Biotechnology Industry Organization (BIO), and past member of the International Society Stem Cell Research Industry Committee. Dr. Snodgrass has published more than 50 scientific papers, is the inventor on more than 17 patents and a number of patent applications, is, or has been, the principal investigator on U.S. federal and private foundation sponsored research grants with budgets totaling more than $14.5 million and is recognized as an expert in stem cell biology with more than 17 years experience in the uses of stem cells as biological tools for drug discovery and development.

The Nominating and Corporate Governance Committee believes that Dr. Snodgrass' expertise in biotechnology focused on developmental biology, including stem cell biology, his extensive senior management experience leading biotechnology companies at all stages of development, as well as his reputation and standing in the fields of biotechnology and stem cell research, allow him to bring to the Company and the Board of Directors a unique understanding of the challenges and opportunities associated with pluripotent stem cell biology, as well as credibility in the markets in which the Company operates.

A. Franklin Rice, MBA serves as VistaGen's Chief Financial Officer and Secretary. Since joining VistaGen in 1999, Mr. Rice has previously served as Senior Vice President, Finance and Administration and Vice President, Business Development of VistaGen. Upon completion of the Merger, Mr. Rice became our Chief Financial Officer and Secretary. Mr. Rice has been employed in the biotechnology industry since 1988 during which time he has held positions of increasing responsibility. From 1988 to 1998, Mr. Rice served as Senior Director of Business Development at Genencor International and from 1998 to 1999 as Vice President of Biotechnology and Pharmaceuticals for Bechtel Group where he was responsible for global sales and marketing of consulting services to biotechnology and pharmaceutical companies. Mr. Rice serves on the Board of Directors of PrognosDx Health, Inc. Mr. Rice earned his B.S.Ch.E. with honors from Clarkson University, an MBA degree with a double major in finance and marketing from University of Rochester's Simon School of Business and a second Master's degree in business from Massachusetts Institute of Technology.

Jon S. Saxe, J.D. has served as Chairman of VistaGen's Board of Directors since 2000. He was also the Chairman of VistaGen's Audit Committee. Upon completion of the Merger, Mr. Saxe became a director of Excaliber. He is the retired President and was a director of PDL BioPharma. From 1989 to 1993, he was President, Chief Executive Officer and a director of Synergen, Inc. (acquired by Amgen). Mr. Saxe served as Vice President, Licensing & Corporate Development for Hoffmann-Roche from 1984 through 1989, and Head Patent Law from 1978 through 1989. Mr. Saxe currently is a director of SciClone Pharmaceuticals, Inc. (Nasdaq: SCLN) and Durect Corporation (Nasdaq: DRRX), and two private biotechnology companies, Arbor Vita Corporation and Arcuo Medical, LLC. Mr. Saxe also has served as a director of other biotechnology and pharmaceutical companies, including ID Biomedical (acquired by GlaxoSmithKline), Sciele Pharmaceuticals, Inc. (acquired by Shionogi), Amalyte (acquired by Kemin Industries), Cell Pathways (acquired by OSI Pharmaceuticals), and other companies, both public and private. Mr. Saxe has a B.S.Ch.E. from Carnegie-Mellon University, a J.D. degree from George Washington University and an LL.M. degree from New York University.

The Nominating and Corporate Governance Committee believes that Mr. Saxe's years of experience as a senior executive with major biopharmaceutical and biotechnology companies, including Protein Design Labs, Inc., Synergen, Inc. and Hoffmann-Roche, Inc. as well as his experience serving as a director of numerous private and public biotechnology and pharmaceutical companies, serving as Chairman, and Chair and member of audit, compensation and governance committees of both private and public companies, provides the Company and the Board of Directors with highly valuable insight and perspective into the biotechnology and pharmaceutical industries, as well as the strategic opportunities and challenges facing the Company.

Stephanie Y. Jones was the President and Chief Executive Officer prior to the Merger and is currently a director of Excaliber. On the date of the Merger, Mrs. Jones submitted her resignation as a director, which will become effective upon the expiration of the Rule 14f-1 Notice Review Period. Mrs. Jones is a bookkeeper for Finishing Touch Lawn Maintenance in Rathdrum, Idaho. Her responsibilities include maintaining accounts payable and receivable and managing customer accounts. She has been in her present position since 2001. Mrs. Jones was previously an elementary school teacher for four years, between 1998 and 2002, at Falls Christian Academy, a private school located in Rathdrum, Idaho, where she taught kindergarten. Prior to her teaching position, Mrs. Jones was a stay-at-home mother, where she began creating gift baskets in her spare time. She attended Northern Idaho College from 1991 to 1993.

Matthew L. Jones is currently a director of Excaliber. On the date of the Merger, Mr. Jones submitted his resignation as a director, which will become effective upon the expiration of the Rule 14f-1 Notice Review Period. Mr. Jones has been employed by Huntwood Industries in Liberty Lake, Washington as a Sales Representative in the custom cabinetry department since October 2005. Mr. Jones was employed by La Mesa RV in Liberty Lake, Washington from 2004 through 2005, where he was a sales representative for several lines of Recreational Vehicles. From 2001 to 2004, Mr. Jones was a department manager at Lowes Home Improvement Center in Rathdrum, Idaho. From 1995 to 2001, he had an active real estate license and was a broker at Coldwell Banker Real Estate in Rathdrum, Idaho. Mr. Jones attended Northern Idaho College from 1991 to 1993. He is a disabled veteran.

Gregory A. Bonfiglio, J.D. joined VistaGen's Board of Directors in February 2007 and will become a director of Excaliber upon the effective date of the resignations of Stephanie Y. Jones and Matthew L. Jones. Mr. Bonfiglio has over 25 years experience working with technology companies. In January 2006, he founded Proteus, LLC and has acted as the managing partner of such company since then. Proteus is an investment and advisory firm focused solely on regenerative medicine ("RM"). Proteus operates three separate businesses: Proteus Venture Partners, which manages RM funds; Proteus Insights, which provides strategic consulting services to RM companies regarding funding, commercialization, clinical development, market entry, and sector analyses; and Proteus Advisors, which provides fundraising and M&A services to RM companies. Mr. Bonfiglio is a Member of the International Society for Stem Cell Research (ISSCR) and is on its Advisory Board, as well as their Industry and Finance Committees. He is also a Member of the International Society for Cellular Therapy (ISCT) and is on its Commercialization Committee. From 2000 through 2005, Mr. Bonfiglio was a General Partner of Anthem Venture Partners, an early-stage venture fund focused on both biotechnology and information technology. Prior to joining Anthem, he was a Partner with Morrison & Foerster LLP, an international law firm, where he worked extensively with technology companies. Mr. Bonfiglio was an Adjunct Professor of Law at Stanford Law School, from 1996 to 2000. Since 1995, he has been a regular Guest Lecturer at the UC Berkley Haas Business School in the Top Down Law program. Mr. Bonfiglio received his B.A. in Mathematics (*magna cum laude*) from Michigan State University in 1975, and his J.D. (*magna cum laude*) from the University of Michigan Law School in 1981.

