Excaliber Enterprises, Ltd.
Form 8-K
May 16, 2011

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

FORM 8-K

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

Excaliber Enterprises, Ltd.
(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 (Address of principal executive offices)		94080 (Zip Code)

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

(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))

Item 1.01. Entry into a Material Definitive Agreement.

On May 11, 2011, Excaliber Enterprises, Ltd., a Nevada corporation ("Excaliber", "we" or "our"), Excaliber Merger Subsidiary, Inc., a California corporation and a newly-formed wholly-owned subsidiary of Excaliber ("Merger Sub"), and VistaGen Therapeutics, Inc., a California corporation ("VistaGen") entered into an Agreement and Plan of Merger (the "Merger Agreement") whereby Merger Sub merged with and into VistaGen, with VistaGen remaining as the surviving corporation and with the shareholders of VistaGen exchanging all of their stock in VistaGen for a total of 6,836,511 shares of common stock of Excaliber, constituting approximately 90% of the outstanding shares of common stock of Excaliber (the "Merger"). Each such VistaGen shareholder received one-half (0.5) of one share of Excaliber's common stock in exchange for each one (1) share of VistaGen common stock. The Merger Agreement provides that our board of directors must, (i) within 15 days of the closing of the Merger, approve a two-for-one (2:1) forward stock split of our common stock, (ii) as soon as practical after the closing of the Merger, file with the U.S. Securities and Exchange Commission ("SEC") a notice of a change in the majority of directors as required by Rule 14f-1 ("Rule 14f-1 Notice") adopted pursuant to the Securities Exchange Act of 1934 whereby H. Ralph Snodgrass, Ph.D., Gregory A. Bonfiglio, J.D. and Brian J. Underdown, Ph.D. shall be appointed to serve as directors of Excaliber effective upon the expiration of the required expiration of the SEC's review period of the Rule 14f-1 Notice (the "Rule 14f-1 Notice Review Period") and (iii) accept the resignations of Stephanie Y. Jones and Matthew L. Jones as directors of Excaliber effective upon the expiration of the Rule 14f-1 Notice Review Period. In addition, we intend to change our name to "VistaGen Therapeutics, Inc." within sixty (60) days of the date of this report. The foregoing summary does not purport to be complete and is qualified in its entirety by reference to the full text of the Merger Agreement, which is filed as an exhibit hereto and incorporated herein by reference.

In addition to the Merger Agreement, Excaliber and VistaGen also entered into the following agreements prior to the Merger.

(a) Agreement Regarding Sale of Shares of Common Stock dated May 9, 2011 by and between Excaliber and Stephanie Y. Jones, whereby Excaliber purchased from Mrs. Jones 4,982,103 shares of Excaliber common stock for $10.00. Prior to the Merger, Mrs. Jones was President and Chief Executive Officer of Excaliber. Mrs. Jones is currently a director of Excaliber and will remain in that role until the expiration of the Rule 14f-1 Notice Review Period.

(b) Agreement Regarding Sale of Shares of Common Stock dated May 9, 2011 by and between Excaliber and Nicole Jones, whereby Excaliber purchased from Nicole Jones 82,104 shares of Excaliber common stock for $10.00.

(c) Joinder Agreement dated May 11, 2011 by and between Excaliber, Platinum Long Term Growth VII, LLC ("Platinum") and VistaGen, whereby we agreed to assume all obligations and indebtedness of VistaGen to Platinum under a loan agreement and the amended and restated promissory note issued by VistaGen to Platinum in the original aggregate principal amount of $4 million (the "Amended and Restated Platinum Note").

(d) VistaGen entered into subscription agreements with certain investors immediately prior to and conditioned upon the Merger pursuant to which VistaGen issued 1,108,056 Units at a price of $3.50 per Unit for aggregate gross proceeds to VistaGen of approximately $3,878,196 ("2011 Private Placement"). Each Unit consisted of one share of VistaGen's Common Stock and a warrant to purchase one fourth of one share of VistaGen's Common Stock at an exercise price of $5.00 per share.

(e) VistaGen entered into that certain Amendment to Letter Loan Agreement dated May 5, 2011 with Platinum whereby Platinum agreed that the Amended and Restated Platinum Note would be convertible upon our consummation of an equity or equity based financing or a series of equity financings resulting in gross proceeds to Excaliber totaling at least $5,000,000 ("$5,000,000 Qualified Financing") into our securities issued in the $5,000,000

Qualified Financing. Platinum further agreed that the approximately $3,878,196 of proceeds (including cancellation of indebtedness) from the 2011 Private Placement shall be deemed to have been received by Excaliber for purposes of the automatic conversion provisions of the Amended and Restated Platinum Note and determining when a $5,000,000 Qualified Financing shall have occurred thereunder.

Item 2.01. Completion of Acquisition or Disposition of Assets.

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

PART I

FORWARD-LOOKING STATEMENTS

Certain statements in this current report on Form 8-K may be "forward-looking statements." Statements about our current and future plans, expectations and intentions, results, levels of activity, performance, goals or achievements or any other future events or developments constitute forward-looking statements. The words "may", "will", "would", "should" "could", "expect", "plan", "intend", "trend", "indication", "anticipate", "believe", "estimate", "predict", "likely" or "potentia or other variations of these words or other comparable words or phrases, are intended to identify forward-looking statements. Discussions containing forward-looking statements in this current report on Form 8-K may be found, among other places, under "Business", "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations". Forward-looking statements are based on estimates and assumptions made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors that we believe are appropriate and reasonable in the circumstances.

Many factors could cause our actual results, level of activity, performance or achievements or future events or developments to differ materially from those expressed or implied by the forward-looking statements, including, but not limited to, the factors which are discussed in greater detail in this current report under the section entitled "Risk Factors". However, these factors are not intended to represent a complete list of the factors that could affect us. The purpose of the forward-looking statements is to provide the reader with a description of management's expectations regarding, among other things, our financial performance and research and development activities and may not be appropriate for other purposes.

Furthermore, unless otherwise stated, the forward-looking statements contained in this current report are made as of the date of this report, and we have no intention and undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law. The forward-looking statements contained in this current report are expressly qualified by this cautionary statement. New factors emerge from time to time, and it is not possible for us to predict which factors may arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

The forward-looking statements in this current report include, but are not limited to:

- our expectation to satisfy post-closing conditions to the Merger Agreement;
- our plans to develop predictive toxicology screening assay systems based on our pluripotent stem cell biology platform;
- our belief that assay systems based upon our pluripotent stem cell biology platform can become capable of discovering, validating and prioritizing drug candidates, or efficiently screening libraries of chemical compounds and drug candidates for potential therapeutic utility or toxicity;
- our anticipation that the recognition of the value of pluripotent stem cell technology for drug rescue, including our Human Clinical Trials in a Test Tubetm platform, will markedly increase at pharmaceutical companies in the coming years;
- our expectation that we will gain access to drug rescue candidates through collaborations with pharmaceutical companies or selective licensing and acquisition transactions;

- our expectation that we be successful in identifying those factors which make a drug candidate toxic to the heart or liver;

- our expectation that we will be able to engage medicinal chemistry partners to assist us in developing drug rescue variants;

- our expectation that we will be able to develop drug rescue variants that are less toxic than the original drug candidates from which they are derived;

- our anticipation that our drug rescue collaborations will include terms addressing the ownership of the drug rescue variants we expect to generate during our drug rescue programs and the underlying intellectual property;

- our expectation that we will derive revenues principally from drug rescue collaborations, research and development fees, technology access fees, license fees, milestone payments and royalties from collaborators and government grant awards;

- our belief that we will have sufficient capital to fund our operations for 12 months from the date of this current report;

- our expectation that we will license or sell drug rescue variants developed by us, or on our behalf by our medicinal chemistry collaborators, to pharmaceutical companies;

- our ability to produce stem cell-derived human liver cells within 12 months after the date of this current report, and our ability to develop a predictive toxicity assay system for liver toxicity using this technology;

- our expectation that we will leverage our stem cell biology platform to develop assay systems for applications beyond predicting heart or liver toxicity of drug candidates, including stem cell therapy;

- our expectations with respect to preclinical stem cell therapy initiatives focused on pluripotent stem cell-based cartilage, heart and liver repair and reconstitution and next-generation autologous bone marrow transplantation; and

- our expectation that we will complete Phase I clinical development of AV-101 in the United States in 2011.