The Nominating and Corporate Governance Committee believes that Mr. Bonfiglio brings to the Board of Directors and the Company valuable finance and sector analytical experience given his position with Proteus, LLC, and Proteus' extensive experience working with development stage companies focused on regenerative medicine. This experience, combined with his venture capital experience, is anticipated to provide substantial value to the Board of Directors as it capitalizes on the opportunities presented by our pluripotent stem cell biology platform.

Brian J. Underdown, Ph.D. joined VistaGen's Board of Directors in November 2009 and will become a director of Excaliber upon the effective date of the resignations of Stephanie Y. Jones and Matthew L. Jones. Since September 1997, Dr. Underdown has served as the Managing Director of Lumira Capital Corp., having started in the venture capital industry in 1997 with MDS Capital Corporation (MDSCC). His investment focus has been on therapeutics in both new and established companies in both Canada and the United States. Prior to joining MDSCC, Dr. Underdown held a number of senior management positions in the biopharmaceutical industry and at universities. Dr. Underdown's past and current board positions include: ID Biomedical, Trillium Therapeutics, Cytochroma Inc., Argos Therapeutics, Nysa Membrane Technologies, Ception Therapeutics and Transmolecular Therapeutics. He has served on a number of Boards and advisory bodies of government sponsored research organizations including CANVAC, the Canadian National Centre of Excellence in Vaccines, Ontario Genomics Institute, Allergen, the Canadian National Centre of Excellence in Allergy and Asthma. Dr. Underdown obtained his Ph.D. in immunology from McGill University and undertook post-doctoral studies at Washington University School of Medicine.

The Nominating and Corporate Governance Committee believes that Dr. Underdown's extensive background working in the biotechnology and pharmaceutical industries, as a director of numerous private and public companies, as well as his venture capital experience funding and advising start-up and established companies focused on therapeutics, provides the Company and its Board of Directors with an in-depth understanding of the myriad of issues facing the Company, from funding development to executing its business plan.

Each of our executive officers is elected by, and serves at the discretion of, the Board of Directors. Each of our executive officers devotes his full time to our affairs.

Family Relationships

Stephanie Y. Jones and Matthew L. Jones are husband and wife.

Board Composition and Committees

The Board of Directors is currently composed of four members, Jon S. Saxe, Shawn K. Singh, Stephanie Y. Jones and Matthew Jones. Mr. and Mrs. Jones have submitted their resignations as directors which will become effective upon the expiration of the Rule 14f-1 Notice Review Period. We anticipate H. Ralph Snodgrass, Gregory A. Bonfiglio and Brian J. Underdown will be appointed as our directors upon the expiration of the Rule 14f-1 Notice Review Period. All actions of the Board of Directors require the approval of a majority of the directors in attendance at a meeting at which a quorum is present.

We currently do not have a standing Audit Committee, Compensation Committee or a Corporate Governance and Nominating Committee. Currently, our entire Board of Directors is responsible for the functions that would otherwise be handled by these committees. However, subsequent to the filing of the Original Report, we established an Audit Committee, a Compensation Committee and a Corporate Governance and Nominating Committee of our Board of Directors, with each Committee comprised of our independent directors consisting of Messrs. Saxe, Bonfiglio and Underdown . The Audit Committee is primarily responsible for reviewing the services performed by our independent auditors, evaluating our accounting policies and our system of internal controls. The Compensation Committee is primarily responsible for reviewing and approving our salary and benefits policies (including stock options) and other compensation of our executive officers. The Corporate Governance and Nominating Committee is responsible for identifying and recommending nominees to our Board of Directors and overseeing compliance with our corporate governance guidelines. Our Board of Directors has made a determination that Mr. Saxe is an audit committee financial expert.

ITEM 15. FINANCIAL STATEMENTS AND EXHIBITS

(b) Exhibit Index:

Exhibit No.	Description
10.46	Notice of Award by National Institutes of Health, Small Business Innovation Research Program, to VistaGen Therapeutics, Inc. for project, Clinical Development of 4-CI-KYN to Treat Pain dated June 22, 2009, with revisions dated July 19, 2010 and August 9, 2011.
10.47	Notice of Grant Award by California Institute of Regenerative Medicine and VistaGen Therapeutics, Inc. for Project: Development of an hES Cell-Based Assay System for Hepatocyte Differentiation Studies and Predictive Toxicology Drug Screening, dated April 1, 2009.

SIGNATURES

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

VISTAGEN THERAPEUTICS, INC.

By: /s/ Jerrold D. Dotson
Jerrold D. Dotson
Acting Chief Financial Officer

Dated: December 20, 2011

EXHIBITS

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EXHIBIT 10.46

Notice of Award

Issue Date: 06/22/2009

SMALL BUSINESS INNOVATION RESEARCH PROG
Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON DRUG ABUSE

Grant Number: 2R44DA018515-02
Principal Investigator(s):
Ralph Snodgrass, PHD

Project Title: Clinical Development of 4-Cl-KYN to Treat Pain

Rice, Franklin
EVP Finance and Administration
384 Oyster Point Blvd #8
South San Francisco, CA 94080

Budget Period: 07/01/2009 - 06/30/2010
Project Period: 07/01/2004 - 06/30/2011

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $2,469,281 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to VISTAGEN THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 15 USC 638 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release or other document that cites results from NIH grant-supported research must include an acknowledgment of NIH grant support and disclaimer such as "The project described was supported by Award Number R44DA018515 from the National Institute On Drug Abuse. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute On Drug Abuse or the National Institutes of Health."

Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central (PMC), upon acceptance for publication, an electronic version of a final peer-reviewed, manuscript resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit http://publicaccess.nih.gov/.

Award recipients must promote objectivity in research by establishing standards to ensure that the design, conduct and reporting of research funded under NIH-funded awards are not biased by a conflicting financial interest of an Investigator. Investigator is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of NIH-funded research or proposed research, including the Investigator's spouse and dependent children. Awardees must have a written administrative process to identify and manage financial conflict of interest and must inform Investigators of the conflict of interest policy and of the Investigators' responsibilities. Prior to expenditure of these awarded funds, the Awardee must report to the NIH Awarding Component the existence of a conflicting interest and within 60 days of any new conflicting interests identified after the initial report. Awardees must comply with these and all other aspects of 42 CFR Part 50, Subpart F. These requirements also apply to subgrantees, contractors, or collaborators engaged by the Awardee under this award. The NIH website http://grants.nih.gov/grants/policy/coi/index.htm provides additional information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Pamela G. Fleming
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

SECTION I – AWARD DATA – 2R44DA018515-02

Award Calculation (U.S. Dollars)	
Salaries and Wages	$70,390
Fringe Benefits	$16,894
Consultant Services	$24,000
Supplies	$829,280
Consortium/Contractual Cost	$960,949
Federal Direct Costs	$1,901,513
Federal F&A Costs	$406,226
Approved Budget	$2,307,739
Fee	$161,542
Federal Share	$2,469,281
TOTAL FEDERAL AWARD AMOUNT	$2,469,281
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$2,469,281

SUMMARY TOTALS FOR ALL YEARS

YR	THIS AWARD	CUMULATIVE TOTALS
2	$2,469,281	$2,469,281
3	$1,714,903	$1,714,903

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

Fiscal Information:

CFDA Number:	93.279
EIN:	1943301660A1
Document Number:	RDA018515B
Fiscal Year:	2009

IC	CAN	2009	2010
DA	8742672	$2,469,281	$1,714,903

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

NIH Administrative Data:
PCC: MF/AP1 / **OC:** 414B / **Processed:** PFLEMING 06/18/2009

SECTION II – PAYMENT/HOTLINE INFORMATION – 2R44DA018515-02

For payment and HHS Officer of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 2R44DA018515-02

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45CFR Part 74 or 45 CFR Part 92 as applicable.
d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at 'http://grants.nih.gov/grants/policy/awardconditions.htm' for certain references cited above.)

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory.
For more information, see NOT-OD-08-033 and the Public Access website:
http://publicaccess.nih.gov/

Treatment of Program Income:
Additional Costs

SECTION IV – DA Special Terms and Conditions – 2R44DA018515-02

PAYMENT INFORMATION: The awardee organization will receive information and forms from the Division of Payment Management of the Department of Health and Human Services regarding requests for cash, manners of payment, and associated reporting requirements. Payment may be made on a cost-reimbursement or advance basis. Cost reimbursements may be requested monthly, quarterly or at other periodic intervals. Advance payments may be requested on a monthly basis only. The telephone number for the Payment Management System Office is 1-877-614-5533. The Division of Payment Management website is: http://www.dpm.psc.gov/

INTELLECTUAL PROPERTY RIGHTS: Normally, the awardee organization retains the principal worldwide patent rights to any invention developed with United States Government support. Under Title 37 Code of Federal Regulations Part 401, the Government receives a royalty-free license for its use, reserves the right to require the patent holder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it substantially in the United States.

Rights and obligations related to inventions created or reduced to practice as a result of this award are detailed in 35 U.S.C. 205 and 37 CFR Part 401. These inventions must be reported to the Extramural Invention Reporting and Technology Resources Branch, OPERA, NIH, 6701 Rockledge Drive, MSC 7750, Bethesda, MD 20892-7750, (301) 435-1986. For additional information, access the NIH link on the Interagency Edison web site (www.iedison.gov) which includes an electronic invention reporting system, reference information and the text to 37 CFR 401.

To the extent authorized by 35 U.S.C., Section 205, the Government will not make public any information disclosing an NIH-supported invention for a 4-year period to allow the awardee organization a reasonable time to file a patent application, nor will the Government release any information that is part of that patent application.

When purchasing equipment or products under this SBIR award, the grantee shall use only American-made items, whenever possible.

The fee provided as part of this Notice of Grant Award is in addition to direct and facilities and administrative costs. The fee is to be drawn down from the DHHS Payment Management System in increments proportionate to the draw down of costs.

Allowable costs conducted by for-profit organizations will be determined by applying the cost principles of Contracts with Commercial Organizations set forth in 48 CFR, Subpart 31.2.

The Code of Federal Regulations (Title 45 Part 74.26) stipulates that a commercial organization is subject to audit requirements for a non-federal audit if, during its fiscal year, it expended $500,000 or more under HHS awards and at least one award is an HHS grant or subgrant. Therefore, the organization must have one grant or subgrant in order to be required to obtain a non-federal audit, but other HHS awards are included in the threshold calculations and the scope of the audit. (See threshold calculation examples, http://oamp.od.nih.gov/dfas/faqexamples.html.)

All grantees must acknowledge funding received from the National Institute on Drug Abuse at the National Institutes of Health when issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with NIDA money. (NIH Grants Policy Statement, Part II, Page 114- Rights in Data (Publication and Copyrighting), December 2003).

In conjunction with this requirement, in order to most effectively disseminate research results, advance notice should be given to NIDA that research finds are about to be published so that we may coordinate accurate and timely release to the media. This information will be embargoed until the publication date. Any press notification should be coordinated with the NIDA Press Officer who can be reached at (301) 443-6245.

We strongly encourage all of our grantees to register in the eRA Commons. The eRA Commons provides grantees with the ability to electronically submit; e-SNAP applications, No cost extensions, Just in Time documents, Financial Status Reports, Final Progress Reports, and allows grantees to register to become e-mail enabled to receive Notice of Grant Awards (NGA).

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Catherine Mills
Email: cmills@nida.nih.gov **Phone:** 301-443-6710 **Fax:** 301-594-6849

Program Official: Amrat Patel
Email: ap79g@nih.gob **Phone:** 301-443-8476

SPREADSHEET SUMMARY
GRANT NUMBER: 2R44DA018515-02

INSTITUTION: VISTAGEN THERAPEUTICS, INC.

Budget	***Year 2***	***Year 3***
Salaries and Wages	$70,390	$72,400
Fringe Benefits	$16,894	$17,376
Consultant Services	$24,000	$16,068
Supplies	$829,280	$555,203
Consortium/Contractual Cost	$960,949	$677,247
FEE	$161,542	$112,190
TOTAL FEDERAL DC	$1,901,513	$1,338,294
TOTAL FEDERAL F&A	$406,226	$264,419
TOTAL COST	$2,469,281	$1,714,903

Facilities and Administrative Costs	***Year 2***	***Year 3***
F&A Cost Rate 1	40%	40%
F&A Cost Base 1	$1,015,564	$661,047
F&A Costs 1	$406,226	$264,419

Notice of Award

Issue Date: 07/19/2010

SMALL BUSINESS INNOVATION RESEARCH PROG
Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON DRUG ABUSE

Grant Number: 3R44DA01815-03S1

Principal Investigator(s):
Ralph Snodgrass

Project Title: Clinical Development of 4-CI-KYN to Treat Pain

Rice, Franklin
EVP Finance and Administration
384 Oyster Point Blvd #8
South San Francisco, CA 94080

Award e-mailed to: rsnodgrass@vistagen.com

Budget Period: 07/01/2010 – 06/30/2011
Project Period: 07/01/2004 – 06/30/2011

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $419,898 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to VISTAGEN THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 15 USC 638 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release or other document that cites results from NIH grant-supported research must include an acknowledgment of NIH grant support and disclaimer such as "The project described was supported by Award Number R44DA018515 from the National Institute On Drug Abuse. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute On Drug Abuse or the National Institutes of Health."

Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central (PMC), upon acceptance for publication, an electronic version of a final peer-reviewed, manuscript resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit http://publicaccess.nih.gov/.