Because the factors discussed in this current report could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any such forward-looking statements. These statements are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. Such risks and uncertainties relate, among other factors, to:

- our ability to rescue a drug candidate;

- our ability to effectively predict toxicity of drug candidates;

- our internal validation study of our first predictive toxicology screening assay system, CardioSafe 3Dtm, has not been subject to peer review or third party validation;

- whether the assay systems based on our stem cell biology platform are more efficient or accurate at predicting the toxicity of drug candidates than current nonclinical testing models;

- our history of operating losses;

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our ability to obtain additional capital in the future to conduct operations, research and development activities and develop our drug rescue pipeline;

- our ability to obtain government grant funding;

- our ability to find collaborators in the pharmaceutical industry for drug rescue using our stem cell technology;

- our ability to license or acquire drug rescue candidates from pharmaceutical companies on terms and conditions acceptable to us;

- our ability to compete against other companies and research institutions with greater financial and other resources;

- pharmaceutical industry need, acceptance and productive application of our stem cell technologies for drug rescue applications;

- our ability to engage with third party medicinal chemistry providers to develop drug variants and our ability to license potential drug rescue candidates on terms and conditions acceptable to us;

- our ability to secure adequate protection for our intellectual property, especially the intellectual property underlying our stem cell biology platform and the drug rescue variants that are created for us by our medical chemistry collaborators;

- our ability (or the ability of our collaborators) to obtain regulatory approval of drug rescue variants; and

- our ability to attract and retain key personnel.

These and other risks are detailed in this current report under Item 1A, “Risk Factors”.

ITEM 1. BUSINESS

Overview of Business of Excaliber Enterprises, Ltd.

On October 6, 2005, we incorporated with the name 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 Tubetm, 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 Tubetm platform.

Our Human ClinicalTrials in a Test Tubetm 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 ("UHN"). 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 Tubetm 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 Tubetm 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 Tubetm 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 Tubetm 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 Tubetm 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 Tubetm 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 Tubetm 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 Tubetm 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 Tubetm 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 Tubetm 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 3Dtm, 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 3Dtm

We have used the proprietary stem cell technologies underlying our Human Clinical Trials in a Test Tubetm platform to develop CardioSafe 3Dtm, 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 3Dtm 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 3Dtm 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 3Dtm were consistent with the known human cardiac effects of all 10 FDA-approved drugs and the experimental research compound. By using CardioSafe 3Dtm, we were also able to distinguish between the cardiac effects of terfenadine (Seldanetm), withdrawn by the FDA due to cardiotoxicity, and the cardiac effects of the closely related fexofenadine (Allegratm), the non-cardiotoxic chemical variant of terfenadine.

The results obtained with CardioSafe 3Dtm 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 3Dtm 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 3Dtm 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 3Dtm, 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 3Dtm

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 3Dtm 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 3Dtm 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 3Dtm 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 3Dtm 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 3Dtm 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 Tubetm 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 Tubetm 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 Capitaltm 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 Capitaltm (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 NIH has awarded us a total of $11.3 million in non-dilutive research and development grants, including $2.3 million for research to support our Human Clinical Trials in a Test Tube™ platform and $8.8 million for 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 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 billion in funding for stem cell research in California, including research involving ES, iPS 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, we have been awarded approximately $1 million of grant funding from CIRM for stem cell research and development related to liver cells and LiverSafe 3D™. This research and development is 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.

NuPotential, Inc.

In January 2011, the National Heart, Lung and Blood Institute of the NIH awarded NuPotential, Inc. and VistaGen a grant of approximately $500,000 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 (NeurontinTM) 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 Tubetm Platform

We have established our intellectual property rights to the technology underlying our Human Clinical Trials in a Test Tubetm 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 Tubetm 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.

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 Tubetm 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 Tubetm 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 Tubetm 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 Tubetm 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.

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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 $38.9 million, and shareholders' deficit of $26 million and $30 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 Tubetm 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 3Dtm has not been subject to peer review or third party validation.

Our internal validation study, conducted to validate the ability of our CardioSafe 3Dtm 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, CardioSafe3Dtm, 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 3Dtm 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 3Dtm 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 $38.9 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 Tubetm 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 Tubetm 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 Tubetm 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 Tubetm platform, particularly in circumstances where it would be preferable to produce iPS Cells to reflect the effects of desired specific genetic variations.

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.