Award recipients must promote objectivity in research by establishing standards to ensure that the design, conduct and reporting of research funded under NIH-funded awards are not biased by a conflicting financial interest of an Investigator. Investigator is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of NIH-funded research or proposed research, including the Investigator's spouse and dependent children. Awardees must have a written administrative process to identify and manage financial conflict of interest and must inform Investigators of the conflict of interest policy and of the Investigators' responsibilities. Prior to expenditure of these awarded funds, the Awardee must report to the NIH Awarding Component the existence of a conflicting interest and within 60 days of any new conflicting interests identified after the initial report. Awardees must comply with these and all other aspects of 42 CFR Part 50, Subpart F. These requirements also apply to subgrantees, contractors, or collaborators engaged by the Awardee under this award. The NIH website http://grants.nih.gov/grants/policy/coi/index.htm provides additional information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Pamela G. Fleming
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

SECTION I – AWARD DATA – 3R44DA018515-03S1

Award Calculation (U.S. Dollars)	
Travel Costs	$12,500
Consortium/Contractual Cost	$354,255
Federal Direct Costs	$366,755
Federal F&A Costs	$25,673
Approved Budget	$392,428
Fee	$27,470
Federal Share	$419,898
TOTAL FEDERAL AWARD AMOUNT	$419,898
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$419,898

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (3)

GRANT NUMBER	TOTAL FEDERAL AWARD AMOUNT
3R44DA018515-03S1	$419,898
5R44DA018515-03	$1,714,903
TOTAL	$2,134,801

SUMMARY TOTALS FOR ALL YEARS

YR	THIS AWARD	CUMULATIVE TOTALS
3	$419,898	$2,134,801

Fiscal Information:

CFDA Number:	93.279
EIN:	1943301660A1
Document Number:	RDA018515B
Fiscal Year:	2010

IC	CAN	2010
DA	8742672	$419,898

NIH Administrative Data:
PCC: MF/AP1 / **OC:** 414C / **Processed:** PFLEMING 07/14/2010

SECTION II – PAYMENT/HOTLINE INFORMATION – 3R44DA018515-03S1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 3R44DA018515-03S1

This award is based on the application submitted to, and as approve d by, NIH on the above titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant programs legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. This award notices, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at 'http://grants.nih.gov/grants/policy/awardconditions.htm' for certain references cited above.)

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory.
For more information, see NOT-OD-08-033 and the Public Access website:
http://publicaccess.nih.gov/

This award represents the final year of the competitive segment for this grant. Therefore, see the NIH Grants Policy Statement (12/1/2003 version) for closeout requirements at:
http://grants.nih.gov/ grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Toc54600151.

A final Financial Status Report (FSR) (SF 269) must be submitted through the eRA Commons (Commons) within 90 days of the expiration date; see NIH Guide Notice NOT-OD-07-078 for additional information on this electronic submission requirement. The final FSR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FSR and the Payment Management System's (PMS) Federal Cash Transaction Report (SF-272).

Furthermore, unless an application for competitive renewal is submitted, additional grant closeout documents consisting of a Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) and a final progress report must also be submitted within 90 days of the expiration date.

NIH also strongly encourages electronic submission of the final progress report and the final invention statement through the Closeout feature in the Commons. If the final progress report and final invention statement are not submitted electronically, copies of the HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm.

Submissions of the final progress report and HHS 568 may be e-mailed as PDF attachments to the NIH Central Closeout Center at: deascentralized@od.nih.gov

Paper submissions of the final progress report and the HHS 568 may be faxed to the NIH Central Closeout Center at 301-480-2304 or mailed to the NIH Central Closeout Center at the following address:

NIH/OD/OER/DEAS
Central Closeout Center
6705 Rockledge Drive, Room 2207
Bethesda, MD 20892-7987 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express mail delivery only)

The final progress report should include, at a minimum, a summary of progress toward the achievement of the originally stated aims, a list of significant results (positive and/or negative), a list of publications and the grant number. If human subjects were included in the research, the final progress report should also address the following:

- Report on the inclusion of gender and minority study subjects (using the gender and minority Inclusion Enrollment Form as provided in the PHS 2590 and available at http ://grants.nih.gov/grants/forms.htm).
- Where appropriate, indicate whether children were involved in the study or how the study was relevant for conditions affecting children (see "Public Policy Requirements and Objectives-Requirements for Inclusiveness in Research Design-Inclusion of Children as Subjects in Clinical Research" in the PHS 398 at URL http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600090)
- Describe any data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information resulting from the research that is available to be shared with other investigators and how it may be accessed.

Note, if this is the final year of a competitive segment due to the transfer of the grant to another institution, then not all the requirements stated above are applicable. Specifically a Final Progress Report is not required. However, a final FSR is required and should be submitted electronically as noted above. In addition, if not already submitted, the Final Invention Statement is required and should be sent directly the assigned Grants Management Specialist.

Treatment of Program Income:
Additional Costs

SECTION IV – DA Special Terms and Conditions – 3R44DA018515-03S1

This award provides supplemental funds of $419,898 Total Costs ($366,755 Direct Costs, $25,673 F&A Costs and $27,470 Fixed Fee) for the purpose of covering the unanticipated FDA mandated changes. These funds are restricted for stated purpose, in request dated 12/8/2009, from H. Ralph Snodgrass, President and CSO, VistaGen Therapeutics, Inc. and may not be used for any other purpose, without Grants Management Branch, NIDA approval.

This award is subject to the current Data Safety Monitoring Plan (DSMP) submitted and previously approved by NIDA. Any changes in the DSMP must be reviewed and approved by the Program Official. If changes are approved, the approval will be reflected on the Notice of Grant Award. If changes are not approved, the Principal Investigator must revise the DSMP to the satisfaction of the Program Official. The Principal Investigator must provide a DSMP for any new trial that is to be conducted under this grant.

This award includes funds awarded for consortium activity with Cambridge Major Labs, Pharmatek, AvivoClin, MicroConstants, and Cato Research. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at http://grants1 .nih.gov/grants/policy/nihgps_2003/ NIHGPS_Part12.htm#_Toc54600251, pages 224-227.

INTELLECTUAL PROPERTY RIGHTS: Normally, the awardee organization retains the principal worldwide patent rights to any invention developed with United States Government support. Under Title 37 Code of Federal Regulations Part 401, the Government receives a royalty-free license for its use, reserves the right to require the patent holder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it substantially in the United States.

Rights and obligations related to inventions created or reduced to practice as a result of this award are detailed in 35 U.S.C. 205 and 37 CFR Part 401. These inventions must be reported to the Extramural Invention Reporting and Technology Resources Branch, OPERA, NIH, 6701 Rockledge Drive, MSC 7750, Bethesda, MD 20892-7750, (301) 435-1986. For additional information, access the NIH link on the Interagency Edison web site (www.iedison.gov) which includes an electronic invention reporting system, reference information and the text to 37 CFR 401.

To the extent authorized by 35 U.S.C., Section 205, the Government will not make public any information disclosing an NIH-supported invention for a 4-year period to allow the awardee organization a reasonable time to file a patent application, nor will the Government release any information that is part of that patent application.

When purchasing equipment or products under this SBIR award, the grantee shall use only American-made items, whenever possible.

The fee provided as part of this Notice of Grant Award is in addition to direct and facilities and administrative costs. The fee is to be drawn down from the DHHS Payment Management System in increments proportionate to the draw down of costs.

Allowable costs conducted by for-profit organizations will be determined by applying the cost principles of Contracts with Commercial Organizations set forth in 48 CFR, Subpart 31.2.

The Code of Federal Regulations (Title 45 Part 74.26) stipulates that a commercial organization is subject to audit requirements for a non-federal audit if, during its fiscal year, it expended $500,000 or more under HHS awards and at least one award is an HHS grant or subgrant. Therefore, the organization must have one grant or subgrant in order to be required to obtain a non-federal audit, but other HHS awards are included in the threshold calculations and the scope of the audit. (See threshold calculation examples, http://oamp.od.nih.gov/dfas/faqexamples.html.)

All grantees must acknowledge funding received from the National Institute on Drug Abuse at the National Institutes of Health when issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with NIDA money. (NIH Grants Policy Statement, Part II, Page 114- Rights in Data (Publication and Copyrighting), December 2003).

In conjunction with this requirement, in order to most effectively disseminate research results, advance notice should be given to NIDA that research finds are about to be published so that we may coordinate accurate and timely release to the media. This information will be embargoed until the publication date. Any press notification should be coordinated with the NIDA Press Officer who can be reached at (301) 443-6245.

We strongly encourage all of our grantees to register in the eRA Commons. The eRA Commons provides grantees with the ability to electronically submit; e-SNAP applications, No cost extensions, Just in Time documents, Financial Status Reports, Final Progress Reports, and allows grantees to register to become e-mail enabled to receive Notice of Grant Awards (NGA).

NIDA has an interest in supporting HIV/AIDS and infectious disease research. The purpose of this support is to develop effective prevention, treatment, and service strategies for drug abusing youth and adults. To that end, awardees conducting HIV/AIDS research are encouraged to make every effort to incorporate scientific questions related to HIV/AIDS and other infectious diseases into research protocols. Principal Investigators will be required to provide information related to the development of research in this area in annual progress reports to allow NIDA to assess progress regarding HIV/AIDS research.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Diana Haikalis
Email: dh84m@nih.gov **Phone:** (301) 435-1373 **Fax:** (301) 594-6849

Program Official: Amrat Patel
Email: ap79g@nih.gov **Phone:** (30l) 443-8476

SPREADSHEET SUMMARY
GRANT NUMBER: 3R44DA018515-03S1

INSTITUTION: VISTAGEN THERAPEUTICS, INC.

Budget	Year 3
Travel Costs	$12,500
Consortium/Contractual Cost	$354,255
FEE	$27,470
TOTAL FEDERAL DC	$366,755
TOTAL FEDERAL F&A	$25,673
TOTAL COST	$419,898

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	7%
F&A Cost Base 1	$366,755
F&A Costs 1	$25,673

Notice of Award

Issue Date: 08/09/2011

SMALL BUSINESS INNOVATION RESEARCH PROG
Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON DRUG ABUSE

Grant Number: 5R44DA01815-03 REVISED

Principal Investigator(s):
Ralph Snodgrass, PHD

Rice, Franklin
EVP Finance and Administration
384 Oyster Point Blvd #8
South San Francisco, CA 94080

Award e-mailed to: rsnodgrass@vistagen.com

Budget Period: 07/01/2010 – 06/30/2010
Project Period: 07/01/2001 – 06/30/2012

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to VISTAGEN THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 15 USC 638 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, that cites results from NIH grant-supported research must include an acknowledgment of NIH grant support and disclaimer such as "The project described was supported by Grant Number R44DA018515 from the National Institute On Drug Abuse. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute On Drug Abuse or the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central (PMC), upon acceptance for publication, an electronic version of a final peer-reviewed, manuscript resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit http://publicaccess.nih.gov/.

Award recipients must promote objectivity in research by establishing standards to ensure that the design, conduct and reporting of research funded under NIH-funded awards are not biased by a conflicting financial interest of an Investigator. Investigator is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of NIH-funded research or proposed research, including the Investigator's spouse and dependent children. Awardees must have a written administrative process to identify and manage financial conflict of interest and must inform Investigators of the conflict of interest policy and of the Investigators' responsibilities. Prior to expenditure of these awarded funds, the Awardee must report to the NIH Awarding Component the existence of a conflicting interest and within 60 days of any new conflicting interests identified after the initial report. Awardees must comply with these and all other aspects of 42 CFR Part 50, Subpart F. These requirements also apply to subgrantees, contractors, or collaborators engaged by the Awardee under this award. The NIH website http://grants.nih.gov/grants/policy/coi/index.htm provides additional information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Diana Haikalis
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

SECTION I – AWARD DATA – 5R44DA018515-03 REVISED

Award Calculation (U.S. Dollars)	
Salaries and Wages	$72,400
Fringe Benefits	$17,376
Personnel Costs (Subtotal)	$89,776
Consultant Services	$16,068
Supplies	$555,203
Consortium/Contractual Cost	$677,247
Federal Direct Costs	$1,338,294
Federal F&A Costs	$264,419
Approved Budget	$1,602,713
Fee	$112,190
Federal Share	$1,714,903
TOTAL FEDERAL AWARD AMOUNT	$1,714,903
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (3)

GRANT NUMBER	TOTAL FEDERAL AWARD AMOUNT
3R44DA018515-03	$1,714,903
5R44DA018515-03S1	$419,898
TOTAL	$2,134,801

SUMMARY TOTALS FOR ALL YEARS

YR	THIS AWARD	CUMULATIVE TOTALS
3	$1,714,903	$2,134,801

Fiscal Information:

CFDA Number:	93.279
EIN:	1943301660A1
Document Number:	RDA018515B
Fiscal Year:	2010

IC	CAN	2010
DA	8742672	$1,714,903

NIH Administrative Data:
PCC: MF/AP1 / **OC:** 414E / **Processed:** HAIKALIS 08/08/2011

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R44DA018515-03 REVISED

For payment and HHS Office of Inspector General Hotline Information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 5R44DA01815-03 REVISED

This award is based on the application submitted to, and as approve d by, NIH on the above titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant programs legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. This award notices, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at 'http://grants.nih.gov/grants/policy/awardconditions.htm' for certain references cited above.)

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory.
For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the Clinical Trials.gov Protocol Registration System Information Website. NIH Encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

This award represents the final year of the competitive segment for this grant. Therefore, see the NIH Grants Policy Statement Section 8.6 Closeout for closeout requirements at: http://grants.nih.gov/grants/policy#gps.

A final Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 90 days of the expiration date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.**gOv**/grants/policy/#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted through the eRA Commons (Commons) within 90 days of the expiration date.
Furthermore, unless an application for competitive renewal is submitted, a final progress report must also be submitted within 90 days of the expiration date. Institute/Centers may accept the progress report contained in competitive renewal (type 2) in lieu of a separate final progress report. Contact the awarding IC for IC-specific policy regarding acceptance of a progress report contained in a competitive renewal application in lieu of a separate final progress report.

NIH strongly encourages electronic submission of the final progress report and the final invention statement through the Closeout feature in the Commons. If the final progress report and final invention statement are not submitted through the Commons, a copy can be emailed or sent to the contacts listed below. Copies of the HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm.

Submissions of the final progress report and HHS 568 may be e-mailed as PDF attachments to the NIH Central Closeout Center at: DeasCentralized@.od.nih.gov.

Paper submissions of the final progress report and the HHS 568 may be faxed to the NIH Central Closeout Center at 301-480-2304 or mailed to the NIH Central Closeout Center at the following address:

NIH/OD/OER/DEAS
Central Closeout Center
6705 Rockledge Drive, Room 2207
Bethesda, MD 20892-7987 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express mail delivery only)

The final progress report should include, at a minimum, a summary of progress toward the achievement of the originally stated aims, a list of significant results (positive and/or negative), a list of publications and the grant number. If human subjects were included in the research, the final progress report should also address the following:

Report on the inclusion of gender and minority study subjects (using the gender and minority Inclusion Enrollment Form as provided in the PHS 2590 and available at http://grants.nih.gov/grants/forms.htm).

Where appropriate, indicate whether children were involved in the study or how the study was relevant for conditions affecting children (see NIH Grants Policy Statement Section 4.1.15.7 Inclusion of Children as Subjects in Clinical Research at URL http://grants.nih.gOv/grants/policy/#gps).

Describe any data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information resulting from the research that is available to be shared with other investigators and how it may be accessed.

Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the final progress report.

Note, if this is the final year of a competitive segment due to the transfer of the grant to another institution, then not all the requirements stated above are applicable. Specifically a Final Progress Report is not required. However, a final FFR is required and should be submitted electronically as noted above. In addition, if not already submitted, the Final Invention Statement is required and should be sent directly the assigned Grants Management Specialist.

Treatment of Program Income:
Additional Costs

SECTION IV – DA Special Terms and Conditions – 5R44DA018515-03 REVISED

REVISED AWARD: The purpose of this revision is to change the budget and project period end-dates from 06/30/11 to 06/30/12 in accordance with the letter of 08/04/11 from H. Ralph Snodgrass, Ph.D., and Franklin Rice, M.B.A./VistaGen. This revision supersedes the NoA issued 06/26/10.

This award includes funds awarded for consortium activity with Cambridge Major Labs, Pharmatek, AvivoClin, MicroConstants, and Cato Research in the amount of $677,247. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at http://grants1.nih.**gOv**/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600251, pages 224-227.

INTELLECTUAL PROPERTY RIGHTS: Normally, the awardee organization retains the principal worldwide patent rights to any invention developed with United States Government support. Under Title 37 Code of Federal Regulations Part 401, the Government receives a royalty-free license for its use, reserves the right to require the patent holder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it substantially in the United States.

Rights and obligations related to inventions created or reduced to practice as a result of this award are detailed in 35 U.S.C. 205 and 37 CFR Part 401. These inventions must be reported to the Extramural Invention Reporting and Technology Resources Branch, OPERA, NIH, 6701 Rockledge Drive, MSC 7750, Bethesda, MD 20892-7750, (301) 435-1986. For additional information, access the NIH link on the Interagency Edison web site (www.iedison.gov) which includes an electronic invention reporting system, reference information and the text to 37 CFR 401.

To the extent authorized by 35 U.S.C, Section 205, the Government will not make public any information disclosing an NIH-supported invention for a 4-year period to allow the awardee organization a reasonable time to file a patent application, nor will the Government release any information that is part of that patent application.

When purchasing equipment or products under this SBIR award, the grantee shall use only American-made items, whenever possible.

The fee provided as part of this Notice of Grant Award is in addition to direct and facilities and administrative costs. The fee is to be drawn down from the DHHS Payment Management System in increments proportionate to the draw down of costs.

Allowable costs conducted by for-profit organizations will be determined by applying the cost principles of Contracts with Commercial Organizations set forth in 48 CFR, Subpart 31.2.

The Code of Federal Regulations (Title 45 Part 74.26) stipulates that a commercial organization is subject to audit requirements for a non-federal audit if, during its fiscal year, it expended $500,000 or more under HHS awards and at least one award is an HHS grant or subgrant. Therefore, the organization must have one grant or subgrant in order to be required to obtain a non-federal audit, but other HHS awards are included in the threshold calculations and the scope of the audit. (See threshold calculation examples, http://oamp.od.nih.gov/dfas/faqexamples.html.)

This award represents the final year of the competitive segment (Phase I or Phase II) for this grant. Therefore, see the NIH Grants Policy Statement, December 2003, Part II, http://grants.nih.**gOv**/grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Toc54600151, pages 139-141, a Financial Status Report (SF 269) must be submitted within 90 days of the expiration date. In addition, unless an application for competitive renewal is funded, grant closeout documents consisting of a Final Invention Statement (HHS 568), and a final progress report must also be submitted within 90 days of the expiration date. The Financial Status Report and Final Invention Statement are available at: http://grants.nih.**gov**/grants/forms.htm

There is no ?form page? for a Final Report. The Final Progress Report may be typed on plain white paper (or you may use the PHS 398 Continuation Page). The recommended length for the narrative portion is 10 pages.

{Include the next paragraph on Phase I only}

Phase I grantees that (1) do not intend to seek Phase II support or (2) are not prepared to submit a Phase II application within four months following the expiration of the Phase I budget period, must submit a final report of their Phase I effort. Otherwise, the Phase I Final Report is a part of the Phase II application.

The format for the Final Report is as follows:

1. State the beginning and ending dates for the period covered by the SBIR/STTR Phase I/Phase II) grant.
2. List all key personnel who have worked on the project during that period, their titles, dates of service, and number of hours devoted to the project.
3. Summarize the specific aims of the Phase I grant.
4. Provide a succinct account of published and unpublished results, indicating progress toward their achievement. Summarize the importance of the findings. Discuss any changes in the specific aims since the project was initiated. Include the Inclusion Enrollment Report with the final enrollment data for clinical research (MS Word or PDF).
5. List titles and complete references to publications, and manuscripts accepted for publication, if any, that resulted from the project?s effort. Submit five copies of such items, except patent and invention reports, as an Appendix.
6. List patents, copyrights, trademarks, invention reports and other printed materials, if any, that resulted from the project or describe patent status, trade secrets or other demonstration of IP protection.
7. Describe the technology developed from this SBIR/STTR, its intended use and who will use it.
8. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued).
9. If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed an 1ND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved).
10. Describe how your company has benefited from the program and/or the technology developed (e.g., firm's growth, follow-on funding, increased technical expertise, licensing agreements, spin-off companies, public offering [include stock exchange and symbol]).
11. List of the generic and/or commercial name of product, process, or service, if any, that resulted from SBIR/STTR funding. If applicable, indicate the number of products sold.
12. Provide the current number of employees (total full time equivalents [FTEs]).

If human subjects were included in the research, the final progress report should also address the following:

- Report on the inclusion of gender and minority study subjects (using the gender and minority inclusion table as provided in the PHS 2590)
- Where appropriate, indicate whether children were involved in the study or how the study was relevant for conditions affecting children (see Public Policy Requirements and Objectives Requirements for Inclusiveness in Research Design Inclusion of Children as Subjects in Clinical Research in the PHS 398 at URL http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600090)
- Describe any data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information resulting from the research that is available to be shared with other investigators and how it may be accessed.

The Final Progress Report and Final Invention Statement should be submitted in an electronic format.

If the grantee institution is registered to do business in the NIH Commons, all required documents should be submitted electronically. The Final Progress Report (FPR) and the Final Invention Statement (FIS) should be submitted electronically through the NIH Commons available at https://commons.era.nih.gov/commons/.

If electronic submission is not feasible, you may fax your documents to our central fax gateway at 301-480-2304.

If the grantee institution is registered to do business in the NIH Commons, the Financial Status Report (FSR) should be submitted electronically through the NIH Commons available at https://commons.era.nih.gov/commons/. Additional information on electronic submission of FSRs is available at the Commons Homepage or by contacting the eRA Helpdesk at: commonsd@od.nih.gov or (866) 504-9552.

If electronic submission is not feasible, paper submission of the Financial Status Report may be mailed to:

Government Accounting Branch
Office of Financial Management
National Institutes of Health
2115 East Jefferson Street, MSU 8500
Ste. 4B432
Bethesda, MD 20892-8500 (Rockville, MD 20852 – Use for FedEx, UPS and other courier services)

This award is subject to the current Data Safety Monitoring Plan (DSMP) submitted and previously approved by NIDA. Any changes in the DSMP must be reviewed and approved by the Program Official. If changes are approved, the approval will be reflected on the Notice of Grant Award. If changes are not approved, the Principal Investigator must revise the DSMP to the satisfaction of the Program Official. The Principal Investigator must provide a DSMP for any new trial that is to be conducted under this grant.

The FDA Modernization Act of 1977 requires that NIH (and companies and universities) register all drug trials for serious or life threatening conditions. The NIH policy is that all NIH supported clinical trials will be registered regardless of whether or not the trial involves serious or life threatening conditions.

It is the responsibility of the Principal Investigator and the grantee organization to identify whether or not this funded research project must be registered. You are required to use the following definition in determining whether this research is/is not a clinical trial.

The NIH defines a clinical trial as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Behavioral human subjects research involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fits these criteria of a clinical trial. Human subjects research to develop or evaluate clinical laboratory tests (e.g. imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test will be used for medical decision-making for the subject or the test itself imposes more than minimal risk for subjects.

If this award is to support research that meets the NIH definition of a clinical trial above, please visit the following URL: <http://prsinfo.clinicaltrials.gov/> to register this award.

This award provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research support as an NIH Phase III Clinical Trial has been updated in Section III.B of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research? Updated August 1, 2000 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-048.html). A description of plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups must be included in clinical trial protocols and the results of the subset analyses must be reported to NIH in the annual progress reports, competitive Renewal Applications (Contract Renewals/Extensions), and in the required Final Progress Report, as stated in Section III.B of the Guidelines. However, as this award is part of NIDA?s Clinical Trials Network, which will have a lead investigator for each protocol, only that lead investigator will be responsible for implementing the requirement for any given protocol.. Nonetheless, each P.I. will still be responsible for providing the minority/gender figures for subjects enrolled under his/her node.

All grantees must acknowledge funding received from the National Institute on Drug Abuse at the National Institutes of Health when issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with NIDA money. (NIH Grants Policy Statement, Part II, Page 114- Rights in Data (Publication and Copyrighting), December 2003).

In conjunction with this requirement, in order to most effectively disseminate research results, advance notice should be given to NIDA that research finds are about to be published so that we may coordinate accurate and timely release to the media. This information will be embargoed until the publication date. Any press notification should be coordinated with the NIDA Press Officer who can be reached at (301) 443-6245.

We strongly encourage all of our grantees to register in the eRA Commons. The eRA Commons provides grantees with the ability to electronically submit; e-SNAP applications, No cost extensions, Just in Time documents, Financial Status Reports, Final Progress Reports, and allows grantees to register to become e-mail enabled to receive Notice of Grant Awards (NGA).

NIDA has an interest in supporting HIV/AIDS and infectious disease research. The purpose of this support is to develop effective prevention, treatment, and service strategies for drug abusing youth and adults. To that end, awardees conducting HIV/AIDS research are encouraged to make every effort to incorporate scientific questions related to HIV/AIDS and other infectious diseases into research protocols. Principal Investigators will be required to provide information related to the development of research in this area in annual progress reports to allow NIDA to assess progress regarding HIV/AIDS research.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Diana Haikalis
Email: dh84m@nih.gov **Phone:** 301-435-1373 **Fax:** 301-594-6849

Program Official: Amrat Patel
Email: ap79g@nih.gov **Phone:** 301-443-8476

SPREADSHEET SUMMARY
GRANT NUMBER: 5R44DA01815-03 REVISED
INSTITUTION: VISTAGEN THERAPEUTICS, INC.

Budget	Year 3
Salaries and Wages	$72,400
Fringe Benefits	$17,376
Personnel Costs (Subtotal)	$89,776
Consultant Services	$16,068
Supplies	$555,203
Consortium/Contractual Cost	$677,247
FEE	$112,190
TOTAL FEDERAL DC	$1,338,294
TOTAL FEDERAL F&A	$264,419
TOTAL COST	$1,714,903

Facilities and Administrative Costs	***Year 3***
F&A Cost Rate 1	40%
F&A Cost Base 1	$661,047
F&A Costs 1	$264,419

EXHIBIT 10.47

SIGN AND RETURN THIS PAGE TO CIRM RT1-01012-1

NOTICE OF GRANT AWARD – CIRM RFA-08-02: Tools & Technologies

California Institute for Regenerative Medicine

Issue Date: April 1, 2009

Grant Number:	RT1-01012-1	Budget Period:	Annual as of 4/1/2009
Grantee Name:	VistaGen Therapeutics, Inc.		
Grantee ID:	PR-Y0002A-SF	Project Period Start:	4/1/2009
Principal Investigator:	Dr. Kristina C. Bonham	Project Period End:	3/31/2011
Project Title:	Development of an hES Cell-Based Assay System for Hepatocyte Differentiation Studies and Predictive Toxicology Drug Screening		

Authorized Organizational Official and Address:
Ralph Snodgrass, PhD
CEO
VistaGen Therapeutics, Inc.
384 Oyster Point Blvd #8
South San Francisco, CA 94080

Official and Address to Receive Payments:
Cell Biology
Attn: Kristina Bonham, PhD
VistaGen Therapeutics, Inc.
384 Oyster Point Blvd #8
South San Francisco, CA 94080

The California Institute for Regenerative Medicine (CIRM) hereby awards a grant in the amount of **$971,558** to be disbursed over a total period of 2 years to **VistaGen Therapeutics, Inc.** (Grantee ID PR-Y0002A-SF) in support of the above referenced project. This award is pursuant to the California Stem Cell Research and Cures Act (Health and Safety Code section 125290.10 *et. seq.)* and is subject to terms and conditions referenced below. (Capitalized terms are defined in the *CIRM Grants Administration Policy for Academic and Non-Profit Institutions* (GAP), a copy of which may be found on the CIRM website at: http://www.cirm.ca.aov/reg/pdf/req100500 policv.pdf.)

In accepting this Grant, the Grantee warrants to CIRM that any funds expended underthe award will be for the purposes set forth in the approved application and agrees to comply with all applicable CIRM regulations. See Item II (page 3) below.

To accept this Grant, the Principal Investigator and Authorized Organizational Official must sign and return this Notice of Grant Award (NGA) to CIRM within 45 days of the issue date. Payment will be issued only after the signed NGA is received by CIRM. Grant funds will be sent to the organization's address listed above under *Official and Address to Receive Payments* unless an updated address is provided in the box below. If the applicant cannot accept the award, including the legal obligation to perform in accordance with the provisions of this NGA, it should notify CIRM immediately.

If you have any questions about this award, please contact the CIRM staff referenced on page 3.

/s/ Marie Csete
Marie Csete, MD, Ph.D.
Chief Scientific Officer
California Instituted for Regenerative Medicine

Updated Address to Receive Payments:

AWARD ACCEPTANCE: The Principal Investigator and Authorized Organizational Official must sign below and return the entire NGA to CIRM to accept the Grant award.

	Principal Investigator	**Authorized Organizational Official**
Name	Dr. Kristina C. Bonham	**Ralph Snodgrass, PhD**
Signature	/s/ Kristina C. Bonham	**/s/ H. Ralph Snodgrass**
Date	**4/8/09**	**4/7/09**

SIGN AND RETURN TO CIRM

NOTICE OF GRANT AWARD
California Institute for Regenerative Medicine

I. AWARD DATA:
AWARD DETAIL (U.S. Dollars):

	Year l		Year 2	
Direct Project Costs				
Personnel (Non -Trainee) Costs	$252,001		$253,127	
Trainee Costs				
Travel	$9,800		$10,000	
Supplies	$30,000		$28,800	
Equipment	$ 0		$ 0	
Consultants/Subcontracts	$8,000		$8,000	
Total Project Costs	**$299,801**		**$299,927**	
Facilities Costs				
Facilities Costs - Category A	$ 52,465		$ 52,487	
Facilities Costs - Category B	$ 52,465		$ 52,487	
Indirect Costs				
Indirect Costs	$80,946		$80,980	
APPROVED BUDGET TOTAL		**$485,677**		**$485,881**

QUARTERLY INSTALLMENTS ON GRANT PAYMENTS
Payments will be made in quarterly installments, issued at the beginning of each quarter. Quarters will be tied to the project start date. The final quarterly installment will be held until completion of Close-Out.

***Any interest accrued by the Grantee from the Grant payment must be used for the CIRM Tools & Technologies Program.**

PROGRESS REPORTS SCHEDULE

	Year 1	Year 2
Programmatic Report	2/1/2010	2/1/2011
Financial Report	7/1/2010	7/1/2011
Close-Out Report	n/a	7/1/2011

NOTICE OF GRANT AWARD
California Institute for Regenerative Medicine

II. TERMS AND CONDITIONS

This award is based on the application submitted to CIRM, and as approved by the Independent Citizens' Oversight Committee (ICOC) on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

A. The *California Stem Cell Research and Cures Act* (Health and Safety Code Section 125290.10 *et. seq*.) and regulations adopted by the ICOC.

B. The *CIRM Interim Grants Administration Policy for For-Profit Organizations* (Title 17, California Code of Regulations, Section 100501), *CIRM Grants Administration Policy for Academic and Non-Profit Institutions* (Title 17, California Code of Regulations, Section 100500), *CIRM Intellectual Property Policy and Revenue Sharing Requirements for For-Profit Organizations*, the *CIRM Medical and Ethical Standards Regulations* (Title 17, California Code of Regulations, Sections 100010-1000110), *CIRM Use of Fetal Tissue* (Title 17, California Code of Regulations, Section 10085), and any subsequently adopted applicable regulations.

C. The terms and requiremenets detailed in RFA 08-02: CIRM Tools and Technologies Awards.

D. Grantee shall not commence work on the K117 hESC line until approval to use this line is granted by the institution's SCRO committee and documentation of that verifies such approval has been received by CIRM.

E. The timing of the distribution of funds pursuant to this grant shall be contingent upon the availability of funds in the California Stem Cell Research and Cures Fund in the State Treasury, as determined by CIRM in its sole discretion.

Please check the following website for updated policy documents: http://www.cirm.ca.gov/req/

III. CIRM CONTACTS:

Andrew McFarland, Grants Management Specialist
Phone: (415) 396-9126 Email: amcfarland@cirm.ca.gov Fax: (415) 396-9141

Sohel Talib, PhD, Scientific Program Officer
Phone: (415) 396-9137 Email: stalib@cirm.ca.gov Fax: (415) 396-9141

The CIRM home page is at http://www.cirm.ca.gov

CIRM Mailing Address:

California Institute for Regenerative Medicine
Attn: Andrew McFarland, Grants Management Specialist
210 King Street
San Francisco, CA 94107

RT1-01012-1
Budget Adjustments
Note 1: None
Note 2:
Note 3:

	Year 1 Requested Amount		Year 1 Approved Budget	Year 2 Requested Amount	Year 2 Approved Budget	Year 2 Expenditure Report	Total Approved Budget
Key Personnel and Trainees I							
Subtotal for all personnel (non-trainee)	$252,001	$252,001	$253,127	$253,127		$505,128	
Subtotal for all trainees						$0	
Personnel and Trainee Costs	$252,001	$252,001	$253,127	$253,127	$0	$505,128	
Other Project Costs							
Travel	$9,800	$9,800	$10,000	$10,000		$19,800	
Supplies	$30,000	$30,000	$28,800	$28,800		$58,800	
Equipment						$0	
Total Consultants/Subcontracts	$8,000	$8,000	$8,000	$8,000		$16,000	
Other Project Costs	$47,800	$47,800	$46,800	$46,800	$0	$94,600	
Total Project Costs							
Total Project Costs	$299,801	$299,801	$299,927	$299,927		$599,728	
Excluded Expenses							
Total Consultants/Subcontracts	$0	$0	$0	$0		$0	
Equipment	$0	$0	$0	$0		$0	
Total Req Trainee Annual Tuition & Fees	$0	$0	$0	$0		$0	
Excluded Expenses	$0	$0	$0	$0		$0	
Adjusted Project Costs							
Adjusted Project Costs	$299,801	$299,801	$299,927	$299,927		$599,728	
Facilities Costs- A							
Rate for Operation/Maintenance Expenses							
Rate for Library Expenses							
Sum of Category A Rates	17.50%	17.50%	17.50%	17.50%			
Category A Costs Requested	$52,465	$52,465	$52,487	$52,487			
Facilities Costs- B1							
Rate for Depreciation or Use Allowances							
Rate for Interest on Capital Debt							
Sum of Category B(1) Rates	17.50%	17.50%	17.50%	17.50%			
Category B(1) Costs Requested	$52,465	$52,465	$52,487	$52,487			
Facilities Costs- Total							
Facilities Costs	$104,930	$104,930	$104,974	$104,974		$209,905	
Indirect Costs							
Sum Adj. Proj.Cost and Facilities Costs	$404,731	$404,731	$404,901	$404,901	$0	$809,633	
Indirect Cost Rate	20%	20%	20%	20%		20%	
Indirect Costs	$80,946	$80,946	$80,980	$80,980		$161,927	
Interest earned on CFRM Funds							
Total Funds Requested							
Total	**$485,677**	**$485,677**	**$485,881**	**$485,881**		**$971,558**	
Disbursements and Adjustments							
Planned Disbursements		$485,677		$364,411	$121,470	$971,558	
Prior Approval and Other Adjustments						$0	
Actual Disbursements						**$0**	

Exhibit 10.47